Strategy for American Innovation
RFI Responses

Index

September 23, 2014

The White House Office of Science and Technology Policy
Attn: Mr. Daniel Correa
Senior Advisor, Innovation Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

RE: Comments on the update of the *Strategy for American Innovation*

AcademyHealth is pleased to submit feedback to the White House Office of Science and Technology Policy (OSTP) and the National Economic Council (NEC) on its update of the *Strategy for American Innovation*. We represent the interests of more than 5,000 scientists and policy experts and 175 organizations that produce and use health services research to improve our nation's health and the performance of the health care and public health systems. Their work, largely funded by the federal government, has helped us understand and improve a complex and costly health system so that we can achieve better outcomes for more people at greater value.

The prior *Strategy for American Innovation* has neglected to address a critical component of America's innovation; one that arguably has an important impact on improving health—the health system itself. Health services research helps us understand health care in the real world, determining what works for whom, in what settings, under what circumstances, and at what cost. In revising the *Strategy for American Innovation*, we urge OSTP and NEC to consider the role of health services research. Understanding how to most effectively and efficiently deliver cures to patients has implications for health care quality, costs, access and ultimately health outcomes.

More recently, the President's Council of Advisors on Science and Technology (PCAST) released a report describing how the tools of systems engineering, which are increasingly used by health services researchers, could transform the health system.[1] This and other types of health services research are being used in universities throughout the United States, in communities, and health systems to promote health care delivery transformation and achieve affordable, high quality care and healthy communities.

In the pages that follow, AcademyHealth has provided background information on health services research and its innovative contributions to health system transformation and improved health. We have also provided responses to questions **1, 2, 7, 13, and 24**, including recommendations for renewed investment to be included in next year's updated strategy. We outline why health services research must be part of any innovation agenda and explain why it is shortsighted to omit this important dimension of science from any innovation framework.

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BACKGROUND: Health Services Research Is Core to Innovation

The federal government has a longstanding role in supporting the health research continuum—from basic research to health services research (see Figure 1). In the same way the federal government built the interstate highway system from which all Americans benefit, the government supports health research and innovation that would not occur in the private marketplace alone and offers benefits to the nation as a whole. As highways are an engine for commerce, development, and expansion, health services research is an engine for increased productivity, innovation, and value.

Figure 1: The Health Research Continuum

These components of the health research continuum work in concert, and each plays an essential role—any one type of research on its own cannot effectively or appreciably improve health. Take heart disease as one example…			
Basic research discovered the contributions of elevated blood pressure, elevated cholesterol, and tobacco use to heart disease.	**Clinical research** determined which treatments were safe and effective to treat hypertension, hypercholesterolemia, tobacco addiction, and to prevent and treat heart disease, in general.	**Population-based research** identified strategies to reduce the risks of heart disease in communities through non-medical interventions, such as reduction of trans fats in food and tobacco control measures to reduce smoking.	**Health services research** determined how to best deploy these discoveries to achieve the best health outcomes. This research helped identify who had the least access, what barriers existed, and innovative strategies to mitigate them. This research also led to new quality measures that are now used to report on the quality of cardiac care.

Source: *AHRQ: 15 Years of Transforming Care and Improving Health,* AcademyHealth, Jan. 2014. Available at: http://academyhealth.org/files/AHRQReport2014.pdf

Imagine the government just built interstate highways and left it to individual drivers to decide how to use them—no speed limits, no traffic signs or lights, no lines, no requirement that vehicles have breaks, no agreement on which side of the road to drive. In many ways, this is the equivalent of our current health system in which insurers and delivery systems work with providers to decide how to deliver health care with little support for understanding what works and for whom. This is where health services research provides critical value–this science seeks to develop and promote the evidence needed so that providers, health systems, and payers can develop voluntary “rules of the road” so that care can be delivered that is more efficient, effective and safe.

The United States spent $2.8 trillion—17.2 percent of our economy—on health care in 2012. Health services research has shown we waste as much as 30 percent of what we spend on health care on unnecessary services, inefficiently delivered services, and missed opportunities for prevention.[2] Finding new ways to get the most out of every health care dollar is critical to our nation's long-term fiscal health and our ability to be competitive in a global market. Health services research is our nation's research and development, or 'R&D,' enterprise for such innovations. Like any corporation making sure it is developing and providing high quality products, the federal government—as the nation's largest health care purchaser—has a responsibility to get the most value out of every taxpayer dollar it spends on Medicare, Medicaid, the Children's Health Insurance Program, and veterans' and service members' health.

While medical research discovers cures for disease***, health services research discovers innovative cures for the health system*.** This research diagnoses problems in health care and public health delivery and identifies solutions to improve outcomes for more people, at greater value (see Figure 2). Innovations from health services research can be used right now by patients, health care providers, public health professionals, hospitals, employers, and public and private payers to improve care today.

Figure 2: Contributions of Health Services Research to Quality Improvement

Thanks to health services research, we know that health care sometimes falls short…
An estimated 1.7 million hospital-acquired infections occur each year, leading to about 100,000 deaths.[3]
Patients do not receive the care recommended for them by evidence. For example, patients with diabetes receive recommended preventive care only 21 percent of the time.
Health care is increasingly complex and for patients with multiple chronic conditions, poor coordination results in unnecessary tests, hospitalization, and readmissions. One study found that almost one-fifth of Medicare patients were re-hospitalized within 30 days.[4]
Thanks to health services research, we know that falling short costs money…
In 2008, costs attributable to medical errors were estimated at $19.5 billion—more than half of the National Institutes of Health's annual budget.[5] Medication errors alone cost as much as $2 billion each year—equivalent to the federal annual investment in health services research.[6]
The average cost of care for a patient with a catheter-related blood stream infection is $45,000, costing up to $2.3 billion annually nationwide.[7]
Medicare spends $12 billion a year on preventable hospital readmissions—more than double the discretionary budget of the Centers for Disease Control and Prevention.[8]
Thanks to health services research, we have identified innovations that work…
Systematic reviews of adverse events have been instrumental in improving health care safety and the wellbeing of patients. For example, a report documenting the adverse events related to ephedra was instrumental in the withdrawal of the substance after a well-known baseball player died after using it.[9] Another report documented the potential harmful side effects of atypical antipsychotics in the elderly, which led to a new FDA black box warning.[10]
Implementation of computerized physician order entry could prevent between 570,000 and 907,000 serious medication errors each year.[11]
Quality improvement approaches, including improved primary care, discharge planning, and follow-up care can prevent or reduce hospitalizations and rehospitalizations.[12]

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Responses and Proposed Actions

(1) What specific policies or initiatives should the Administration consider prioritizing in the next version of the Strategy for American Innovation?

(2) What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?

Health-related inefficiencies and less than optimal quality of care are a significant threat to American competitiveness and innovation. As documented in the National Research Council and Institute of Medicine report *Shorter Lives; Poorer Health*, health outcomes in the United States across all ages groups are significantly worse compared to other high-income countries.[13]

One of the contributors to suboptimal health outcomes is the failure to consistently deliver existing innovations to the patients who can benefit. This results in widespread variations in care quality, outcomes and costs. This in turns contributes to substantial health burdens in some communities, which then have repercussions to the economic wellbeing of the community as a whole, as employers increasingly seek healthier communities, with lower health care costs in which to locate their businesses. There is far too little understanding of, or support for, innovations that can revolutionize how health systems, providers, and patients can more quickly and reliably benefit from discoveries and improve the care of patients and populations today.

- **Action:** To advance our ability to improve care, we need to establish federal policies that build a robust environment to produce health services research and includes:
    - Federal funding for research and the infrastructure—data, methods, and people—needed to produce it.
    - Policies that encourage—and do not unnecessarily restrict—the production of health services research.
    - Policies that enhance the quality, availability, timeliness, and affordability of data and tools used to produce research.

(7) What emerging areas of scientific and technological innovation merit greater Federal investment, and how can that investment be structured for maximum impact?

During the first 40 years of investment in health services research, the emphasis was on documenting, describing, and understanding the many factors that drive ultimate health outcomes for patients and their quality of life. More recently, health services research has focused on interventions that improve care. To address the suboptimal performance of the U.S. health system, a concerted focus on health services research that discovers new and effective ways to bring biomedical discoveries (past and future) from the bench, to the patient's bedside, to the community's curbside is needed. This is a vast country and many types of approaches and modalities will likely be needed to meet the needs of diverse populations and communities.[14] For example, one cannot assume that strategies to improve the care for a patient with diabetes and heart disease that are effective with urban, African American patients will be effective in a remote town of New Mexico with a largely Native American population.

Different population, community, system and employer characteristics factor into whether health care innovations actually reach the patients and communities who need them. Finding out what works, for whom, under what circumstances is critical to improving the care and health of Americans and eliminating health disparities, which are further reducing our productivity.

As part of this enhanced focus, the growing role and potential for information and communication technologies, including health information technology, is enabling breakthrough opportunities to improve the delivery of effective innovations to individuals and populations that are tailored to their specific needs and thus move us to a system that is truly delivering personalized medicine.

- **Action:** Increased and sustained funding for health services research is needed across the federal government, including the Department of Health and Human Services (HHS) (including the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, and the National Institutes of Health), the Veterans Health Administration, the Department of Defense, the National Science Foundation, and the Patient Centered Outcomes Research Trust Fund. This research needs to include behavioral, social science, and economic research, a focus on the six dimensions of quality as defined by the Institute of Medicine, as well as the comparative effectiveness of the interventions.[15]

<u>Skilled Workforce Development</u>

(13) What emerging areas of skills are needed in order to keep pace with emerging innovations or technologies? What are successful models for training workers with these skills to keep up with emerging innovations?

The strength, relevance, and important contributions of the field of health services research to improved health rest on its human capital and its multidisciplinary nature. The federal government supports the development of the health services research workforce through essential individual and institutional training grants. While a majority of the field has historically worked in academic settings, the explosion of new health-related data and the evolution toward a learning health system has expanded employment opportunities in the private sector. Thus, training and career development activities are evolving to ensure a workforce that is trained in new and innovative methods and data and able to advance innovation regardless of the setting of their work. At the same time, the underrepresentation of certain racial and ethnic minority groups in science also exists in health services research. Thus concerted attention to diversifying the workforce is also needed.

- **Action:** Sustained and expanded federal support of a variety of training grants for both individuals and institutions is needed.

(24) Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise.

As noted above, the suboptimal performance of the U.S. health system is contributing to health outcomes for Americans that fall short of other high-income countries. Just as important is the fact that health outcomes and health care also varies significantly by geography, type of insurance, and patient/community characteristics.[16] The diffusion of life saving innovations often occurs differentially thus worsening existing disparities.

- **Action:** The next draft of the *Strategy for American Innovation* needs to include specific attention and innovations to overcome existing disparities in health and health care and ensure that future innovations are deployed such that they do not create new disparities.

Health care innovations will fall short of their potential if we don't determine how to best deploy them to physicians and patients. Put plainly, health services research helps maximize the return on investment in basic and clinical research, ensuring that patients have access to and truly benefit from drug discoveries and medical advances. We look forward to working with OSTP and NEC in determining how to best to better integrate health services research into the *Strategy for American Innovation*, and move biomedical discoveries from the bench, to the bedside, to the curbside and beyond.

If you have questions about these comments, please don't hesitate to contact Dr. Lisa Simpson, President & CEO of AcademyHealth, at [redacted] or [redacted]

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[8] Report to Congress: Promoting Greater Efficiency in Medicare. MEDPAC. June 2007. Ch. 5, p 108.

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[12] The Commonwealth Fund Commission on a High Performance Health System, Why Not the Best: Results from the National Scorecard on U.S. Health System Performance, 2008, The Commonwealth Fund, July 2008.

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[15] Institute of Medicine (US). Committee on Quality of Health Care in America.*Crossing the quality chasm: A new health system for the 21st century*. National Academies Press, 2001.

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ADVANCED-MANUFACTURING COALITION FOR TECHNOLOGY & INNOVATION (ACTI)

September 23, 2014

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RE: Comments Regarding the upcoming update of the Strategy for American Innovation

Dear Mr. Correa:

Attached are comments, on behalf of ACTI, the Advanced-manufacturing Coalition for Technology & Innovation, with respect to the upcoming update of the Strategy for American Innovation (the "Strategy") which helps to guide the Administration's efforts to promote lasting economic growth and competitiveness through policies that support transformative American innovation in products, processes, and services and spur new fundamental discoveries that in the long run lead to growing economic prosperity and rising living standards.

From an advanced-manufacturing industry perspective, key building blocks for an effective American Innovation Strategy include, but are not limited to:

(i) Education, skills, and creating a world-class American workforce, including enhanced access for high-skilled foreign workers;

(ii) Innovative, open, and competitive markets, including through free trade and investment agreements and an increased focus on TPP, TTIP, EGA and ITA negotiations in particular;

(ii) A smart, innovation-, and business-friendly U.S. tax policy; and

(iv) Effective protection for and enforcement of patents, trade secrets, and other forms of industrial and advanced-manufacturing IPR, as highlighted in the 2011 Strategy, including additional support for Congressional efforts to further strengthen U.S. trade secrets legislation, and active efforts to enhance trade secrets protection globally and defend U.S. industry against compulsory licensing and other worldwide IPR-erosion threats.

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About ACTI

Members of the *Advanced-Manufacturing Coalition for Technology and Innovation (ACTI)* employ hundreds of thousands of people, and have invested billions of dollars in innovation-driven manufacturing and industrial sectors in the United States, and around the world. Sectors in which ACTI members are active include clean technology, energy, medical technology, advanced chemicals, and industrial and manufacturing-focused internet products and services. In each of these sectors, our members tend to be the leading companies, as well as among the most innovative. ACTI members include many of the leading U.S. and Transatlantic companies. ACTI supports policies that encourage and enable innovation, trade, and the market-based development and dissemination of technology around the world.

Key Building Blocks for American Innovation and Innovation-Driven Growth from the Advanced-Manufacturing Sector's Perspective

In the 2011 National Innovation Strategy, the Administration rightly noted that U.S. innovation is essential to long-term growth and competitiveness. In certain instances, the Government can act as an innovation facilitator; but the private sector is critical both to actually perform innovation (particularly beyond the basic research level), develop technology to the point of commercialization, and place it on the market – in the U.S. and abroad – in economically efficient ways that create value for the U.S. economy and enhance our ability to create and maintain good paying U.S. jobs. There are a number of key building blocks, some of the main ones of which we outline below.

Education, Skills, and Creating a World-Class American Workforce

Educational investments and workforce training, says the 2011 Strategy, "provide the essential building block – a capable workforce – from which new ideas come and through which good ideas spread." Indeed, the United States' educational edge has often been the backbone of our lead in a broad range of technology and innovation-driven sectors, be it energy, clean technology, information technology, or the biosciences. Continuing to build on the educational excellence of our universities and schools, worker training, and a smart but effective immigration policy are critical components of a successful U.S. innovation policy for the years to come. Our members support a continued focus on science, technology, engineering, and math (STEM) education, areas in which the United States is able to excel but has increasingly fallen behind. Smart immigration policies can be a key factor as well. Such reforms should improve the ability of U.S.-based companies to recruit and retain highly-skilled foreign graduates and professionals including through the abolishment of per-country caps on employment-based permanent resident visas (green cards), expansion of entrepreneurial and investor green cards, and making green cards more readily available to those with advanced degrees in STEM fields.

Innovative, Open, and Competitive Markets, in the United States, and Around the World

Innovative, open, and free markets, both domestically and around the world, are a key factor. They provide the very basis for efficient technology development and commercialization, and allow companies to produce new and existing products or provide services at the lowest possible cost. Ongoing and recently launched trade and investment negotiations are critical. We note in particular the Trans-Pacific Partnership (TPP) negotiations with the fast-growing Asia-Pacific region; Transatlantic Trade & Investment Partnership (TTIP) negotiations with the EU; as well as sectoral and plurilateral negotiations such as those for an Environmental Goods Agreement (EGA) and an updated Information Technology Agreement (ITA2). Each of these, alone and in combination, should form a key part of any ongoing U.S. innovation and economic growth strategy. We urge the Administration to make trade in general, and the conclusion of these negotiations in particular, a key priority.

Tax Policy that supports the deployment of Americans oversees to enhance innovation and export of U.S. products

Much of the world's markets and talent is located outside the country. U.S. competitiveness depends on being able to tap the pockets and the talent pool located in foreign markets. However, current tax policy impedes companies from deploying Americans abroad, hindering access to information that will further domestic innovation as well as the best channels to promote our own exports. For example, our U.S citizenship-based taxation requires Americans employed abroad to pay taxes both to the U.S. and within the countries they work. Such schemes make it costly to employ U.S. citizens compared to their foreign counterparts. The result is that many companies forego sending their employees abroad and miss out on critical foreign market insight that could be used to enhance innovation at home. Or instead, companies may hire foreign nationals to do the same work, who may not have the same passion to promote the fruits of American innovation. In many jurisdictions where trade secret protection is less than adequate, American firms may be further disadvantaged – as they may be sharing the most confidential and commercially sensitive details with employees more likely to join a local competitor than return to the U.S. with a deeper understanding of the needs of customers outside the U.S. Similar policies, such as the U.S. fiscal reporting required by foreign subsidiaries and the Foreign Account Tax Compliance Act, present challenges for innovative companies seeking knowledge and markets for their exports.

The Critical Role of Patents, Trade Secrets and Other Forms of Industrial IPR for the Advanced-Manufacturing Sector

Intellectual property (IP) rights, as the 2011 Strategy states, "provide critical incentives for commercial innovation. IP further allows new ideas to be traded between firms, finding their best uses in the marketplace, and is an important determinant of entrepreneurial funding. Because IP supports both innovation and entrepreneurship, public policy must ensure that innovators receive high-quality IP rights in a timely manner, while maintaining public access to basic discoveries and room for healthy experimentation."[1]

Indeed, our ability to out-innovate most other countries, for most of the 20th and early 21st Century has been, at least in part, a result of our country's smart and effective use of IPR policy

[1] 2011 Strategy, p. 21.

as a mechanism to encourage innovation and the commercialization of innovations and technology development. For at least several decades now, and across all industries, from manufacturing, to aerospace, to (bio)medical technology, clean technology, and the internet, our companies and innovators have benefited from one of the most effective systems of protection and enforcement of industrial IPR.

Patents and other forms of advanced manufacturing IPR encourage innovation and give our innovators and advanced manufacturing companies a critical basis to invest in the further development of early technologies, their commercialization and placing on the market. They also play a critical role in enabling firms of all sizes, but especially smaller and mid-sized companies and early manufacturing start-ups, to gain access to financing and the capital markets. For many early technology and advanced-manufacturing ventures, their patents and other forms of IPR, represent the vast majority of their market value and, as such, a key point of financial leverage. Intellectual property provides an avenue to monetize the value of an investment of time, labor and money into the development and commercialization of a new technology. Without robust IPR, it may be more rational to market less innovative products or services, or to move out of the innovation-space altogether. This is important in manufacturing and industrial sectors in particular, where even incremental, follow-on innovation can involve significant upfront investments and where follow-on, as opposed to large breakthrough innovations are commonplace.

Box 1: The Importance of IPR in Enhancing Clean Technology Innovation and Dissemination Around the World

Intellectual Property Rights (IPR) are exhaustively regulated in the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS), as well as a range of other existing international IPR agreements. They have been found by the UN, UNFCCC, World Bank, OECD and others: (1) to play a key role in enabling and encouraging innovation and the development of critical new technologies to achieve global sustainability, development, green growth and climate objectives; and (2) to help countries achieve such goals at a reasonable and affordable cost, and in ways that are inclusive of the poorest and most vulnerable developing countries alike.

Over the years, numerous economists and others have reviewed the literature and evidence on environmental innovation, technology dissemination, financing and the role of Intellectual Property Rights (*e.g.*, Johnson/Lybecker; Barton; Newell; Copenhagen Economics; UNFCCC; WTO; OECD; WEC[2]). Their studies find broad agreement that IPRs play a positive role in low-carbon technology markets; that criticisms of IPR as a "barrier" to technology transfer lack economic and analytical rigor (and ignore the essential character of IPR as encouraging and

[2] See, *e.g.*, Johnson, D.K.M., Lybecker, K.M., Innovating for an Uncertain Market: A literature review of the constraints on environmental innovation, Colorado College Working paper 2009-06 (July 2009), p. 11; Barton, J.H., Intellectual Property and Access to Clean Energy Technologies in Developing Countries, ICTSD, Trade and Sustainable Energy Series, Issue Paper 2/2007, p. 4; barton, J.H., Mitigating Climate Change Through Technology Transfer: Addressing the Needs of Developing Countries, Chatham House, Energy, Environment and Development Programme Paper 08/02, October 2008; Newell, R., International Technology Strategies, Discussion paper 08-12, Harvard Project on International Climate Agreements, October 2008, p. 25; Copenhagen Economics, Are IPR a Barrier to the Transfer of Climate Change Technology?, 19 January 2009; UNFCCC, Enabling Environments for Technology Transfer, 4 June 2003; World Trade Organization, Trade and Transfer of Technology, Background Note by the Secretariat, WT/WGTTT/W/1, 2 April 2002; UNCTAD, Transfer of Technology, 2001 (http://unctad.org/ed/docs//psiteiitd28.en.pdf), pp. 18-19; World Economic Council, Energy Sector Environmental Innovation: Understanding the Roles of Technology Diffusion, Intellectual Property Rights, and Sound Environmental Policy for Climate Change (2011).

enabling technology development and transfer); and that "IPRs offer a potential means of countering the basic problems in global technology markets. Enforced patents and trade secrets raise appropriability ... IPRs offer legal certainty about ownership of rights and responsibilities, reducing the costs of achieving mutually agreeable licensing contracts. They also offer tools with which to deter opportunism, lowering coordination costs." (Maskus 2012[3]) Finally, "[w]ith few exceptions, the studies point squarely toward the conclusion that patent reforms [i.e., strengthening of patent rights up to TRIPS and other global standards] have positive effects on inward technology transfer". (Maskus 2012)

Responses to Specific Questions

Question 1: Specific Policies or Initiatives that should be Prioritized

Without being exhaustive, we believe the following are among the key policies and initiatives that the Administration should prioritize in the next version of its Strategy for American Innovation:

1. Maintain today's business model-neutral patent system

It is difficult to predict where the most critical advances in technology will originate and how they will ultimately come to fruition in the market. Gone are the days when technology could be considered in discrete domains. Today multidisciplinary approaches have become the norm. It is also not uncommon for seemingly obsolete ideas to be resurrected and reinvented to solve modern challenges.

With both technology and the business models that support their commercialization becoming increasingly intertwined, our innovation system must strive to provide an even-handed approach regardless of the origin of the ideas. The merit of the idea and its potential fit for the market should be the decisive factor for its success. However, recent legislative proposals have advocated the U.S. back off from this longstanding approach which has served as the cornerstone to incentivize American innovators.

Patent owners play a variety of roles in the innovation chain. Some offer breakthroughs while others connect the dots by translating ideas into offerings. It is not uncommon for the most prolific inventors to never be the ones to bring their products to market. Whether due to a lack of resources, desire or skill, the patent system enables these innovators to recoup their investments and let others execute them. The ability for all types of actors in this chain to enforce IP rights is critical to ensuring the U.S. has access to the best ideas and growth of our economy. The value of a patent should depend on its viability in the market and not who owns it. Yet Congress is being asked to consider legislation that would disfavor patent owners who do not manufacture their innovations. These innovators, including individuals, universities, startups and other research organizations, serve as important sources of technology that are brought to the market by others. Increasing the difficulty for such entities to enforce their IP, would limit their ability to improve U.S. competiveness. The Strategy needs to look for ways to encourage the participation of all American innovators regardless of their manufacturing capacity, encouraging their contributions rather than discouraging their efforts.

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3 Keith E. Maskus, Private Rights and Public Problems, The Global Economics of Intellectual Property in the 21st Century, Peterson Institute for International Economics (September 2012).

2. Enhance the effectiveness of the domestic system for trade secrets protection and enforcement

The United States already has one of the most advanced and effective systems of trade secrets protection in the world. Nonetheless, key challenges and opportunities for improvement remain that could significantly reduce the cost of the system as a whole, increasing its effectiveness. A first-rate U.S. system of trade secrets protection and enforcement is also central to convincing other countries around the world to develop similarly robust levels of protection.

Right now, the U.S. Congress is considering a federal civil cause of action to protect against trade secret misappropriation and to provide trade secrets with protections similar to other intellectual property rights. This federal law could provide for national service of process (to reach alleged violators across the various states) and options for remedies to private industry, including damages, injunctions, *ex parte* seizures in limited and extraordinary circumstances, and mandatory royalties. Moreover, U.S. policymakers could consider amending the Economic Espionage Act to strengthen criminal penalties for trade secret theft, including creation of a statutory minimum sentence, broadening the definition of misappropriation of a trade secret to include those that *affect* manufacturing processes, source code, and other non-physical assets (and not just the processes/codes themselves), and expanding the types of non-U.S. entities that could be prosecuted.[4]

The most recent and seemingly most promising development in this respect is a pair of co-pending bills[5] which would amend the Economic Espionage Act to create a federal civil cause of action for trade secret misappropriation; provide for injunctions and damages, to preserve evidence, prevent disclosure, and account for the economic harm to American companies whose trade secrets are stolen; and create consistency with the approach taken to protecting other forms of intellectual property, such as patents, trademarks and copyrights.[6] The Administration itself specifically discussed the critical importance of trade secrets protection for the U.S. economy in its 2013 Trade Secrets Strategy and it should support further efforts in this regard in its updated U.S. Innovation Strategy.

3. Encourage other countries to improve their systems of trade secrets protection and enforcement

Globally, the momentum for enhanced trade secrets protection is also growing and the Administration has already made strengthening global trade secrets protection a policy priority.[7] We see positive signs, in particular, in Europe, where the EU is in the process of further

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[4] Currently, the Economic Espionage Act only applies to conduct occurring outside the U.S. if "(1) the offender is a natural person who is a citizen or permanent resident alien of the United States, or an organization organized under the laws of the United States or a State or political subdivision thereof; or (2) an act in furtherance of the offense was committed in the United States." 18 U.S.C. § 1837.

[5] Defend Trade Secrets Act S. 2267 and Trade Secrets Protection Act H.R. 5233

[6] Press Release, Office of Senator Chris Coons, *Senators Coons, Hatch introduce bill to combat theft of trade secrets and protect jobs*, Apr. 29, 2014.

[7] Administration Strategy on Mitigation the Theft of U.S. Trade Secret. February 2013

harmonizing trade secrets protection across EU Member States.[8] China's government also has repeatedly recognized the importance of trade secrets in the context of bilateral discussions with the United States, including in the 2012, 2013 and 2014 U.S.-China Strategic & Economic Dialogues ("S&ED"). At the 2014 S&ED, China noted in particular that the protection of trade secrets was included among the State Council's April 2014 "Priorities of the Nationwide Crackdown on Intellectual Property Infringement and Production of Counterfeit and Shoddy Products".[9]

Economic analyses show that robust protection and effective enforcement of trade secrets and other intellectual property is a key tool to incentivize innovation, in developed and developing countries alike; and to grow both domestic and foreign direct investment, including through commercial partnerships and technology supply chain integration; develop a country's workforce and domestic industrial sectors; protect companies against unfair competition from those who have misappropriated or outright stolen their confidential information; and support broader economic, development and social and public policy goals. Given the clear commercial and economic benefits to the U.S. economy enhancing trade secrets protection globally should continue to be a key priority for this Administration and should be reflected as such in the next version of the Strategy for American Innovation.

4. Defend against global challenges of US advanced-manufacturing IPR

Globally, we also continue to see more active threats against U.S. advanced-manufacturing technology and IPR in general. In addition to a lack of effective trade secrets protection and less effective patent systems in numerous countries around the world, a key threat are global calls for compulsory licensing of certain technologies and other forms of "IPR erosion". Right now, threats against IPR are particularly pronounced in the ongoing United Nations Framework Convention on Climate Change (UNFCCC) negotiations, as well as in the context of Sustainable Development Goals (SDG) discussions within the United Nations (UN). In each of these fora, calls to weaken IPR threaten to undermine the environmental or sustainable development goals that the negotiations are trying to achieve. In fact, the evidence confirms the key role that patents and other forms of IPR play in encouraging new clean technology developments and innovation, ensuring the availability of financing, and enabling the global supply and dissemination of key climate change and sustainable development-related technologies and products. The U.S. economy, moreover, clearly stands to gain, with an innovative prowess and clean technology and sustainable development sector that is second to none. Thus, continued, active U.S. Government efforts to fend off efforts at global IPR erosion and the compulsory licensing or other forms of weakening of U.S. advanced-manufacturing and other IPR should continue to be a key Administration priority.

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[8] *Proposal for a Directive*, *supra* note 28, at 17 ("Trade secrets must meet all of the following requirements: (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.").

[9] *See* Press Release, U.S. Dep't of the Treasury, *UPDATED: U.S.-China Joint Fact Sheet Sixth Meeting of the Strategic and Economic Dialogue* (July 11, 2014), *available at* http://www.treasury.gov/press-center/press-releases/Pages/jl2561.aspx.

5. Continue to negotiate effective international trade and investment agreements

As indicated above, trade and investment negotiations play a key role in enhancing the U.S. technology and advanced-manufacturing sector's ability to accelerate economic growth, create jobs, and continue innovating as well. Ongoing negotiations such as TPP, TTIP, EGA and ITA2 are key and should be a core focus of any updated National Innovation Strategy.

6. Enhance the U.S. tax system so as to encourage innovation and the development of effective global technology supply chains

As discussed above, U.S. competitiveness depends on our ability to access knowledge and markets outside our borders. However current tax policy makes such efforts unnecessarily challenging. U.S. citizens based abroad are taxed twice, paying both to the country where income is generated as well as to the U.S. Thus our tax scheme creates a disincentive to hire Americans to work abroad, since foreign nationals are not subject to the same double taxation. U.S. companies are faced with a needlessly difficult decision – choose not to engage in these critical markets and miss out on opportunities to enhance their innovation and channels for their goods and services or hire foreign nationals that may not promote American products with the same enthusiasm. This dilemma as further complicated by inadequacy of trade secret laws in many countries. In these regions companies may be unwilling to share their most confidential and commercially valuable information with lesser known employees, for the fear that that knowledge may leak to their local competitors.

American citizens working overseas also face difficulty establishing and maintaining relationships with banks, making it very difficult to function in their temporary environments. The Foreign Account Tax Compliance Act (FACTA) subjects foreign banks to severe penalties if they fail to provide detailed reports to the IRS on the source, disposition and income of accounts held by U.S. citizens, even if it violates local privacy laws. It has resulted in foreign banks closing accounts of U.S. citizens. From a practical standpoint, these types of policies make it even harder to attract U.S. talent to work outside the country.

U.S. business that operate overseas, are subject to similarly difficult reporting requirements. Foreign subsidiaries must set up three accounting systems: one in local currency to comply with local laws plus two more in equivalent U.S. dollars converted per complex rules to meet IRS requirements. For many companies this is cost prohibitive and keeps them from seeking new knowledge in foreign markets which could accelerate their capacity to innovate.

Question 5: Policies and Practices of Other Countries

Globally, innovative U.S. firms are facing increasingly challenging policy environments for innovation and the commercialization of new technology solutions. Given the extent to which R&D and production are now globally dispersed, U.S. Government efforts to fight attempts to weaken global intellectual property (IP) protection are critically important.

Misguided policies that weaken intellectual property (IP) protection in order to promote availability of technologies are increasingly pervasive. More advanced developing countries with imitative capacity routinely take actions to enable their domestic firms to use foreign-owned proprietary technologies at lower prices. Such policies are enacted in the hopes that they will help domestic firms to become more competitive but, in reality, they harm both local firms and the economy. For example some governments have embraced industrial policies that deliberately undermine foreign-owned IP rights, issuing compulsory licenses and limiting availability of patents in certain fields of technology, notably pharmaceuticals. These policies create uncertainty and risk for innovators, which tend to lock down their most valuable technologies and know-how, refraining from making investments and undertaking collaborative projects with firms in the relevant country. The risk of losing control over the knowledge, to the benefit of competitors, becomes too great. As a result, technology flows and innovations that could have resulted from collaboration are lost. Local firms lose the opportunity for technological partnering with more advanced firms from abroad. It is critical that the United States reject IP weakening as a path to advancement, and continue to promote robust, business model-neutral IP protection at home and abroad.

Questions 6 and 21: The innovation process, models of innovation, and IPR

Growing adoption of the open innovation model and other collaborative approaches to R&D and commercialization, is forcing large and small firms to re-organize their innovative processes in order to stay competitive. IP protection supports collaboration, and enables firms to invest in R&D that generates disruptive as well as incremental innovations that improve lives. This is particularly true in advanced-manufacturing and other industrial sectors.

To enable U.S. firms to work with the best talent, wherever located, thus driving technological advancement more quickly and at lower cost, requires effective protection for technology and knowledge that is shared with partners. The robust IP system in the U.S. has enabled partnerships in this country to thrive, by making it less risky for innovators to collaborate, and by enabling universities, SMEs, and other actors with fewer resources to seize new opportunities and participate in open innovation.

In contrast, policies that weaken IP protection or that *force* technology and knowledge transfer will ultimately undermine collaborative innovation and technology development. Faced with greater risk, firms become less willing to share valuable information and work with others, resulting in missed opportunities. The USG must continue to push back on efforts, both domestically and globally, including within the UN system – at UNFCCC, WIPO, WHO, and within the SDG process at the United Nations, and by advanced middle-income countries (who have most to gain in terms of their own industrial policies) – to weaken (foreign-owned) IP rights. Such policies have little impact on open innovation, new business models, or a lack of access to key technologies, but do harm U.S. firms and the competitiveness of the U.S. market, as well as firms in the country enacting the policy, over the long-term. It is also important to note that nothing precludes a rights holder from sharing its IP on a voluntary basis. The same is true for patent pools and other forms of innovative collaborative research and development efforts. When they make commercial sense, the market will engage in them.

Finally, it is important to note that most innovation builds on what came before. In other words, true disruption is the exception to the rule and "incremental innovation" is the norm.

Incremental innovation can be extremely beneficial. For instance, new software that enhances the energy efficiency of a wind turbine by 30%, while not necessarily a major technological break-through, nonetheless contributes great value for customers and the environment. Incremental innovation still requires significant investments in R&D and IPR protection can help justify such investments, for management and investors alike, and allows the innovator to share his knowledge with commercial and technology partners, and the scientific and industrial community more broadly. Such an outlay of resources, however, requires the ability to achieve return on R&D investments if successful in the marketplace. IP protection, once again, is a tool that companies use to achieve that goal.

Question 8: Institutional innovation (business model of the USPTO)

Intellectual property assets are critical tools in managing risks related to innovation. Yet the institution that issues these assets faces significant roadblocks to improving the quality and productivity of their services. Despite being entirely funded by user fees, the United States Patent and Trademark Office (USPTO) does not automatically have access to the fees it generates. Funds are regularly withheld from the USPTO and diverted to unrelated government spending.

While the situation has improved with the American Invests Act, (AIA) the USPTO still faces significant challenges. Last year during sequestration the USPTO was forced to limit expenditures, including but not limited to restricting the hiring of new patent examiners, training, and IT modernization, even though the agency had already secured the needed capital.

The Strategy should consider new approaches that will allow the USPTO to provide better support to American innovators by giving the agency control over its own budget. For example, the agency could be transformed into a wholly-owned federal corporation or at the very least be given control over the reserve account created by the AIA without having to have the language reinserted into every appropriations bill.

The Advanced Medical Technology Association's (AdvaMed) Comments:
A Strategy for American Innovation
Submitted to the Office of Science and Technology Policy and the National Economic Council

AdvaMed appreciates the opportunity to comment on the proposed update of the *Strategy for American Innovation.* AdvaMed is the world's largest trade association representing the medical technology industry.

The medical technology industry is central to the development of the medical devices and diagnostics that will provide the life-saving and life-enhancing treatments of the future. These treatments not only improve the lives of millions of patients, they play an important role in expanding GDP, by increasing labor force participation and productivity. Moreover, medical technology is one of the few manufacturing industries in which America continues to lead the world, and it is an important engine of economic growth and job creation. The combination of opportunities for rapid development of new products based on the explosion of scientific knowledge in this century of the life sciences, the aging of the population in the U.S, and worldwide, and the rapid growth in middle class populations demanding advanced medical care in countries like China, India, and Brazil offer immense opportunities for economic growth if American retains its world leadership in this industry.

But the innovation ecosystem that supports our industry is severely stressed. Policy improvements are essential if America is to continue to be the competitive leader and the potential for medical progress in this century of the life sciences is to be fulfilled. Failure to act will mean lost lives, unnecessary suffering, reduced job formation, and diminished economic growth.

Summary of Recommendations

To restore the innovation ecosystem, maximize the opportunities for development of new treatments, diagnostics and cures, and sustain the competitiveness of our industry, AdvaMed recommends:

1. Creation of a streamlined, seamless path for FDA approval and public program coverage of breakthrough technologies that offer the opportunity for significant improvements in human health.
2. Continued improvement of the speed and consistency of FDA review, including pre-submission aspects of review, to achieve the recent FDA device center vision statement of making the U.S. once again the best place in the world to develop and first introduce medical technology.
3. Reforms to reduce the time and expense of conducting clinical trials.

4. Improvements in CMS coding, coverage and payment for new technologies to speed the availability of FDA-approved therapies to Medicare beneficiaries and creation of a culture at CMS that recognizes the importance of medical innovation to current and future Medicare and Medicaid beneficiaries.
5. Tax reform that will create a level playing field with competitor nations for U.S. based R&D and manufacturing and stimulate investment in early stage start-up companies developing innovative products.

These recommendations are discussed in more detail below.

Background on the medical technology industry

The medical technology industry is composed of companies that develop and manufacture medical devices and diagnostics. These products are diverse, running the gamut from tongue depressors to the most complicated molecular diagnostic tests, advanced imaging machines, and cardiac implants.

Structurally, small firms are a key part of the medical technology industry. A 2007 study by the U.S. International Trade Commission (USITC) found a total of 7,000 medical technology firms in the U.S.[1] The U.S. Department of Commerce estimated that 62% of medical technology firms had fewer than 20 employees and only 2% had more than 500.[2]

Small firms, often funded by venture capital, are particularly critical to the future of U.S. scientific and technology leadership because they are the source of a disproportionate number of the breakthrough technologies that drive medical practice and industry growth.[3]

Whether created by large or small firms, medical technologies are characterized by a rapid innovation cycle. The typical medical device is replaced by an improved version every 18-24 months. To fuel innovation, the medical device industry is research intensive. U.S. medical technology firms spend over twice the U.S. average on research and development. Medical device companies specializing in the most complex and technologically advanced products devote upward of 20% of revenue to R&D.[4]

In part because of this rapid innovation cycle, the medical technology industry is highly competitive. A study of medical device prices from 1989 to 2009 found that they increased, on average, only one-fifth as fast as other medical prices and less than one-half as fast as the regular CPI. Because the highly competitive market kept prices low, medical devices and diagnostics accounted for a relatively constant 6% of national health expenditures throughout the 20-year period despite a flood of new products that profoundly changed medical practice.[5]

The U.S. medical technology industry is a source of economic growth and good jobs. The industry employs more than 420,000 people in the U.S. It generates an additional four jobs in suppliers, component manufacturers, and other companies providing services to the industry and its employees, for every direct job—for a total of more than two million jobs nationwide.[6]

The jobs the medical technology industry provides are good jobs. The average medical technology worker enjoys wages that are almost 40% higher than average pay for the economy as a whole and 22% higher than the average for manufacturing wages.[7].

In no small measure as the result of the diagnostics, treatments, and medical tools developed by the medical technology industry, the health advances of recent years have been breathtaking. Between 1980 and 2010, medical advancements helped add five years to U.S. life expectancy.[8] Fatalities from heart disease were cut by 57 percent;[9] Deaths from stroke were reduced by 59 percent;[10] Mortality from breast cancer was cut by 31 percent;[11] and disability rates declined by 25 percent.[12] Moreover, the pace of positive change has quickened. In the most recent decade, between 2000 and 2010, life expectancy increased by nearly two years.[13] Fatalities from heart disease were cut by 30 percent;[14] Deaths from stroke were reduced by 36 percent;[15] and mortality from breast cancer was cut by 18 percent.[16]

The dramatic improvements in health have gone beyond reduced mortality to improved quality of life. The proportion of the elderly with a functional limitation has declined and the years of disability-free life expectancy have increased.[17] To cite one example of technology's impact, patients who received total hip or total knee replacements typically transitioned away from disability within one year. Their risk of dying was cut in half and their risk of a new diagnosis of heart failure or depression was significantly reduced.[18]

The impact of medical technology on economic growth and competitiveness goes well beyond the jobs and economic activity associated with industry R and D and manufacturing. A recent study by the Milken foundation examined four diseases and a limited number of technologies used to treat those diseases. It found significant increases in labor force participation and productivity directly attributable to the technologies' contribution to reducing the burden of illness. These increases in labor force participation and productivity, in turn, had expanded 2010 GDP by $106 billion.[19]

While the gains in health over the last thirty years have been impressive, and those of the last ten years even more striking, past progress pales compared to future opportunities. In this century of the life sciences, technological advances driven by fundamental advances in knowledge of human biology and continued progress in computing, communications, materials science, physics and engineering can be expected to fuel creation of new and better medical technology products—if there is a sound innovation ecosystem supporting not only continued scientific progress but the translation of scientific advances into better health

The innovation ecosystem under stres**s**

These gains in health and the associated economic benefits—as well as maintaining the U.S. technology industry's competitive edge—require a healthy innovation ecosystem that supports the key steps in the innovation process. Unfortunately, however, for the nation's medical technology industry, every part of the innovation ecosystem is under stress.

The danger signs include:

- Reduced investment. Venture capital flowing to the medical device sector is both an essential generator of future progress and an index of the attractiveness of investing in the development of new treatments and cures. Many of the true breakthrough therapies and diagnostics in the medical technology industry flow from venture funded start-ups. Venture investment in medical technology declined by one-third between 2007 and 2012.[20] It declined an additional 17 percent in 2013.[21] Even more ominous is the decline in investment for start-up companies at the earliest stage—the seed corn for the next generation of treatments and cures. First time funding for medical technology start-ups dropped by three-quarters between 2007 and 2012.[22]

- Movement of clinical trials and first product introduction out of the United States. For more complex products, the new normal is to conduct the first clinical trials and product introductions outside the U.S. Often, patients in other nations get the second or even third version of a novel treatment or diagnostic while patients in the U.S. are still waiting to get the first version. Among other factors, the decisions to introduce abroad first are driven by the higher cost and time involved in conducting clinical trials in the U.S.; delays and inconsistencies in FDA review; and, increasingly, uncertainties about coverage and payment.

- Increasing difficulty in achieving coverage by public and private insurers for new medical devices and diagnostics. The openness of the U.S. medical system to new treatments and diagnostics has been a major strength in stimulating U.S. leadership in development of new products and rapid patient access to improved care. Public and private insurers, however, are raising the evidentiary threshold for coverage. Over time, it has become increasingly difficult for new technologies to gain a favorable national coverage decision.[23] When coverage was granted, it was more limited than the FDA approved indications in 40 percent of the cases.[24] A survey of insurers reported that large proportions said that they had raised their requirements for coverage in the last three years and a larger proportion expected to raise requirements further over the next three years.[25] New payment methods such as ACOs and bundling and other provider risk-sharing programs spreading rapidly in both the public and private sector and can have the effect of penalizing providers who adopting new, more costly treatments, even if they represent therapeutic improvements.

Start-up companies are reporting that the one of first questions that investors now ask is often about the prospects for coverage and payment, while the previous focus was almost exclusively on the FDA.

The solution is not to move back from appropriate incentives to provide high value care or to suggest that products that do not offer therapeutic benefits should be covered; rather it is to make the public policy changes necessary to assure that the new emphasis on cost does not result in the unintended and unwanted consequence of undermining development and adoption of new and better treatments.

- Declining U.S. competitiveness. Other countries are anxious to wrest leadership from the U.S. in biomedical research and in the life sciences industries. The U.S. medical technology industry has been the unchallenged world leader for many years. We still lead, but our continued leadership is threatened. A study in 2011 by Price Waterhouse Coopers showed U.S. leadership on each of five pillars of medical device innovation to be eroding.[26] All the factors mentioned above contribute to this decline, but the noncompetitive U.S. tax system is unquestionably a key element driving medical technology R&D and manufacturing abroad. Medical technology companies pay an average effective federal tax rate of 31 percent on activities conducted and taxed in the U.S. versus 14 percent on activities conducted and taxed abroad.[27] The medical device excise tax raised the federal tax obligation of medical device companies by 29 percent.[28] The corporate income tax and the medical device excise tax, taken together, raise the effective tax rate on medical technology companies' U.S operations to 40 percent, surely one of the highest corporate tax burdens of any industry in the world.

AdvaMed recommendations for consideration by OSTP and NEC

Streamlined, seamless pathway for breakthrough products

Nothing would do more to stimulate investment in breakthrough products then the presence of a streamlined, seamless path to rapid FDA approval and Medicare/Medicaid coverage and payment. Uncertainties in both areas are a key component in the drying up of venture capital investment described above, and the certainty that a clinically successful and significant new product could count on prompt FDA approval and revenue flow from the public programs would play a transformational role in innovation.

Improvements at FDA

The user fee agreement and the accompanying bipartisan enacted in 2012 has set the FDA on an improved course, and the commitment from the leadership of the device center to make the U.S. the most attractive place in the world to introduce new products is heartening, as are recent improvements in FDA performance on such measures as increased clearance and approval rates and PMA review times. However, while performance in now better in some important respects than the nadir reached in 2010, it is still well below both the standards of the recent past and what is achievable.

Keys to further progress include:

- Continued implementation of the user fee agreement, with the goal of reaching and exceeding the MDUFA performance goals.

- Sustained focus on management improvement and reviewer training to achieve increased timeliness and consistency of review. Successful implementation of the recommendations of the independent management study mandated by the user fee agreement will be especially important.

- Continued development and expansion of the reciprocal inspection program to reduce cost of U.S. manufacturing, while maintaining rigorous standards.

- Improvement of procedures for evaluation and approval of combination devices. Devices that combine both device and drug elements to provide effective treatments are expected to become more common and more important. FDA’s current procedures result in inappropriately long reviews for these products and difficulty in coordinating the work of the FDA centers involved.

- Increased use of international consensus standards in product review. Certification to international standards is allowed for elements of PMA and 510(k) review, and can be the sole basis for approval of special 510(k) products. Expanded use of international consensus standards could speed review and expedite approval in both U.S, and international jurisdictions.

- In the diagnostic space:

  --Rapid implementation of a transitional approach to diagnostics approval, as specified in the user fee agreement. Diagnostics, especially molecular diagnostics, represent in many ways the future of medicine. They are key to personalized medicine. They assist in rapid and precise diagnosis, in targeting existing treatments, and in pointing the way to the development of new treatments. The transitional approach described in the user fee agreement is an important step toward speeding development and availability of these new medical tools.

  --Improvement in the CLIA Waiver by Application Process. CLIA waivers are needed to allow diagnostic tests at the bedside or in the doctor's office, rather than requiring that a specimen be drawn and sent to a laboratory. Sophisticated on-the-spot testing is increasingly technologically feasible. Rapid turnaround of test results can reduce costs and improve care—but to make such tests available, FDA needs to improve its process for waiving CLIA requirements.

<u>Reduce the time and expense of clinical trials</u>

- OSTP and NEC should consider initiatives to reduce the time and cost of clinical trials, Negotiating different requirements imposed by IRBs in different sites for multicenter trials and the process of contract negotiation between sites and developers have added very substantially to the cost and time associated with clinical trials. Reducing unnecessary preclinical trial data required by the FDA and improving the IDE process are also important.

<u>Payment and Coverage</u>

As noted above, increased difficulty in achieving insurance coverage by public and private payers and financial incentives that discourage providers from adopting new treatments are emerging as substantial impediments to investment in development of new treatments and to their diffusion once approved by the FDA. Ironically, even new treatments that potentially lower costs can be disadvantaged if the savings occur over a longer time period than the normal measurement period used by payers. And, of course, savings that accrue to individuals and society outside the health care system—through reduced disability, increase labor force participation, and reduced burdens on caregivers—are never factored into calculations of the cost versus the benefits of treatments.

AdvaMed recommends that OSTP consider a number of changes to the Medicare program. These changes would help support development of new treatment and cures without undercutting the bipartisan goal of reorienting the program to do more to reward reduced expenditure growth and higher quality.

- Automatic Medicare coverage of clinical trials approved or sponsored by FDA, NIH, or other government agencies. The current requirement that Medicare cover certain costs associated with clinical trials was never intended to be based on whether the information gathered would support Medicare coverage. Instead, it was intended to support the general research endeavor to develop new treatments and cures and to provide the opportunity for enrollees to participate in trials that might benefit them. Most trials are ultimately approved for coverage by Medicare, but the process for gaining approval can be time-consuming and costly. The new centralized approval requirement that Medicare is establishing could turn into an unnecessary bottleneck for launching trials. Separate Medicare review of the study design and protocol of a clinical trial should not be necessary if the trial has already been scrutinized to assure that it is scientifically sound and has appropriate protection for participants by specialized reviewers at the NIH, FDA, or another government agency.

- Establish a requirement that Medicare, in making national and local coverage decisions, should take into account patient views of what is "reasonable and necessary," just as FDA is implementing a requirement to take into account patient views of risk and benefit in making approval decisions. While CMS includes some patient representatives on the MedCAC advisory committee, this has not provided a systematic or adequate method of assessing patient views and giving them appropriate weight. The proposed requirement would help assure that coverage decisions take adequate account of the views and needs of Medicare beneficiaries.

- Establish a legislative mission statement for Medicare that includes promoting the development and adoption of better treatments and cures for Medicare beneficiaries, analogous to the addition to the FDA mission statement approved in 1997, providing for "advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable." While the President's executive order 13563 stated that "each agency shall also seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation," it is not clear that CMS sees promoting innovation in the development of new treatments as part of its mission, despite the very strong interest of elderly and disabled Americans in the most rapid medical progress possible and the equally strong impact, for good or for ill, that CMS's approach to coverage and payment determinations can have on the whole innovation ecosystem. In a more general sense, NEC and OSTP should consider whether the President's executive order could be made more effective in driving agency decision-making by requiring agencies to include an "innovation impact statement" with major rules.

- Assure adequate oversight of CMS' implementation of the historic diagnostics payment reform provisions in the recently-enacted Protecting Access to Medicare Act (H.R. 4302; Pub.L. 113–93) to ensure an effective transition to the new market-based diagnostics reimbursement system, adherence to new transparency requirements, and effective adoption of the new diagnostics coding requirements. Medicare should also promote expanded quality measures for use of diagnostics.

- Direct CMS to provide transparency in monitoring the quality of care provided under Medicare payment methodologies that involve provider risk-sharing to assure adequate mechanisms to protect patients' access to medically appropriate treatment. New payment methodologies such as Accountable Care Organizations and bundled payments are designed to create incentives for quality and cost reduction. At this point, however, the incentives for cost reduction are strong, while the measures of quality are relatively limited. There are many ways to reduce costs that do not involve stinting on care but there is also the possibility that the new incentives could lead to inappropriate shortcuts that reduce access to needed technology. If this occurs, it is not only a problem for individual patients but could reduce incentives for development of new treatments for the whole population. The Medicare program has made a commitment to monitoring the care received by beneficiaries to assure that stinting does not occur; the methods used in monitoring should be transparent so that gaps can be identified and addressed.

- Direct Medicare to provide transparency on the amount of payments received by individual providers under risk-sharing programs, as well as the methodology used by entities participating in such programs to establish reimbursement bonuses and penalties. Such transparency would be another important and appropriate tool to guard against stinting on care.

- Direct Medicare to establish a time limited reimbursement add-on or pass through for the additional cost of new technologies in ACO or similar programs if these new technologies offer the potential for significant clinical improvements and would add to costs during the payment period. The goal would be to assure that the incentives in the new systems are neutral and neither encourage nor discourage adoption of treatments that will improve the health of beneficiaries, so that providers can make the critical decision to be early adopters of new technology based solely on clinical considerations. The process would be analogous to the inpatient new technology add-on payment or the outpatient transitional pass-through payment that CMS now applies to hospital payments. Congress established these programs because it recognized that the DRG and outpatient payment system provided inappropriate disincentives for hospitals to adopt new technologies. The same disincentives exist in the new provider risk-sharing programs such as ACOs and bundled payments, and a similar remedy should be provided.

- Improved administration of the Coverage with Evidence Development (CED) program. The CED program was originally designed with the desirable goal of providing temporary coverage for promising therapies for which the existing evidence was inadequate to fully meet the reasonable and necessary criteria. In the industry view, CED has frequently been used, however, to inappropriately limit coverage for therapies. Regulation should stipulate that the purpose of CED is to expand coverage rather than limit coverage. In addition, CED study requirements have sometimes not provided clear endpoints for data collection or standards for determining when a therapy merits full coverage, and have added unnecessary burdens to the post-market requirements already imposed by FDA.

- Streamline the process for assigning billing codes to new technologies. Although receipt of a code is often a prerequisite to coverage and payment, it can take up to two years after FDA approves a new technology for a code to be provided—effectively depressing the timeliness of reimbursement and delaying patient access to new treatments and cures.

- Consider additional steps to encourage investment in development of new treatments and their prompt availability to patients under Medicare, including routine coverage for the full FDA labeled indications when coverage is granted, improving the new technology add-on payment program by establishing less limiting criteria and a payment adjustment closer to the full cost of the new treatment and using the most timely cost data for assignments of new technologies to DRGs.

Tax Policy

As noted above, American tax policy sets up powerful disincentives to locate medical technology R&D and manufacturing in the U.S. Moreover, tax policy can be an important tool for encouraging investment in small start-up companies which are such important engines of innovation but are currently suffering from a drought of investment capital.

To level the playing field between the U.S. and its foreign competitors, AdvaMed recommends:

- Repealing the medical device excise tax.
- Lowering the general corporate tax rate.
- Making the R&D tax credit permanent and more generous, so that it is comparable to the R&D incentives of competitor nations.
- Adopting an "innovation box" which provides further reductions in the corporate tax obligations for profits derived from developing intellectual property and from manufacturing utilizing that property. Competitor nations recognize the extraordinary value added that comes from the high tech sector and have created a variety of specialized tax incentives for high tech firms. The most straightforward and easiest to emulate would be to establish an "innovation box" regime. Such a regime should seek to lower the tax rate on these industries to an internationally competitive level.
- Reforming the U.S.'s system of taxing foreign profits earned by U.S. domiciled countries so that it is consistent with the practices of our major competitors.

To incentivize investment in small start-up companies with the most innovative products, AdvaMed recommends:

- Liberalize Section 469 R&D partnership structures to incentivize investors to finance companies at an earlier stage when capital is most needed. This provision is included in the Start-up Jobs and Innovation Act (S. 1658), introduced by Senators Menendez and Toomey in November 2013.

- Reform Section 382 Net Operating Loss carry forward to NOLs generated by qualifying research and development conducted by a small business from Section 382. Currently, the usage of NOLs by companies who have undergone an "ownership change" is restricted, effectively limiting the availability of NOL carry forwards for companies that receive successive waves of investor financing, as is typical of start-up medical technology companies. Such reform would help make such businesses more attractive to investors.

- Section 1202 capital gains reform to change the qualified small business (QSB) definition to include companies with gross assets up to $150 million (from $50 million), with that cap indexed to inflation. This change would also include S-Corps and LLCs in the definition of a QSB and would exclude the value of a company's IP when calculating gross assets. A similar provision is also included in the Start-up Jobs and Innovation Act (S. 1658), introduced by Senators Menendez and Toomey in November 2013.

- Permanent Extension of Sections 992-996 IC-DISC Status would assist small companies by continuing their eligibility for a 15% tax rate on income earned from export sales. This would encourage small companies to locate their R&D and manufacturing in the U.S. rather than overseas, as well as making them more attractive to investors.

Conclusion

AdvaMed appreciates the opportunity to present these recommendations to the Office of Science Technology Policy and the National Economic Council. As Americans, we understand that the economic future of our county will depend in no small measure on our continued leadership in the life sciences. And from a scientific viewpoint, we know that opportunities for rapid advances in the understanding of human biology and the development of life-changing diagnostics, treatments, and cures are breathtaking. But our ability to realize the goals implicit in these understandings depends on wise public policies.

Today, the innovation ecosystem is frayed and repair is needed. We are heartened by the continued interest of the OSTP and NEC in developing policies to make the needed changes.

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[3] Michaela Platzer, *Patient Capital: How Venture Capital Investment Drives Revolutionary Medical Innovation, 2007.* http://www.contentfirst.com/past/Patientcapital/NVCAPatientCapital.pdf

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[6] The Lewin Group, "State Economic Impact of the Medical Technology Industry," June 7, 2010 and February, 2007. http://www.socalbio.org/studies/MTI_Lewin_2010.pdf

[7] *Ibid*.

[8] National Center for Health Statistics. "Health, United States, 2012: With Special Feature on Emergency Care." Hyattsville, MD. 2013.

[9] National Center for Health Statistics. "Health, United States, 2012: With Special Feature on Emergency Care." Hyattsville, MD. 2013.

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S. Lovald, et al. "Downstream Costs and Health Outcomes for Hip Osteoarthritis Patients after Total Hip Arthroplasty." Data presented at the American Academy of Orthopaedic Surgeons 2013 Annual Meeting, Chicago. http://icjr.net/news_66_aaos_lovald.htm#.UZ2TeNJJM1I. Data also reported March 28, 2013, in Medscape Medical News (by Kathleen Louden) at http://www.medscape.com/viewarticle/781620

[19] Anusuya Chatterjee, Jaque King, Sindhu Kubendran, and Ross DeVol, *Health Savings: Medical Technology and the Burden of Disease,* July 2014.

[20] National Venture Capital Association, Patient Capital 3.0, April 2013.
[21] PWC and National Venture Capital Association, "Venture Capital Investments Q1. 2014—Money Tree Results," April, 18, 2014.
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[23] James D. Chambers, et al., "Factors Predicting Medicare National Coverage, An Empirical Analysis," *Medical Care*, March, 2012.
[24] James D. Chambers, et al., "Factors Predicting Medicare National Coverage: an Empirical Analysis," Medical Care, March 2012.
[25] The Analysis Group, unpublished study.
[26] PwC, "Medical Technology Innovation Scorecard: The Race for Global Leadership," January, 2011.
[27] Survey of AdvaMed member companies.
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Question 11 from "A Notice by the Science and Technology Policy Office and the National Economic Council on 07/29/2014":

Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

Response:

Program Directors at the Alfred P. Sloan Foundation, as individuals, share the Federal Government's concern about how best to promote the reproducibility of scientific results.

A philanthropic, not-for-profit grantmaking institution based in New York City, the Alfred P. Sloan Foundation makes grants primarily to support original research and broad-based education related to science, technology, economic performance and the quality of American life.

The Alfred P. Sloan Foundation believes that a carefully reasoned and systematic understanding of the forces of nature and society, when applied inventively and wisely, can lead to a better world for all. The Foundation makes grants to support original research and broad-based education related to science, technology, and economic performance; and to improve the quality of American life. Though founded in 1934 by Alfred P. Sloan Jr., then-President and CEO of General Motors, the Foundation is an independent entity and has no formal relationship with the General Motors Corporation.

The Foundation is unique in its focus on science, technology, and economic institutions. It believes the scholars and practitioners who work in these fields are chief drivers of the nation's health and prosperity. In each grant program, the Foundation seeks proposals for original projects led by outstanding individuals or teams.

The Alfred P. Sloan Foundation is interested in projects that it expects will result in a strong benefit to society, and for which funding from the private sector, the government, or other foundations is not widely available.

Accordingly, there are two major ways that the Sloan Foundation promotes reproducibility as a funder: 1) through our grantmaking processes; and 2) through our grantmaking priorities.

1. Grantmaking Processes

a. Applicants seeking Sloan support for empirical research are now required to submit a detailed appendix about their methodological plans. (See page 7 of the guidelines posted at www.sloan.org/apply.) Reproducibility can be enhanced in advance of collecting data, by rigor about statistical power and sample sizes, about selection and identification strategies, and about modeling and error specifications.

b. Applicants seeking Sloan support for empirical research are now also required to submit a detailed appendix about their plans for "information products." (See page 8 of the guidelines posted at www.sloan.org/apply.) Reproducibility can be enhanced in advance of collecting data by commitments to register and report on experimental designs, to open sharing of data and code as far as possible, and to proper annotating and archiving of results.

c. The Sloan Foundation works with other private philanthropic funders of scientific research to coordinate standards that promote reproducibility, to study the costs and benefits of reproducibility policies, and--through the Science Philanthropy Alliance, for example--to encourage more grantmaking in support of high quality and reproducible research.

2. Grantmaking Priorities

a. The Sloan Foundation has funded grants that support research and coding that set high standards for design, methodology, and openness. Examples of such grants include: to JPAL at MIT to launch a research network that promotes the rigorous empirical study of economic issues in North America through randomized controlled trials; and to Australian National University to improve teaching and research in quantitative economics through the development of compelling, open, and reproducible models; and to Johns Hopkins University to develop a hosted platform for managing and linking scientific data by combining and extending tools that were developed within the context of the Sloan Digital Sky Survey Archive and the Virtual Astronomical Observatory.

b. The Sloan Foundation has funded grants that support the development of tools that facilitate reproducible research. Examples of such grants include: to the Center for Open Science to help move the Open Science Framework (OSF) to version 1.0 and to foster the development of an open source/open science community; to NYU to support a workshop and requirements gathering meetings on software infrastructure for reproducibility in science UC Berkeley to develop open source R software and training to support various parts of the research process including data publication, data integration, and reproducibility.

c. The Sloan Foundation has funded grants that promote transparent and reproducible research practices. Examples of such grants include: to the American Economic Association to launch a study registry for randomized controlled trials in economics; to BITSS at UC Berkeley to investigate and promote transparency standards for social science research; and to Columbia to support a community forum to bring together stakeholders such as scientists, journal editors, funding agencies, to discuss the reproducibility in the computational sciences.

d. The Sloan Foundation has funded grants that promote data and code sharing. Examples of such grants include: to ICPSR at the University of Michigan to develop and promote data-sharing standards in the social sciences; to IQSS at Harvard to help social science journals process and publish the data associated with research articles; to BPEA at Brookings to demonstrate new ways an economics journal can help curate, visualize, and update the empirical data linked to its articles; to Columbia to further develop RunMyCode, a platform that links data and code for real-time reproduction of published studies; and to the Association of Research

Libraries to develop a proof of concept prototype for the SHared Access Research Ecosystem (SHARE) federated digital repository for the public access, text and data mining, and long term preservation of research articles and data produced by higher education.

e. The Sloan Foundation has funded grants that investigate how researchers can share access to private and proprietary data. Examples of such grants include: to CSAIL at MIT to organize and run a workshop on technical, practical, and research questions about big data privacy; and to Stanford to develop practical techniques for allowing researchers to extract aggregate statistics from large datasets while protecting the privacy of information contained in individual entries.

f. The Sloan Foundation has funded grants to prepare the next generation of data scientists. Examples of such grants include ones made jointly with the Gordon and Betty Moore Foundation to NYU, UC Berkeley, and the University of Washington to advance data-intensive scientific discovery through new methods, new tools, new partnerships, and new career paths.

AAUW
empowering women since 1881

September 23, 2014

John P. Holdren, Director
The White House Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave NW
Washington, DC 20504
Submitted via www.regulations.gov

Re: Comments on the Office of Science and Technology Policy's update of *Strategy for American Innovation*

Dear Dr. Holdren:

On behalf of the more than 170,000 members and supporters of the American Association of University Women (AAUW), I am pleased to share AAUW's comments on the Office of Science and Technology Policy's update of the *Strategy for American Innovation* report.[1] AAUW supports promoting and strengthening science, technology, engineering, and math (STEM) education, especially for girls and other underrepresented populations. These efforts will increase America's competitiveness by reducing barriers that deter women from pursuing academic and career goals in these fields.

AAUW commends OSTP for updating the *Strategy for American Innovation* report, and will comment on questions (2) and (12) listed in the *Federal Register* notice:

(2) What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?

> The biggest challenge facing American innovation is building and sustaining a gender-diverse workforce. This is also its biggest opportunity.
>
> Workforce projections for 2018 show that nine of the 10 fastest-growing occupations that require at least a bachelor's degree will require significant scientific or mathematical training.[2] STEM jobs are expected to grow by 17 percent from 2008 to 2018, while non-STEM jobs are expected to grow by 9.8 percent.[3] The supply of new workers in STEM fields is struggling to keep up with demand, and women remain severely underrepresented.
>
> Before Title IX, many opportunities to advance in STEM were denied to women, such as participation in some advanced courses and math and science clubs. Today, girls' participation in STEM courses has increased. However, to meet the needs of the 21st century global economy, we must increase girls' interest in STEM and encourage more women to pursue and maintain STEM careers. Title IX remains and excellent tool to help us meet these goals.

In 2009-2010, 57 percent of undergraduate degree recipients were women,[4] up from 42 percent in 1970.[5] Despite this incredible growth, women's underrepresentation in STEM continues at four-year colleges. In 2008, women earned 43.9 percent of bachelor's degrees in mathematics, 20.2 percent of physics degrees, 17.7 percent of computer science degrees, and 17.5 percent of engineering degrees.[6]

Although women and girls are interested in STEM, the "leaky pipeline" loses them along the way to careers in this field. We must address the stereotypes and climate issues that drive women away. AAUW delves into this issue in more detail below.

(12) What novel mechanisms or models might facilitate matching skilled STEM workers with employers and helping individuals identify what additional skills they may need to transition successfully into new roles?

We can improve the underrepresentation of women in STEM by addressing challenges that cause girls and women to step away from this path. AAUW has found that school climate plays a significant role in women's decisions to stay in STEM studies.[7] Stereotypes, gender bias, and the sometimes hostile climate of STEM classes and departments continue to block women's participation and progress.[8]

AAW recommends the following steps to address barriers that keep women and girls from pursuing STEM education and maintaining successful STEM careers:

1. Use Title IX to improve school climates for women and girls, especially as it relates to stereotypes and harassment. Title IX requires recipients of federal education funding to evaluate their current policies and practices, adopt and publish a policy against sex discrimination, and implement grievance procedures providing for prompt and equitable resolution of student and employee discrimination complaints. Title IX could be a powerful tool to protect the rights of women and girls as they pursue their education.

2. Emphasize STEM skills for all students in early education, K-12, and higher education; with special attention to the needs of other girls and other unrepresented populations.

3. Cultivate girls' achievement by exposing them to female role models in STEM and encouraging high school girls to take calculus, physics, chemistry, computer science, and engineering classes.

4. Revise teacher training techniques to recognize and minimize implicit gender bias.

5. Support teacher training to include awareness of stereotype threat. This represents the threat of being viewed through the lens of a negative stereotype or the fear of doing something that would confirm that stereotype.[9] For example, when a student is told that she isn't supposed to be good at math, she underperforms on math tests, often unconsciously.

6. Promote education techniques to improve spatial skills.

7. Train teachers on ways to promote a growth mindset in students. As AAUW's 2010 *Why So Few? Women in Science, Technology, Engineering, and Mathematics* explained:

   > Women who reported that their classrooms communicated a fixed mindset where negative stereotypes were widespread showed an eroding sense that they belonged in math during the semester, and they were less likely to express a desire to take math in the future. Women who said that their classrooms promoted a growth mindset were less susceptible to the negative effects of stereotypes, and they were more likely to intend to continue to take math in the future. At the beginning of the semester, no difference was seen in interest, excitement, sense of belonging, or intention to continue in math, but by the end of the study, girls who were continually exposed to the fixed-mindset message along with the stereotype that girls don't do well in math lost interest. *A growth-mindset environment can help cultivate and maintain girls' interest in STEM fields*.[10]

8. Measure student achievement in STEM, including disaggregating and cross tabulating by gender.

9. Recruit more women into nontraditional fields and STEM fields. AAUW's 2010 *Why So Few* report found that "College and university administrators can recruit and retain more women by implementing mentoring programs and effective work-life policies for all faculty members."[11]

10. Ensure that institutional practices such as academic and career pathway advising do not reinforce gender stereotypes or promote discrimination of women.

11. Develop educational and career advising pathways to help students navigate STEM requirements for various majors and to advance in STEM fields.

12. Use creative instructional approaches, like learning communities, to support students. A learning community is designed to foster peer support and subject-matter engagement. In this approach, a designated group of students take their math and science courses together in a cluster, which facilitates relationships among students and with faculty. This approach has been shown to improve student performance, especially in the first year of college.[12]

13. Partner with local employers to connect students to available internship, mentoring, and career opportunities.

14. Engage students in reviewing transfer requirements early and often in their college career. This will particularly benefit women, who are more likely than their male counterparts to attend community college at some point on the path to a STEM bachelor degree.[13] Women who may not have taken or had access to advanced courses in math and science in high school can take those courses in community college at low cost.

15. Develop and implement transfer policies that link community colleges and four-year institutions in each state.

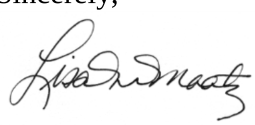
16. Child care
    a. Increase the availability of on-campus child care to support student parents.
    b. Develop a referral system with local child care providers.
    c. Assign staff to work with student parents to promote student retention and success.
    d. Support student parent groups.

17. Strengthen the gender equity provisions of the Carl D. Perkins Vocational and Technical Education Act. The Act is the federal law that funds career and technical education programs at secondary and postsecondary institutions across the country. The 2006 law, known as Perkins IV, contains gender equity provisions intended to increase the number of women in nontraditional careers. The provisions require federally funded state and local institutions to promote gender equity and hold them accountable for students' participation and completion rates in programs nontraditional for their gender. Schools that do not meet preset performance goals must implement improvement plans or face sanctions or loss of funding. The law's gender equity provisions signal that career and technical training is critical to ensuring women's access to the education and career preparation they need to be competitive in the global economy. The Perkins Act is due for reauthorization, and AAUW supports continuing the accountability measures for student success in nontraditional fields as Perkins V is developed.

Although women fill close to half of all jobs in the U.S. economy, they hold less than 25 percent of STEM jobs.[14] If women and members of other underrepresented groups joined the STEM workforce in proportion to their representation in the overall labor force, the STEM worker shortage would disappear.[15] Innovation and economic growth would result and benefit all of us.

Thank you for the opportunity to submit comments on this important issue. I look forward to working with you to increase women and girls' engagement in STEM. If you have any questions, please feel free to contact me at [redacted] or Beth Scott, regulatory affairs manager, at [redacted]

Sincerely,



Lisa M. Maatz
Vice President of Government Relations

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Pursuing Justice

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September 23, 2014

Via Electronic Mail: innovationstrategy@ostp.gov

Mr. Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building,
1650 Pennsylvania Ave N.W.
Washington, D.C. 20504

Re: Comments Regarding Strategy for American Innovation

Dear Mr. Correa:

I am writing on behalf of the American Bar Association Section of Intellectual Property Law (the "Section") to provide comments regarding the development of an updated *Strategy for American Innovation*. These comments have not been approved by the American Bar Association's House of Delegates or Board of Governors and should not be considered to be views of the American Bar Association.

The Section appreciates the opportunity to comment on the Administration's policy initiatives, and strongly supports the Administration's efforts to promote lasting economic growth and competitiveness through policies that support transformative American innovation. Accordingly, the Section provides the following comments on questions 2, and 21-23.

(2) What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?

A. Support for Pro Bono Legal Services for Small Businesses

The Section supports the continuation and expansion of programs to reach out to the small inventor community, including the America Invents Act Pro Bono Advisory Council[1]. This should include consideration of providing federally-sponsored malpractice insurance to attorneys without their own coverage who want to participate in providing pro bono services. A study directed to the appropriateness of the current pro bono income requirements and a determination as to whether raising of the threshold annual income is warranted.

Support for this recommendation is based upon the following research. In 2011, there were 28.2 million small businesses, and 17,700 firms with 500 employees or more. In particular, small businesses make up:

99.7 percent of U.S. employer firms;
63 percent of net new private-sector jobs;
48.5 percent of private-sector employment;
42 percent of private-sector payroll;
46 percent of private-sector output;
37 percent of high-tech employment;
98 percent of firms exporting goods; and
33 percent of exporting value.[2]

Of high patenting firms (15 or more patents in a four-year period), small businesses produced 16 times more patents per employee than large patenting firms.[3] Research also shows that increasing the number of employees correlates with increased innovation while increasing sales does not.[4] While the number of new employer businesses has recovered from the recessionary dip, the average employment of these businesses has been declining over the past decade.[5]

A state's stock of patents proxies for the state's ability to innovate new products and production techniques that could give it an economic edge and lead to higher relative per capita personal

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[1] By an executive decision led by Robert O. Lindefjeld, Immediate Past Chair of the Section, and approved by the ABA Board of Governors, the Section participated in the signing of a Charter founding the America Invents Act Pro Bono Advisory Council in the Chambers of Randall R. Rader, Chief Judge of the Court of Appeals for the Federal Circuit, on October 25, 2013.
[2] http://www.sba.gov/sites/default/files/FAQ_March_2014_0.pdf
[3] *Id.*
[4] *Id.*
[5] *Id.*

incomes.[6] A state with a larger stock of patents is presumed to be more innovative in creating new products and production techniques.[7]

Congress has noticed the disparity of patent-protection accessibility between large and small companies.[8] In particular, Section 32 of the America Invents Act encourages the USPTO to "work with and support intellectual property law associations across the country in the establishment of pro bono programs designed to assist financially under-resourced independent inventors and small businesses."[9] Accordingly, the USPTO has implemented patent pro bono programs in twenty states.[10] However, acceptance into a regional pro bono program requires each potential pro bono client to be screened for certain criteria.

Accordingly, the Section recommends that the Administration consider providing federally-sponsored malpractice insurance to attorneys without their own coverage who want to participate in providing pro bono services, and conducting a study directed to the appropriateness of the current pro bono income requirements and a determination as to whether raising of the threshold annual income is warranted.

B. Maintain Integrity of Confidential Business Information During Regulatory Proceedings

The growing fluidity and interconnectedness of domestic and global electronic information networks can allow state, federal, and international regulatory bodies to obtain, and, where legally authorized, share, confidential business information provided by regulated entities in support of environmental, energy, health, safety, and financial regulatory efforts. The Section recommends that the updated strategy also reinforce the need for continued diligence by regulatory agencies to establish, maintain, and update programs to protect confidential business information submitted during regulatory proceedings from improper appropriation or disclosure and in this way avoid a business threat that could discourage or undermine market innovation.

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[6] http://www.clevelandfed.org/research/Workpaper/2006/wp0606.pdf

[7] *Id.*

[8] United States House of Representatives, Committee on the Judiciary, Committee Report, America Invents Act, H.R. Rep. No. 112-98 pt. 1, p.56 (2011) ("The Committee acknowledges the importance of individuals and small businesses to the patent system and our national culture of innovation. Consistent with this sentiment, the Act requires the USPTO Director to support intellectual property law associations across the United States to establish pro bono programs to assist under-resourced independent inventors and businesses.").

[9] *See* USPTO, *Pro Bono*, http://www.uspto.gov/inventors/proseprobono/, (Last Modified: 5/16/2014 1:19:57 PM); USPTO, *Legal Assistance Programs for Independent Inventors*, http://www.uspto.gov/inventors/proseprobono/ProBono_Transcript.docx, (Last Modified: 5/16/2014 1:19:57 PM) ("After the America Invents Act passed in 2011, the USPTO began working with intellectual property law associations across the country to help them establish pro bono inventor assistance programs in their specific regions.")

[10] *Id.*

Question 21: What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation (including, e.g., through the growing use of open innovation, combinatorial innovation, user innovation, internet-enabled innovation, and big data-driven innovation)?

A. Patent Office Funding

The Section recommends the enactment of legislation that permanently provides that all fees collected from patent operations shall be available to fund those operations without any diversions. Such legislation should provide that any Congressional oversight of the USPTO budget should not involve any escrowing of such fund to match any across the board budget cuts and manpower ceilings imposed on the general operations of federal government.

B. Eligibility of Software-Implemented Inventions

The Section is concerned with the fact that the Patent Office is assessing whether many software-implemented inventions are patent-eligible or patent-ineligible without any significant analysis. The Supreme Court of the United States recently rendered a fact-specific decision deeming claims directed to the abstract idea of "intermediated settlement" to be patent-ineligible. *Alice Corporation Ply. Ltd. v. CLS Bank Intl., et al.* The *Alice* decision was not meant to conclude that all software-implemented inventions are patent-ineligible, yet the Patent Office appears to be applying the decision broadly to many software and even machine-implemented inventions.

Although *Alice* provides several examples where a claim was directed to an "abstract idea," the decision did not outline a concrete test for identifying an "abstract idea." In this regard, *Alice* is limited in scope. The Section recognize that the absence of a clear-cut test will present difficulties for the Patent Examining Corps as they attempt to identify whether a claim is directed to an "abstract idea." Nevertheless, *Alice* is not without bounds, and does provide some important guidance. In finding that the concept of intermediated settlement is an abstract idea, the Court relied on the existing evidence in determining that intermediated settlement is "a fundamental economic practice long prevalent in our system of commerce." *Alice*, slip op. at 9. Further, it is well established that findings of fact made by the Office must be supported by substantial evidence. *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000).

Accordingly, to the extent that an examiner determines that a claim is directed to an abstract idea that is a "fundamental economic practice," an "idea itself," or a "mathematical relationship/formula," the examiner must support such a finding with existing evidence that is supported by a clear showing on the record. As such, the Section cautions the Office to instruct Examiners to avoid simply stating that a claim is directed to a "fundamental economic principle," an "idea itself," or a "mathematical relationship/formula" and is therefore directed to an abstract idea, without also providing examples, supported by substantial evidence, demonstrating that the claimed subject matter is indeed "[a] principle, in the abstract, [ ] a fundamental truth; an original cause; a motive….” *See Alice*, slip op. at 9 quoting *Le Roy v. Tatham*, 14 How. 156, 175 (1853).

After determining whether a claim is directed to an abstract idea, *Alice* provide a second step to determine whether a claim is directed to something “significantly more” than an abstract idea itself to be a patent-eligible invention. *Alice,* slip op. at 6. *Alice* went into detail with respect to the second step, and used the example of “a computerized method for using a mathematical formula to adjust alarm limits for certain operating conditions” in *Parker v. Flook*, 437 U. S. 584 (1978), as not being patent-eligible, whereas the use of “a ‘thermocouple’ to record constant temperature measurements inside the rubber mold” in combination with a computer algorithm in *Diamond v. Diehr,* 450 U. S. 175 (1981); did satisfy Part 2. *Alice,* slip op. at 8, 12-13.

The Section is working with the Patent Office to ensure that examiners clearly understand the boundaries of *Alice,* such that the decision does not swallow all of patent law. Slip. op. at 6. Software-implemented patents are critical to American innovation, as small start-up companies and large companies alike rely on the patent system to obtain investment and recoup research expenses. The Section further recognizes the public perception that the patent system is a drag on innovation, but this is largely due to misunderstandings of the prevalence of litigation, how to read a patent, and the unfortunate term “patent troll.” Patent litigation will always increase during periods of significant innovation such as now. The Section will continue to educate the public on these issues, and would appreciate the administration’s continued support of the patent system by increasing patent clarity, but also would like the administration to make clear that software patents promote innovation and are therefore patent-eligible as they “promote the Progress of Science and useful Arts.” U.S. Const. Article I, Section 8, Clause 8.

C. Additional Suggestions

The Section recommends the creation and maintenance of a function within the USPTO to continually monitor the operation of patent and trademark operations in other countries and by international agencies for concepts that could improve operations of the USPTO.

The Section recommends that selection of judges to serve on the Court of Appeals for the Federal Circuit such that at least some members have practical experience in patent law.

The Section is in favor of the expansion of a federal program to assign patent litigation to U.S. district court judges with a particular interest in handling such litigation.

The Section recommends a careful review of the information made available to the public and particularly small businesses on their rights and obligations with regard to the U.S. patent system. It is suggested that this include a fair and balanced review of the “Patent Litigation Online Toolkit” currently on the USPTO website, and consideration of enhancing the information made available on the litigation of specific patents currently made available by the

USPTO in the PAIR system, perhaps to providing a searchable database of patents in litigation and the status of the litigation.

The Section recommends conducting a study of whether to recommend to the states that they amend their UCC laws to make the warranty of non-infringement provided by Uniform Commercial Code Section 2-312(3) non-waivable or to at least require that any waiver be as explicit as the waivers of merchantability and fitness for a particular purpose and to explicitly expand the warranty to the expected normal and customary use of goods sold by a merchant. It is believed that there is an important public policy question as to whether merchants and manufacturers should be able to put goods they designed into the stream of commerce and yet escape any responsibility for defending their customers from charges of patent infringement for using those goods in the manner the merchants contemplated or even instructed.

The Section recommends the creation of a certification program through a government body for technical advisors that can be made available to the U.S. district courts for the handling of patent litigation.

(22) What are specific areas where a greater capacity for experimentation in law, policy, and regulation at the Federal level is likely to have large benefits? Are there useful models of experimental platforms in the public or private sectors that the Federal Government can adopt? How might the Federal Government encourage state and local experimentation?

One of the challenges faced by the Federal Government is the lack of flexibility it has with respect to issues that are fundamental to the private sector. As such, changes which not only encourage but mandate flexibility typically will provide the greatest benefit. Currently, the Federal Government is at a crossroads for its procurements whereby there is a decrease in competition matched by an increase in regulations. In order to overcome these issues, the Federal Government needs to increase the use of innovative acquisition mechanisms which provide more options to increase industry participation in Federal research and development options, and especially to tap into the commercial research and development efforts. Therefore, the Federal Government should use tools which are more compatible with such efforts, including greater emphasis on commercial item acquisitions under FAR Part 12 as well as using underutilized agreements such as Other Transaction Authorities, such as 10 USC 2371 for Department of Defense. In short, and as similarly noted by the Defense Business Board in its briefing entitled "Innovation Attracting and Retaining the Best of the Private Sector", the Federal Government already has most of the tools it needs to increase industry participation in Federal Government procurements and research activities, but it needs to experiment more in ensuring that these tools are used.

Examples of successful efforts, both ARPA-E and DARPA both use non-FAR based agreements to obtain wider industry participation. Both are highly successful based largely in part to this usage of non-traditional procurement mechanisms for obtaining industry participation, including use of Other Transactions (or its related form of a Technology Investment Agreement). However, these models have not translated into procurement commands, who conduct large research and development projects while trying to use agreements which are incompatible with private industry (i.e., using FAR Part 15 acquisitions). The Under Secretary of Defense for Acquisition, Technology, and Logistics has attempted to use the limited flexibility allowed under FAR Part 15 regulations to obtain greater industry participation using Open Systems concepts, but such efforts are likely to fail so long as the fundamental acquisition model is adverse to private industry expectations. By combining the Open Systems concepts with commercial items simplicity and non-traditional agreements already used by ARPA-E and DARPA, there is a greater likelihood of obtaining maximum participation by the private sector to stimulate technology transfer with minimal changes in existing law.

(23) Beyond current Federal efforts to promote open data and open application programming interfaces (APIs), what other opportunities exist to open up access to Federal assets (such as data, tools, equipment, facilities, and intellectual property from Federally-funded research) in order to spark private sector innovation?

While the efforts to open up data exist, the problem faced by private industry is the vast majority of it remains restricted. For reasons ranging from export regulations to restricted licenses, the existing data sets available to the public through such portals as data.gov or through Defense Technical Information Center (DTIC) are only those which are both cleared for export and are unlimited rights data. Moreover, the portals themselves lack the user-friendly interfaces which would allow a researcher to simply, and easily, access the appropriate data in the same manner a purchaser can find the same data using online stores such as Amazon® or iTunes®. Such a search interface should have clear and simple mechanisms for obtaining such data. These interfaces are currently lacking.

Further, Cooperative Research and Development Agreements (CRADAs) under 15 USC 3710a are a popular way to access Federal research, personnel, and facilities. Of particular benefit to private industry are IP protections which are unusual and encourage the use of Federal research. However, 15 USC 3710a has a limitation which is harmful to such cooperation in that it only will protect results from the CRADA research and development activities for five (5) years after development. Such a limitation is too short for certain industries to successfully commercialize the results of such CRADA research, which therefore works as a disincentive to commercializing Federal Government research and development using a CRADA. As such, in order to provide maximum flexibility to the Federal Laboratories to work with the largest number of private sector entities, 15 USC 3710a should be changed to allow the Federal Laboratory to extend this 5 year data protection to a time frame which more closely matches the commercialization expectation of the private party to the CRADA, and to confirm that such research results would not be used in competition with the private party during this timeframe.

In conclusion, the Section of Intellectual Property Law appreciates the opportunity to provide these comments to the Office of Science and Technology Policy. If you have any questions on the above comments please feel free to contact us.

Very truly yours,

Lisa A. Dunner
Section Chair
American Bar Association
Section of Intellectual Property Law

American Chemical Society

In response to the OSTP request for ideas and feedback related to what a future Strategy for American Innovation should include, the American Chemical Society solicited input from ACS members. Below is a summary of the suggestions received.

(1)What specific policies or initiatives should the Administration consider prioritizing in the next version of the *Strategy for American Innovation*?

Development and Support of a World-Class Workforce

- Update education, training, workforce and immigration policies to ensure that the United States has the highly educated and innovative workforce necessary to grow the economy as well as support American enterprises and jobs.
  - Strengthen effective STEM education programs at all levels: K-12, undergraduate, graduate, and continuing education.
  - Recruit and retain highly skilled STEM teachers, improving the content knowledge skills of the K-12 STEM teacher workforce, and improving the resources available in STEM classrooms.
  - Encourage more of the best and brightest students, including those from under-represented or disadvantaged groups, to study and work in STEM fields.
  - Enable lifelong inquiry-based science education for everyone, in both formal and informal settings, to improve the scientific literacy of all U.S. citizens.
  - Enhance training opportunities, retirement security, and professional mobility for STEM professionals.

Predictable and Sustained Commitments to Research and Technology Development

- Strengthen and sustain federal investments for all phases of R&D, including R&D infrastructure, to develop the foundations for innovation and to address immediate and future economic and national security needs.
- Expand the university R&D infrastructure and interactions with industry in order to increase technology transfer and commercialization of breakthroughs.
- Promote a strong, scientific publishing enterprise that enables open exchange of scientific ideas with appropriate access, peer review, management, searchability, and information archiving.

Development of a Sustainable Infrastructure for Innovation and Entrepreneurship

- Minimize the impact of a shifting, global, job environment by reducing economic and regulatory barriers to the development of new technologies and the manufacture of related products in the United States.
  - Foster U.S. corporate tax and trade policies that will make U.S. firms competitive with our international rivals.
  - Provide incentives to encourage capital investments and entrepreneurship activities from domestic and international citizens.
  - Foster improvements in the U.S. and international systems for patent protection and voluntary consensus standards.
  - Foster the development and adoption of economically, environmentally, and socially sustainable products and processes.

(2) What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?

The world is now a much more competitive place than it was even 10 years ago. Only two of the top 10 chemical companies with the highest R&D investments are U.S.-based companies. And yet, the nation's chemical industry is a $812 billion enterprise that touches 96 percent of U.S.-manufactured products and generates nearly 17 percent of all U.S. patents.. Deloitte anticipates that, even in a “worst-case” economic scenario for the coming decade, “the demand for innovative uses for chemicals and chemical-based products will remain strong.”

The scientific and technological innovation that underpins our economic competitiveness results from sustained investments in scientific research and in a strong educational system. Yet, the United States ranks 10th in the OECD in the fraction of our economic activity (GDP) that we invest in the science and technology that underpin a more prosperous future.

To complement this technological advancement, our nation’s business laws, tax code, trade policies, and regulatory environment should work together to assure that the products of U.S. science and technology companies can be introduced to the international marketplace competitively and without facing inappropriate barriers. The United States should be the most welcoming place to start, maintain, or expand science- and technology-based activities. Specific policy choices to improve our business climate include

Tax and Trade – ACS supports efforts to foster U.S. corporate tax and trade policies that will make American firms competitive with our international rivals by

- Making the Research and Experimentation tax credit permanent and accessible to start-up businesses by making them refundable or transferable.
- Encouraging more states to provide tax credits for research and experimentation or investment in technology startups.
- Maintaining taxation of carried interest at the capital gains level for long-term, venture and angel capital invested in high-risk startup companies.
- Providing tax incentives to spur U.S. science and technology investment and job creation.
- Assisting displaced science and technology workers with retraining and job searching.
- Reducing the incentives to locate businesses or jobs outside the United States to avoid taxation.
- Advocating a more flexible international trade framework to better balance security considerations with the partnerships that advance science and technology development.

Intellectual Property – ACS supports reforms to the U.S. patent and intellectual property framework that will promote, not impede, innovation by

- Staffing the U.S. Patent and Trademark Office (PTO) to expedite the evaluation of patent applications and thereby reduce the patent backlog.
- Allowing the PTO to apply all fees directly to a more efficient patent review process.
- Strengthening intellectual property protection in trade policy to reduce instances of foreign violation of American copyright and patent holdings.

Technology Transfer and Commercialization – ACS supports policies to improve technology transfer and commercialization of breakthroughs spurred by federal research investments by

- Expanding university research infrastructure and developing communities of innovation centered on academic research environments and national laboratories.
- Providing grants, low-interest loans, and accelerated depreciation tax incentives to mitigate the high start-up or retooling costs associated with high technology businesses.
- Expanding federal programs that provide targeted support for commercialization activities at science research agencies.

Small Business and Entrepreneurship – ACS supports policies that foster the growth of small research and development businesses and encourage entrepreneurship by

- Expanding funding for the Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR), Small Business Investment Companies (SBIC), and Small Business Administration microloan programs and reforming these programs to make direct research funding for small businesses more readily available.
- Providing incentives for larger companies to expand investments in start-up research and development businesses.

(5) What innovation practices and policies have other countries adopted that deserve further consideration in the United States? What innovation practices and policies have been adopted at the state or local level that should be piloted by the Federal Government?

Germany and Canada have well-established biomonitoring programs, and several U.S. states have initiated them as well. The ACS also suggests looking into the process chemistry training at the university level in Switzerland, as well as the trade schools in the United Kingdom. Further review of global Master's degree programs and global academic funding models would also be beneficial.

(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

The Federal Government should cautiously observe and verify the extent of this problem prior to taking administrative or legislative action that will potentially damage the open, interactive scientific process. The response to these incidents is best left with the agencies and partner institutions best positioned to develop best practices. For instance, scientific societies and higher education organizations can work with research agencies to help identify ways to change laboratory culture in order to improve data reliability.

(12) What novel mechanisms or models might facilitate matching skilled STEM workers with employers and helping individuals identify what additional skills they may need to transition successfully to new roles?

An "in-person" or virtual job clearinghouse designed specifically for technical/professional positions could be used to match employer requirements with employee skills. These clearinghouses could be managed by the science and engineering societies with specific industrial involvement. Industrial placements on a rotating basis for mature PhD-level scientists to fill short-term technology needs could also be managed through the clearinghouses. Data mining of unfilled employment opportunities from these centralized sources could facilitate better targeting of both educational and (re)training programs. Funding sources could include government grant or non-profit organization donations.

(13 and 14) What emerging areas of skills are needed in order to keep pace with emerging innovations or technologies? What are successful models for training workers with these skills to keep up with emerging innovations? What mechanisms or programs can effectively increase the supply of workers with technical training, from industry-recognized credentials and postsecondary certificates to two- and four-year degrees?

In the current economic environment, employers cannot or do not want to train a new employee for a specific task. They desire a candidate that meets their specific requirements at a certain price point.

The government could incentivize employers, through policy, to do in-house training or establish internships. For example, employees could commit to work for the company for minimum period of time following the training program to enable companies to recoup their investment in the employee

Skill voids could also be filled by additional cooperation between academia and industry. If specific new skills are required for technician level jobs, industry partnering with two-to-four-year colleges may be most effective. The government can foster this through grants for innovative programs and the dissemination of information about these programs so that they can be used as models for others.

Another suggestion would be industry-accredited training "modules" that would prepare either undergraduates or graduate students for employment in specific industrial roles. Whereas in the past, these skills could be obtained "on the job," now potential employers can select those candidates who already have that skill-set. The demand for technical training could vary with geographic location and may best be addressed regionally.

Some examples might include process chemistry (the University of Zürich already does this as additional training), preparation and application of organic semiconductors to OLED, sensors and OPV, environmental analysis, high-throughput screening, etc. You could get a better idea of what such modules might contain by looking through requirements listed in the current job postings. This kind of skills targeting would give the graduate student a better chance on the job market, which would increase student interest in STEM careers.

Another option would be to institute industry-sponsored trade schools, like they used to have in the UK.

(15) What new or existing investment models should be explored to support entrepreneurship in new geographies, as well as in technologies and sectors that are capital-intensive, relatively high-risk, and require sustained investment over long periods of time?

Flexibility in government funding could address different business sectors and companies at different stages. Currently, there are very limited investors funding capital-intensive companies that are pre-revenue. SBIR/STTR funding does serve as a mechanism to infuse a limited amount of cash into these small companies, but companies that are commercializing products that need governmental approval are in desperate need to get sustainable funding. Each sector has a variable amount of time before a company is able to generate revenue. Thus a funding agency that had knowledgeable investors of each sector would be in the best position to vet these early stage needs. The funding agencies may need incentivized programs to help the companies find partners that can assist in the establishment of infrastructure so the company could offer the whole product concept to its customers at an earlier stage.

(16) For new technologies and products, how might “proof of manufacturability” be gauged sooner, and what entities would most appropriately provide the necessary resources and facilities? What sectors represent the most promising opportunities for the application of such models?

The 2015 *Strategy for American Innovation's* policy initiative to “invest in the building blocks of American Innovation” should first and foremost improve the K-12 education system. Breakthroughs will not occur in any areas without a solid investment in the early education of our future workforce.

We would then like to see the U.S. government fund centers of excellence in the areas of national importance in both universities and the private sector. This would drive the levels of expertise much more quickly and generate industrial growth at the same time. Allowing the centers of excellence to apply their superior knowledge within tightly focused areas would give them the ability to gauge the manufacturability of new products and technology, especially if industry is working closely with academia and magnifying the knowledge across both.

The government has set the long-term goals and now businesses working with universities can begin to coordinate the building blocks in an open source method to achieve those goals. Multiple groups working on individual areas of the same goal can assemble a functional solution in a relatively short time. This has been proven with drug research, and the results were amazing. The OSTP could coordinate the research and match the appropriate entities, then fund the solution by increasing SBIR/STTR and related grants. All of this would contribute to the industrial commons now and in the future.

(17 and 18) What tools, business model innovations, financial innovations, or other developments hold promise for reducing the cost of starting and scaling a business in capital intensive sectors like the life sciences, advanced materials, and clean energy? What can the Federal Government do to accelerate these trends? What investments, strategies, or technological advancements,

across both the public and private sectors, are needed to rebuild the U.S. “industrial commons” and ensure the latest technologies can be produced here?

The I-Corps™ program has been extremely successful in vetting business models. The ability to locate an early evangelist is extremely important so the company can capture a market by offering a whole product, since most capital intensive start-up companies cannot afford to build all of the product features it needs to be acceptable to the majority customer markets. The government could help by incentivizing companies that currently have the equipment and testing capabilities for product approval and help in the addition of product features. A funding agency with sector experts would be best to distribute this incentive package.

(24) Which new areas should be identified as “national priorities,” either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?

Key factors affecting chemical manufacturers that enable advancement of micro-and nano-electronic technologies include

- raw material supply chain.
- intellectual property considerations.
- technological challenges.
- highly skilled workforce.

Raw material supply chain
Small differences in the raw materials can have a great impact on the quality of desired final product. As the supply chain involving ultra-pure chemicals for electronic industry is highly globalized, effective supply-chain management is crucial. “Some best-in-class companies have already achieved 5-6% cost reduction by employing effective supply-chain management solutions.” [D. Huang, IEEE Trans. On Semiconductor Manufacturing, 2009]

Intellectual property (IP) considerations, advocating U.S.-based manufacturing
The manufacturing process is complex and involves a great deal of research and development; thus, manufacturing is knowledge-intensive and IP-sensitive. Any set of parameters or processes that significantly improves our manufacturing capabilities is our nation’s intellectual property. Problematically, details related to manufacturing that represent our IP can be potentially revealed to other countries (in cases of overseas manufacturing). The “first-to-invent” system has amped up the already vigorous IP race to an even more aggressive one. This situation makes setting business strategy even more tenuous than it already is in a fast-paced, high-tech industry, as chemical manufacturers are forced to make a decision regarding whether or not to direct valuable, significant resources toward patenting a technology before it knows if the project could garner seed support. One specific recommendation to help correct this problem is to lower the effective corporate tax rates for our manufacturers. Evidence from the report by the Information Technology and Innovation Foundation shows that the United States ranks 35 when corporate tax rates were used as an indicator to benchmark U.S. innovation and competitiveness against EU countries. The top five countries giving 9-16 percent effective corporate tax rates are Latvia (9 percent), Hungary, Slovakia, Chile, and Singapore (16 percent). [ITIF, European-American business council, Atlantic Century II, July 2011]

Technological challenges
To advance next generation semiconductor electronic technologies, it is urgent that our nation leads in technologies such as e-beam lithography, extreme UV lithography and other alternative techniques such

as directed self-assembly to address limitations of Moore's law. Government investment in R&D and production of highly skilled workforce would rapidly solve these technological challenges.

Highly skilled workforce
Automation is taking over human-interfaced systems. More than ever, retaining a skilled force is crucial as a highly skilled workforce is the backbone of our nation's economic growth. As per the "Science and Engineering Indicators 2014" report by the NSF, Science and Engineering (S&E) degrees, important for an innovative knowledge economy, are more prevalent in some countries than others. Globally, the number of first university degrees in S&E reached about 5.5 million in 2010. Almost a quarter of those degrees were conferred in China (24 percent), 17 percent in the EU, and 10 percent in the U.S. Differences in engineering are especially large: whereas 5 percent of all bachelor's degrees awarded in the U.S. were in engineering, 31 percent of such degrees in China were in this field.

Additional information relevant to the goal of promoting innovation in the United States:
Passion for research, education, and innovation are core values of the ACS and our original national charter calls for the increase and diffusion of chemical knowledge to foster public welfare and education, aid the development of our country's industries, and add to the material prosperity and happiness of our people. For this reason, as well as our deep roots in the scholarly community, we share the interest of the federal government in maximizing the dissemination and discoverability of knowledge. We support universal access to the results of scientific research via publishing models and federal policies that are economically sustainable and that ensure the integrity and permanence of the scholarly record upon which scientific progress is based. Sustainable access to the authoritative scientific record as embodied in peer-reviewed journal articles is essential to basic research innovation and ensuring that the United States remains a competitive global economic leader.

We believe that it is in the public interest to foster this economically beneficial publishing activity and invest heavily in staff and technology resources required to be successful. We recommend dialog and collaboration to craft viable federal policies and develop public-private partnerships that respect our fundamental intellectual property rights in these articles, as well as allow us to recover the significant investments we have made in their development and dissemination to promote a sustainable scholarly communication enterprise that supports innovation and the creation of new jobs and industries that can arise from scientific advances. Strong intellectual property protections underpin sustained investment in innovation, and federal policy must take as its starting point the goal to adequately protect fundamental intellectual property rights, respect value-adding publisher contributions, and uphold long-established principles of government information policy to ensure continued incentives for creativity and investment.

One example of the partnership models we recommend is the Clearinghouse for Open Research in the United States (CHORUS, http://www.chorusaccess.org/). CHORUS is a not-for-profit, public-private partnership that serves the public interest by creating a streamlined, cohesive way to access peer-reviewed publications that report on federally funded research. It provides a full solution for federal agencies to comply with the OSTP memo on public access to peer-reviewed scientific publications reporting on federally funded research by building on existing private sector infrastructure and services; thereby avoiding duplication of effort, minimizing cost to the government and ensuring the continued availability of the research literature. CHORUS has reached out collaboratively to federal agencies to make sure it can meet government needs, and DOE has included the initiative in its recently released public access plan.

Where the federal government seeks to support innovation through mandates that focus on public availability of the final accepted manuscript after an embargo period, so-called "green" open access, we recommend an approach that allows agencies to set appropriate embargo periods through a transparent and collaborative process involving all stakeholders that can be set and adjusted based on evidence, data, and the practices of different research disciplines rather than using an arbitrary and uniform embargo length. Policymakers around the world have recognized the need for flexible approaches to public access and the need to proceed carefully when implementing public access mandates. The wrong policies could undermine the efforts of ACS, and organizations like ours, to ensure the integrity of the scientific record, provide high-quality, peer-reviewed research communication, and support American innovation, jobs and economic growth.

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ALA AmericanLibraryAssociation

Before the
Office of Science and Technology Policy
and the National Economic Council
Washington, DC

In the Matter of	)	
Request for Information Concerning Revision	)	**Notice FR 2014-17761**
of the Strategy for American Innovation	)	

PRELIMINARY COMMENTS OF THE AMERICAN LIBRARY ASSOCIATION

The American Library Association ("ALA"), the nation's oldest and largest professional library association, is pleased on behalf of its 57,000 members to provide the Office of Science and Technology Policy ("OSTP") and the National Economic Council ("NEC") with the following preliminary comments in response to the Notice of Request for Information in FR Doc. 2014–17761 ("Notice") concerning revision of the nation's "Strategy for American Innovation."

While mindful of the Notice's encouragement of specific submissions of up to 5,000 words, ALA's principal and most fundamental policy recommendation is necessarily broad and requires but two words: *think libraries*. As OSTP and NEC wrestle with the myriad details of revising America's innovation strategy, we respectfully urge both bodies to "bake into" the analytical process from the outset (and at every stage and in every relevant context) the simple but profoundly important question: "What about libraries?"

Neither the recommendation nor the question is rhetorical. America's more than 100,000 libraries serve over 200 million Americans more than 2 *billion* times per year. They are already at the core of every virtually every community and educational institution in America. As such, libraries of every kind are and can be enormous logistical assets in impleme-ntation and optimization of the nation's innovation strategy.

Libraries also are: access points to the internet for tens of millions of Americans seeking employment and retraining information; "maker spaces" that enable entrepreneurs with mark-eting and other information, convening facilities, 3D printers and more; and windows on the world of work for almost every school child in America.

Moreover, libraries are an integral part of the innovation ecosystem in higher education. Faculty and other researchers depend on the information resources of university libraries for their innovative work. Academic libraries are also central to supporting the undergraduate and graduate programs that help develop tomorrow's innovators.

So viewed, 21st Century libraries are indispensable engines of the nation's innovation-driven economy.

Even more importantly for purposes of the Notice, however, properly resourced and engaged libraries have almost limitless potential to be an even more powerful lever for lifting millions of lives and, with them, the social and economic fortunes of the nation. Alternatively put, the health of America's "entrepreneurial culture, flexible labor markets, world-class research universities, [and] strong regional innovation ecosystem," as framed at Question 3 of the Notice, can be seen as a direct function of the health and productivity of public, school, academic, research and all other libraries.

ALA urges OSTP and NEC to employ such a perspective – a "library lens" – as this important docket unfolds and looks forward to providing additional detailed information to further focus and facilitate that inquiry.

Respectfully submitted,

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Comments by the American Society for Biochemistry and Molecular Biology to the White House Office of Science and Technology Policy Request for Comments on the "Strategy for American Innovation" September 23, 2014

The vibrant culture of freedom and curiosity that abounds in the United States' scientific research enterprise has produced astounding breakthroughs in every field of science, from astrophysics to zoology. Specifically, federal investments in biomedical research through the National Institutes of Health, the National Science Foundation, the Food and Drug Administration and others, have resulted in a steadily increasing life expectancy for Americans. From the invention of vaccines and the prevention of myriad diseases to the most recent advances in molecular medicine, federally funded biomedical research saves lives.

Anyone who has ever received hospital care has benefited from the federal investment in biomedical research. The vaccines, drugs, medical devices and techniques that save the lives of millions of people on a daily basis often trace their origins to federally funded research. However, systemic flaws in the biomedical research enterprise, such as inconsistent funding and poor interactions among enterprise stakeholders, threaten the discovery, development and delivery of novel therapeutics to patients.

The major stakeholders in the biomedical research enterprise—government, academia and industry—each face serious challenges that must be addressed to keep the U.S. at the forefront of research. The federal investment in science has faltered over the past decade, and federal regulations slow the pace with which discoveries are made and translated to beneficial products. Improvements in academic Ph.D. training programs are necessary to prepare young scientists for the current job market and to enhance collaborations with the other stakeholders. And an industry that is more transparent with regard to experimental results and funding strategies will allow for an alignment of research goals among all stakeholders. Together, academia, government and industry can make significant changes that will ensure that biomedical research remains an attractive career path for our most talented young people and ensures that the American research enterprise remains second-to-none in the world.

The American Society for Biochemistry and Molecular Biology has embarked on an initiative to move the biomedical research enterprise onto a more sustainable path. In our view, a sustainable biomedical research enterprise (SBRE) should train the right number of scientists to fill the needs of the marketplace; have a sustainable and robust funding stream and enable government, academia and industry to work together in a more seamless fashion to improve the rate that discoveries are made and moved to the market. The ASBMB white paper on the SBRE was released in August 2013[1,2]. We also held a well attended panel discussion at a recent national meeting that brought together representatives from the different stakeholder groups to discuss the barriers to sustainability. Our next step will be to further delve into the issues facing each stakeholder and come to an agreement on how best to break down these barriers.

A SBRE not only benefits those working within the enterprise, but also those who depend on a functioning research system to discover, develop and deliver therapies for the variety of diseases

[1] Berg, Jeremy. "Imagining a sustainable biomedical enterprise." *ASBMB Today*. 2013. http://bit.ly/1n53mfn
[2] ASBMB Public Affairs Advisory Committee. "Toward a Sustainable Biomedical Research Enterprise." 2013. http://bit.ly/1n4GOel

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afflicting humans today. Thus, we are delighted that the White House Office of Science and Technology Policy is revising its Strategy for American Innovation. Below are the ASBMB's responses to several of the questions posed in the request for information.

(1) What specific policies or initiatives should the Administration consider prioritizing in the next version of the *Strategy for American Innovation*?

Years of growth of the biomedical research enterprise has yielded many benefits for the American people, but it has also created a system that is now out of balance, placing the U.S. at risk of losing its position as the global leader in biomedical innovation. The success of the American biomedical research enterprise is dependent on implementing a plan for sustainable growth. A sustainable biomedical research enterprise (SBRE) will meet national strategic goals by training a scientifically competent workforce, creating new knowledge and technologies, and feeding an ongoing and vibrant innovation stream that will improve health and drive economic growth. The Administration should pursue initiatives and institute policies that will promote sustainability of the American research enterprise.

Sustainability will require close integration and cooperation among the enterprise stakeholders – government, academia and industry. These stakeholders must each make significant reforms while working together to solve problems in workforce training, technology transfer, education, regulatory burden, product development and many other areas. Our comments below elaborate on policies the Administration should consider in order to make the American research enterprise more sustainable and more productive and maintain our global leadership.

(2) What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?

When taking inflation into account, the purchasing power of many federal funding agencies has declined over the past decade. Because the vast majority of money appropriated to federal funding agencies is distributed to all 50 states, the decline in research funding is felt primarily by nonfederal scientists across the country who use this money to create jobs and fund their research. Sequestration in 2013 magnified this loss and appears to have resulted in over 1,000 NIH-funded scientists losing grant funding for their research and a general disillusionment with the state of the research enterprise.[3,4]

For a SBRE to thrive, the federal government must regain its position as the enduring foundational investor in basic research. The first step toward this goal is for the Administration to recommend funding the NIH at $32 billion and the NSF at $7.6 billion for fiscal 2016 and then encourage Congress to make significant, predictable increases in NIH funding each year after that.

Furthermore, predictable increases in funding are crucial to the success of scientific endeavors. Research cannot be stopped and restarted like a construction project, and even temporary stoppages can render years of work worthless. Thus, to improve funding predictability and protect the national investment in research, the Administration should institute a cross-agency, multiyear, financial plan similar to the Department of Defense's Future Years Development Plan. As suggested in the "Transformation and

[3] Berg, J. "The impact of the sequester: 1,000 fewer funded investigators." *ASBMB Today*. March 2014. http://bit.ly/TdeWvF

[4] American Society for Biochemistry and Molecular Biology. "Unlimited Potential, Vanishing Opportunity." 2013. http://bit.ly/1nXxAlH

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Opportunity" report from the President's Council of Advisors on Science and Technology, a government-wide science FYDP would be an important step to providing the certainty needed for everyone involved in the research enterprise.[5]

Finally, the research enterprise is driven by individual scientists from across the nation who have brilliant ideas and make breathtaking discoveries every day. However, research projects initiated at the federal level and the growth of intramural federal research programs threaten the individuality and intellectual freedom that have been the hallmarks of American research. <u>The Office of Science and Technology Policy should encourage federal funding agencies such as the NIH, NSF and others to emphasize extramural, investigator-initiated research over other mechanisms in order to maintain the vibrancy of the American research enterprise.</u>

Increasing funding and improving predictability are crucial to promoting innovation in the scientific enterprise. These key changes will provide stability to researchers and improve sustainability and innovation of the enterprise, allowing scientists to make the important discoveries that will drive economic growth and job creation.

(3) What specific actions can the Federal Government take to build and sustain U.S. strengths including its entrepreneurial culture, flexible labor markets, world-class research universities, strong regional innovation ecosystems, and large share of global venture capital investment?
The biggest strength of the American research enterprise is its workforce. The country with the most innovative workforce will be the one that recruits and trains the most driven, creative and talented people from around the world and provides them with sufficient resources to achieve their dreams. The United States is still the global leader in this regard, primarily because we still have the best higher education system and an unsurpassed research infrastructure. To maintain this advantage, however, training programs must be updated to prepare students for the variety of careers available to them not only in academia, but also in government, industry and elsewhere. In addition, visa reform is needed so that we can retain the talented foreign scientists who train here, and allow them to make their groundbreaking discoveries here, to the benefit of all Americans.[6,7]

The current system provides excellent training in academic research. However, there is also a need to institute new programs that better train students for the variety of careers available to them outside of academia. This will benefit all of the stakeholders by reducing the time and money required to retrain talented individuals to do a variety of different jobs. Furthermore, students with the skills to work outside of academia will serve as ambassadors from one stakeholder group to another, facilitating the movement of knowledge and technology. <u>Thus, the Administration should encourage all federal science funding agencies to implement programs that will ensure the American research workforce is trained for the variety of available careers so that the enterprise works at maximal efficiency.</u> These reforms will keep the American training system the best in the world, and it will serve as a beacon to all scientists that the U.S. is the best place to conduct research.

[5] President's Council of Advisors on Science and Technology. "Transformation and opportunity: The future of the U.S. research enterprise." November 2012. http://1.usa.gov/1nBkviF
[6] ASBMB. "Unlimited Potential, Vanishing Opportunity." 2013. http://bit.ly/1nXxAlH
[7] Fritze, John. "U.S. cuts could lead to 'brain drain' in medicine." *The Baltimore Sun*. 2013. http://bit.ly/1tbmZ8R

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The American research enterprise benefits greatly from the work of foreign scientists who come to the U.S. to learn and conduct research in the best university system in the world. However, training these bright young scientists only to have them return to their home country to compete against American scientists represents a wasted investment. Thus, to protect the Federal Government's investment in the training of foreign scientists, the Administration should work to make sure that immigration policies should, if possible, provide an incentive for these scientists to remain in the U.S. or at the very least, they should not provide a disincentive.

(6) How has the nature of the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?
We must ensure that we are conducting research into the many deadly and costly diseases that afflict humans, and we should emulate models of collaborations that have provided benefits. Industry has already taken the lead to develop treatments for these conditions. However, the fact that we do not yet have a treatment for Alzheimer's disease, for example, indicates the need for a closer partnership among all research enterprise stakeholders. One step toward these closer relationships is the NIH's Advancing Medicines Partnership project, which is a collaboration among academia, industry and government.[8] The AMP provides a model for how future collaborations can be constructed to make advances on the serious diseases that afflict humans today.

The mechanism for researching and pursuing leads on these diseases is already in place. The NIH, NSF and others already have a robust system of peer review that evaluates and funds promising research into the underlying mechanisms of human biology and disease. Minimizing the boom-and-bust cycle of research funding, promoting closer relationships among stakeholders and improving the training of bright, young scientists will move the entire research enterprise onto a more sustainable path and resolve many of the issues that slow discovery, development and delivery of beneficial therapies and cures. A smoothly functioning enterprise will provide sufficient incentive to ensure that American researchers are making progress as fast and efficiently as possible.

Furthermore, improving partnerships among research enterprise stakeholders is critical for fixing the systemic flaws in the biomedical research enterprise and improving the pipeline from discovery to delivery. The PCAST report on propelling innovation suggests a high-level partnership among the stakeholders that should (1) identify key needs and opportunities to accelerate therapeutics; (2) prioritize these needs and opportunities; (3) formulate specific solutions and develop detailed plans to achieve those solutions and (4) ensure projects are launched by building coalitions of the right partners.[9] To promote the stability and sustainability of the American research enterprise, the Administration should set up this partnership as soon as possible.

However, the charges of this partnership should be expanded to address the critical issues that exist with today's enterprise. Due to a decade of flat federal funding, talented and highly trained investigators are turning away from careers in research, restricting both discovery and development of therapeutics. Graduate training at our universities does not adequately prepare Ph.D. graduates for the variety of careers available to them. Intellectual property, technology licensing and conflicts of interest keep academia and industry at arm's length. Government regulation of academic and industrial research

[8] National Institutes of Health. "Accelerating Medicines Partnership." 2014. http://1.usa.gov/1eQrFYk
[9] President's Council of Advisors on Science and Technology. "Propelling innovation in drug discovery, development and evaluation." September 2012. http://1.usa.gov/1tIXn1G

creates increasing layers of complexity that limit an investigator's time that could be used for productive experimentation.

We suggest the Administration charge any broad-based partnership with the additional tasks of (1) identifying barriers to interactions among all of the stakeholder groups that slow innovation and create inefficiencies and (2) making specific recommendations for each stakeholder to undertake in order to overcome these barriers. Once these barriers to sustainability are removed, discovery, development and delivery will occur at a much more rapid pace than they do today benefitting everyone from basic researchers to patients.

(8) What are important needs or opportunities for institutional innovation and what steps can the Federal Government take to support these innovations?
Although basic research has always been a winning long-term investment, short-term outcomes are unpredictable. The freedom to fail and try again is an integral aspect of scientific exploration and is essential to the success of the research enterprise. The federal government is the only institution that is positioned to invest substantial capital in long-term, high-risk projects such as basic research, and it must therefore remain the enduring foundational investor in basic biomedical research.

Important investments in research are made by industrial and philanthropic organizations. Industry has always played a leading role in identifying promising therapeutics and developing them into useful products. The result is that industrial investments in research are short-term, risk-averse and bottom-line driven. Differences between federal and industrial investment strategies are evident in expenditure distributions: in 2011, industry funded 63 percent of all U.S. R&D, but this investment was focused on applied research and development. When it comes to basic research, the federal government provided 55 percent of the funding, underscoring the federal government's important role in the research enterprise.[10] Similarly, philanthropic investments in research, though critical, are often focused on development-ready, disease-focused research projects.

Despite their fundamentally different roles and investment strategies, improved partnerships between academic, industrial and governmental researchers are critical for innovation in the science and technology marketplace. One barrier to innovation is the handling of intellectual property issues among those that invest in basic research. While academia and industry have a reasonable mechanism for tech transfer, the Administration should encourage these stakeholder to unify tech transfer procedures across all university and company partnerships to reduce the time and cost associated with renegotiating every collaboration. Additionally, as noted by the PCAST, Congress and the administration can do more to improve tech transfer at the National Labs to speed the development and delivery of promising new discoveries to all Americans.[11] These reforms will forge closer ties among the stakeholders and allow for more private investment in basic research.

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[10] National Center for Science and Engineering Statistics. "Science and Engineering Indicators 2014." http://1.usa.gov/Sfx4UY
[11] President's Council of Advisors on Science and Technology. "Transformation and Opportunity: The Future of the U.S. Research Enterprise." 2012. http://1.usa.gov/1nBkviF

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The ASBMB is a nonprofit scientific and educational organization that was established in 1906 by 28 biochemists and has since grown to an organization with more than 12,000 members worldwide. Most members conduct research and teach at colleges and universities, government laboratories, nonprofit research institutions and industry. We are proud to include 102 Nobel Prize winners among our members.

We are pleased that the White House Office of Science and Technology Policy is examining so many critical issues confronting the biomedical research enterprise today. We believe the entire enterprise must move in a direction of sustainability with regard to workforce, funding, and interactions among stakeholders. Ultimately, this will accelerate the rate of discovery and reduce the costs of the technology and drug development, all in a safe and effective manner that improves the health and economic well-being of Americans. The ASBMB and the Public Affairs Advisory Committee stand ready to help the Administration with this crucial endeavor.

American Society of Plant Biologists

Cultivating a better future through plant biology research

Official Response to White House Request for Information on the
Strategy for American Innovation
Submitted on
September 23, 2014

The American Society of Plant Biologists (ASPB) applauds the Administration for its reassessment of the *Strategy for American Innovation*. ASPB, a professional scientific society representing 4500 members and serving 40,000 plant biologists and related professionals in the U.S. and abroad, promotes the growth and development of plant biology, encourages advancements and breakthroughs in plant science, and publishes transformative research that improves the bioeconomy enterprise. We share your commitment to constantly surveying the innovation landscape for the most promising and impactful potential federal investments. In particular, our comments with regard to the opportunities in plant science address the White House Office of Science and Technology Policy and the National Economic Council's solicitation of input for the following topical areas:

- **Overarching Questions:** Goals the Administration could explore to promote economic competitiveness, and ways the federal government can better leverage existing economic strengths such as research institutions.
- **Science, Technology, and R&D Priorities:** Opportunities to build on the Administration's ongoing initiatives to facilitate the development of platform technologies that "reduce the time and cost associated with the 'design, build, test' cycle for important classes and systems," and additional investments that can be made to fill gaps in the Administration's innovation research portfolios with regard to national challenges.
- **Skilled Workforce Development:** Effective models to assist skilled workers in science technology and manufacturing (STEM) fields as they transition to new roles and adapt to emerging innovations or technologies.
- **National Priorities:** Areas that should be identified as "National Priorities" because they pose a major threat to national security or living standards or they present an opportunity for significant scientific breakthroughs, as well as federal policies to encourage private sector support for existing priorities.

The goal of a sustainable future, with a more nimble and innovative workforce and a highly competitive research enterprise, is in the national interest. The challenge, however, is to execute this strategy in an era of economic limits, when anticipated outcomes must justify the investment of limited resources. Through an iterative, strategic visioning process, representatives of the plant science community developed the *Plant Science Decadal Vision* (http://bit.ly/197Eph9) that responds to the urgent needs and tremendous opportunities that confront our nation and the world. We cannot meet the food, feed, shelter, and energy demands of the burgeoning global population—especially with climate instability as a backdrop—while the American investment in plant-related research stagnates. Ending that stagnation, instead, can leverage the new technologies that have transformed biology, accelerating the pace of discovery and promising solutions that can be both creative and sustainable. We strongly believe that the following recommendations are a critical tool for the Administration to advance American innovation and stimulating economic growth.

The initiative proposed here, which will dramatically increase the ability of plant scientists to understand, predict, and alter plant behavior, is synergistic with other national calls to action, including *A New Biology for the 21st Century*, the *National Bioeconomy Blueprint*, and the *Report to the President on Agricultural Preparedness and the Agricultural Research Enterprise*. Achieving the *Decadal Vision* will require cooperation among many stakeholders, including academia, federal agencies, the private sector, foundations, and international partners.

Failing to realize the promise for advances in plant science research will have sobering consequences. Chronic underinvestment leads to loss of competitiveness, missed opportunities, and environmental and community degradation through use of outmoded technologies. The 2012 *Report to the President on Transformation and Opportunity: The Future of the U.S. Research Enterprise* detailed this situation and argued for an investment in research and development (R&D) of 3% relative to gross domestic product. In the case of agriculture, in which current R&D investment languishes well below this number and other indicators are equally grim, an inability to deliver nutritious food and therapeutics could be catastrophic, ultimately posing a national security threat reminiscent of riots associated with recent commodity price spikes in the developing world.

The unique value of the *Decadal Vision* arises from its embodiment of a consensus agenda developed by international and domestic plant scientists, its linkage to other calls to action, its anticipated economic impact, and the clear and urgent need to reimagine how the research enterprise can and must support the agricultural sector.

Five interwoven components are recommended to accomplish the objectives:

1. Increase the ability to predict plant traits from plant genomes in diverse environments. Plant genetic blueprints underlie productivity, resistance to pests and diseases, and the ability to flourish in a wide array of environments and climatic conditions. However, the ability to interpret those blueprints, which reflect a complex evolutionary history, is only in its infancy. To bridge this knowledge gap, we recommend programs that will (1) link genome to performance during environmental change and biotic interactions by establishing the interconnections among a plant's genes, their myriad cellular products and functions, and the ways these determine agronomically important plant traits; (2) expand plant phenotyping capabilities, in particular drawing on advances in computation and robotics; (3) define how plant species have naturally adapted to stressful or extreme environments, specifying biological mechanisms that can be harnessed for agriculture; (4) understand the dynamics of plant communication, from the intracellular to the interorganismal scale; and (5) establish a comprehensive plant attribute database that integrates genetic, molecular, and chemical data with developmental, architectural, field performance, and environmental parameters.

2. Assemble plant traits in different ways to solve problems. Newly discovered traits will need to be introduced into crop species through 21st-century breeding strategies or the virtually unlimited possibilities of synthetic biology. To establish and implement these capabilities, we recommend (1) funding relevant research using challenge grants, collaboration strategies, and training programs that combine biology, breeding, engineering, and computational talent and (2) investing in large-scale genetic, genomic, and biochemical characterization of wild or heritage germplasm related to crop species.

3. Discover, catalog, and utilize plant-derived chemicals. One of Earth's greatest assets is its immense diversity of life forms, yet we have only scratched the surface in cataloging plant-derived chemicals and their biological purposes, even as species are lost through extinction. These uncharacterized chemicals constitute a virtually inexhaustible but mostly untapped resource for agricultural, bioproduct, and biomedical applications. To realize this potential, we recommend (1) determining the chemical composition and biosynthetic pathways in 20,000 ecologically and medicinally important species to understand the synthesis and biological purposes of plant-derived chemicals and (2) utilizing plant chemistry for applications in human health, agriculture, and manufacturing.

4. Enhance the ability to find answers in a torrent of data. For plant biology to become a reliably predictive science, data analysis must undergo a paradigm shift. De-fining the complex relationships that underlie plant behavior will require (1) integrating data through the perfection of statistical models, application of machine learning, and validation of functional predictions from models and (2) facilitating data storage, retrieval, and analysis through incentivizing, enabling, and training scientists to share data freely and habituating scientists to develop or test hypotheses through intensive data analysis before conducting wet lab or field experiments.

5. Create a T-training environment for plant science doctoral students. Innovation in agriculture will flourish only if training environments keep pace. The current doctoral training system, with its slow pace and focus on a traditional academic pathway with limited job prospects, is associated with dissatisfaction and attrition, stagnant trainee numbers, and stubbornly poor gender diversity at the faculty and executive levels. We propose implementation of a T-training format that retains the vertical, discovery-based scientific apprenticeship in a mentor's laboratory but adds horizontal skills that cross-train students and prepare them for a wide variety of careers while shortening the time to degree. To engage institutions, federally supported training grants would require suitable commitments from institutional and industrial partners.

Outcomes

Basic research has a tremendous track record of producing jobs, economic activity, and far-reaching societal benefits. Fundamental laboratory discoveries currently drive agricultural improvements in most major crops because the agricultural sector excels at implementing promising technologies. A recent example is submergence-tolerant rice; a gene identified through USDA-funded research has now been bred into multiple varieties grown worldwide. Likewise, the research proposed in the *Decadal Vision* can lead us to novel solutions for improving the sustainability of agriculture and the bioeconomy, even in the face of challenges such as climate change, population growth, and limited natural resources such as water and arable land.

A National Call to Action

The plant research community is not alone in recognizing the importance of 21st-century investments in plant and agricultural sciences and imperatively recommending substantial action to ensure the necessary infrastructure and human capital in research, education, and application. The specific recommendations for plant science defined here are synergistic with, and emergent from, several recent reports that highlight this watershed moment in plant science research.

A New Biology for the 21st Century is a 2009 National Academies study whose recommendations are meant to ensure that "the United States leads the coming biology revolution." One major recommendation of *New Biology* is that initiatives address societal challenges in food, energy, environment, and health. The *Decadal Vision* tackles each of these through the lens of interdisciplinary, plant-driven science. *New Biology* further assigns priority to information technologies, cross-disciplinary collaborations and curricula, and inter-agency collaborations, all of which are components of the *Decadal Vision*.

The *National Bioeconomy Blueprint* was published by the White House Office of Science and Technology Policy in April 2012. The blueprint extensively covers plant-based bioproducts and points to synthetic biology and bioinformatics as key modalities to achieve these goals. In the *Decadal Vision*, the emergence of new plant-inspired industries is envisioned in part through advances in these areas.

Finally, the President's Council of Advisors on Science and Technology (PCAST) *Report to the President on Agricultural Preparedness and the Agricultural Research Enterprise*, published in December 2012, concludes that the nation is not prepared for future agricultural challenges and recommends major R&D investments achieved through expanding the role of competition at USDA and increasing support through NSF.

Each of these three reports, like the *Plant Science Decadal Vision*, imparts a sense of urgency and arose from a collaborative process among research scientists, policymakers, and the private sector. Together they point unambiguously to both the threats and the opportunities that face the nation and illuminate a path forward.

To sustain crop productivity in an increasingly unstable climate, to deploy agricultural systems that protect natural resources, to use nature's biological and chemical innovations to solve problems that crops increasingly face (water, thermal, salinity, and nutritional stresses), and to capture the economic opportunities in improved crop varieties and novel plant bioproducts all require a visionary and interdisciplinary research capacity that is accompanied by coordination and openness in data sharing. These requirements entail not only an unwavering commitment to excellence and innovation by the research community, but also a serious commitment to reforming the existing model of graduate education. Each of these research and educational goals is addressed through one or more components of the *Plant Science Decadal Vision*.

The overarching objective of the *Decadal Vision* is to build across disciplines including plant science, chemistry, engineering, and computational sciences to advance research through the continuum of observational to predictive to synthetic. Among the possibilities within reach are improving the agronomic properties of crop varieties through, for example, rapid deployment of resistance to emerging pathogens; designing plants for new functions; using native plants as "libraries" to harness their adaptive mechanisms and novel products for medicine and industry; and understanding the roles and regulation of plant genes in thousands of species. To preserve and increase agricultural productivity in a wide range of environments will require a much deeper understanding of everything from photosynthesis, in which sunlight is initially captured, to the means by which plants perceive and communicate with many thousands of organisms that directly interact with them above and below ground. The exceptional ability of U.S. industry to implement technologies that have advanced through proof of concept is a further impetus to action.

Timely execution on the *Decadal Vision* is critical for many reasons. The goals being proposed are designed to protect and improve crop productivity, quality, and nutrition. They leverage conservation management activities that maintain and improve natural resources and precious, dwindling biodiversity, and they support the creation of new plant-inspired industries and “innovation ecosystems” directly in line with PCAST’s recommendations.

The objectives of the *Decadal Vision* are also aligned with international plant science priorities, which should facilitate the cooperation that will be required to understand the extreme complexity and diversity of plant life and to use the resultant insights. An international workshop held in 2009, for example, identified as high-level objectives resource conservation, data collection and sharing, and integration of information to understand plant function. International consensus on these research thrusts is perhaps not surprising given that the challenges facing agriculture are global.

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September 23, 2014

Re: *Strategy for American Innovation*

To the National Economic Council and the Office of Science and Technology Policy:

Pursuant to the Request for Information ("RFI") published in the Federal Register on July 29, 2014 (79 Fed. Reg. 44064), I am pleased to submit the following comments on behalf of the Association of American Publishers Professional and Scholarly Publishing division ("AAP/PSP") regarding the upcoming update of the *Strategy for American Innovation* to be undertaken by the Office of Science and Technology Policy ("OSTP") and the National Economic Council ("NEC").

The core mission of the scholarly and professional publishers who make up the membership of AAP/PSP is to support innovation through the communication of scholarship and technical information. Our members create the vast majority of materials used in the U.S. by scholars and professionals in science, medicine, technology, business, law, reference, social science and the humanities. Our members include the worldwide disseminators, archivists, and developers of the public record on scientific research via print and electronic means. They are non-profit professional societies, commercial publishers and university presses that produce books, journals, computer software, databases and electronic products in virtually all formats and all areas of human inquiry and activity.

The primary goals of the peer-review publishing activity undertaken by our members is to enable the creation of quality content and broadly disseminate, provide access, and offer a high-quality and user-friendly environment in which to discover, analyze, and link to the latest breakthroughs and developments in scientific and other scholarly research. In particular, publishers of scientific journals have, for more than 100 years, played an integral role in building and documenting the unrivalled U.S. scientific research enterprise, and their continuing innovation and investment in high-quality publication of scientific research is critical to any strategy that would promote that innovation. Publishers have supported innovation not only in existing disciplines and the areas in which they publish, but also have recognized and nourished emerging fields of discovery. We welcome the opportunity to support any efforts to maximize the dissemination and discoverability of knowledge, consistent with publishing models that are economically sustainable. The latter is critical to ensure the integrity and long-term availability of the scholarly record upon which innovation is built.

Such sustainability is essential to support America's historic and future economic strength and innovation leadership. Not only are the products of professional and scholarly publishing key ingredients for such innovation, but publishers also are critical contributors to the American economy. Collectively, members of AAP/PSP represent tens of thousands of publishing employees, editors and authors throughout the country who regularly contribute to the advancement of American science, learning, culture and innovation in America. They comprise the bulk of a $10 billion commercial and non-profit publishing industry that contributes significantly to the U.S. economy.

Because of publishers' focus on developing new models for the communication and dissemination of information and contributions to developments in the sharing of digital data, we believe that we are uniquely situated to comment on Question 21 and Question 23 of the OSTP/NEC RFI. Moreover, we believe that the comments we offer above and in response to the questions also bear relevance to the entire effort being undertaken in the Strategy for American Innovation. In submitting these comments, we therefore also express our willingness to offer our expertise to contribute to any further discussions in support of the Strategy for American Innovation.

Question 21: Intellectual Property/Antitrust

Advances in technology continue to create significant opportunities for increased use and dissemination of material in digital form. In this continually innovating and evolving space, the diversity of models of innovation and distribution are a positive feature, enabling creators, rightsholders, and users to experiment and develop appropriate models to support the creation and sharing of content. In all cases, protecting copyright is essential to ensure continued innovation and constantly improving availability of the scholarly content that underpins innovation.

In considering the role of copyright in the digital age, it is important to remember that the essential principle – enshrined in the Constitution – is that copyright is designed to "promote the progress of science and useful arts," to wit, innovation. This incentive role for copyright is not limited to simply the creation of original works, but also to promote their dissemination and use. In this, research shows that intermediaries like scholarly publishers are critical to ensure the availability and innovative use of such materials.[1]

The government has recognized the critical importance of the incentivizing effect of intellectual property with respect to federal investments in research with the Bayh-Dole Act, to great effect. Under this rule, researchers (and their institutions) preserve the right to patent discoveries funded by the federal government in order to enable and accelerate commercialization. This wisely balanced approach has reaped benefits for the public in the form of increased innovation and the leveraging of federal investments for additional research and development. The same principle of allowing researchers to have exclusive rights, for a limited period, to reports of federally funded research in peer-reviewed articles also accrues benefits for the communication of science. Copyright provides a healthy balance between essential protection and exceptions and limitations that permit innovative uses that do not conflict with the rightsholders. In addition, copyright provides the incentives for the dissemination of ideas which are not protected and that are used to advance innovation. High-quality peer-reviewed research articles, curated into journals and disseminated in forms and fora that researchers use, enable the further scholarship upon which innovation depends.

In the publishing industry, copyright has provided an incentive for investments in new technologies and publishing models that meet the needs of today's digitally-based users, as well as the infrastructure needed to peer review, publish and distribute scientific communication. As the technology for disseminating works has changed and improved, so have the investments publishers have made to meet new user demands. Therefore, the need for investment incentives has become even more crucial for the publishing industry.

[1] *See* Adam Mossoff, *How Copyright Drives Innovation in Scholarly Publishing (April 2, 2013). George Mason Law & Economics Research Paper No. 13-25. Available at SSRN: http://ssrn.com/abstract=2243264* (describing how copyright continues to be important in the digital age to spurs both authors to invest in new works and publishers to invest in innovative, private-ordering mechanisms to distribute these works) and Mark Schultz, *Copyright, Economic Freedom and the RSC Policy Brief*, Copyright Alliance Blog (Nov. 20, 2012), *available at* http://www.copyrightalliance.org/2012/11/copyright_economic_freedom_and_rsc_policy_brief (explaining that copyright's constitutional mandate is rooted in both utilitarian and natural rights theory, which justify why copyright is a valid property right secured both to creators and to the private firms who disseminate their works).

The current intellectual property regime has spurred scholarly publishers, harnessing the power of the internet, to develop new models that enable innovators to build on knowledge and use scholarly material in new and previously unimagined ways. To cite just two examples that illustrate a theme:

1. Many publishers have developed new discovery tools to support researcher practices – enabling researchers to find material that supports their researcher more quickly and efficiently, or enabling them to find and use research in other disciplines that connects to their area of study in new and different ways that they otherwise would not come across. Such tools increase the speed of research and innovation across science and scholarship.
2. Many publishers have also developed tools to enable researchers to make more extensive use of the research literature once they have found articles of interest. These include extensive interlinking to related articles or associated data, as well as tools for interacting with the findings in an article in new and different ways. Such tools not only encourage individual discovery and innovation, but allow new forms of collaboration.

Of course, AAP/PSP members and other publishers are continually innovating, so new examples are being created all of the time.[2]

The best way to preserve such innovation is to ensure strong support for copyright, and enable the use of copyrighted material through licensing. Such approaches have proven to be viable and appropriate in a wide variety of settings, and are flexible enough to allow creators and rightsholders to set the appropriate permissions without undermining their rights. The rights conferred under license can be extremely broad (as in an "attribution rights reserved" regime) or narrow to accommodate any purpose. In addition, scholarly practice has provided a pragmatic system to balance formal intellectual property rights with certain informal practices that support the research needs of the communities served by their journals. While technically coming close to the rights held by publishers and other rightsholders, these practices – which include the sharing with colleagues of various versions of articles - do not undermine the most critical protections provided by copyright and demonstrate the continued viability of existing copyright regimes.

Where more explicit rights are required, licenses have proven to be a flexible tool to enable such rights consistent with copyright. For example, licenses can enable researchers to utilize text and data mining ("TDM") tools to analyze text to find patterns and connections between words in a document and between documents. For example, a researcher might want to search through the research literature to discover similarities between manufacturing processes. Data mining is an analytical process that looks for trends and patterns in data sets that could reveal new insights. It is expected that other technologies and research tools not yet imagined will be consistent with copyright and licensing, and we encourage OSTP and NEC to tread carefully before upending the successful intellectual property regime that continues to enable such innovation.

Question 23: Novel Government Tools for Promoting Innovation

Publishers are extensively engaged in international efforts to support the sharing of data and intellectual property, and hope to continue to do so in support of private sector innovation both within and beyond the scholarly communication space. As mentioned above, publishing organizations have actively developed tools to enable more productive use of data and IP, including manipulation, visualization, TDM, and more.

The dissemination of information is an area of publishers' professional expertise. AAP/PSP members are experimenting in expanding access to data not only as publishers of peer-reviewed scientific journals, but also as disseminators of information whose innovative products and services enhance and add value to taxpayer-funded research activities. This innovation and these contributions are expected to do continue to reap benefits for America.

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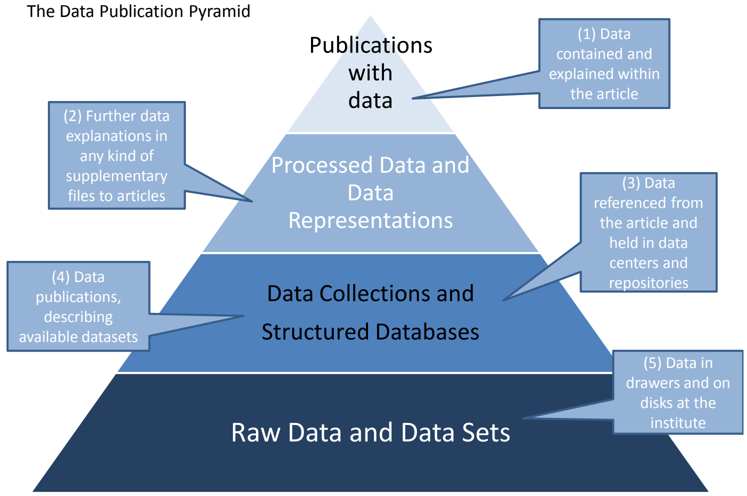
[2] As noted in AAP's testimony before the House Judiciary Committee, "key themes for the future of innovative business models for digital content delivery [include]: (1) the importance of on-demand access to content; (2) seamless portability across devices; and (3) new partnerships between content, technology, and consumers." (http://www.publishers.org/_attachments/docs/copyright_policy/aapnewbusinessmodelsphs112613.pdf)

It is important to recognize that Federal assets that support innovation come in many forms, even if the assets under consideration are limited to simply data and intellectual property. The Data Publications Pyramid displayed here,[3] derived from open science pioneer Jim Gray's e-science pyramid, provides a model for understanding how research data can be presented in a variety of ways with increasing levels of curation and analysis. It is critical that the federal government continue to distinguish between data and various types of presentation of data and preserve and respect intellectual property protection and copyright ownership as appropriate. By doing so, policies will continue to allow the engine of innovation to be harnessed to the rights inherent in intellectual property. Innovation is best supported by federal policies that account for these differences between information products at different levels of the pyramid.

The Data Publication Pyramid



Publishers are already working collaboratively with stakeholders, including primary researchers, secondary researchers, funders, libraries and data centers, on projects that will enable innovation in both the dissemination and use of data in the lower tiers of the pyramid. To cite just a few examples, publishers are very active with the Research Data Alliance (rd-alliance.org), Codata (www.codata.org), and others, and were instrumental in supporting Dryad (www.codata.org) and other initiatives to make research data more discoverable and usable. Individual publishers are pursuing their own solutions to enhance the availability of primary research data as well. These include such diverse approaches as data-focused journals such as the Geoscience Data Journal (www.geosciencedata.com); extensive data linking within peer-reviewed journals as described in Elsevier's Article of the Future projects (www.articleofthefuture.com); and approaches to surface the data through links as in Thompson Reuters' Data Citation Index (wokinfo.com/products_tools/multidisciplinary/dci). AAP/PSP members and other publishers are continuing to innovate in this area, and these projects can scale to support the sharing of government data.On the other hand, with other intellectual property, including especially the data evidenced at the top tier of the pyramid, it is important to balance the need for "openness" with a respect for the private sector investments and innovations that make the material available in the first place. When it comes to federally-funded research, it is critical to note that publishers' "peer-reviewed scholarly publications" that report, describe, explain, analyze or comment on federally funded research do NOT "result from" such research in any sense that can legally justify the assertion of Federal Government control over the contents or distribution of such publications. Although federal funding may facilitate or otherwise contribute to the research processes and discoveries that are the subjects of peer-reviewed articles published in scientific journals or other scholarly publications, the creation of the articles themselves – as well as the creation of the publications containing them – are a separate creative act. Activities including certifying quality control; improving accessibility; ensuring integrity, reliability, and provenance; enabling discovery; promoting global dissemination and collaboration; standardizing outputs; and preserving the scholarly record for future generations are not funded by or otherwise attributable to the Federal Government. Instead, such articles and publications are literary works that are subject to the rights of copyright ownership that belong to their authors or their authors' exclusive licensees, which are typically the publishers who have provided significant added-value to the work, such as extensive pre-publication editing and style processes that include peer review. As noted above, such copyright is critical to the innovation in presentation, dissemination, and preservation upon which other innovation relies.

[3] As appearing in the October 17, 2011 *Report on Integration of Data and Publications*, a report of Opportunities for Data Exchange which brings together stakeholders including researchers, publishers, libraries and data centers to support a more connected and integrated scholarly record. Full report available at http://www.alliancepermanentaccess.org/wp-content/uploads/downloads/2011/11/ODE-ReportOnIntegrationOfDataAndPublications-1_1.pdf

In fact, the government recognizes the difference between the peer-reviewed article and other outputs of research is explicitly recognized in such policies as the National Institutes of Health public access mandate. In this policy, the NIH asks only for the final, peer-reviewed manuscript, not any other report of the research, despite the fact that the NIH already receives extensive reports on funded research as a condition of any grant it issues. That the government prefers the peer-reviewed article over any report is clear evidence of the contributions being made by publishers in stewarding this research communication to publication and the importance of those contributions to the advancement of science, and, subsequently, innovation.

That said, publishers – both as a fundamental character of our organizations and as a reason for being – share the government's interest in ensuring the widest possible dissemination and discoverability of all of the knowledge we publish, including that which reports on federally-funded research. We support the OSTP and NEC's goals of broadening access while preserving the high-quality, peer-reviewed articles on which the science community and the public rely. The key to the success of the policy, however, depends on how the agencies use their flexibility to avoid negative impacts to the successful system of scholarly communication that advances science, technology and innovation.

AAP/PSP members provide a variety of ways to support such access, and all rely on an economic model to support access and the initial creation of material. These methods include subscriptions as well as sponsored, author-enabled, and editor-selected approaches to ensure the availability of high-quality peer-reviewed articles at no cost to the public. Where policies, mechanisms, and approaches appropriate to each journal and the disciplines and communities it serves are put in place, there is no conflict between providing broad access and ensuring a healthy and sustainable business. This has been shown in countless individual journal policies, and also in a broad study by the European Union.[4] However, the wrong policies can undermine the very innovation that OSTP and NEC seek to promote by reducing the ability of publishers, like the members of AAP/PSP, to ensure the quality and integrity of the scholarly record that support American innovation, jobs, and economic growth.

In particular, while efforts at openness that build on publicly accessible material do have the potential to increase innovation, the viability and usefulness of the copyright in that material must be respected. Where the material in question is the final accepted manuscript of a peer-reviewed article, periods of exclusivity, often called embargoes, are critical. Studies have suggested that different embargo periods would be appropriate for different disciplines.[5] Policymakers around the world have recognized the need for flexible approaches to public access, and the need to proceed carefully when implementing public access mandates. We recommend that federal agencies that fund science, in setting any public access policies, use a transparent, collaborative, and evidence-based process involving all stakeholders to determine appropriate embargo periods based on the practices of individual funded disciplines.

The opportunities for collaborative approaches to yield success are strong. For example, to respond to an increasing interest and opportunity to provide public access to the peer-reviewed publications that report on federally funded research, publishers envisioned and set-up a new non-profit organization to develop and implement a system called the Clearinghouse for the Open Research of the United States (CHORUS). This system will provide readers with the full text of peer-reviewed articles, free of charge (after an embargo if applicable); ensure ongoing, long-term access to and preservation of these articles; support federal agencies in advancing science and promoting public access through a public-private partnership that minimizes government costs, as encouraged in the OSTP memo on public access;[6] and, ensure continued innovation and sustainability in the delivery of scholarly communication. By working collaboratively, CHORUS envisions being able to support the

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[4] The Publishing and the Ecology of European Research (PEER) project indicated that when a journal can choose an embargo period for free access to the articles it publishes there are no adverse effects http://www.peerproject.eu/fileadmin/media/reports/20120618_PEER_Final_public_report_D9-13.pdf

[5] See, for example, www.publishers.org/usagestudy

[6] "Increasing Access to the Results of Federally Funded Scientific Research" issued February 22, 2013. http://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

Administration's "Open Government" framework[7] while maintaining the sustainability of their various publishing business models. CHORUS was recently recognized for its efforts and usefulness in the Department of Energy's public access plan (see http://energy.gov/sites/prod/files/2014/08/f18/DOE_Public_Access%20Plan_FINAL.pdf) and AAP/PSP sees this as a valuable contribution to American Innovation.

Tools such as CHORUS represent a potential model of novel tools to support innovation, developed in collaboration with the government but not simply government tools. To promote the greatest possible innovation, the government should leverage private sector expertise. In this case, publishers are in the business of disseminating knowledge, so they understand the importance of investing in top-of-the-line digital infrastructure to support dissemination. Therefore, CHORUS includes a number of technical aspects to ensure its interoperability and support for further innovation, including:

- A system to identify articles that report on or analyze federally funded research and a real-time dashboard for agencies, institutions and the public to demonstrate compliance and accessibility;
- An open API infrastructure to enable search and discovery through familiar search engines such as Google Scholar, Microsoft Academic Search, government and library search systems or new products and services;
- A framework to allow text and data mining tools to be applied across publishers' platforms under protocols protecting the user and the source content; and
- The use of existing and developing communication tools, resources and protocols for discoverability, search, archiving and preservation, including CrossRef, FundRef and ORCID.

Conclusion

Publisher activities and investments over the last decades have contributed to U.S. economic growth directly through the high-skilled workers they employ, as well as through the dissemination of knowledge that leads to innovations beneficial to the safety and health of all Americans. We invest heavily in staff and technology resources to promote quality and integrity in this system, and, as private-sector entities, are continually innovating to ensure we meet new needs. With respect to peer-reviewed articles reporting on federally funded research, sustainable partnership with publishers is the best way to continue supporting the U.S. economy, thus ensuring a robust peer-review publishing system and the productivity of the scientific enterprise that supports innovation and the creation of new jobs and industries. With respect to other federal assets mentioned, our expertise can be helpful to ensure the most efficient and innovative development of new systems and tools to enable such products to promote innovation.

AAP/PSP and its members stand ready to work in partnership with the Federal Government and its research funding agencies toward shared goals of increasing the dissemination of research discoveries, improving access to published scholarly works, and advancing science, innovation and the U.S. economy. We would welcome the opportunity to have further discussions on these or any related issues with OSTP and/or NEC personnel.

Sincerely,

John Tagler
Executive Director
Professional and Scholarly Publishing

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[7] As articulated in Memorandum for the Heads of Executive Departments and Agencies on Transparency and Open Government (January 21, 2009), available at http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment and Memorandum for the Heads of Executive Departments and Agencies on Open Government Directive available at http://www.whitehouse.gov/open/documents/open-government-directive

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September 23, 2014

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RE: Strategy for American Innovation

Dear Sir/Madam:

ASTM International (ASTM) is pleased to submit these comments in response to the Office of Science and Technology Policy (OSTP) and the National Economic Council (NEC) request for public comments to provide input into an upcoming update of the *Strategy for American Innovation.*

ASTM, a not-for-profit organization, is dedicated to developing and publishing international voluntary consensus standards. For more than 116 years, ASTM has served society by providing a global forum to develop and publish voluntary consensus standards for materials, products, systems, and services that are utilized by ninety industrial sectors in the United States and most geographic regions of the world.

Over 30,000 individuals from 150 countries serve on ASTM's 144 technical committees to develop over 12,000 quality standards. Over 1,400 representatives from Federal agencies are actively engaged in 93 percent of ASTM's technical committees. ASTM is accredited by the American National Standards Institute (ANSI) and meets the World Trade Organization's (WTO) six principles[1] for the development of international standards.

1. **What specific policies or initiatives should the Administration consider prioritizing in the next version of the *Strategy for American Innovation*?**

The Administration should prioritize such policies as the Office of Management and Budget (OMB) Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities. Circular A-119 outlines a preference and encouragement for Federal agencies to use voluntary consensus standards in lieu of government-unique standards given such standards are developed under valuable principles and processes like openness, balance of interest, due process, and consensus. The Government's use of voluntary consensus standards developed under these principles and processes allow it to achieve the important goals of cost-savings, innovation and efficiency, and reliance on the private sector for quality, efficient goods and services.

Shortly after the President released the 2011 *Strategy for American Innovation: Securing Our Economic Growth and Prosperity,* the Office of Science and Technology Policy (OSTP), the Office of Management

[1]G/TBT/1/Rev. 10, Annexes to Part 1.B, para. 1; WTO's *Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement*.

and Budget (OMB), and the Office of the United States Trade Representative (USTR) issued a memorandum to clarify principles guiding Federal Government engagement in standards activities that can help address national priorities.[2]

> *The vibrancy and effectiveness of the U.S. standards system in enabling innovation depend on continued private sector leadership and engagement. Most standards developed and used in U.S markets are created with little or no government involvement. This approach -reliance on private sector leadership, supplemented by Federal Government contributions to discrete standardization processes as outlined in Office of Management and Budget (OMB) Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" remains the primary strategy for government engagement in standards development. Consistent with the Administration's commitment to openness, transparency, and multi-stakeholder engagement, all standards activities should involve the private sector.*

The OSTP, OMB and USTR further noted that in instances where a national priority has been identified in statute, regulation, or administration policy, the Government should work with private sector standards organizations to accelerate standards development and implementation.[3]

Federal policies and the Administration have supported a private-public partnership for standards development because private sector standards organizations effectively and efficiently provide the essential resources necessary to develop high quality voluntary consensus standards. Developing voluntary consensus standards is a complex process that involves, among many other things, professional staff, housing and administration of the process, technology to allow for broad and virtual participation, and publication and distribution of the documents. ASTM, like other standards development organizations (SDOs), supplies all of the necessary resources and bears much of the costs for developing and providing access to the standards.

As products continue to reach global consumers and U.S. based companies export products around the world, the standards policies of other countries and regions are often more restrictive and often result in U.S. companies having to comply with unfamiliar technical standards that were developed with limited U.S. input. ASTM's standards development process is designed in accordance with the World Trade Organization (WTO) Technical Barriers to Trade Agreement (TBT) six principles: transparency, openness, impartiality and consensus, relevance and effectiveness, coherence, and developing country interests. This successful framework provides for the development of ASTM's high technical quality international standards that are used in the global marketplace and in regulations in 75 countries around the world.

As required under the WTO TBT Agreement and found by the WTO Appellate Body, standards developed under the principles outlined in the WTO TBT Decision are considered "international standards" and should be used as the basis for technical regulations whenever possible. When regulators look to reference international standards as part of Federal regulations, they fulfill their WTO commitments. Furthermore, by the Government looking to the WTO principles as a framework for the development of international standards, the U.S. promotes the use of standards based on technical merit and encourages choice in both the public and private sectors given that there are multiple sources of international standards. The Government should continue to foster and support the unique character and strengths of the public-private partnership in standards development as it pursues trade and other international agreements, regulatory cooperation, and legislative and regulatory approaches. In particular, this is an important consideration when promoting

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[2] Memorandum for the Heads of Executive Departments and Agencies: http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf

[3] *Id.*

international regulatory cooperation as a part of the Transatlantic Trade and Investment Partnership. The Government should continue to seek full implementation of the WTO TBT Agreement and annexes as well as decisions taken in the WTO TBT Committee.

2. **How can the Federal Government augment its overall capacity for analysis of both the forces that determine the competitiveness of specific sectors and the impact of Federal policies—including, but not limited to, science, technology, and innovation policies—on sector specific productivity and competitiveness? What are the most important outstanding questions about innovation policy and process and how might government promote systematic research and program evaluation in those areas?**

Congress established the National Institute of Standards and Technology (NIST), a non-regulatory agency of the U.S. Department of Commerce, to improve the competitiveness of American industry by setting and maintaining the nation's measurement standards and advancing the measurement science that underpins those standards. Within this charter, NIST's mission has expanded to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. NIST's active engagement in numerous ASTM standards activities has had a positive impact on long-established and emerging industries worldwide.

ASTM International has been developing voluntary consensus standards for 116 years and for 113 of those years NIST has proven to be a reliable partner, not only through memberships but also through formal and informal cooperative programs custom-tailored to industry's changing needs. NIST continues to lead in new and innovative areas and some of their workshops and research served as a catalyst for ASTM technical committees in areas such as 3D imaging. Since its inception, ASTM Committee E57 on 3D Imaging Systems has worked with NIST to develop voluntary consensus standards and test methods for the performance and use of 3D imaging systems of importance to a wide variety of industries, including construction, mapping, manufacturing, mining and forensics. The labs at NIST provide an excellent amount of technical research that feeds into the work of technical committees at ASTM and numerous other standards developers.
NIST and other government agencies should continue to foster and support the unique character and strengths of the public-private partnership in standards development. The US government should collaborate with other U.S. stakeholders to do more to help global stakeholders understand the benefits of the approach embodied in the U.S. standards system.

7. **What emerging areas of scientific and technological innovation merit greater Federal investment, and how can that investment be structured for maximum impact?**

Many of today's most complex problems require the deployment of new technologies that are, in part, linked to the development and application of standards. The 2011report, *A Strategy for American Innovation* identified some of the national priorities as nanotechnology, advanced manufacturing, clean energy, and biotech just to name a few. ASTM technical committees are working in these new and often fast moving areas to assist industry as they create standards that cover the terminology, design, materials, test methods and other necessary processes. ASTM committees E56 on Nanotechnology, F42 Additive Manufacturing, E44 on Solar, Geothermal and other Alternative Energy Sources, E48 on Biotechnology and E62 on Industrial Biotechnology were all created by a broad spectrum of stakeholders to address emerging technical issues.

Stakeholders from public and private sectors collaborate most effectively in standards development when they are united in a purpose and committed to address a demonstrated market or regulatory need. As suggested in OMB Circular A-119, the Government should redirect funding to ensure strategic government engagement in the private-sector standards development process rather than using federal funds to develop and deploy government-unique standards. Today's marketplace requires federal agency engagement in standards for technologies that are multidisciplinary and address specific national priorities. While government engagement is necessary at all points in the development process, it is most effective when invested at the front end of standards development activities. Government engagement at the technical committee level provides critical technical information and strategic input—such as the projection of regulatory needs for improving public safety or advancing the competitiveness of U.S. industry. Overall, both the quality and volume of government engagement in the activities of standards development should be enhanced.

Currently, ASTM E56 on Nanotechnology is chaired by a government scientist from NIST and government experts from the National Institute for Occupational Safety and Health and the Consumer Product Safety Commission are helping to guide and shape the standards development activities of the committee.

Numerous federal and state agencies have an interest in ASTM committees because of the environmental, health and safety aspects covered by standards, and ASTM enables agencies to be directly positioned in the process to provide input into and shape the development of relevant standards. Ideally, government technical experts would capitalize on the opportunity to engage their peers from industry and academia early in the process by contributing a projection of the regulatory needs and by investing their data, analysis and technical expertise.

Conclusion

Our nation has a strong, flexible and vibrant standards system that is devoted to continuously improving to meet the demands of industry, government and consumers. U.S. companies and industries that actively leverage standards foster innovation in the marketplace and, in turn, shorten the cycle between initial concept and global market access. Small- to medium-sized companies provide the majority of private sector jobs, drive innovation, and claim at least 50 percent of the U.S. gross domestic product; these companies provide important contributions to ASTM International standards at the same time that they benefit from their equal voice in standards development. At ASTM International, more than half of the experts participating in standards development are from small- to medium-sized companies. Because ASTM's committee structure ensures that all stakeholders have an equal voice and vote, these companies have an essential role to play in creating the technical documents that ensure product quality, safety and interoperability; expedite trade; and underpin international legislation and regulation.

The U.S. system of standardization is based on a long-standing public-private partnership that accelerates market-based innovation and advances competition and trade. In addressing the important role of standards as a part of our nation's innovation policy, the Government will address a vital part of America's innovative capacity for the future.

Sincerely,

James A. Thomas

James A. Thomas

Strengthening Innovation Policy:

Response to Request for Comment on the *Strategy for American Innovation*

Kenan Patrick Jarboe* and Stephen Merrill†

September 23, 2014

The following is a response to the Request for Information (RFI) (FR Doc. 2014-17761) issued on July 29, 2014 issued by Office of Science and Technology Policy and the National Economic Council request public comments to provide input into an upcoming update of the *Strategy for American Innovation.* This response contains four sections with specific comments on questions raised within the RFI:

- Understanding How Intangible Assets Fuel Economic Growth (Question 2)
- Enhancing Policy Development and Implementation (Question 4)
- Evaluating Administration Initiatives (Question 4)
- Foster Design Thinking (Question 6)
- Financing Innovation Through Intellectual Property (Questions 15 & 17)

Understanding How Intangible Assets Fuel Economic Growth

Response to Question (2) which asks "What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?"

The biggest opportunity is to build upon our intangible capital. Our biggest challenge is understanding how to carry out that task. Increased investment in intangibles is not enough.

* President, Athena Alliance

† Director emeritus, National Academies' Board on Science, Technology, and Economic Policy (STEP). The views expressed in this paper do not represent positions of the Academies, the STEP Board, or any of the institution's other appointed committees.

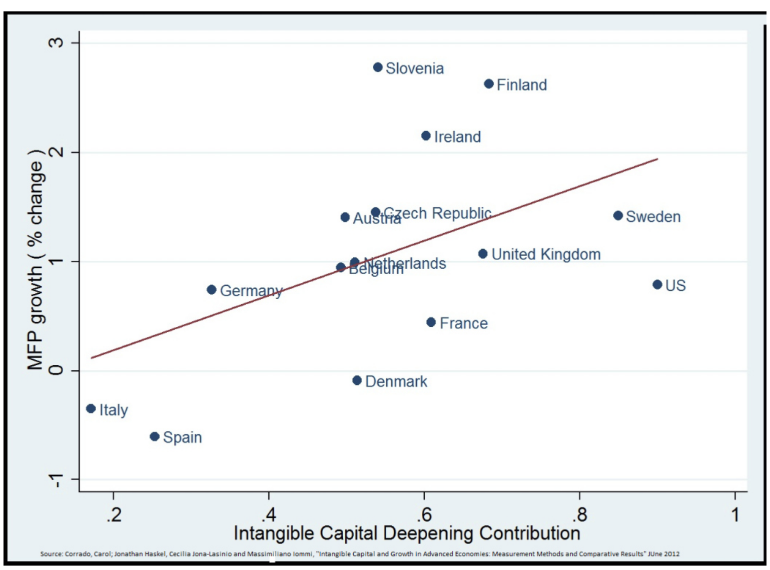
Investments must be effective in raising productivity. **We propose a research agenda to understand why the U.S. lags other nations in translating intangibles investment into productivity gains.**

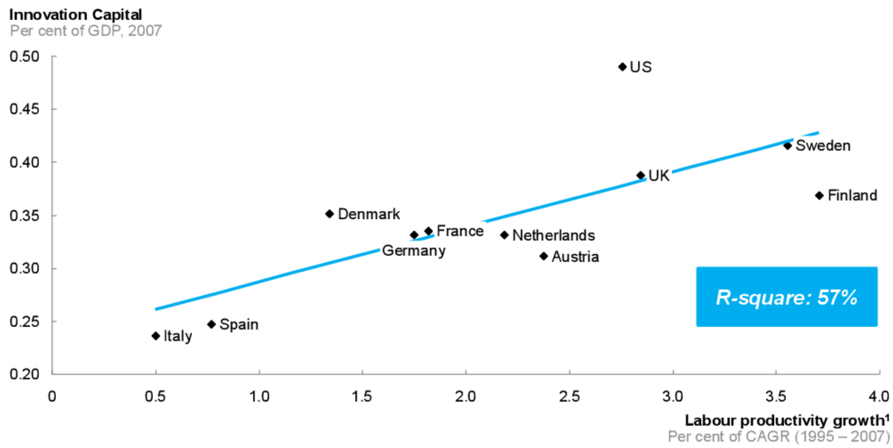
The Organization for Economic Cooperation and Development (OECD) has recently concluded a large study on impact of intangible assets—what they refer to as Knowledge Based Capital (KBC).[1] As the OECD notes:

> Business investment in KBC helps boost growth and productivity. Studies for the European Union and the United States show business investment in KBC contributing 20% to 34% of average labour productivity growth.[2]

However, we do not understand how intangibles raise productivity and what are the most effective policies for fostering investment and raising productivity. We propose a research project to survey of efforts in other countries to advance the understanding of intangibles and their role in corporate performance and economic growth, promote financial investments in intangible assets, and foster the utilization of intangibles.

Our lack of understanding can be summarized by analyzing the following two charts. The first is from Corrado, et. al. "Intangible Capital and Growth in Advanced Economies: Measurement Methods and Comparative Results" which uses the now widely accepted framework for measuring intangible capital.[3] The second is from a McKinsey report on *Innovation Matters: Reviving the Growth Engine*.[4] The McKinsey report introduces an index of "Innovation Capital" as a combination of "Physical Capital" (i.e. ICT infrastructure), "Knowledge Capital" and "Human Capital" which builds on (but is different from) the work of Corrado, Haskel and others.





1 2005 real prices

SOURCE: Corrado, Carol, Jonathan Haskel, Cecilia Jona-Lasinio and Massimiliano Iommi (2012), "Intangible Capital and Growth in Advanced Economies: Measurement Methods and Comparative Results" available at www.INTAN-Invest.net; McKinsey analysis

From: McKinsey, *Innovation Matters: Reviving the Growth Engine*, June 2013

In both cases, the graphs confirms that innovation capital (or intangible capital) is important for productivity growth. The striking feature, however, is that the U.S. gets less productivity growth from its investments in innovation capital than other nations. The first graph shows that other nations, such as Finland, Ireland and even Slovenia get greater productivity growth from their investments in intangible capital than the United States. The second graph tells the same story. The U.K. gets the same amount of labor productivity growth as the U.S. from a smaller investment in innovation capital and Finland gets a much higher rate of labor productivity growth with about the same level as the U.K. investment. [Note the axis are reversed in this graph from the McKinsey graph.]

The data presented here makes an important point: increasing investment in intangibles is not enough. Policy must also look at the effectiveness of that investment in raising productivity. Why is it that the U.S. does so badly in the productivity return on its intangible asset investments compared to other nations (as point out in the first chart)? This will require a new line of research as to how intangibles actually work in boosting productivity in the economy.

We suggest the research agenda include at least the follow items:

- Creation of a more refined set of metrics about investment in specific types of intangible assets.
- An evaluation of whether the composition helps account for the national differences.
- An expansion and augmentation of current efforts to collect data on these investments with better official data.

- A more detailed understanding of policies in those more effective countries. A great deal of cross country studies have been done on innovation policy but there are no studies that look specifically at the particular country policies that affect how investments in intangible assets translate into productivity increases.

Enhancing Policy Development and Implementation

Response Question (4) which asks "How can the Federal Government augment its overall capacity for analysis of both the forces that determine the competitiveness of specific sectors and the impact of Federal policies—including, but not limited to, science, technology, and innovation policies—on sector-specific productivity and competitiveness?"

We propose the creation of a new system for the review and implementation of U.S. economic competitiveness policy. Specifically, we support an earlier proposal from the Center for American Progress (CAP) report *A Focus on Competitiveness: Restructuring Policymaking for Results* to create the following review structure[5]:

- A Quadrennial Competitiveness Assessment by an independent panel of the National Academies whose objectives are to collect input and information from many sources and perform a horizon scan that identifies long-term competitiveness challenges and opportunities;
- A Biannual Presidential Competitiveness Strategy that lays out the president's competitiveness agenda and policy priorities, and captures the attention and buy-in of cabinet principals;
- An Interagency Competitiveness Task Force led by a new deputy at the National Economic Council that develops the biannual strategy, oversees White House coordination of competitiveness initiatives, and monitors their implementation by agencies; and,
- A Presidential Competitiveness Advisory Panel of business and labor leaders, academics, and other experts who assist the administration in developing policy details.

As an alternative to the last point, we note that there was an independent organization carrying out this task. The Competitiveness Policy Council was created in the Omnibus Trade and Competitiveness Act of 1988 (specifically the Competitiveness Policy Council Act, 15 U.S.C. §4801 et seq.). However, it has not had an appropriation since FY 1996.

Evaluating Administration Initiatives

Response to Question (4)

In the past six years the Administration has instituted or expanded several measures to promote innovation and improve our understanding of it. A partial list includes:

- The Science of Science and Innovation Policy (SciSIP) program (NSF)
- STAR METRICS (NSF, OSTP, and NIH)
- The Advanced Research Projects Agency-Energy (ARPA-E) (DOE)
- The National Nanotechnology Initiative (multiple agencies)
- Innovation prize competitions (multiple agencies)
- The JOBS Act (multiple agencies)
- Regional Innovation Cluster Initiative (SBA and other agencies)
- The America Invents Act patent reforms (USPTO)
- The National Center for Advancing Translational Sciences (NIH)
- Capitalization of more intangible assets (e.g., R&D) in the national economic accounts (DOC/BEA)
- National Network for Manufacturing Innovation (DOC/NIST and other agencies)

A full evaluation of many of these initiatives is premature, yet the history of innovation measures in previous Administration is not encouraging. They are often temporary and tend to be under-resourced. **We propose that the Administration strengthen its legacy by commissioning an independent interim assessment of good practices as well as the shortcomings of the most important measures.** In a few cases such evaluations have been mandated by Congress and are underway (e.g., NNI, ARPA-E). There should be an effort to capture the lessons of other important measures, such as the many prize competitions and challenges carried out across the government.

Foster Design Thinking

Response to Question (6) which asks "How has the nature of the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?"

Two of the major shifts in the innovation process have been the increasing importance of non-technological aspect especially the role of design and the emphasis on user input in an iterative process. These two have combined to create an innovation process know as design thinking. **To foster design thinking, we propose funding 5 colleges or universities to create design schools (d.schools) similar to the Stanford d.school (Hasso Plattner Institute of Design).**

The proposal builds upon the "manufacturing universities" proposal to grant 25 universities $5 million each per year for four years to revamp their engineering teaching and research activities toward manufacturing and engage in greater joint industry-university research projects. At $5 million per year for 5 schools, the total budget for creating new design schools would be $25 million.

The linkage between design and manufacturing is well established. Both are key elements in sustaining competitive advantage as the MIT Production in the Innovation Economy (PIE) project has pointed out.[6] The National Academy of Engineering (NAE) report of a workshop on *Making Value: Integrating Manufacturing, Design, and Innovation to Thrive in the Changing Global Economy* makes a similar point. As one workshop participant said, "The new model is that we are all producers, we are all designers."[7]

But design is more than the physical and visual attributes of a product. Design thinking is an approach to problem solving and the innovation process involving iterative proposals and prototypes in close interaction with the ultimate user. Rather than a linear analytical flow from problem definition to final optimal solution, the process involves feedback and rapid prototyping of possible solutions. Design thinking integrates analytics with experimentation and iterative learning. Following the design thinking view, innovation is the process of crafting solutions to customer needs rather than creating a product or a service. Those solutions can be customer-specific or scalable to a large number of like customers.

This new model of innovation calls for people trained in the interface of design-engineering-business. Which is exactly what the Stanford d.school does:

> The d.school is a hub for innovators at Stanford. Students and faculty in engineering, medicine, business, law, the humanities, sciences, and education find their way here to take on the world's messy problems together. Human values are at the heart of our collaborative approach. We focus on creating spectacularly transformative learning experiences, and inevitably the innovations follow. Along the way, our students develop a process for reliably producing creative solutions to nearly any challenge. This is the core of what we do.[8]

As the New York Times noted in a story last year on the Stanford d-school:

> In the eight years since the design school opened, students have churned out dozens of innovative products and start-ups. They have developed original ways to tackle infant mortality, unreliable electricity and malnutrition in the third world, as well as clubfoot, a common congenital deformity that twists a baby's feet inward and down.[9]

Other examples of similar institutions include the Rotman School of Management at the University of Toronto[10] and the Institute of Design at the Illinois Institute of Technology.[11] As the Wall Street Journal reported in a 2012 article "Forget B-School, D-School Is Hot," "more and more business schools are incorporating courses on "design thinking."[12]

More to the point was this statement in the New York Times story: "Sarah Stein Greenberg, a D.school alum and managing director, says she receives inquiries every week from universities looking to mimic the D.school curriculum."[13] It is time to push the envelope on this new approach to innovation by helping fund these efforts and create five new d.schools.

It should also be noted that Question (9) of the RFI asks "What additional opportunities exist to develop high-impact platform technologies that reduce the time and cost associated with the 'design, build, test' cycle for important classes of materials, products, and systems?" The overarching answer to that question lies in changing the mindset of those using those platforms. Using new technologies (platforms) in the old linear process defeats the purpose. Design thinking needs to be incorporated into these platforms.

Thus, other steps beyond the 5 new d.schools could be taken as well. The Manufacturing Extension Partnership (MEP), EDA and SBA services should be expended to explicitly include design thinking assistance. Some portion of the numerous programs to help fund STEM education should go to support design thinking, especially in K-12.

Financing Innovation Through Intellectual Property

Response to Question (15) which asks "What new or existing investment models should be explored to support entrepreneurship in new geographies, as well as in technologies and sectors that are capital-intensive, relatively high-risk, and require sustained investment over long periods of time?"
and to
Question (17) which asks "What tools, business model innovations, financial innovations, or other developments hold promise for reducing the cost of starting and scaling a business in capital intensive sectors like the life sciences, advanced materials, and clean energy?"

Both of these questions concern the development of new mechanisms for financing innovation. Our proposal is for a first step in better utilizing intellectual property (IP) in the lending process. **The Small Business Administration (SBA) and U.S. Patent and Trademark Office (USPTO) should convene a working group of lenders, regulators and other interested parties to develop a common template to be used when describing and valuing IP and intangible assets used implicitly or explicitly as collateral.** The Intellectual Property Office in the United Kingdom (UK IPO) is already undertaking such an activity.[14] Any U.S. effort should communicate, and to the extent possible coordinate, with that activity .

Companies have long been able to raise money based on their physical and financial assets. In contrast, intangible assets—such as patents, trademarks, and copyrights—are largely hidden, and therefore generally unavailable for financing purposes. That is not to say that intangibles are completely missing from financing activities. The first trade secrets case in the United States involved the debt on a bond secured in part by a secret chocolate-making process in 1837.[15] In 1884, Ara Shipman loaned Lewis Waterman $5,000 to start a pen-manufacturing business, secured by Waterman's patent.[16] More recently, William Mann found, based on USPTO filings of a creditor's security interest in a patent, "20% of patents held by domestic corporations during the 1990s had been used as collateral at some point in their lives."[17] Research by Maria Loumioti found that "twenty-one percent of U.S.-originated secured syndicated loans during 1996-2005 have been collateralized by intangibles, with intangible asset collateralization significantly increasing over this time period."[18]

Such deals, however, continue to be more like "one-off" activities. Intangibles are not yet part of the routine loan evaluation. A huge opportunity cost is imposed on the U.S. economy when such a large source of potential financing is locked up. Because intangible assets are not generally available as a source of investment and risk capital, innovative companies may face higher capital costs—or even a dearth of capital—to fund new ideas. Unable to use their intangible assets as a financial tool, prospective borrowers face a system that does not understand their true revenue potential and is unable to judge operational risks appropriately.

The failure to overtly include intangible assets in the underwriting process may also have the consequences for the stability of the financial system. Lack of transparence can result in both an underestimation in the amount of collateral a lending institution has to call on in case of default and a miscalculation of a lending institution's ability to recapture collateral if the lending institution is dealing with an asset it does not understand. Banks don't necessarily have an inventory of the IP collateral in their loan portfolios. Standard terms of loans are often all inclusive liens, which cover everything including the kitchen sink. IP is not necessarily explicitly listed. In some case, there may actually be a "negative pledge agreement" -- where the borrower is explicitly forbidden from using their IP as collateral (a condition a VC investor might put on a company in order to protect their investment). Likewise, the IP might be already somehow encumbered by previous liens or licensing agreements.

In the past year, both the UK IPO and the World Bank have issued reports calling for a more proactive public policy stance to foster the utilization of intangibles generally and IP specifically in the financing process.[19] Over the past few years we have also undertaken a number of studies of intangible asset backed financing.[20]

As noted earlier, the UK IPO has already begun and has established working groups in a number of areas. One group is focused on ways to increase awareness in the business and financial communities of the role of IP and to help the two sides of the financing process to better understand each other. The second is focusing on building templates building based on existing methods for describing and valuing IP to common language so that the process is more standardized.[21]

The US PTO and the SBA should undertake a similar activity.

Additional actions could be taken once a common template has been developed. Bank regulators could use this foundation take steps to study and collect information on the role of intangibles in the financial system—and to underscore the risks of ignoring them.

The information gained combined with a common template would serve as the foundation for the SBA to take the next step in developing underwriting standards for IP. SBA provides a vital role in financing new and small businesses through loan guarantee programs—such as the 7a Program. SBA revised its Standard Operating Procedure (SOP) for the 7a Program to make it clear that loans can be used for the acquisition of intangible assets when buying an ongoing business. However, the rules are unclear as to whether intangible assets can be used as collateral. Building upon the SBA can working with commercial lenders to develop standards for the use of intangible assets as collateral, similar to existing SBA underwriting standards.

Notes:

[1] See OECD, *New sources of growth: Knowledge-based capital*, http://www.oecd.org/sti/ind/newsourcesofgrowthknowledge-basedcapital.htm.

[2] OECD, *Supporting Investment in Knowledge Capital, Growth and Innovation*, Organization for Economic Cooperation and Development, Paris 2013, p. 17, http://www.keepeek.com/Digital-Asset-Management/oecd/industry-and-services/supporting-investment-in-knowledge-capital-growth-and-innovation_9789264193307-en.

[3] Carol Corrado, Jonathan Haskel, Cecilia Jona-Lasinio and Massimiliano Iommi, "Intangible Capital and Growth in Advanced Economies: Measurement Methods and Comparative Results," Co-Invest, June 2012, http://www.coinvest.org.uk/pub/IntanInvest/WebHome/Methods_and_Comparative_Data_-_June_2012-7.pdf.

[4] McKinsey, *Innovation Matters: Reviving the Growth Engine*, London, UK, June 2013, http://www.mckinsey.com/%7E/media/McKinsey%20Offices/United%20Kingdom/PDFs/Innovation%20matters%20v8_McKinsey%20branded.ashx.

[5] *A Focus on Competitiveness: Restructuring Policymaking for Results*, Center for American Progress, December 2010, http://www.americanprogress.org/issues/economy/report/2010/12/01/8730/a-focus-on-competitiveness/.

[6] http://web.mit.edu/pie/

[7] National Academy of Engineering, *Making Value: Integrating Manufacturing, Design, and Innovation to Thrive in the Changing Global Economy*, Washington, DC, 2012, http://www.nap.edu/catalog.php?record_id=13504.

[8] http://dschool.stanford.edu

[9] Nicole Perlroth, "Solving Problems for Real World, Using Design," *New York Times*, December 29, 2013, http://www.nytimes.com/2013/12/30/technology/solving-problems-for-real-world-using-design.html.

[10] http://www.rotman.utoronto.ca

[11] https://www.id.iit.edu

[12] Melissa Korn and Rachel Emma Silverman, "Forget B-School, D-School Is Hot," *Wall Street Journal*, June 7, 2012, http://online.wsj.com/article/SB10001424052702303506404577446832178537716.html.

[13] Perlroth, op. cit.

[14] *Banking on IP: An Active Response*, UK Intellectual Property Office, Newport, UK, March 2014, http://www.ipo.gov.uk/ipresearch-bankingip-2014.pdf.

[15] Appendix B. *Vickery v. Welch.* In R. Mark Halligan and Richard F. Weyard, *Trade Secret Asset Management,* Aspatore Books, Boston, 2007, pp. 181–186.

[16] Stephen van Dulken, *Inventing the 19th Century*. New York University Press, New York, 2001, p. 86.
Also, this transaction led to a major patent law case, *Waterman v. Mackenzie*, 138 U.S. 255 (1891), where the Supreme Court ruled that a licensee without title cannot sue for infringement. William J. Murphy, "A Proposal for a Centralized and Integrated Registry for Security Interest in Intellectual Property, Appendix 19—*Waterman v. Mackenzie*," *IDEA: The Journal of Law and Technology*, Vol. 41, Nos. 3 & 4, 2002, pp. 561–562.
http://www.idea.piercelaw.edu/articles/41/41_3-4/Appendices/19.Appendix.pdf.

[17] William Mann, "Creditor Rights and Innovation: Evidence from Patent Collateral," November 17, 2013, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2356015.

[18] Maria Loumioti, "The Use of Intangible Assets as Loan Collateral" November 1, 2012, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1748675.

[19] Martin Brassell and Kelvin King, *Banking on IP? The role of intellectual property and intangible assets in facilitating business finance*, UK Intellectual Property Office, Newport, UK, November 2013, http://www.ipo.gov.uk/ipresearch-bankingip.pdf.
Juan Mateos-Garcia, *Using intellectual property to raise finance for innovation*, Innovation Policy Platform, World Bank, 2014, https://innovationpolicyplatform.org/sites/default/files/rdf_imported_documents/Case_Study-IP_for_Financing.pdf.

[20] Ian Ellis, *Maximizing Intellectual Property and Intangible Assets: Case Studies in Intangible Asset Finance*, Athena Alliance Working Paper #07, November 2009, http://www.athenaalliance.org.
Kenan Patrick Jarboe and Roland Furrow, *Intangible Asset Monetization: The Promise and the Reality*, Athena Alliance Working Paper #03, April 2008, http://www.athenaalliance.org.

[21] Personal communications, Tony Clayton, Chief Economist, UK Intellectual Property Office, September 10, 2014.

BioBricks FOUNDATION

23 September 2014

Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave NW
Washington, DC 20504

Via email: innovationstrategy@ostp.gov

Dear Mr. Correa,

My colleagues at the BioBricks Foundation (BBF) and I appreciate the opportunity to provide comments for the upcoming update of the *Strategy for American Innovation.*

The BBF is a 501(c)(3) public-benefit organization dedicated to ensuring that the engineering of biology is conducted in an open and ethical manner to benefit all people and the planet. In the ten years since its founding, the BBF has become the world leader in promoting standards for the engineering of biology, in building and protecting a commons of foundational biotechnologies, and in educating and supporting a vibrant community of biological engineers. We are the presenter of the SBx.0 Conference series, the preeminent meeting in the field of synthetic biology, and have hosted over 3,000 attendees from 31 countries since its inception as SB1.0 in 2004. We champion high-throughput biological design/build facilities (BIOFABs) that are being developed around the world to produce reliable, standardized biological parts for public benefit. We also created the BioBrick™ Public Agreement (BPA), the world's first legal tool that enables free exchange and use of standard biological parts.

We would like to offer our response to Question 6: "How has the nature of the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?"

Innovation in the life sciences has changed dramatically with the advent of synthetic biology – an emerging field that aims to transform biotechnology from an expensive, unreliable and ad hoc research process to an efficient engineering discipline. Advances in DNA synthesis and assembly technologies, innovations in computer-aided design, and the creation of automated strain engineering platforms and associated technical standards are improving efficiencies in the design, construction and testing of biological systems. As such, the tools of synthetic biology can help address unmet grand challenges in health, energy, environment, and agriculture and enable next-generation sustainable manufacturing and economic growth driven by bio-based approaches.

Synthetic biology has now begun to enable significant coordination of labor around the tools and transactions underlying the US and global bioeconomy. Technical standards for the engineering of biology – including standards for (i) physical assembly of DNA, (ii) functional composition of biomolecules, (iii) reference materials and metrology, and (iv) data exchange – are enabling researchers, for the very first time, to cooperate in significant ways across institutional and international boundaries. The Departments of Defense (via DARPA) and Commerce (via NIST) have started to invest significant resources in creating common free-to-use platforms for engineering biology. Many new business and organizational opportunities are emerging as a result, and it is paramount that the US property rights frameworks adapt to support ongoing innovation in improving the tools and communities working to advance the engineering of biology and resulting bioeconomy.

As one specific example, intermediaries have emerged who are supporting the reuse of engineered genetic materials, either as physical material or as information. These intermediaries – which include companies providing DNA synthesis and assembly services as well as organizations that maintain registries of biological parts – are at risk of accruing liability for patent infringement. Patent infringement is a strict liability offense in that actual or constructive knowledge of the existence of a patent is not necessary to support a claim for patent infringement. As such, intermediaries who specialize in DNA synthesis and assembly may unknowingly risk patent infringement should the DNA molecules they construct for their customers be subject to patent protection by third parties.

Similarly, intermediaries who maintain registries of biological parts are faced with potential liability for patent infringement. Registries of biological parts typically provide DNA sequence information together with functional information and performance specifications to speed and simplify the engineering of biology. The Registry of Standardized Biological Parts, for example, was the first registry developed in 2004 by innovators participating in the International Genetically Engineered Machines (iGEM) competition. Other registries have since begun to come online, including those created by the Joint BioEnergy Institute (JBEI), the Synthetic Biology Engineering Research Center (Synberc), and many others. The establishment of registries of biological parts is rapidly expanding, and it is anticipated that multiple registries will soon be linked through a distributed semantic framework that will enable a global network of researchers to collectively describe, remotely query, share, and retrieve information about standard biological parts. However, for the vast majority of these registries, the property rights status of the biological parts is unknown. Without this information, the use of registries as a source for biological parts that can be developed for commercial purposes is limited. Even research use of the biological parts contained within these registries may be threatened, at least in the United States, by the lack of a formal research exemption.

Registries of biological parts are vital for global harmonization in the engineering of biological systems. Given the risk of patent infringement liability, commercial entities are reluctant to contribute to public registries of biological parts. Indeed, commercial entities that rely on registries of biological parts for their own research and development purposes are likely to maintain independent registries in secret. Researchers in academic laboratories who fear potential patent infringement liability also may be reluctant to contribute parts to shared registries. One possibility for addressing the needs of intermediaries would be to create a type of carrier exemption, or safe harbor, that would enable more scaling and sharing of tools for engineering biology while respecting the rights of patent holders. A safe harbor for intermediaries could be one step towards building a more flexible property rights framework for the engineering of biology.

As Bill Joy from Sun Microsystems once observed, "No matter who you are, most of the smartest people work for someone else." True to Joy's principle, innovation in synthetic biology requires a research and development infrastructure that can meet the challenge of accessing tools and knowledge that reside outside the boundaries of any one organization. Realizing the full potential of synthetic biology requires a distributive innovation system in which researchers can freely share data, methods, standards and practices across institutional and international boundaries. Creating a more flexible property rights framework that will support distributed innovation will advance the engineering of biology and resulting bioeconomy.

Again, my colleagues and I appreciate the ability to contribute to your work. I invite you to visit our website at www.biobricks.org and to contact me should you have any questions or need additional information. We look forward to seeing the updated *Strategy for American Innovation*.

With respect and appreciation,

Linda J. Kahl

Linda J. Kahl, Ph.D., J.D.
Director, Legal Program
The BioBricks Foundation

Biophysical Society Public Affairs Committee Comments on the OSTP Strategy for American Innovation
September 23, 2014

1) *What specific policy or initiatives should the administration consider prioritizing in the next version of the Strategy for American Innovation?*

As the federal government looks to retool its strategy for American Innovation, it must remember that all technological and scientific advances share one common feature: these advances stand on the shoulders of fundamental research. Consequently, the success of the Strategy for American Innovation relies on investment in unfettered fundamental research. In biology, this translates into recognizing that an important part of the U.S. federal-funded research portfolio must include projects seeking to understand how something works, even before identifying the application of the new knowledge. The history of breakthroughs and important advances shows clearly that such fundamental understanding enhances the ability to address effectively newly defined diseases, epidemics, to discover new therapies and drugs, improve health and advance treatments, with the end result of better and longer living.

One of the most recent examples of fundamental research resulting in better outcomes are the drugs introduced recently to cure hepatitis C infections. Based on gaining a fundamental understanding of the biophysical properties of the proteins involved, including their molecular structures and function of the proteins required for the viral life cycle, the development was successful and also had a direct impact on related advances in biotechnology.

Another example of widespread and powerful impact of fundamental biophysics in society, is the science of imaging. The ability gained from fundamental biophysical discoveries to see non-invasively within the body at the levels of tissues, cells, and now molecules is rapidly implemented in medical testing and in fundamental biological research. Coupled with spectroscopic techniques these images are translated into functional understanding of regulatory mechanisms, transport systems and biological motors. Essentially the same tools are used in various aspects of engineering and in biotechnology. Driven by scientific discoveries and successful uses, the revolution in imaging is continuing today, discovering new ways to produce further advances in medicine and biotechnology in the future. This continues the way it began, in the context of basic biophysical research that led to the imaging technologies from which we benefit today.

Other areas of basic biophysics will surely lead to major advances in the future. While it is impossible to predict the big winners in terms of near-term vs. far-term contribution to national innovation, we can already recognize a few candidate areas of biophysics that include mechanical properties of cells and tissues, computational modeling of biological systems from genes to protein assemblies and cells, and the molecular and nano-engineering of biological systems for both technology and medicine.

To enable this progress and foster new discoveries and implementations, the government must single out university-based research for special attention. Much research and development occurs outside universities in private industry, research institutes, and government laboratories. But essentially 100% of all researchers are trained in universities. The universities uniquely have the dual role of research and training. If university-based research is not nurtured and sustained, we could lose generations of researchers and damage all of our institutions that engage in R&D.

6) How has the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?

The innovation process has become more interdisciplinary. It has also become increasingly important to understand how our technology interacts with, and impacts, humans and natural systems. In addition to enabling interdisciplinary teams of researchers it is vital for individuals to be taught and trained to be competent across disciplines. Decades ago, the Biophysical Society was created in recognition of the need to integrate biology and physics. Biophysicists continue to be at the heart of basic interdisciplinary science.

7) What emerging areas of scientific and technological innovation merit greater Federal investment, and how can that investment be structured for maximum impact?

Biotechnology and Nanotechnology continue to be areas of great promise. Fundamental biophysical research constitutes the core of these two areas. Advances in materials research is leading to a revolution in magnet technology for Magnetic Resonance Imaging and Spectroscopy that has the potential for describing the chemistry of human behavior through spectroscopy of the human brain.

22) What are specific areas where a greater capacity for experimentation at the federal level is likely to have large benefits? Are there useful models of experimental platforms that the government can adopt?

In 2005, the NIH reauthorization included a demonstration program entitled Bridging the Sciences, which aimed to fund cross-disciplinary research proposals that would normally fall through the cracks—research perceived as too health related for NSF or DOE, and too fundamental for NIH. Key tenets of this program were to make sure review panels included reviewers from a variety of disciplines (including some with expertise in the scientific, mathematical and engineering language of those submitting the proposal); enabling the federal agencies to provide funds at a variety of award levels; and allowing researchers to submit such proposals through the agency with which they are most comfortable. Making sure this cross-disciplinary research receives the resources it needs and that the right proposals are funded requires updating and growing the Bridging the Sciences program.

24) Which new areas should be identified as national priorities either because they address important challenges confronting US security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish US leadership faster than what might be possible otherwise.

Within the domain of the competence of biophysicists, the broad area of complex molecular engineering (bridging biophysics, genomics, and nanoscience) has enormous potential. Complex biological molecules are amazing machines at the nanoscale level. From imaging these structures to detailed characterizations of their functional mechanisms and an understanding of how their rates of action are achieved is providing a uniquely biophysical approach. We have barely begun to tap the potential of engineered complex molecules built on the same physical principles that govern the actions of biological molecules.

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BOSTON UNIVERSITY

Via email: innovationstrategy@ostp.gov
Subject: Strategy for American Innovation

September 23, 2014

On behalf of Boston University (BU), I am pleased to respond to the Office of Science and Technology Policy and the National Economic Council's request for input on an update to the Strategy for American Innovation. We appreciate the Administration's focus on investing in the building blocks of American innovation, promoting market-based innovation, and catalyzing breakthroughs for national priorities. In addition to our views on promoting government-university-industry collaborations below, we also support many of the recommendations included in the comments submitted jointly by the Association of American Universities and the Association of Public and Land Grant Universities.

Innovation Trends, Question (8)
Government-University-Industry Partnerships

BU recommends the Administration renew its focus on government-university-industry partnerships as a means to capitalize on federal investments in a constrained budget environment. In particular, we suggest bolstering federal support for efforts to scale up and replicate successful university-industry collaborations.

BU has consistently focused on using research to develop prototypes and models that address both industry and government needs. The BU Photonics Center, for example, has partnered with the Department of Defense to create sniper detection and biological threat detection tools important to military needs. The Center also hosts a business incubator on site, giving our researchers direct knowledge of the needs of the local photonics industry.

Building on our record of success in university-industry partnerships, BU recently launched the Engineering Product Innovation Center (EPIC), a

15,000-square-foot, $9 million facility in the heart of the Boston University's Charles River Campus. Boston University built EPIC to create a new generation of engineers capable of understanding and leading the entire new product innovation process, from design through manufacturing, in a global environment. Many universities in the U.S. have manufacturing-oriented centers that focus on basic manufacturing research, but EPIC focuses on educating both undergraduates and graduate students in the entire range of relevant skill sets—from design to prototyping to manufacturing to lifecycle management—that are vital to product innovation. Hands-on manufacturing is now an integral part of students' overall engineering curriculum.

EPIC was made possible in part through support from GE Aviation, Procter & Gamble, PTC, and Schlumberger, among others. These industrial partners joined with BU to create this pioneering facility because they recognized the significant impact it will have on future of the innovation workforce.

While the university-industry partnerships we have developed have arisen organically through our local ties and outreach to our industry partners, we believe the federal government can play an important role, too. We recommend that OSTP and NEC further develop mechanisms for the federal government to invest in successful university-industry partnerships in order to increase their size and replicate their success around the country. By investing in collaborations that have already proven their success on a small scale, the federal government can leverage its limited resources to grow larger partnerships with more impact.

OSTP and NEC might also consider incremental support for university-industry collaborations. The National Science Foundation could encourage the use of small supplements to existing grantees who take advantage of regional resources to produce prototypes essential to industry or government partners. For example, an NSF program officer could offer a principal investigator studying how the brain processes noise a supplement so she can prototype a hearing device that blocks noise interference.

Thank you again for your solicitation of feedback on the next iteration of the Strategy for American Innovation.

Best,

Gloria Waters

Gloria Waters
Vice President and Associate Provost for Research
Boston University

Brookings Institution – Climate and Energy Economics

I'd like to respond to your request for information for next year's Strategy for American Innovation.

Today Brookings hosted an event to showcase three new papers suggesting ways to promote more efficient radio spectrum use by federal agencies. (Event page: http://www.brookings.edu/events/2014/09/23-new-directions-for-public-sector-spectrum-policy).

As the Chair of the President's Council of Economic Advisers, Jason Furman, said at our event this afternoon, one important contributor to productivity growth is the expansion of wireless technologies, and further growth in the sector will need additional spectrum. One way to provide that is to ensure that federal agencies use spectrum as efficiently as possible and relinquish resources they don't need. Our papers relate directly to that challenge and suggest pragmatic and promising ways forward.

I respectfully submit the papers for your consideration.

With best regards,
Adele Morris

Adele C. Morris, Ph.D.
Fellow and Policy Director, Climate and Energy Economics
The Brookings Institution

Economic Studies
at BROOKINGS

September 2014

Towards Gaining Support for Federal Spectrum Reform

Joel Brockner
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Abstract

Gaining support for federal spectrum reform requires not only the right incentives but also a high quality process for bringing about change. Drawing on the organizational change literature, I describe the driving and restraining forces that comprise a high quality process. The driving forces entail surfacing dissatisfaction with the current state, providing a vision of the future state, and putting plans and resources in place to transition from the dissatisfying current state to the better future state. The restraining forces form the bases of people's resistance to change; they are the perceived costs of change. Support for federal spectrum reform is more likely to occur when the driving forces outweigh the restraining forces.

The author is grateful to Adele Morris for her outstanding contributions to an earlier version of the manuscript.

I. Introduction

The research literature on organizational change has direct implications for the President's initiative to incentivize federal agencies to share or relinquish radio spectrum to make it more available to burgeoning commercial uses. Essentially, the policy problem is one of changing the behavior of federal spectrum-using agencies. This involves creating incentives, to be sure, but research suggests that the underlying challenge is likely to be more complex than that.

In this paper, I look at two ways the literature frames stakeholders' perceptions of change, and I review the implications of these frameworks for federal spectrum policy. The first framework, reported in Section II, draws on literature reviewed by Brockner (2010) that shows that two broad categories of factors influence people's tendencies to support change initiatives: the perceived outcome of the change itself and the process used to get there.[1] Outcomes and processes interact to influence both stakeholders' reactions to the prospect of change and the cost effectiveness of success, with clear lessons for spectrum policymakers.

Section III introduces the second framework for organizational change and describes how a set of motivating forces that drive change must dominate the forces that impede change.[2] Section IV explains how to structure a transition process successfully. Section V describes ways to reduce the perceived costs of change, and Section VI concludes.

II. Outcomes and Process

When confronted with a potential major change, people quickly size up whether the change will make them better off or worse off. For example, does the change affect their financial well-being? Will their work become easier or more difficult or more or less interesting? All else equal (and not surprisingly), people are more likely to embrace change if they think the outcomes of the change will be favorable.

In the spectrum policy context, this observation explains the strong emphasis on creating "incentives." For instance, Section 6 of the President's 2013 spectrum policy memorandum asks the Spectrum Policy Team to recommend "market-based or other approaches that could give agencies greater incentive to share or relinquish spectrum, while protecting the mission capabilities of existing and future systems that rely on spectrum use."[3] The myriad proposals to create these incentives, surveyed in IDA (2014), include ways to provide bigger carrots and larger sticks, such as through

[1] Brockner, J. (2010), *A contemporary look at organizational justice: Multiplying insult times injury*, New York: Routledge Press.

[2] Jick, T. (2002). Managing change. In A. R. Cohen (Ed.), The portable MBA in management (2nd ed.). New York: Wiley.

[3] Presidential Memorandum, *Expanding America's Leadership in Wireless Innovation*, 78 Fed. Reg. 37431, 37434 § 6 (June 20, 2013). http://www.whitehouse.gov/the-press-office/2013/06/14/presidential-memorandum-expanding-americas-leadership-wireless-innovatio

greater agency compensation or spectrum fees.[4] They also include technological approaches that could facilitate sharing.

Certainly, financial incentives matter, and enabling technology is useful. But the focus on these outcomes suggests that a neglected dimension of the challenge is the *process*. We know from the research that over and above outcomes (and also in interaction with them), people are more likely to embrace change if they approve of the process. For example, support for a change initiative tends to be higher if the reasons for the change are clear and opinion leaders agree that the change is necessary. A good process also means including people and giving them advance notice, appropriate training, and validation that the change isn't an implied criticism of them. I return to these important process elements in Section 4.

In fact, research shows that, at least to some extent, what a proposed change lacks in benefits can be made up with a better process. The nature of this "process/outcome" interaction appears in Figure 1. One can think of the rows of figure one as the means to the end, and the columns as the end itself.

Figure 1. Employees' Reactions to Organizational Change

Process Quality	Outcome Favorability: Low	Moderate	High
Low	1	4	7
High	5	7	8

Scale Range: 1-10

Higher numbers reflect greater support for a change initiative (e.g., reflected in productivity and morale)

The values in the table suggest that if people are happy with the outcomes associated with the change, then the quality of the process doesn't matter as much. In other words, the incremental effect of a good process relative to a poor process is small if people are already happy with where they end up (e.g., comparing the 7 and 8 in the last column of Figure 1); "the ends justify the means."

In contrast, the benefit of a good process is much higher when outcomes are perceived to be unfavorable. In fact, even for undesirable outcomes, leaders can gain support for the change by handling the process well (i.e., instigating a move from 1 to 5 down the first column of Figure 1). Relatedly, if people are already happy with the process and the outcome is moderately favorable, the incremental effect of a better outcome is fairly low (for example, a move right from the 7 to the 8 in the bottom row of Figure 1).

[4] IDA Science & Technology Policy Institute, *A Review of Approaches to Sharing or Relinquishing Agency-Assigned Spectrum*, IDA Paper P-5102 (Jan. 2014), *available at* https://www.ida.org/upload/stpi/pdfs/p5102final.pdf.

Whereas doing the process well reduces the influence of the outcome (and a favorable outcome reduces the influence of the process), process and outcome are not interchangeable in one important respect. Providing greater benefits to those affected by change can be substantially more financially costly than offering a high quality process. In the spectrum policy context, this could mean that agencies and their spectrum managers may be more willing to relinquish or share spectrum if the process needed to "go there" was handled well, e.g., if the affected parties have more technical support, more time, more flexibility, and more input into how the reforms will be instituted.

III. Driving and Restraining Forces

Research identifies three driving forces that bring about support for change initiatives: (1) dissatisfaction with the current state; (2) a belief in an attractive alternative state; and (3) a workable process in moving from the dissatisfying current state to the better future state. Jointly these driving forces must exceed the costs of change (or restraining forces). In summary, one can think of a successful change effort meeting the following condition:

$$(D \times V \times P) > C$$

where D is dissatisfaction with the current state, V is a superior vision of the future, P is an effective transition process, and C is the perceived costs of change (or bases of resistance). This framework also suggests that the driving forces of D, V, and P must all contribute positively; 100 times 100 times zero is still zero. Let us look more closely at each of D, V, P, and C.

Dissatisfaction

The first driving force, dissatisfaction, is the perception that the current situation is not acceptable or sustainable. Crystallizing dissatisfaction with the current state requires two things from leaders. First, they must fully understand and communicate the external and internal factors that make change necessary, or at least desirable. Second, they must create a sense of urgency. This is particularly important when the current state is not particularly dissatisfying.

Currently, one challenge to spectrum reform is that most federal agencies have radio systems and other spectrum-using equipment in place that work reliably. Advances in technology generally allow them to replace aging systems and increase performance without occupying additional bandwidth. However, agencies have similar growing demands for wireless applications that private sector actors do, and they are naturally reluctant to relinquish their resources. Even when they can economize on spectrum for one system, they may understandably want to reserve the surplus for another future need.

So what could motivate a sense of dissatisfaction and promote buy-in to a different approach? Federal agencies may be more receptive to a new spectrum management approach if leaders point out that the current pattern of ad hoc mandates to clear bands is unproductive, that it undermines planning for future mission effectiveness, and that it is likely to worsen as pressure from the commercial sector mounts. In that light, agencies may find it preferable to take the initiative to reduce spectrum use on their own terms than face disruptive dictates from Congress.

Vision

A singular focus on current and prospective problems is ineffectively negative. Leaders must also offer a better way forward (i.e., a vision). A convincing picture of a better future also can create a sense of urgency by demonstrating that although the current state is not particularly troubling, things could be so much better.

The research identifies three key challenges associated with the vision aspect of the overall framework. First, the vision should be clear, compelling, and attainable. Second, it should be widely understood by employees at all levels. Third, employees should embrace the vision. Effective leaders will show staff how they stand to benefit if the organization realizes its vision and explain the role each person plays in helping to realize the vision.

In the spectrum context, then, a successful reform will clarify how agencies stand to gain by more efficient spectrum use, in budget terms or otherwise. For example, Congress could grant federal agencies broad authority to raise and spend revenues from spectrum transactions, giving federal spectrum users more control of the process and the outcome and providing resources agencies can apply towards a range of priorities. At the same time, Congress could pledge to refrain from new relocation mandates for a set period of time pending review of how agencies use their new authority. The vision here would be that agencies receive both respite from ad hoc reforms and new authorities and resources to accomplish their mission. The more flexibility agencies have in how they can use spectrum revenue, the more they are likely to value those revenues and the more compelling the vision will be.

IV. Improving the Process (P)

Research suggests a clear set of measures to improve a reform process:

Respect the past.

One impediment to change is the experience by some that the change invalidates or implicitly criticizes past practices (and sometimes, by extension, the people themselves). Leaders should reassure stakeholders that previous approaches may have made sense in the realities of the environment at that time, but that the environment has changed and therefore change is necessary. One way to respect the past is the use of ceremony, which facilitates transition by acknowledging transition.

Walk the talk.

Whatever the changes in policy, it is essential that political appointees and senior executives show they intend to achieve them. That means that the White House must give agency administrators clear guidance on their expectations and follow proclamations with concrete deliverables and clear accountability for them.

Work with opinion leaders.

Successful reformers of federal spectrum management will identify key opinion leaders and spend extra effort to ensure that they are on board. These influential individuals could derive their status from seniority, expertise, forceful personality, or internal connections. With their support, the change process is likely to proceed smoothly. Furthermore, their resistance can scuttle what would otherwise be a sound process.

Develop an implementation plan.

A successful change plan requires "who, what, where, when, and how" details. Status quo management structures and resources will not typically be sufficient to implement the change, no matter how well-reasoned and necessary it is. This suggests that federal agencies should not be short changed on the budget, staff, expertise, equipment, and time they need to make a spectrum deal work. In other words, given the potential net social benefits of a more efficient spectrum allocation, skimping on the process may be a false economy. At the same time, agencies should develop a clear articulation of what resources they need and why to assure policymakers that the resources they are given will be well spent.

Communicate early and often.

Successful change, particularly if it's disruptive to current practices, requires regular communication with stakeholders. Change can confuse and distract people and provoke a state of denial about the change. Regular ongoing communication, including by opinion leaders and those in authority, will reinforce the message that change is really happening and all need to get on board. This includes following up with people after communicating with them to learn whether they've interpreted the change in the same way that the change agents had in mind.

Involve people in decisions.

In planning and implementing complex technical changes, it is particularly important to involve the people who will be affected by them. First, they likely have an informed and valuable view, if not on where to go, then perhaps on how to get there. Second, even if the affected parties don't provide new ideas, the fact that they were involved in decisions is likely to help motivate them to follow through. This suggests providing an authentic role for the Interdepartment Radio Advisory Committee and spectrum teams within agencies.

V. Reducing Costs of Change (C)

The organizational change literature describes a wide variety of costs of change that can provoke resistance. Stakeholders may believe that change could bring a loss of power, prestige, control, or job security. Change also involves uncertainty and risk, both financial and to mission effectiveness, and it likely requires attention diverted from other responsibilities. Addressing managers' concerns about making their mission more complicated or demanding is a critical element of successful reform.

For example, shifts in spectrum use may require new equipment, new systems, and new competencies. The change itself requires effective management and the capabilities to analyze the technical and economic implications of different options and make responsible decisions across important tradeoffs. These analyses are not necessarily natural strengths of many federal spectrum users, and these new responsibilities could provoke discomfort and resistance, especially given the other growing demands on managers' time and resources. One way to reduce such costs of change and thereby lower resistance would be to make these tasks easier for agencies.

Astute change agents diagnose the root causes of resistance to change and tailor measures to those causes. One source of resistance to sharing or relinquishing spectrum could derive from burdensome requirements to adopt and learn new technologies or procurement rules. In that case, leaders could establish appropriate training programs and allocate time and resources for them. Agencies may be more likely to embrace new requirements by the Office of Management and Budget (OMB) to compare the spectrum needs of potential future systems if they receive training and analytical tools.[5] Likewise, OMB and the National Telecommunications and Information Administration (NTIA) may do a better job enforcing those procurement requirements if they have the staff to assist agencies and review their analyses.

Alternatively, if resistance arises because agencies are unsure whether they will later need the spectrum they could relinquish now, then policymakers can encourage approaches that allow temporary (but potentially long term) leasing or sharing with commercial users, seeking a balance between agencies' concerns and market demands. Agencies could also write contingent contracts, which allow spectrum sharing only under certain circumstances. Further, the federal government could support the development of technologies, such as interruptible devices, that give agencies assurance that the spectrum they share will become available under the conditions in which agencies need it.

A successful reform process will encourage agencies to determine and articulate clearly ways risks can be acceptably mitigated and allow innovative contracts and technologies to meet those needs. The market can price whatever risk is off-loaded to commercial users with discounts for contingent spectrum access or technological constraints.

Finally, agencies may resist change because any change is one more demand in an already demanding job. Increasing demands with fewer resources are already an issue for federal managers in this contentious budget environment. In a review of the federal career executive corps the Senior Executive Association wrote earlier this year:

"With increasing frequency many career senior executives are avoiding risk and are becoming inclined to make 'safe decisions' as opposed to the 'right decisions' – or decisions (in their minds) that could potentially be career

[5] OMB Circular No. A-11 (2014), Section 31.12. http://www.whitehouse.gov/sites/default/files/omb/assets/a11_current_year/s31.pdf.

damaging in the current climate. Unfortunately, avoiding the more difficult and critical issues (and the tough decisions associated with them) diminishes opportunities for breakthroughs in technological innovation and productivity, increased cost savings, process and program enhancements, and improved resources utilization."[6]

Any approach that reduces agencies' perception that spectrum reforms are yet one more unfair unfunded mandate could promote success.

VI. Conclusion

This paper reviews lessons from the organizational change literature as they pertain to the reform of federal spectrum use. It argues that incentives matter, as is widely recognized, but the process matters as well. Indeed, the outcome and process are likely to interact to influence commitment to spectrum reform. Not only might a good process help compensate for a less beneficial outcome, but a good process can also be more cost effective.

[6] "A Review of the State of the Federal Career Executive Corps," Senior Executive Association, Washington, DC, January 2014. . https://seniorexecs.org/images/documents/A_Review_of_the_State_of_the_Federal_Career_Executive_Corps.pdf

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Greasing the Wheels of Federal Spectrum Deals

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Abstract

This paper reviews the numerous impediments to encouraging greater sharing or relinquishment of spectrum to commercial users. The paper offers five pragmatic policy proposals to make federal spectrum transactions easier, faster, and more attractive to agencies. First, nearly every proposal to promote more efficient federal spectrum use will work better if agencies have clear, technology-neutral rights to the spectrum they occupy. Second, federal agencies should track how commercially valuable their spectrum rights are by preparing regular balance sheets for their most commercially valuable spectrum rights. Third, the paper argues that agencies should be able to keep and spend most of the revenue from spectrum transactions. In this context, the numerous policies designed to prevent agency over-spending are actually hurting American consumers by impeding efficiency-enhancing spectrum transactions. Fourth, policymakers should task trusted intermediary institutions, such as federally funded research and development centers or contractors, to develop potentially mutually beneficial spectrum deals between federal agencies and the private sector. Finally, the paper argues that greater spectrum sharing would be feasible with more creative contingent contracts and supporting technology.

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"We must unlock the economic value and entrepreneurial potential of U.S. spectrum assets while ensuring that sufficient spectrum is available to support critical Government functions." -- President George W. Bush, June 30, 2003

"We must continue to make additional spectrum available as promptly as possible for the benefit of consumers and businesses. At the same time, we must ensure that Federal, State, local, tribal, and territorial governments are able to maintain mission critical capabilities that depend on spectrum today, as well as effectively and efficiently meet future requirements."

--President Barack Obama, June 14, 2013

I. Introduction: The Challenge

Federal agencies have made significant efforts to relinquish commercially valuable spectrum, but pressure to do more is mounting with the growth in the value of spectrum for commercial uses. All sorts of challenges arise in promoting efforts to share and relinquish federally controlled spectrum, so it is not surprising that Republican and Democratic administrations face many of the same issues a decade apart.[1]

First, federal agencies have many legitimate and high-value uses for spectrum. Agencies rightfully argue that many benefits of government activity, such as those from a secure national defense, scientific advances, protected natural environments, and safe air traffic systems are difficult to quantify, much less monetize, but are nonetheless extraordinarily valuable to society. Thus, they would say, it is not obvious that putting their spectrum in commercial hands is moving it to a higher and better use.

In some cases, only mission experts with security clearances are in a position to assess alternatives to the current spectrum use in a given band. Further, agencies face conditions of rapidly changing technology and mission demands, creating a large option value to irreversibly clearing a band and relinquishing it to non-federal uses.

In many cases, multiple agencies with safety-of-life missions occupy a band, so any spectrum transacted to commercial users (including sales, leases, sharing, and barter arrangements) requires extensive technical and economic analysis, systems engineering, and a substantial bureaucratic process. Given the idiosyncratic nature of the missions, equipment, and uses involved, most transactions are unique and few economies of scale in doing them arise.

Another complication is that federal spectrum users do not own their spectrum, so they can't directly sell it even if they wanted to. And agencies are not compensated in a way that makes it worthwhile to study their options. While the Spectrum Relocation Fund (SRF) covers costs and a little more, it provides little net incentive.

[1] This paper draws in part on: Morris, Adele and Martin Cave. 2005. "Getting the Best Out of Public Sector Spectrum," September 8. 2005 TPRC, Research Conference of Communication, Information, and Internet Policy.

Given a history of disruptive ad hoc spectrum reallocations, some agencies may believe that they have "given at the office," and further reallocations from federal use are unfair when some commercial spectrum (say, broadcast television bands) are at least as inefficiently deployed as federal bands.

Moreover, even in the long run, special factors make some public sector spectrum demands highly inflexible:

- Physical laws determine certain frequencies that are vital to science, especially for passive bands used for radio-astronomy and remote sensing.
- International spectrum conventions and rules, such as those for air and marine communications, may reserve certain frequencies for specific uses.
- Certain frequencies may have special intelligence or security applications, for example for radar or satellite communications.
- Some frequencies are reserved for coordination with state and local first responders.

Critics might claim that oversight of federal agencies' spectrum use is lax, but given the extremely technical and often classified nature of agency systems, it is difficult to observe the genuine "needs" of the agencies. And "needs" is not really the right word when there are complicated tradeoffs across spectrum, other inputs, and mission performance. In any case, agencies have little incentive to cooperate with efforts to deprive them of resources. To make it even more difficult, the agency responsible for managing the federal spectrum inventory, the National Telecommunication and Information Administration (NTIA) at the Department of Commerce, is funded in significant part by charges to the agencies whose spectrum use they oversee. It is a challenge for any organization to balance serving clients and overseeing them at the same time.

Despite all these challenges, some federal-to-commercial spectrum transactions have succeeded, and potential remains to do more. Proposals for how achieve this potential abound.[2] This paper grapples with how to lower the costs of federal spectrum transactions. A lot can be done to make them faster, easier, and more satisfactory for agencies without blowing up the whole system. The recommendations here are more prosaic, perhaps, than dramatic revisions to the statutory authority of existing institutions, but probably more doable.

Experience suggests that making changes in the interest of the agencies is critical. As implied in the Presidential quotes above, NTIA and federal interagency teams have been working for over a decade on plans-to-make-plans-for-further-planning to implement "market-based economic mechanisms" and other incentives for spectrum management.[3] I participated in those

[2] A review of policy proposals appears in IDA Science & Technology Policy Institute, *A Review of Approaches to Sharing or Relinquishing Agency-Assigned Spectrum*, IDA Paper P-5102 (Jan. 2014), *available at* https://www.ida.org/upload/stpi/pdfs/p5102final.pdf.

[3] See for example, NTIA, 2008. *Spectrum Management for the 21st Century: Plan to Identify and Implement Incentives that*

processes in the mid-2000's when I was the Department of the Treasury's staff representative to the Federal Government Spectrum Task Force, and I know how difficult progress is.[4]

Even with strong White House leadership and Congressional pressure, changes that work against agency interests, such as imposing spectrum fees, are nearly impossible to implement. Energetic and spectrum-savvy political appointees come and go, so those in the bureaucracy that oppose change can usually wait out the initiative du jour. Moreover, it is hard to keep spectrum policy in the spotlight long enough to accomplish much. The administration is busy fighting wars, enforcing laws, managing wildfires, and accomplishing other critical missions that at any particular point in time are arguably far more important than promoting efficient spectrum management. This motivates my focus here on practical, actionable policies that agencies, at least at the higher levels of management, could accept or even embrace.

Promote More Efficient and Effective Use of the Radio Spectrum. (See Task II-C in Appendix 1) http://www.ntia.doc.gov/files/ntia/publications/incentives_plan.pdf. Also, NTIA, 2006. *Spectrum Management for the 21st Century: Plan to Implement Recommendations of the President's Spectrum Policy Initiative,* (See Project G), *http://www.ntia.doc.gov/files/ntia/publications/implementationplan2006.pdf And Spectrum Management for the 21st Century Report 1: Recommendations of the Federal Government Spectrum Task Force,* (see Recommendation 8 in Appendix B), 2004. *http://www.ntia.doc.gov/files/ntia/publications/spct_pol_part_1_rl.pdf*

[4] A Presidential Memorandum issued June 5, 2003, established this task force. http://www.ntia.doc.gov/files/ntia/publications/presmemoonspectrumpolicy.pdf

Section II argues that defining and devolving clear rights to agencies for the spectrum they occupy is an important enabling condition for successful reforms. Section III makes the case for keeping a transparent record of spectrum asset values -- a balance sheet of a sort. In Section IV, I argue that Congress and OMB should allow agencies to keep much of the revenue from their spectrum transactions. I explain why policies designed to prevent unauthorized federal spending are lowering net social benefits by impeding an improved allocation of resources. Section V recommends engaging trusted third parties to do the heavy analytical lifting in constructing promising spectrum transactions, and Section VI calls for creative thinking about the structure of such transactions and development of technology that supports those arrangements. Section VII concludes.

II. Clarify Agency Spectrum Rights

U.S. law divides authority over spectrum between the independent Federal Communications Commission (FCC) and the President, who delegates executive branch powers to NTIA. Agencies describe and defend their spectrum requests to NTIA, and NTIA gives them spectrum "assignments." NTIA maintains the inventory of federal spectrum resources, and agencies are expected to return any unused frequencies to NTIA for potential reassignment to other agencies.

An assignment includes parameters such as frequency, bandwidth, geographical location, power of transmission, and where relevant, the direction of propagation. In some cases, however, assignments detail the authorized equipment rather than the physical parameters of the allowable radio signals. That can tie agency spectrum rights to legacy systems and complicate shifts to new technologies, particularly if such a shift simply frees up spectrum for use by another agency.

I would argue that **nearly every proposal to promote more efficient federal spectrum use will work better if agencies have clear, technology-neutral rights to the spectrum they occupy.** That is because virtually any kind of spectrum contract or transaction is easier to construct if a clear exchange of rights is involved.[5]

Others demur. IDA (2014) concludes that the potential for spectrum property rights to "incentivize Federal agencies to improve spectrum efficiency and to share or relinquish excess spectrum is unclear." One concern about spectrum property rights appears in a report by President's Council of Advisors on Science and Technology (PCAST): "[S]pectrum should be managed not by fragmenting it into ever more finely divided exclusive frequency assignments, but by specifying large frequency bands that can accommodate a wide variety of compatible uses and new technologies that are more efficient with larger blocks of spectrum."[6]

To these concerns I would say that by themselves, spectrum rights probably won't do much to incentivize federal agencies to share or relinquish spectrum. Rather, having clear rights is a necessary condition for other incentives to work. **Agencies will "own" their spectrum choices more if they have property-like rights to their spectrum. Those rights should be articulated like the flexible use, technologically neutral, FCC licenses.** Only when agencies bear the costs and benefits of different options will they be invested in new management approaches. In addition, an agency may be more willing to consider giving up some of the rights in an assignment (such as certain geographic areas) if there is no question whether the agency can keep the remainder.

I say "property-like" rights because my recommendation centers on the articulation and broad control of the spectrum. This does not necessarily mean that agencies should be able to conduct any and all spectrum transactions without oversight or guidance and keep all the revenue and spend it however they want. That degree of true property rights is generally inconsistent with how the federal government works.

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[5] See: Matheson, R. and A. Morris, "The Technical Basis for Spectrum Rights: Policies to Enhance Market Efficiency," *Telecommunications Policy* 36 (2012), pp. 783-792. Working paper: http://www.brookings.edu/~/media/research/files/papers/2011/3/03%20spectrum%20rights%20matheson%20morris/0303_spectrum_rights_matheson_morris.pdf

[6] President's Council of Advisors on Science and Technology (PCAST). 2012. "*Report to the President: Realizing the Full Potential of Government-Held Spectrum to Spur Economic Growth*. Executive Office of the President (July). http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_spectrum_report_final_july_20_2012.pdf

For example, one can imagine different criteria in different bands that spectrum transactions should meet, and undoubtedly some limits on the retention and use of spectrum revenues will apply. But like in any market, striking deals will be easier if buyers and sellers are clear about what goods are available.

III. Keep Spectrum Balance Sheets

Federal agencies should know the market value of their spectrum rights. Quantifying and monetizing federal spectrum assets, particularly by agency, is not straightforward, but it is worth the effort. It is far more likely that policy officials will under-manage an asset if they have no idea how much it is worth. The new rules from the Office of Management and Budget (OMB) around procuring spectrum-using equipment go part way to asking agencies to monetize the spectrum they use, but the guidance only applies to spectrum used by new systems and the analysis is not regularly updated.[7]

OMB should ask agencies to prepare regular spectrum balance sheets, particularly for their assignments in the most commercially valuable bands.[8] The balance sheets should be updated at least every few years as assignments and market conditions evolve.

Of course, spectrum is different than typical federal capital assets such as "land (including parklands), structures, equipment (including motor and aircraft fleets), and intellectual property (including software) which … have an estimated useful life of two years or more."[9] Nonetheless, spectrum is a durable asset, in some cases with profound market value, and it behooves the federal government to treat it as such. Preparing a balance sheet doesn't have to be as formal as ordinary federal accounting, but some kind of standardized asset calculation is warranted.

OMB and/or NTIA should develop guidelines for preparing these balance sheets to address certain analytical challenges. For example, government and non-government entities share large swaths of spectrum in some bands. Maritime communications and air traffic control communicate across the two sectors in the same bands. Federal electrical power systems interconnect with both domestic and international non-federal power systems, and Civil Air Patrol stations communicate with the military. In other cases, such as some satellite applications, both government and non-government users access the same bands, but it is not clear who "uses" how much. One approach would be for agencies to estimate of the share of available transmission capacity occupied by their emissions and apply that to the overall band asset value.

[7] OMB Circular No. A-11 (2014), Section 31.12. http://www.whitehouse.gov/sites/default/files/omb/assets/a11_current_year/s31.pdf.
[8] The "balance sheet" framing comes from a conversation with John Leibovitz.

[9] Capital Programming Guide v 3.0, Supplement to OMB Circular A–11: Planning, Budgeting, and Acquisition of Capital Assets. http://www.whitehouse.gov/sites/default/files/omb/assets/a11_current_year/capital_programming_guide.pdf

IV. Allow Agencies to Benefit from Spectrum Transactions

As IDA (2014) relates, a number of existing policies prevent federal agencies from retaining and spending revenues from spectrum transactions. The Governmental Accountability Office (GAO) explains that, as a general proposition, an agency may not augment its appropriations from outside sources without specific statutory authority.[10] The objective of this prohibition is to prevent a government agency from undercutting the Congressional power of the purse.

To be sure, in general, good governance requires careful spending oversight by OMB and Congress. In this case, however, **Congress should allow federal agencies to keep revenue from spectrum transactions for flexible use in authorized categories of spending.** Looser rules would make everyone better off, including American taxpayers. First, agencies highly value flexible pots of money, and the SRF in its current form is hardly motivating. Second, more flexible rules could prompt spectrum transactions that will create significant new consumer and producer surplus that will benefit the economy and American households. Third, to the extent that a greater supply of spectrum in commercial uses raises corporate income, American taxpayers will recapture some of those gains through the corporate income tax and personal income taxes on dividends and capital gains. Fourth, social benefits will likely accrue from the additional federal spending even if Congress hasn't specifically authorized every dollar. Given tight budgets these days, it is unlikely that federal agencies will squander their spectrum revenues.

One recent draft bill goes in the right direction, but not nearly far enough. The bipartisan bill, H.R. 3674, The Federal Spectrum Incentive Act of 2013, would give an agency one percent of the revenue generated by the auction of spectrum vacated by that agency. The money could be used by the agency to offset sequester budget cuts or for other federal efforts to relinquish spectrum. The broad parameters of the bill are promising, but agencies would need far more than one percent of the revenue to provide a meaningful incentive. Probably more like half the revenue would do it. In addition, the limits on what agencies could spend money on may be too restrictive. It may work better to identify broad categories of pre-authorized spending. **The Administration should work with Congress to find mutually agreeable terms, recognizing that scrupulous fiscal prudence is a false economy in this context.**

While some appropriators might blanch at the idea of pre-authorized spending, a few relevant precedents apply. One is "enhanced use leasing," as authorized for the Department of the Defense.[11] These laws allow authorized agencies to lease out underutilized real property and keep a share of the proceeds for purposes such as the "alteration, repair, improvement of property or facilities; construction or acquisition of new facilities; lease of facilities; or

[10] GAO (2006) Principles of Federal Appropriations Law, Third Edition, Volume II. http://www.gao.gov/special.pubs/d06382sp.pdf

[11] See *U.S. Code 10, Subtitle A, Part IV, Chapter 159, Section 2667.*

facilities operation support."[12] Similar provisions could apply to underutilized federal spectrum.

Another precedent appears in Forest Service law such as the Pueblo de San Ildefonso Claims Settlement Act of 2005.[13] This law allows "all monies received by the Secretary of Agriculture from the sale of National Forest System land as authorized by this Act…shall be deposited into the fund established in the Treasury of the United States pursuant to the Sisk Act and shall be available, without further appropriation, authorization, or administrative apportionment for the purchase of land by the Secretary of Agriculture for National Forest System purposes in the State of New Mexico, and for associated administrative costs." This means that when the Forest Service sells certain forest land, it can keep the money and spend it on other eligible land.

Of course, appropriators or OMB may simply cut the budget of agencies that have available spectrum revenues, but this would be a mistake. An agency may have little reason to lease out spectrum if it must give up a more certain revenue source (budget authority) in exchange with an uncertain revenue source (spectrum lease payments). If the White House and Congress are truly supportive of making more spectrum available to the private sector, then **OMB and appropriators should do what they can to preserve incentives for agencies, even if it means making unusual exceptions to budget policies**.

[12] *U.S. Department of the Army guidance on enhanced use leasing* at http://eul.army.mil/aboutEUL.htm.
[13] Public Law 109-286, Sept. 27, 2006.

The net benefits to society of a significant spectrum trade are likely to far outweigh any possible efficiency losses from sub-optimal agency spending.

V. Engage Trusted Intermediaries

It is unreasonable to expect agencies, with existing staff, to develop mutually attractive spectrum deals with the private sector. It is a lot of work to analyze spectrum use and figure out ways to do things differently to free up the commercially valuable resources. Identifying profitable spectrum transactions is not the government's core competency, and managers have other mission priorities. Although a few agencies have a deep bench of radio engineers, those experts are busy perfecting warfighting systems. If agency engineers can design new systems to economize on spectrum use, their first goal would be to free up resources for redeployment to other internal needs. And to my knowledge, very few economists are currently involved in federal radio system analyses.

Fortunately, the federal government has ways to tap external experts. One is in the form of federally funded research and development centers, or FFRDCs, and the other is through private contractors. My proposal is to **empower trusted intermediaries to research and develop promising spectrum transactions between federal agencies and commercial users.** If the funding is available, agencies could welcome offloading the burden of this analysis to external experts.

The intermediaries' work would specifically include examining alternatives to existing federal spectrum uses and identifying potential transactions with promising net benefits to both federal and commercial users. This would require expertise in engineering, cost analysis, commercial spectrum markets, and finance. The goal would be to identify and develop appropriate contract structures, lease terms, sharing parameters, and geographical boundaries. I am unaware of any existing FFRDC or private contractor that currently has all of these skill sets immediately ready to deploy, but several have the demonstrated capacity to gear up for the tasks I've described. A request for proposals would be necessary to identify the best intermediaries.

FFRDCs, as the name implies, are generally funded by the federal government, although some have subsidiaries that do commercial work. They perform all sorts of technical, economic, and security analyses and functions for federal agencies. Some have staff (with security clearances) already familiar with federal radio operations. These non-profit shops include RAND, MIt is Lincoln Laboratory, MITRE, and the Center for Naval Analysis. According to federal regulations, an "FFRDC meets some special long-term research or development need which cannot be met as effectively by existing in-house or contractor resources."[14]

[14]48 CFR 35.017 - Federally Funded Research and Development Centers, http://www.law.cornell.edu/cfr/text/48/35.017

The role I describe may be suitable for private contracting as well, and a number of firms have staff with security clearances and radio expertise. Private contractors may also have better access to experts with commercial spectrum market experience. FFRDCs have the advantage of broad existing sole-source relationships with federal agencies.[15] Using FFRDCs would not necessarily be less expensive than using a private contractor, but it could be easier and faster. On the other hand, FFRDCs usually have only one or two sponsoring agencies. That raises the question whether it would be difficult for any one particular existing FFRDC to work with a collection of agencies that share spectrum in a particular band. It may work better for NTIA to be the FFRDC sponsor.

Resolving the question of how the intermediation should be funded will take some thought. If agencies keep most of the revenue from their spectrum transactions, then they could finance further the development of further transactions themselves (if given the authority). A broadened SRF could also be a fit. Agencies may have more confidence in intermediaries that take only public funds, and it would avoid any appearance of a conflict of interest. But the current SRF authority would have to be revised to use funds to develop profitable transactions that do not specifically lead to spectrum "assigned by competitive bidding," such as barter arrangements.

[15] A critique of these relationships appears in "Federally Funded Research and Development Centers: A Strategic Reassessment for Budget-Constrained Times'" by the Professional Services Council, June 5, 2010.

Another potential source of funding is the private sector. Industry stakeholders have the best information about their willingness to pay for new spectrum, and only they can estimate how they would value (or more accurately discount) non-exclusive or temporary arrangements. All else equal, it makes sense for the private sector entities that could benefit from these transactions to have some skin in the game. It would require a suitable funding vehicle, though.

One approach would allow industry consortia or foundations to supplement federal funds and/or work directly with the intermediaries. Federal regulations allow agencies to determine whether the FFRDCs they sponsor can accept work from other entities, including other federal agencies, and nonprofit or for-profit organizations.[16] If it makes sense in a particular band for only one firm to work out a deal with an intermediary, then it may be feasible to have firms bid for the right to enter into that negotiation.

Another way to put non-federal capital at risk is to allow the intermediary to benefit from a "share-in-savings contract" or other incentive arrangement. The Federal Acquisition Regulation states that "[i]ncentive contracts … are appropriate when a firm-fixed-price contract is not appropriate and the required supplies or services can be acquired at lower costs and, in certain instances, with improved delivery or technical performance, by relating the amount of profit or fee payable under the contract to the contractor's performance." The challenge would be to construct an incentive contract that rewards intermediaries for developing successful transactions and at the same time preserves agencies' confidence in them.[17] Certainly, if agencies control their spectrum, they must sign off on spectrum transactions. That means a well-designed incentive contract would give intermediaries extra compensation if they develop transactions that agencies approve.

At the very least, agencies or NTIA could issue requests for information to which firms could respond with suggestions and data pertinent to potential transactions. FFRDC restrictions allow industry stakeholders to provide sensitive or proprietary information without fear of improper use or disclosure. The Commerce Spectrum Management Advisory Committee (CSMAC) advises the NTIA on a broad range of spectrum policy issues and could be a conduit for suggestions from industry, but as an official federal advisory committee, any information it provides to the government would be public.

VI. Develop Creative Deals and Technology

As much as wireless firms value unencumbered spectrum rights, the potential supply of exclusive permanent nationwide rights from federal agencies is limited. This means it is time to **develop creative transactions that**

[16] 48 CFR 35.017-1 - Sponsoring agreements. http://www.law.cornell.edu/cfr/text/48/35.017-1

[17] Federal Acquisition Regulation, Subpart 16.4—Incentive Contracts https://acquisition.gov/far/current/html/Subpart%2016_4.html#wp1078212

accommodate some continued government use or control but make available resources that firms value. Leasing is a particularly promising arrangement. Like its commercial analog but perhaps to a greater degree, government agency demand for spectrum may contain a speculative component because of the large uncertainties around how spectrum management policies, mission requirements, budgets, and technologies will evolve. In particular, agencies may wish to hold spectrum now, in excess of their current needs, because they project that their needs will grow over time, or because an emergency could erupt. They may also fear that budget limitations or future rules may make it more difficult to obtain greater spectrum in the future. The demand for temporary access to spectrum is uncertain, but temporary access may be better than no access, so it seems worth the effort to see if leases can work.

One concern agencies may have with leasing is that leasees could install equipment dependent on the spectrum they lease and then lobby Congress to keep their spectrum when the time comes for the lease to expire. Federal users have little incentive to make spectrum available temporarily to users who would be difficult to displace later. One way around this would be to mandate frequency-flexible equipment or other ways to help prevent stranded capital. Another would be to make the lease long enough to allow the full depreciation of the equipment by the time the lease is up. Given the rapid decline in equipment live cycles this may be more feasible now than it would have been even a few years ago.

Another option would be to embed a lease-to-own provision in the lease that specifies the sale price and other terms should the leasee wish to acquire the spectrum at the end of the lease period. Agencies could thus be assured that if they must permanently relinquish the spectrum, they will be appropriately compensated.

Another approach could be to lease or sell spectrum under the proviso that agencies could access it in the event of a national emergency. This will require technical solutions to ensure that federal agencies can reliably override private sector uses, and it would need contract provisions that describe the contingencies under which agencies may recall their spectrum. Commercial users would bear the risks associated with unpredictable service degradation, but they would get access to the spectrum under normal operating conditions.

Geographic sharing is another promising approach. This seems to be working well in recent spectrum transactions, in which private sector operators promise to steer clear of certain military installations. New technologies that prevent emissions in unauthorized locations could make agencies more comfortable with relinquishing spectrum.

Other creative transactions would allow federal agencies to barter spectrum rights for other goods and services, in temporary arrangements (barter lease) and permanent reallocations. If agencies can trade spectrum for, say, wireless communications services or new equipment, both parties and the American economy could be better off.

Again, I acknowledge the multitude of budget and appropriations rules that make creative deals challenging, but the welfare gains from these unorthodox trades could be extraordinary. **Congress and the White House should allow some financial innovation in their efforts to promote technological innovation.** At the same time, **they should invest in developing technologies that support more creative spectrum transactions.**

VII. Conclusion

This paper reviews the numerous impediments to encouraging greater sharing or relinquishment of spectrum to commercial users. The paper offers five pragmatic policy proposals to make federal spectrum transactions easier, faster, and more attractive for agencies.

- First, nearly every proposal to promote more efficient federal spectrum use will work better if agencies have clear, technology-neutral rights to the spectrum they occupy.
- Second, federal agencies should track how commercially valuable their spectrum rights are by preparing regular spectrum balance sheets for their most commercially valuable spectrum rights.
- Third, the paper argues that agencies should be able to keep and spend most of the revenue from spectrum transactions. In this context, the numerous policies designed to prevent agency over-spending are actually hurting American consumers by impeding efficiency-enhancing spectrum transactions.
- Fourth, I argue that policymakers should task trusted intermediary institutions, such as FFRDCs and private contractors, to develop potentially mutually beneficial spectrum deals between federal agencies and the private sector.
- Finally, the paper argues that greater spectrum sharing would be feasible with more creative contingent contracts and supporting technology.

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Buildings and Bandwidth: Lessons for Spectrum Policy from Federal Property Management

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Abstract

As the demand for commercial wireless services continues to grow at a steep rate, there is mounting pressure on the federal government to reduce its spectrum holdings. Several recent proposals for reforming the management of federally used spectrum are inspired by institutions or approaches used for the management of federal property, including creation of a General Services Administration (GSA) for spectrum and the use of the Department of Defense's (DoD) Base Realignment and Closure (BRAC) process to clear federal spectrum. Based in part on her recent experience as the senior federal property manager at GSA and DoD, the author critiques these and other proposals for institutional reform of federal spectrum management. She also looks at the relevance for federal spectrum policy of the economic tools used to incentivize federal agencies to economize in their use of federal building space and to dispose of underutilized property. A major lesson for spectrum policy is that the ability to retain proceeds from the disposal of property is a key motivator for federal agencies if the incentive is properly structured. Key statutory authorities used to promote federal property disposal, including long-term outleasing and property exchange (barter), also seem applicable to federal spectrum management, as do public-private ventures as a way to address agencies' need for the capital to upgrade older radio systems with newer, more spectrum-efficient systems.

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I. Introduction

As the demand for commercial wireless services continues to grow at a steep rate, there is mounting pressure on the federal government to reduce its spectrum holdings. The federal government uses a significant amount of spectrum to meet its own mission needs for wireless services.[1] The largest federal user by far is the Department of Defense (DoD), followed by the Federal Aviation Administration (FAA), the Department of Homeland Security (including Coast Guard) and the Department of Justice.[2]

Those who argue for a reduction of federal spectrum—a disparate set of firms, trade associations, think tanks and public interest groups that disagree with one another on many other aspects of spectrum policy—maintain that the federal government uses spectrum inefficiently. The quantitative evidence for this is controversial (it is hard to define much less measure spectrum efficiency), and the critics largely ignore the fact that federal demand for wireless services is increasing for many of the same reasons that commercial demand is growing.[3] The critics may also overstate the absence of incentives for efficiency: federal agencies have relinquished a large amount of spectrum in the last two decades and that, combined with their growing demand for wireless services, has increased the pressure for efficient usage. Moreover, technical improvements that enhance mission performance—e.g., the compression of a signal to make it harder to jam or intercept—can improve spectrum efficiency, which is why some of the key technologies on which the wireless industry is based have come out of the military.

Nevertheless, it is fair to say that the incentives for efficient use of spectrum facing federal agencies are not as strong as those facing commercial firms. Wireless carriers pay billions of dollars to acquire spectrum and then invest billions more to upgrade their networks: efficient usage gives them a competitive advantage because they can provide more or better services in a fixed amount of spectrum. By contrast, federal agencies are endowed with spectrum that was given to them for free; they cannot sell or lease it; and their acquisition of spectrum-using systems does not consider the opportunity cost of the spectrum. A key problem is the lack of up-front funding to upgrade older radio systems with

[1] Of the most highly valued frequencies—those between 225 and 3700 MHz—federal agencies have exclusive use of about 18 percent, and nonfederal users have exclusive licenses to about 33 percent. The remainder is allocated to shared use. According to the General Accountability Office (GAO), depending on the estimate used, the fraction of this spectrum used exclusively or predominantly by federal agencies ranges from 39 to 57 percent. GAO. 2012. "Spectrum Management: Incentives, Opportunities, and Testing Needed to Enhance Spectrum Sharing." GAO-13-7 (November), p. 6. http://www.gao.gov/products/GAO-13-7.

[2] GAO (2012), p. 6.

[3] For example, U.S. operations in Iraq and Afghanistan required more than 40 times the bandwidth used in the 1990 Gulf War. Center for Strategic and International Studies (CSIS). 2003. "Spectrum Management for the 21st Century," a Report of the CSIS Commission on Spectrum Management (October), p. vi.

newer, more spectrum-efficient systems.

A great many reports and white papers have been written in the last few years about how to reallocate spectrum resources from federal to commercial use.[4] The major focus has been on ways to reduce directly the amount of "federal spectrum" (spectrum used exclusively or primarily by federal agencies), particularly through the use of economic incentives and/or technology that facilitates sharing. A secondary focus has been on institutional reforms to improve the management of federal spectrum, which is the responsibility of the Department of Commerce's National Telecommunications and Information Administration (NTIA).

As a one-time spectrum policy analyst who spent the last five years managing real property at DoD and the General Services Administration (GSA), I have been struck by the degree to which recent proposals for spectrum policy reform look to institutions or approaches used to manage federal real property (buildings, land and structures).[5] Several proposals call for the creation of a "GSA for spectrum," to impose more discipline on federal users, in part through the imposition of spectrum fees comparable to the market-based rents that GSA charges federal agencies. Another proposal calls for the application of a BRAC-type approach, referring to DoD's Base Realignment and Closure process, to free up federal spectrum for commercial use.

This paper critiques some of the existing proposals and offers additional ideas. In Section II, I look at proposals for institutional reform. In addition to examining proposals inspired by two institutions with which I have firsthand experience (GSA and BRAC), I look at proposals to transfer NTIA's spectrum management functions to the Federal Communications Commission (FCC) and to privatize those functions. In Section III, I look at the potential for economic incentives to promote more efficient use of federal spectrum. I comment on the much-discussed proposals for spectrum fees based on my GSA/DoD perspective and identify other tools for and lessons from federal property management that may have application to spectrum. Section IV provides a brief conclusion.

II. Reform of Federal Spectrum Management

NTIA has received a great deal of criticism from the disparate set of organizations that believe that "the federal government hoards spectrum." The gist of the criticism is that NTIA lacks the authority and expertise to discipline the demands of federal spectrum users, in particular, DoD. A related criticism is that, because NTIA is both an advocate for federal spectrum users and a kind of regulator, its role is confused.

[4] For an excellent summary, see IDA Science and Technology Policy Institute. 2014. "A Review of Approaches to Sharing or Relinquishing Agency-Assigned Spectrum" (January). https://www.ida.org/upload/stpi/pdfs/p5102final.pdf.

[5] Baumol, William J. and Dorothy Robyn. 2006. *Toward an Evolutionary Regime for Spectrum Governance*. Brookings Press.

The various governance reform proposals are similar in their desire to have federal spectrum managed by an entity that can enforce more discipline. However, the proposals—ranging from unified control of spectrum by an independent agency (the FCC) to outright privatization—are more striking for their differences. The fact that these proposals go in such different directions (an activity conducive to regulation by an independent agency would generally not also be a candidate for privatization and vice versa) suggests a lack of clear thinking about the nature of federal spectrum management.

In this section, I briefly summarize the institutional history of federal spectrum management. Next I highlight the insights of Ronald Coase, the Nobel Laureate whose "other" spectrum report, on the management of federal spectrum and proposals to reform it, is still relevant 50 years after it was written.[6] Finally, I review the major contemporary proposals for reform of federal spectrum management.

[6] Coase, Ronald, William Meckling and Jora Minasian (Coase et al.). 1995. "Problems of Radio Frequency Allocation." RAND Corporation. http://www.rand.org/pubs/drafts/DRU1219.html RAND suppressed the 200-page report for over 30 years out of fear of its political implications. Coase's first report on spectrum, an analysis of FCC regulation, concluded that well-defined property rights in spectrum would go a long way toward solving the problem of radio signal interference. Coase. 1959. "The Federal Communications Commission." Journal of Law and Economics (JLE) 2, no. 1. Coase was awarded the Nobel Prize in Economic Sciences in 1991 for an article that was directly inspired by his study of the FCC. Coase. 1960. "The Problem of Social Cost." JLE 3, no. 1.

Short History of the Management of Federal Spectrum

NTIA was created in 1978 to serve as the President's telecommunications advisor.[7] Among other responsibilities, NTIA exercises the President's power to authorize the use of spectrum for "government owned stations," as codified in Section 305 of the Communications Act of 1934. In that capacity, NTIA oversees the Interdepartment Radio Advisory Committee (IRAC), the group of federal agency representatives that has coordinated federal frequency assignments for more than 90 years.

The IRAC was established following the first national Radio Conference convened by then-Secretary of Commerce Herbert Hoover in 1922. The IRAC's major function was to assign radio frequencies to federal agencies and to coordinate federal spectrum use for broadcasting and radio communications. The watchword was coordination as opposed to control. The Committee's 1925 Statement of Policy emphasized the autonomy of the individual federal departments it represented. The Statement of Policy also stressed that the IRAC's role was advisory, and it explicitly rejected centralization of control ("Centralized control of Government Radio Communications … is not at present either practicable or desirable.")[8]

The IRAC functioned relatively autonomously until 1951, when

[7] NTIA now describes itself as the President's telecommunications and information policy advisor.
[8] Coase et al. (1995), pp. 29-30.

President Truman created the position of Telecommunications Advisor to the President, with oversight of the IRAC, and expanded the IRAC's responsibilities to include formulating and recommending policies and plans related to the federal government's management and usage of spectrum. For the next 27 years, the IRAC reported to different agencies in the White House, including the White House Office of Telecommunications Policy (OTP) created by President Nixon.[9] NTIA was created when President Carter merged the OTP with the Department of Commerce's Office of Telecommunications, which had supported OTP.

The "Other" Coase Report

The debate about how to reform federal spectrum management goes back more than half a century. In 1962, Coase, Meckling and Minasian (Coase et al.) did a detailed report on the IRAC for the RAND Corporation at the request of the nascent National Aeronautics and Space Administration (NASA). Their analysis is instructive for two reasons. One, the IRAC was the target of criticism then, just as NTIA is now, and the complaints were remarkably similar to those voiced today. Two, although the RAND report, like Coase's earlier report on the FCC, ultimately argued for allocating spectrum rights using prices as opposed to administrative controls, Coase et al. were far more sympathetic to the IRAC's decentralized, consensus-based approach to decision-making than to the FCC's highly procedural approach or to proposals calling for greater top-down control from within the executive branch.

Coase et al. described at length the criticisms of the IRAC, based largely on two studies done in the 1950s at the request of the White House. The RAND authors distilled the views of the critics, many of whom favored having the IRAC report to an independent agency ("Board") in the executive branch, down to three objections. One, the IRAC is a committee of users, and as such is "inevitably inferior as an organization for the allocation of resources to a Board (not representative of users) doing the same job." Two, the IRAC is "inefficient and unbusinesslike." Three, "the present arrangements result in too great an allocation of radio frequencies for the use of government departments and too small an allocation … for private users…."[10]

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[9] President Eisenhower eliminated the position of Telecommunications Advisor and transferred the functions to the Director of the Office of Defense Mobilization (ODM), a powerful White House agency whose first director (under President Truman) was former General Electric President Charles ("Engine Charlie") Wilson. In 1961, President Kennedy replaced ODM's successor agency, the Office of Civil and Defense Mobilization, with the Office of Emergency Planning and delegated his Section 305 authorities to the Director of Emergency Planning, who in turned delegated them to his Director of Telecommunications Management. In 1969, President Nixon transferred those authorities to the director of his newly created Office of Telecommunications Policy (OTP). The first head of OTP was the legendary Clay Whitehead, and Supreme Court Justice Anton Scalia served as OTP general counsel. Coase et al., pp. 24-32. GAO. "Interdepartment Radio Advisory Committee." GAO-04-1028 (September), pp. 4-5.

[10] Coase et al. (1995), p. 65.

Coase et al. took issue with the critics' first objection: "The argument that a dictatorship is superior to a democracy always has some plausibility; in some circumstances, it is no doubt right; but it is not necessarily always right." They also dismissed the second objection, which they surmised was based on the contrast between the relative informality of the IRAC's proceedings and the highly formal nature of FCC proceedings.[11] The authors quoted the critics' description of the IRAC's culture of "trading" (a "complex process of bargaining and accommodation" with "compromise and trading back and forth") and marveled that the critics appeared to view it as a defect rather than an advantage. Coase et al. acknowledged that the third objection "may well be true," but they questioned whether superimposing a Board on the IRAC process would alter the outcome. "Would not a Board in the executive branch of Government be as reluctant as the IRAC to surrender frequencies for non-Governmental use?"[12]

Proposals to Reform Federal Spectrum Management

Much like the proposals that Coase et al. described, the current proposals to reform the management of federal spectrum seek to exert greater top-down or outside control over the process.

1. Transfer NTIA's Spectrum Functions to the FCC

The IRAC reported to the FCC for a brief period in the 1930s, and proposals to transfer the management of federal spectrum to the Commission have been put forward regularly ever since.[13] Current proponents argue that unified spectrum management would reduce duplication and maximize efficiency, and they hint that it would serve the goal of getting more federal spectrum into commercial use.

Whatever its advantages, an arrangement that would give the FCC unified control of spectrum management is a non-starter. First, it would put an independent agency—an agency outside of the executive branch that does not report to the President—in charge of the radio operations of the U.S. military.[14] Second, because it is far

[11] According to Coase et al., "When one takes into account the expense of FCC proceedings, the long delays extending often to years before decisions are made, the FCC's susceptibility to political and other pressure, the apparent errors in the decisions it has taken, it would seem the height of folly to adopt the FCC form of organization and procedures as a model for the allocation of frequencies to Government departments, unless one is convinced that the IRAC functions in a way that is not merely inefficient but extraordinarily inefficient." Coase et al. (1995), p. 68.

[12] Coase et al. (1995), pp. 65-69.

[13] See Coase et al. (1995), pp. 59-71. For a recent version of this proposal, see CTIA. 2014. "Response to House Energy and Commerce White Paper on Modernizing U.S. Spectrum Policy." (April 1), pp. 5-9. http://www.ctia.org/docs/default-source/default-document-library/ctia-response-to-house-white-paper-on-modernizing-spectrum-policy.pdf?sfvrsn=2.

[14] In most countries, the military manages the spectrum that it uses and a civilian agency manages commercial and non-military government spectrum. The U.S. system is unusual in that all federal spectrum, not just military spectrum, is managed separately from commercial spectrum. It is unthinkable that the President, who is the Commander in Chief, would allow an agency that he or she does not control to manage military spectrum.

more familiar with non-federal uses and users of spectrum, the FCC would find it hard to weigh the competing needs of government and industry.[15]

If there is a case for consolidation, it is strongest with respect to spectrum allocation, which represents the fundamental "architecture" of the frequency spectrum. However, NTIA would be the more logical home for that activity, because spectrum allocation requires making tradeoffs between competing groups and interests, a policy function better performed in the executive branch than by an independent agency. The key question is whether the gains from consolidating spectrum allocation in the executive branch would outweigh the increase in transaction costs that would result from separating the FCC's allocation functions from its ongoing spectrum licensing and enforcement functions.

If one were designing a spectrum management scheme from scratch today, it would make sense to put all of the functions (allocation, licensing and enforcement) for federal and non-federal users in a single, executive branch agency. Given our history, however, consolidation under either the FCC or NTIA, with the possible exception of spectrum allocation, seems unworkable. That need not be a serious handicap, however. In its 2003 report on spectrum management, the Center for Strategic and International Studies (CSIS) pointed to the close coordination between the Federal Reserve Board, an independent agency, and the Treasury Department, to implement economic and monetary policies.[16] As CSIS concluded, the United States can use a similar combination of independence and coordination to manage spectrum.

2. *Privatize Federal Spectrum Management*

At the other extreme from unified FCC control of spectrum are proposals to privatize federal spectrum management. In a recent article, the Phoenix Center argues that, having shown itself unable to manage its own spectrum efficiently, the federal government should divest itself of its entire spectrum holdings and lease back what it needs from the private sector.[17] The paper cites a report published by NTIA in 1991 that included a similar suggestion:

> …federal users could have a private contractor build and operate a "pooled" system using government spectrum to meet existing federal needs. As an incentive to operate most efficiently, the contractor could sell to the public any excess capacity on its system once

[15] Wiley, Richard E. and Paul E. Misener. 1996. "Whither Goest NTIA? The Fate of a Federal Telecommunications Agency." *Federal Communications Law Journal*, Vol. 48, Issue 2. http://www.repository.law.indiana.edu/cgi/viewcontent.cgi?article=1099&context=fclj.

[16] CSIS (2003), p. ix.

[17] Beard, T. Randolph, George S. Ford, Lawrence J. Spiwak and Michael Stern (Beard et al.). 2014. "Market Mechanisms and the Efficient Use and Management of Scarce Spectrum Resources." Vol. 66, Issue 2 (April), pp. 297-298. http://www.fclj.org/wp-content/uploads/2014/06/66.2.2_Spiwak-Final.pdf.

federal needs were met as its first priority.[18]

To be sure, privatization is the implication of Coase's proposal to propertize spectrum and allocate it, like any other scarce resource, using prices. And the federal government can go much farther than it has in that direction. However, federal spectrum management as a whole is an unlikely candidate for privatization.

The basic test for whether a government activity can be privatized is this: can you write a contract? That is, can the functions (or objective) be reduced to an operational description such that a contractor can perform them and the performance of the contractor can be evaluated? If federal spectrum were propertized, the federal government could no doubt specify many of its static requirements in a contract. However, it would be impossible to fully spell out contingent and future requirements. Nor could one reduce to contractual terms the criteria for or approach to resolving potential conflicts among federal users or between federal users and non-federal users.[19] The close link between spectrum and national security and life safety missions makes privatization particularly challenging because of the need to make tradeoffs between spectrum efficiency and reliability.

In short, federal spectrum management is not entirely a business enterprise. Some of the core functions require a degree of policy judgment, negotiating skill and political savvy that no contract can capture.[20]

The major advantage of privatization would be the ability to tap private capital—e.g., to upgrade older radio systems with newer, more spectrum efficient technology. As I discuss in Section III, it should be possible for a federal agency to access private capital without completely privatizing federal spectrum management, although federal budget rules admittedly make that difficult.

3. *Apply the BRAC Process to Federal Spectrum*

BRAC (Base Realignment and Closure) refers to a process designed to give Members of Congress the political cover needed to support a desired action (military base closures) that would impose severe economic pain on a subset of communities. Congress first authorized the use of the process, which Rep. Dick Armey is credited with devising, for the 1988 BRAC round; it has since authorized four additional rounds (1991, 1993, 1995 and 2005).

[18] NTIA. 1991. "U.S. Spectrum Management Policy: Agenda for the Future." http://www.ntia.doc.gov/report/1998/us-spectrum-management-policy-agenda-future.

[19] The FCC's role in resolving conflicts among different interests over non-federal spectrum is well understood because of the transparency of the FCC process. NTIA and the IRAC confront similar conflicts over federal spectrum; they are just less visible.

[20] For an analysis of a federal activity that meets the criteria for privatization, see: Robyn, Dorothy. 2008. "Air Support: Creating a Safer and More Reliable Air Traffic Control System," Hamilton Project, Brookings Institution (July). http://www.brookings.edu/research/papers/2008/07/air-traffic-robyn.

Two elements of the BRAC process are key to its success. One is the independent commission, which reviews a set of recommendations that DoD puts forward following an elaborate internal review. The Commission can take individual bases off of DoD's list. It can also add bases to the list, although that requires extra procedural steps and is far less common. The other key element is the requirement that Congress accept or reject the Commission's recommendations in their entirety. (Approval is tacit if there is no joint action to reject.) By making it impossible for them to cherry-pick bases for removal from the list, the process gives Members plausible deniability as to the outcome.

Proposals to BRAC the spectrum have been around for almost as long as BRAC. George Mason University's Mercatus Center recently revived the idea, and several bills have been introduced that would authorize a BRAC-style process.[21] The application of the BRAC approach to spectrum is off the mark, however.

The BRAC process works because two conditions are met: one, all the players agree that an action that will impose losses on the few is good for the many; and, two, the action is not related to policy, ideology or any other substantive issue that divides Congress—i.e., local politics is the only impediment. By contrast, with spectrum, there is no agreement between the Executive Branch and Congress that a reduction in federal spectrum is desirable. And Congress (i.e., local politics) is not the impediment. Thus, the expedited congressional approval process serves no purpose.

In the future, Congress might become an impediment to what some groups define as spectrum reform. But if that were to occur, it would likely reflect the substantive objections of certain congressional committees (e.g., Armed Services), in which case spectrum policy would be like many other contentious issues, and Congress would never authorize a BRAC-like process in the first place.

There may be value in having a group of outside experts to help identify spectrum bands that the executive branch could analyze as candidates for "realignment or closure." This is different from the "appellate" role served by the BRAC commission, which reviews and tweaks judgments made by the agency (DoD), but it may respond to a need for expertise in finding potential opportunities.[22] However, unlike in

[21] Skorup, Brent. 2013. "Reclaiming Federal Spectrum: Proposals and Recommendations." Mercatus Center, No. 13-10 (May). http://mercatus.org/sites/default/files/Skorup_FederalSpectrum_v1[1].pdf. Under the proposed legislation, the Secretary of Commerce would identify the initial list of "closure" candidates and a Federal Spectrum Reallocation Commission would review them. See http://hdl.loc.gov/loc.uscongress/legislation.113s2155.

[22] Spectrum reformers face an information problem: where are the opportunities for "closure or realignment?" By contrast, BRAC is the solution to what economists call a "public good" problem. A round of base closures, like clean air or national security, is something that benefits everyone and that no one can be excluded from enjoying. The challenge with public goods is to pay for them. The BRAC

BRAC, the recommendations of the Spectrum Commission could not be conditionally binding, because that would preempt agencies' decisions on a complex matter closely tied to their missions.

4. *Create a GSA for Spectrum*

GSA was created in 1949 to help perform and manage the federal government's basic business functions. The Public Buildings Service (PBS), one of GSA's two business lines (the other is the Federal Acquisition Service), specializes in real property management, including building design and construction, building operation and maintenance, leasing, and property disposal. The centralized provision of these functions by PBS is designed both to reduce the overhead associated with having redundant agency operations and to use the federal government's buying power to get a better price for goods and services.

In the last few years, several prominent reports have proposed the creation of a "GSA for spectrum."[23] Proponents see GSA as a model for a federal spectrum management agency for two reasons. One is GSA's (referring to PBS) practice of charging federal agencies a commercial-equivalent rent for the space they occupy in federal buildings, which presumably incentivizes agencies to economize on the use of space. Two, they see GSA as an executive branch agency that has the statutory authority and subject-matter expertise to impose discipline on other federal agencies.

PBS Traits to be Emulated

PBS is a wonderful agency that rarely gets the recognition it deserves (no one loves their landlord). I was privileged to lead it for 18 months, from September 2012 to March 2014. NTIA would do well to emulate some of PBS's key traits and practices. (Although I focus here on management traits and practices, there is unavoidable overlap with the economic tools discussed in Section III.) At the same time, PBS's reach and resources are more limited than people in the spectrum community may realize, and the reasons for that are themselves relevant to the spectrum debate.

PBS is a good model for NTIA to emulate for at least three reasons. First, PBS has valuable assets that it treats the way a business would. PBS introduced the practice of charging rent in the 1970s; the rent goes into the Public Buildings Fund to pay for the upkeep of buildings and a small amount of new construction. Although severe budget constraints mean that PBS is

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process provides a politically acceptable way to pay for (i.e., impose the cost of) this particular public good.

[23] Lenard, Thomas M., Lawrence J. White and James L. Riso. 2010. "Increasing Spectrum for Broadband: What are the Options." Technology Policy Institute, pp. 26-27. http://www.techpolicyinstitute.org/files/increasing_spectrum_for_broadband1.pdf. See also Hundt, Reed and Blair Levin. 2012. *The Politics of Abundance: How Technology Can Fix the Budget, Revive the American Dream, and Establish Obama's Legacy.* Odyssey Editions. Although Lenard, White and Riso call for a "Government Spectrum Ownership Corporation (GSOC)" modeled after GSA, their proposal does not countenance a true government corporation, since GSA is not a government corporation and since the authors envision that revenues from GSOC spectrum fees would go back to the U.S. Treasury, which would not be the case with a government corporation.

underinvesting relative to industry benchmarks, the agency uses portfolio management techniques to decide which buildings to dispose of, and it prioritizes investments based on their rate of return. Recent investments have as one goal to increase building utilization through use of open office designs (see discussion below of the real property analog to spectrum "sharing").

Second, PBS has a passion for property disposal: GSA was created at a time when disposal of assets from World War II was a major issue, and property disposal (personal as well as real property) was a separate business line ("Service") in GSA for many years. The culture is still deep. Federal property disposal is a complex process that faces environmental and other legal hurdles and that by law must serve multiple constituencies, including state and local governments and the homeless. PBS is skilled at navigating the process on behalf of all federal agencies, and it uses GSA's online auction process (gsaauctions.gov) to sell everything from warehouses to lighthouses.

Third, PBS plays a dual role in its dealings with federal agencies—cop and trusted partner. PBS's function is quasi-regulatory; it has an unofficial dotted-line relationship to the Office of Management and Budget (OMB) and oversees day-to-day implementation of Presidential initiatives such as "Freeze the Footprint."[24] At the same time, PBS views agencies as clients and opts for carrots over sticks where possible. It is hard to strike the right balance between trusted partner and cop, and the history of PBS might resemble a pendulum that swung slowly from one side (cop) to the other (partner) before it settled in the middle. It is a challenging problem but one that is not unique to PBS.[25]

Limits on PBS Reach and Resources

Despite its deep expertise and experience, PBS's reach is circumscribed. Its portfolio (general office space and multi-agency federal buildings, as well as federal courthouses, agency headquarters and other monumental buildings) represents only about 12 percent of the total federal inventory (34 percent of the civilian inventory) by square footage. Most federal buildings are on military bases, which DoD controls.[26] Likewise, specialized space, such as Veterans Administration hospitals, Department of Energy laboratories and Coast Guard stations, is controlled by the respective agency. Another limit on PBS's reach takes the form of delegated authority. Agencies sometimes want to operate and maintain the GSA buildings they occupy (e.g., a headquarters facility), and many agencies pushed for and received the authority to do their own leasing of

[24] See memo from OMB at http://www.whitehouse.gov/blog/2013/03/14/freezing-footprint.

[25] Corporate real estate offices (e.g., AT&T facilities) have the same challenge. Insurance companies play a dual role as well—helping policyholders collect on claims but also challenging some claims to ensure their validity.

[26] The Pentagon was a GSA property prior to the late 1980s, when the building needed a multi-billion dollar renovation that GSA did not have the funds to undertake. DoD used GSA's lack of resources as grounds to wrest control of the building.

commercial space. Finally, some of PBS's bigger tenant agencies have created large internal real estate organizations ("shadow GSAs") to exercise these delegations and to monitor and challenge PBS's performance.

To be sure, some of these practices run counter to good management, and the large shadow organizations in particular represent exactly what GSA's creators sought to avoid. To some extent, however, these practices reflect the genuine value of specialization and control: agencies want to "own" assets that they see as key to their missions, particularly when the assets are specialized.

In short, a GSA for Spectrum would not provide the level of centralized management control that some envision. The factors that limit GSA's reach (agencies' desire to control specialized and mission-critical assets) are even more dominant when it comes to spectrum than they are for real property. That said, the similarities between spectrum and real property are striking, and there is much about PBS that NTIA could emulate.

5. *Strengthen White House and OMB Oversight*

Policy advocates invariably call for the White House to play a bigger role in supporting their issue, and spectrum policy reformers are no exception. Most of their recommendations focus, appropriately, on process--e.g., the creation of an interagency coordinating committee on spectrum management or a White House Spectrum Management Team. Although a few proposals urge the White House to play a more direct role managing federal spectrum, the White House cannot run operations; a guiding principle for White House staff is: "Steer but Don't Row."

A number of recommendations recognize the importance of OMB as a way to institutionalize change. OMB is key to GSA's efforts to manage real property effectively. Individual leases and construction projects get scrutiny by the budget side of OMB. In addition, property management is a priority item on the President's management agenda (President Bush added it to his agenda in 2004 and it has stayed), which means it receives attention from the Deputy Director of OMB for Management and her agency counterparts.

OMB's Circular A-11, which instructs agencies to take into account the value of spectrum when they invest in new systems, is a potentially powerful tool.[27] But OMB cannot be a front-line spectrum auditor. Moreover, it is important to understand that OMB has a different relationship with DoD, given its sheer size and complexity, than it does with other agencies. When OMB sneezes, most federal agencies get a cold. By contrast, when it comes to DoD, OMB just manages the budget top line.

III. Economic Incentives

Proposals on ways to reduce directly the amount of federal spectrum focus

[27] OMB Circular No. A-11 (2014), Section 31.12. http://www.whitehouse.gov/sites/default/files/omb/assets/a11_current_year/s31.pdf.

on two different approaches—economic incentives and technology that facilitates spectrum sharing among federal and non-federal users. Although the relative merits of these two approaches is the subject of a lively debate, in reality there is considerable overlap, in that many of the economic incentives facilitate sharing.

Although this section focuses on incentives, not sharing, I note that spectrum sharing has a direct analog in the real property world, where office buildings are going the way of Uber, BikeShare and AirBnB. The shift to collaborative workspace reflects advances in technology and a related rise in the amount of space in a traditional work environment that is vacant at any given time. GSA is leading by example in its own headquarters building in downtown Washington, DC, where by doubling the number of occupants, it was able to vacate leases in the suburbs and save more than $20 million a year. Moreover, GSA is using some of its economic tools to facilitate the shift to collaborative workspace.

Spectrum Fees

Spectrum is an unpriced input for federal agencies, in contrast to most other goods and services they use. If NTIA charged agencies spectrum fees, analogous to GSA rents, it would incentivize them to use spectrum more efficiently. Under most versions of this proposal, the fees would go back to Treasury, in which case a system of fees would be budget neutral.

A great deal has been written about the compelling logic behind this proposal as well as the daunting implementation problems.[28] Let me add three points based on my GSA/DoD perspective.

First, federal spectrum is not unique in being an unpriced input. Federal agencies use federal land at no cost. DoD occupies 28 million acres, much of it "withdrawn" from the Bureau of Land Management's inventory. Although some of that land has a relatively low opportunity cost, some of it is quite valuable.

Second, the transaction costs required to implement spectrum fees would be exceedingly high. GSA devotes considerable resources to determining its rent charges, which are based on commercially equivalent space and vary by building. Even though there is good data on commercial real estate transactions and accepted methods for rent estimation, it is not uncommon for federal tenants to challenge their rent assessment, and issues such as the appropriate way to measure and charge for atrium (vertical) space have been debated in congressional hearings and analyzed in reports by the Government Accountability Office that GSA sharply contested.

Spectrum fees would be even more difficult and contentious to implement.

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[28] For an analysis of the benefits of spectrum fees, see Bazelon, Coleman and Giulia McHenry. 2014. "Spectrum Sharing: Taxonomy and Economics," The Brattle Group. http://www.brattle.com/system/publications/pdfs/000/004/983/original/Spectrum_Sharing_-_Taxonomy_and_Economics_Bazelon_McHenry_020614.pdf?1391797552.
For a discussion of the impediments to effective use of fees, see Beard et al. (2014).

There are many more frequency assignments than there are federal buildings and leases. Unlike GSA space assignments, many spectrum frequencies are shared (geographic and time-of-day sharing) by a number of users. And although economists disagree about how difficult it would be to calculate the opportunity cost of individual spectrum assignments, there is unquestionably far more room for agencies to contest the methodology.

Third, although I do not discount their incentive effect, the major reason to adopt fees would be to generate the revenue for capital investment. Federal agencies use spectrum inefficiently in good part because they cannot afford the up-front cost of the upgrades to older, spectrum-intensive radio systems. A dedicated Federal Spectrum Fund, analogous to the Federal Buildings Fund, could help address that need.

That vision of fees would not be budget neutral, however, which would make it even more challenging than budget-neutral fees to get approved. Moreover, there is a risk that Congress would divert some of the money for unrelated activities.[29]

Even if the fees were budget-neutral, in the current budget environment, policymakers are very unlikely to support a reform that raised the cost of an input for which agency demand is inelastic, at least in the short run, and for which there is no competition on the supply side.

One partial step toward fees would be the use of shadow prices. OMB is moving in that direction with its Circular A-11 instruction to agencies to make spectrum part of their investment calculus. With actual prices—which there is sufficient data to estimate for all of the federal bands–that exercise would be far more meaningful.

Another partial step, building on A-11, would be to begin to formalize the consideration of spectrum costs in the acquisition process. For example, the Joint Strike Fighter has 30 different features that require spectrum to function. One could require contractors to build the cost of the spectrum for those features they control into the price of the weapon system, so that it becomes part of any competition on price and performance.

Making that kind of change to the acquisition process is challenging and can take years to fully implement (it is similar to the Obama Administration's effort to get DoD's acquisition process to take energy consumption into account in designing a weapon system). In the short run, possibly on a pilot basis, DoD could make spectrum efficiency a competitive discriminator—i.e., a factor that it would use qualitatively to evaluate bids. Currently, contractors have no incentive to propose an approach that will reduce spectrum usage, or substitute less valuable spectrum for more valuable spectrum, if it will increase non-spectrum costs.

[29] The Federal Buildings Fund and other user fee-based funds have experienced diversion in recent years. The BRAC Fund has not faced this problem because it has a privileged budget status that allows receipts to be spent without an annual appropriation.

Lessons from Real Property Disposal

In addition to spectrum fees, the spectrum reform debate has focused on ways to get the federal government to relinquish spectrum rights that the FCC could then auction off. For example, legislation introduced by Reps. Brett Guthrie and Doris Matsui would let agencies keep one percent of the revenue generated from the sale of spectrum they relinquish.

GSA and DoD have a similar challenge in getting agencies (the Military Services, in DoD's case) to dispose of real property. Their experience points to three broad lessons.

One lesson is that the ability to retain the proceeds from the disposal of property is a key motivator for federal agencies. (Agencies that have this authority generally can keep 100 percent of the proceeds.) Some participants in the spectrum policy debate have argued that federal agencies are not motivated by the opportunity to generate revenue, because appropriators will simply take it out of their hide the next year. That has emphatically not been my experience.

Consider the BRAC Fund. In 1987, when the Office of the Secretary of Defense (OSD) wanted to motivate the Services to undertake another round of base closures, it held out the prospect that they could retain the proceeds from the sale of excessed property. At the time, GSA was responsible for all federal property disposal, and the proceeds went into a land conservation fund. At DoD's urging (and despite opposition from GSA), Congress delegated GSA's disposal authority to DoD for base closure property and created a BRAC Fund into which the proceeds would go, to be used for real property upkeep. The ability to retain proceeds from the sale of property was key to getting Service participation in the early BRAC rounds and it continues to be a strong motivator.[30]

A corollary to the first lesson, based on DoD's experience with Enhanced Use Leases (EULs), is that agencies are sensitive to which organization within the agency gets to keep the revenue. An EUL is a long-term lease of underutilized property for which the developer pays the agency rent in the form of cash or in-kind services. Initially, DoD's statutory EUL authority specified that "the Department" could keep 100 percent of the revenue. An EUL requires a significant commitment of time and effort by the staff of an individual military installation, and the installations at first showed little interest in using the new authority. However, after the statute was changed to allow 50 percent of the revenue to stay with the installation, "the projects flowed," in the words of one observer.

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[30] OSD and the Services reached an internal agreement that each Service would keep half of the proceeds from the sale of its property and OSD would allocate the other half to the Services on the basis of need. The Navy participated very little in the first two BRAC rounds, and DoD insiders say it was because the Navy felt that the 50/50 arrangement was unfair, given that the Navy bases most likely to be closed, many of them located on the California coast, were more valuable than those of the Army or Air Force.

The implication of these lessons for spectrum management is that federal agencies might be quicker to part with unneeded bands if they could keep a meaningful share of the disposal proceeds. Although the retained share for federal real property share (100 percent) might not be the right number for spectrum, the current share for agencies that relinquish spectrum (0 percent) is clearly inadequate. The Guthrie-Matsui legislation is a start, but the one-percent share specified in that bill is wholly inadequate.

A second lesson from the GSA and DoD experience is that it matters who exercises the disposal authority. For example, DoD wanted to dispose of its BRAC property directly in part because it wanted to keep the sale proceeds. But DoD also wanted disposal authority because the disposal agent has a significant say in determining the environmental remediation standard—and the resulting remediation costs—for the relevant property.[31] Given that the financial stakes were high, DoD wanted to be able to control the process itself rather than entrust GSA.

The implication of this lesson is that it might make sense to give NTIA the authority to sell federal spectrum directly, rather than having the FCC perform that function in all cases. There is an unstated assumption in the spectrum debate that only the FCC can sell spectrum. Presumably that reflects the fact that spectrum buyers need a license, and only the FCC can assign that license. The licensing issue seems like one that NTIA and the FCC could handle through close coordination, however.

The case for giving NTIA auction authority is that the disposal of excess federal spectrum should be a core mission of the agency. If NTIA could sell federal spectrum directly, it would help to create the culture needed to support that core function. It would also help to regularize the process if NTIA had its own auction website and a constant stream of opportunities for potential bidders to explore. Although NTIA lacks the expertise to sell spectrum, it could draw on the FCC's expertise.

The counter argument is that the sale of federal spectrum necessarily involves the FCC, which must do a great deal of pre-sale planning to ensure compatibility with nonfederal assignments. Thus, it may not make sense to create a separate auction capability outside of the FCC.

A third lesson from GSA and DoD is that property disposal means more just the sale of property. There are a range of statutory authorities that are available depending on the need.

One tool is the long-term "outlease" of property that the federal government does not have an immediate use for but wants to retain over the long term. PBS recently did a 60-year outlease of the Old Post Office in downtown Washington, DC, to the Trump Organization. The Trump Organization,

[31] The agency that has the authority to dispose of a piece of property also writes the deed for the transfer of property, and the deed determines the environmental remediation standard for the disposal (for example, will the property be cleaned up to a level suitable for industrial use or to a higher, residential standard). If GSA were to sign a "clean" deed, DoD would bear a higher remediation cost.

which was selected through a rigorous competition, is investing $200 million to turn the historic building into a luxury hotel and will pay the federal government an annual rent.

EULs are another example of this approach. The Military Services have used their EUL authority to accommodate renewable energy projects or commercial development on underutilized property at the edge of their installations, with the in-kind payments (services) used to construct or renovate buildings on the same installation.

A second valuable authority is real property exchange: GSA and certain other agencies have the ability to swap an underutilized federal property either for another property or for construction services. Exchanges have long been common in the real property arena, because they reduce transaction costs. The use of exchanges by public agencies can also be a way to avoid show-stopping risks associated with the budget or property disposal process.

GSA's latest use of its exchange authority is directed at a problem that is directly analogous to federal hoarding of prime spectrum. The Department of Transportation's National Transportation Systems Center (Volpe Center) occupies a large, aging building on 14 acres in the heart of Kendall Square in Cambridge, MA. Kendall Square, located adjacent to the Massachusetts Institute of Technology, has some of the most valuable real estate in the country. GSA is exploring ways to use its exchange authority to convey significant portions of the DOT land to a developer in exchange for construction services to transform the Volpe Center into a state-of-the-art facility.[32]

The implication of this lesson is that NTIA and the spectrum user agencies should be considering forms of disposal other than just the sale of spectrum. Leasing is one.[33] For example, one can imagine DoD leasing 10 megahertz of spectrum to, say, T-Mobile with the proviso that T-Mobile has to quit using it within 100 miles of a certain point within two minutes of being notified to do so. As this example implies, it may make sense for a large user such as DoD to have its own authority to enter into leases (i.e., that authority should not necessarily be reserved to NTIA).

Exchanges are another real property authority that has direct application to spectrum. Much as with the Volpe Center, DoD or the FAA (or NTIA on behalf of the user agency) could convey some portion of a valuable band in exchange for the services required to replace an older system in that band with a newer, more spectrum-efficient system.

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[32] "GSA Seeks Ideas for First-Of-Its-Kind Redevelopment of Volpe Center," Aug. 26, 20014. http://www.gsa.gov/portal/content/196375. See also GAO. 2014. "Federal Real Property: GSA Should Better Target Its Use of Swap-Construct Exchanges." GAO-14-586 (July). http://www.gao.gov/products/GAO-14-586.

[33] Public Knowledge has proposed a concept that incorporates leasing of federal spectrum. See Feld, Harold and Gregory Rose. 2010. "Breaking the Logjam: Creating Sustainable Spectrum Access Through Federal Secondary Markets," Public Knowledge. https://www.publicknowledge.org/pdf/pk-spectrum-fed-secondary-markets-whitepaper.pdf.

The argument against giving user agencies the authority to lease and exchange spectrum is that it could have the perverse effect of encouraging hoarding. To elaborate, in order to exercise those authorities, agencies would need to have what amounts to property rights in the spectrum they use, which NTIA frequency assignments do not currently confer. If agencies had property rights, according to this argument, they would hoard spectrum in order to get the revenue from leasing or exchanging it.

Although one should always consider the potential for unintended consequences, that seems like a risk worth taking. Economists have looked at the issues involved in giving federal agencies property rights in spectrum, and the benefits far outweigh the costs.[34]

Public-Private Ventures

As mentioned repeatedly, federal agencies use spectrum inefficiently in part because they cannot afford the cost of the upgrades to older radio systems. This problem has a direct parallel in the federal real property arena. Public-private ventures may be a way to address both problems, although they face an uphill battle with OMB.

To elaborate, unlike private firms and most state and local governments, the federal government does not have a capital budget, which means that agencies must fund capital investments up front rather than over time. In recent decades, this requirement has become a major deterrent to needed investment in federal real property, and that lack of investment has driven long-term costs even higher.[35]

Public-private ventures are one important way to address this problem. The best illustration is DoD's Military Housing Privatization Initiative (MHPI), in which the Services were allowed to partner with the private sector to address the lack of adequate housing for military families. In response to a $2.3 billion contribution by DoD, including a 50-year outlease of the underlying land, developers have invested $14 billion and generated 200,000 units of new and renovated housing built and maintained to market standards.

Federal property managers at DoD and GSA can point to many other unmet funding requirements that would lend themselves to MHPI-type partnerships. For example, GSA could replicate what it did in its own headquarters—renovating a deteriorating facility in a way that allows for far greater utilization—in many other federal buildings.

Public-private ventures may also be a useful tool for federal spectrum management. With federal property, what makes a public-private venture possible is the ability to leverage a stream of revenue such as agency rents or (in the case of MHPI) family

[34] Morris, Adele. 2014. *Greasing the Wheels of Federal Spectrum Deals*, Brookings, September 23, 2014.

[35] See Robyn, Dorothy. 2014. "Reforming Federal Property Procurement: The Case for Sensible Scoring." http://www.brookings.edu/blogs/fixgov/posts/2014/04/24-federal-property-procurement-sensible-scoring-robyn.

housing allowances. With spectrum, there is no parallel revenue stream in the form of spectrum fees. Nevertheless, a "developer" might agree to upgrade a radio system for the FAA in exchange for the right to capture the revenues from leasing out underutilized spectrum in the same band. Alternatively, a communications technology firm might build a new aero-telemetry system for DoD in exchange for being able to have communications devices use the same frequencies on a non-interfering basis.

Public-private ventures would provide some of the same advantages as spectrum overlays, a proven approach in which the FCC grants secondary rights to the winning bidders in an auction of federal spectrum as a way to speed the transition to nonfederal use. According to Tom Hazlett, spectrum overlays have worked well because the for-profit player has a) an incentive to move spectrum to higher valued uses, b) the means (access to the capital markets) to pay off the current users (replacing their radio equipment with newer and better equipment), and c) the knowledge as to where the higher-valued uses are as well as where the efficient substitutes for existing users lie.[36]

Likewise, public-private ventures could be a tool with which to implement the "shared-use spectrum superhighway" proposed by the President's Council of Advisors on Science and Technology (PCAST).[37] Recognizing that it is becoming increasingly difficult to clear and reallocate federal spectrum, PCAST's plan calls for a new spectrum architecture featuring large bands that can accommodate a wide variety of compatible uses (nonfederal as well as federal) and technologies. Toward that end, a public-private venture can provide a way for an incumbent federal user to transact with a real marketplace operator so as to get underutilized federal spectrum into more intensive use.

Unfortunately, most proposed public private ventures run afoul of federal budget rules, because they are seen as a form of off-budget financing of capital investment. Nevertheless, there is growing support for a reexamination of the budget rules.

IV. Conclusion

This brief review of options for reforming federal spectrum management makes clear what spectrum policy reformers should *not* do. They should not fold NTIA's spectrum functions into the FCC, fully privatize them or subject federal spectrum to a BRAC process.

It is harder to say what *to* do. Although spectrum policy reformers almost all want to see more central control over federal spectrum, Coase et al.'s insights on the limits of central planning in this area ("The attempt to control everything from the center is liable to

[36] Email communication with Hazlett, September 10, 2014.
[37] President's Council of Advisors on Science and Technology. 2012. "Report to the President: Realizing the Full Potential of Government-Held Spectrum to Spur Economic Growth." (July) http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast_spectrum_report_final_july_20_2012.pdf.

lead to paralysis.") still ring true.[38] Coase et al. also reminded us that the delegation of authority necessarily entails some misallocation of resources.

The implicit criticism of NTIA is that it is not tough enough on DoD, the dominant user of federal spectrum. But that may be unfair. DoD is an admitted "control freak," because of the nature of its mission, and spectrum is mission-critical. (According a T-Mobile employee who worked with DoD on the transition of a federal band to nonfederal use, "They [the military] have backup plans for their backup plans.") Even OMB is no match for the military and contents itself with managing DoD's top line.

Since GSA faces many of the same challenges as NTIA, creation of a GSA for Spectrum would not provide the level of management control that some want. That said, there is much about GSA (PBS) for NTIA to emulate, including its asset management mentality, the focus on property disposal as a core mission, and the balancing act it performs as both cop and trusted partner.

GSA is also a model in terms of its use of economic incentives and tools. Although spectrum fees, modeled after GSA rent charges, would have prohibitively high transaction costs in my view, GSA and DoD have a lot to teach us when it comes to promoting the disposal of excess property. The most powerful lesson is that the ability to retain the proceeds from the disposal of property is a key motivator for federal agencies if the incentive is properly structured.

The GSA and DoD statutory authorities, including long-term outleases and exchanges of underutilized property, also seem applicable to spectrum. To use these authorities, federal agencies would need to have property rights in the spectrum they use. Although some fear that could encourage hoarding of spectrum, the potential upside seems far greater.

Another borrowed tool, public-private ventures, may be a way to address one of the biggest problems in federal spectrum management—namely, agencies' inability to afford the up-front cost of replacing older radio systems with newer, more spectrum-efficient systems. Among other benefits, public-private ventures could be a tool with which to implement the "shared-use spectrum superhighway" proposed by PCAST. Although many proposed public private ventures run afoul of federal budget rules, there is growing support for a reexamination of the budget rules.

[38] Coase et al. (1995)

September 23, 2014

Office of Science and Technology Policy
Attn: Mr. Dan Correa
Eisenhower Executive Office Building
1650 Pennsylvania Ave NW.
Washington, DC 20504

Via email: innovationstrategy@ostp.gov

Re: Request for Information on the Strategy for American Innovation

To Office of Science and Technology Policy and the National Economic Council:

BSA | The Software Alliance (BSA) appreciates this opportunity to respond to the Office of Science and Technology Policy and the National Economic Council's request for public comments (the "Request") to provide input into the upcoming update of the Administration's Strategy for American Innovation. BSA is the leading advocate for the global software industry in the United States and around the world. Our members are among the world's most entrepreneurial and innovative companies, creating software solutions that spark economic growth and improve modern life.[1]

BSA applauds the Administration for developing a Strategy for American Innovation. The initial strategy and the 2011 update focused policy attention on innovation as a driver of the American economy. The Administration's Strategy has been important in three key areas: (1) calling for the necessary building blocks of a sustainable innovation economy; (2) promoting innovation-friendly policies; and (3) accelerating the development and commercialization of breakthrough technologies.

The nature of innovation is, by its definition, constantly evolving. BSA therefore commends the Administration for updating its Strategy.

The 2011 Strategy for American Innovation recognized that innovation does not happen in a vacuum. Innovation requires investment in research and development. Smart policies, guided by a Strategy for American Innovation, can incentivize the needed investment. In turn, this investment will bring jobs and opportunity in innovative industries to the United States. Several of the questions in the Request identify aspects of the key policy areas for American innovation: developing and providing access to a skilled workforce; and maintaining a legal system that encourages capital investments by allowing a return on the investment.

[1] BSA's members include: Adobe, Altium, Apple, ANSYS, Autodesk, Bentley Systems, CA Technologies, CNC/Mastercam, Dell, IBM, Intel, Intuit, Microsoft, Minitab, Oracle, PTC, Rockwell Automation, Rosetta Stone, salesforce.com, Siemens PLM, Symantec, Tekla, The MathWorks, and Trend Micro.

I. Skilled Workforce Development

In questions 12 to 14, the Request seeks information and comments about developing a skilled workforce. Here, BSA encourages support for a two-prong approach to develop the workforce needed for American innovation: 1) a long-term effort to establish an education system to build for the future and 2) a near-term effort to adopt comprehensive immigration reform to address immediate workforce needs.

The 2011 Strategy rightly focused on the importance of science, technology, engineering and mathematics ("STEM") education. A skilled American workforce should be developed at home, and the necessary focus on such skills must start at an early age. Investment in STEM education will ensure that students are prepared for the jobs in the United States that require specific skills crucial to an innovation economy. STEM education benefits not only those who receive it, and are therefore prepared for 21st century jobs, but also the entire economy because companies will invest where the talent is being educated. The US education system will be one of the key determinants of the country's economic success.

We must recognize that investment in STEM education will create the next generation of skilled workers, but we also need a specialized workforce today to fill positions. That requires hiring foreign-born workers. If companies are unable to fill key positions, the jobs — including those that are currently filled by US workers — will move overseas. BSA therefore continues to support comprehensive immigration reform that modernizes and improves the H-1B program.

The combination of an improved STEM education system to train the workforce of tomorrow and improved access to foreign-born, specialized workers today will significantly improve US Innovation.

II. Intellectual Property Protection

In question 21, the Request asks what new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation. The Administration's 2011 Strategy for American Innovation provides an excellent starting point. It reflected an understanding that dedicated investment in research and development, incentivized by the Constitution's imperative that Congress provide exclusive rights in intellectual property for limited times, continues to drive innovation among American businesses.

The Strategy for American Innovation should continue its focus on the United States' historic support of effective intellectual property rights as a means to incentivize innovation. In the 2011 Strategy, the Administration noted that innovation is tied to America's well-being and to our conception of the essential American character. This character — and the United States' innovative spirit and economy — developed based on the Founders' choice to build into our Constitution the authority to grant inventors the exclusive rights in their discoveries. The patent right, developed from this Constitutional power, as President Lincoln famously put it, "added the fuel of interest to the fire of genius."

This constitutional basis for our intellectual property laws is relevant to the question posed in the Request. The right that Congress directed be provided to inventors incentivizes the investment in research and development needed for innovation. Absent such a temporary right, those who do the hard work of research and development risk having others free-ride on their investments.

The security and resilience of the patent right's temporary exclusivity incentivizes these investments, including for software companies. The United States, collectively, continues to outspend every other nation in the world on research and development, and is projected to spend $465 billion on research and development by the end of 2014.[2] In 2008, software companies invested approximately $46.9 billion in research and development for software and computer-related services -approximately 16 percent of total industrial R&D expenditures nationwide.[3] More than three-quarters of firms engaged in software development report introducing new products or services compared to a national average of 7 percent for all nonmanufacturing industries.[4]

The knowledge that a company can control how its patented inventions are used, made, and sold ensures that inventors will continue to undertake significant work and investment in driving innovation, and that the public will benefit from the inventor's work.

The patent's flexibility as a type of personal property[5] encourages patent owners to adapt to changing business models and customer demands. While one patent owner may find the greatest benefit from his or her invention comes from maintaining exclusive control of their invention, another inventor may find that licensing on an exclusive or nonexclusive basis to others presents the best option for the market. This flexibility promotes the overall market, but the ability of the inventor to retain the exclusive right in the invention is necessary for the investment in the first place.

For most industries, especially the software industry, BSA believes that intellectual property rights are cornerstones of innovation giving creators confidence that it is worth the risk to invest time and money in developing and commercializing new ideas. Software patents are an indispensable part of these protections. As the then-director of the United States Patent and Trademark Office noted recently: "Software patents, like all patents, are a form of innovation currency. They are also ecosystem enablers, and job creators. The innovation protected by software patents is highly integrated with hardware. All of it must remain eligible for protection."[6]

The flexibility of a patent right has always coexisted with the complementary structure of competition law. As the Department of Justice and the Federal Trade Commission agree, competition pushes companies to innovate in order to satisfy the needs of increasingly sophisticated consumers, and the protection offered by intellectual property rights — plus the trade-off to the public of the limitation of the period of exclusivity — ensures that inventors continue to engage in research and development.[7] Certain conduct involving a patent may

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[2] Batelle, 2014 Global R&D Funding Forecast (Dec. 2013), available at http://www.battelle.org/docs/tpp/2014_global_rd_funding_forecast.pdf.

[3] Nat'l Sci. Bd., Science and Engineering Indicators, at 4-21 & 4-23 (2012), http://tinyurl.com/amb2uao.

[4] *Nat'l Sci. Bd., supra,* at 6-47.

[5] 35 U.S.C. § 261 (2014).

[6] David Kappos, Under Secretary of Commerce for IP & Director of the U.S. Patent and Trademark Office, An Examination of Software Patents (Nov. 20, 2012), available at http://www.uspto.gov/news/speeches/2012/kappos_CAP.jsp.

[7] Christine A. Varney, Assistant Attorney General for Antitrust, Promoting Innovation Through Patent and Antitrust Law and Policy, Remarks as Prepared for the Joint Workshop of the U.S. Patent and Trademark

violate the competition laws, but the simple exercise of an exclusive right granted by the patent does not. If it did, the constitutional imperative would also be violated and the system that has fostered innovation would begin to put research and development at risk.

Accordingly, as the Administration considers the challenges and opportunities for intellectual property and competition policy posed by the increasing diversity of models of innovation, BSA urges that the Administration remain focused on the complementary balance of intellectual property and competition law. Competition law should not eclipse the exclusivity of patent rights. The United States is a world leader in research and development largely because of the artful design of our patent system and the strength it lends to inventors.

Countries that have been less committed to research and development have attempted to misuse competition laws to obtain access to US technology for protectionist purposes. The United States should not follow this lead by degrading the importance of patent protection to the innovation economy. Upsetting the exclusive right in an invention through the competition laws serves only to harm the long-term innovation that has preserved the United States' status as the world leader in innovation.

BSA supports legislation to reform the patent system in a way that would disincentive abusive litigation that is currently a drag on our innovation economy. The ability of an inventor to exercise the exclusive right in a valid patent on a true invention, however, should not be diminished through the antitrust laws.

* * * * *

Thank you again for the opportunity to share our views on these important issues.

Office, the Federal Trade Commission, and the Department of Justice on the Intersection of Patent Policy and Competition Policy: Implications for Promoting Innovation (May, 26, 2011), available at http://www.justice.gov/atr/public/speeches/260101.htm.

BT's response to the Office of Science and Technology Policy and the National Economic Council's request for public comments on updating the *Strategy for American Innovation*

September 23, 2014

BT welcomes the opportunity to respond to the Office of Science and Technology Policy and the National Economic Council's request for public comments on updating the *Strategy for American Innovation.*

BT is a leading communications services provider. In the UK, we sell products and services to consumers and small and medium-sized enterprises. Around the world, as well as in the UK, we provide managed networked IT services for large multinational corporations, domestic businesses and national and local government organisations. We also sell wholesale telecoms services to communications providers in the UK and internationally.

BT provides service to around 7,000 large corporate and public sector customers in more than 170 countries worldwide. We have one of the largest networks in the world and more than 60% of our employees are based outside the UK. The United States is a vital market for us and is key to our business. In the US, we serve customers from offices in more than 25 key cities and employ 2600 people.

Communications services are vital in a modern world. The US has led the globe when it comes to innovation, particularly in the ICT sector. The US approach has been underpinned by conditions that have led to success, including a culture of willingness to take innovative risks, leading educational institutions, access to venture capital, and more. As a global company, BT has witnessed first-hand the drivers for innovation and the positive impact of an innovation nation on jobs, growth, the economy, and forward-looking technology. It's our belief that innovation flourishes in a truly competitive market. To sustain the US's leading role, and to remove impediments to future innovation, we would recommend addressing an issue in the telecommunications sector that we have found to be a barrier to progress: a lack of competition in access inputs for business broadband services.

A fundamental focus on competition law principles enables markets to function, and in the ICT sector, promotes broadband deployment and evolving technologies. Policymakers can protect and encourage such innovation by addressing infrastructure bottlenecks and market power that allows providers to discriminate unfairly. As we have seen in "special access" services in the US business broadband market – the last mile facilities that both wireline and wireless providers use to reach their customers and connect their networks – a lapse in such policies can result in a failed market.

Targeted regulation of infrastructure bottlenecks and next generation infrastructure investment can co-exist, and must be embraced to achieve full broadband potential. In the UK, BT is continuingly upgrading our network so that Internet access service is improving in parallel to the introduction of innovative new services – these are mutually reinforcing and occur against the backdrop of equal, non-discriminatory access to essential inputs. Competition in the provision of communication services in the

UK has delivered real benefits for consumers in terms of choice, quality and value for money, including real GDP growth for the UK economy. Consumers in the UK are benefiting from one of the world's most price competitive marketplaces for communications services.[1] Oversight of BT's market power in UK has not disincentivized investment; on the contrary, it has resulted in greater coverage, faster speeds, and lower prices, with the fastest fibre roll-out of any major European country. [2] In contrast, the failure to effectively regulate the US wholesale access market has left Americans with higher prices and slower speeds.[3]

Competition also drives job growth and investment. As detailed in studies, if the Federal Communications Commission were to address competitive policy issues in the business broadband space, we could see "the hiring of as many as 650,000 new employees in to the ranks of the telecom sector over the next five years." If competitive policies are not put in place, however, the sector could lose as many as 300,000 jobs.[4] Supporting a competitive broadband industry similarly adds billions of dollars of investment in the telecom sector.[5]

One of the biggest opportunities, in our opinion, for innovation in the US lies in remedying the lack of competition in this important space, benefitting the economy and all players in the broadband ecosystem.

BT appreciates the opportunity to share our views.

For Further Information:
Jennifer Taylor Hodges
VP, US Government Affairs
BT
[redacted] | [redacted]

[1] *International Communications Market*, Ofcom (December 2013).
[2] Ibid.
[3] Ookla Net Index and OECD Broadband Portal both show broadband prices higher and speeds lower in the US than in parts of Europe.
[4] *The Benefits of a Competitive Business Broadband Market*, Gately and Golding (April 2013).
[5] Ibid.

charles river

Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave, NW
Washington, DC 20504

Attn: Dan Correa,
Office of Science and Technology
innovationstrategy@ostp.gov

Re: ***Strategy for American Innovation- (11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?***

Dear Dr. Correa:

Kindly accept this as our response to the Notice of Request for Information with regard to the above-referenced matter.

Creation of an independent life science reproducibility network.
Contributions by Dave Sheppard, George McAllister, Melody McDonough, Joe Cornicelli and Julie Frearson, Discovery Services Charles River Laboratories.

The low levels of reproducibility in life-science-based academic research, despite publication in reputable scientific journals, has been highlighted as a major concern for research policy makers, scientific press and the pharmaceutical healthcare industry *(Begley and Ellis (2012) Raise standards for preclinical cancer research, Nature 483, 531-533; Prinz et al. (2011) Believe it or not: how much can we rely on published data on drug targets? Nature Rev. Drug Discov.**10**, 328–329; Editorial (2013) Reducing our irreproducibility, Nature 496, 398*). In particular, key academic discoveries are highly vulnerable to invalidation as they transition into more industrialized, high stringency evaluation for drug discovery. The pharmaceutical and biotechnology sectors rely heavily on discoveries made by curiosity-led academic endeavor to develop disease biology understanding and provide the confidence for the industry to pursue first in class medicines and diagnostics that address genuine, unmet need. A reputable, stakeholder approved and independent mechanism for the pressure testing of key discoveries will focus industry efforts on validated phenomena and thereby reduce attrition in the earliest phase of drug discovery- target validation.

Charles River Laboratories (CRL) is a US headquartered global contract research organization (7,500 staff, based at 60 facilities in 17 countries) with the critical mass, expertise, quality management infrastructure and independence to support a life sciences reproducibility platform. CRL has already demonstrated its commitment to addressing the issue of reproducibility in partnership with Science Exchange through donation of animals for their oncology reproducibility initiative plus a recently launched collaboration in reproducibility for neurodegenerative diseases (Appendix I). Additionally, CRL has published a number of their reproduction study findings (Appendix II) demonstrating both positive validation and invalidation of academic findings.

We propose that the federal government can proactively influence the quality of academic research and help provide mechanisms whereby key impact discoveries can be rapidly and independently validated and enriched through development of a reproducibility network.

As part of a proposed network, we suggest the following concepts for consideration by the federal government in partnership with the NIH and funding bodies:

1 Develop new granting policies which actively encourage principal investigators to submit their discoveries for reproduction in accredited third party organisations- and reward them for doing so.
2 Develop a new scheme to identify and qualify a number of organisations to act as independent agents for reproduction of scientific studies to industry standards. Such organisations would be required to be independent (i.e. not participating in internal IP-generating activities), have expertise in disease biology aligned with key areas of unmet need (likely fulfilled by a combination of large organisations with breadth plus smaller niche organisations with domain-specific expertise), deep drug discovery and development expertise and demonstrable quality management processes in place.
3 Develop a new scheme to identify organizations capable of monitoring life science publications for their potential impact on healthcare. Such organisations would require the IT, statistics expertise and infrastructure to establish and curate the necessary databases and develop systems to prioritise publications for reproduction. These systems should also be a capable of recording the output of said reproduction studies and making the results available in the public domain.
4 Develop publication polices in conjunction with scientific journal publications to enable the rapid, open access publication of reproducibility studies whether the outcome is positive or negative.
5 Launch a new granting scheme which enables PIs or third party organisations to secure funding to support reproducibility studies. Such studies will be conducted in one of a group of verified reproducibility organisations. This scheme could be leveraged in key disease areas by co-operative funding from patient and disease foundations.

A fully enabled reproducibility network will therefore have clear funding channels to support projects, key reproducibility advocates to manage and promote the objectives of the enterprise plus a number of reproducibility centers with the operational and management expertise to conduct reproducibility studies. The functional network will most likely consist of organizations with fundamental cell biology, pharmacology, chemistry and antibody generation capabilities plus centers of excellence with domain specific expertise in key platforms (genomics, proteomics) and disease areas. An organization such as CRL would be well placed to be a key reproducibility hub offering the following key attributes:

1 Industry-standard quality management infrastructure and practices
2 Non-biased approach to studies
3 Staff trained in conducting projects to the highest quality standards in a time lineated manner
4 Broad therapeutic expertise
5 Fundamental platforms in cell biology, pharmacology and chemistry
6 Experience in working with academically founded projects

As previously indicated, CRL plans to perform key reproducibility experiments for relevant to neurodegeneration studies (examples shown in Appendix I) as selected by Science Exchange based on their citation, relevance and impact ranking platform. In the short term, there is an immediate opportunity to increase the scale and scope of this endeavor through federal funding.

The problem of irreproducibility in life science research significantly erodes its potential value to future healthcare. Whilst we must protect the fundamental practices of academic research, being curiosity-driven with the freedom to follow new ideas, it is clear that additional systems need to be put in place to smooth out the 'lack of experimental rigor' and 'speed to publish' issues in evidence. Our belief is that the federal government has a role to play in working with the NIH and equivalent bodies to create a life science reproducibility platform which will provide a route to rapid assimilation, prioritization, validation and publication of key discoveries in a quality managed, statistically powered and independent manner. Such a platform has the potential to become one of the key channels the pharmaceutical industry uses to derive data to support novel target validation concepts, furthermore it also could influence the conduct of the next generation of academic investigators- future investigators will be judged not only on publication rate and quality but also on how often their discoveries feature in federally funded reproducibility programs.

Respectfully Submitted,

Nancy Gillett

Nancy Gillett, DVM, PhD, DSc (Hon), DACVP
Corporate Executive Vice President and Chief Scientific Officer

John C Ho

John Ho, MD
Corporate Senior Vice President, Corporate Strategy

Professor Julie Frearson, PhD
Executive Director Scientific Alliances

Appendix I: Exemplar Projects in the Science Exchange Collaboration

Alzheimer's Disease

AD Project 1 (Paper ranking 9/50)

Soluble amyloid beta-protein dimers isolated from Alzheimer cortex directly induce Tau hyperphosphorylation and neuritic degeneration
Jin, M; Shepardson, N; Yang, T; Chen, G; Walsh, D; Selkoe, DJ
PNAS, 108, p5819-5824(2011)

Abstract
Alzheimer disease is a major cause of cognitive failure, and a pathogenically related but more subtle process accounts for many cases of mild memory symptoms in older humans. Insoluble fibrillar plaques of amyloid beta-proteins (Aβ) and neurofibrillary deposits of hyperphosphorylated tau proteins are the diagnostic lesions of AD, but their temporal mechanistic relationship has long been debated. The recent recognition that small, diffusible oligomers may be the principal bioactive form of Aβ raises the key question of whether these are sufficient to initiate cytoskeletal change and neurite degeneration. A few studies have examined the effects of oligomers of synthetic Aβ peptides of one defined length at supra-physiological concentrations, but the existence of such assemblies in the AD brain is not established. Here, we isolated Aβ dimers, the most abundant form of soluble oligomer detectable in the human brain, from the cortices of typical AD subjects and found that at subnanomolar concentrations, they first induced hyperphosphorylation of tau at AD-relevant epitopes in hippocampal neurons and then disrupted the microtubule cytoskeleton and caused neuritic degeneration, all in the absence of amyloid fibrils. Application of pure, synthetic dimers confirmed the effects of the natural AD dimers, although the former were far less potent. Knocking down endogenous tau fully prevented the neuritic changes, whereas overexpressing human tau accelerated them. Co-administering Aβ N-terminal antibodies neutralized the cytoskeletal disruption. We conclude that natural dimers isolated from the AD brain are sufficient to potently induce AD-type tau phosphorylation and then neuritic dystrophy, but passive immunotherapy mitigates this.

Significance
This is a key study linking amyloid and tau pathology. Understanding how amyloid dimers cause tau hyperphosphorylation could be fundamental to developing therapies to

treat AD. For example, how do they get into the cell and which kinases mediate the tau effects? If we understand those processes several intervention targets may emerge.

Key elements to try to reproduce

The key elements of this study we wish to reproduce are:

a) demonstrate human AD brain derived amyloid dimers induced hyperphosphorylation of tau at AD-relevant epitopes in hippocampal neurons and cause neuritic degeneration in the absence of amyloid fibrils[Fig 1]

b) demonstrate that synthetic amyloid dimers also show similar properties[Fig S5; important for follow-up studies despite being a supplementary] demonstrate the effects are blocked by anti-Aβ N-terminal antibodies [Fig 5].

Multiple Sclerosis

MS Project 1 (Paper ranking 32/50)

Rejuvenation of regeneration in the aging central nervous system.

Ruckh JM[1], Zhao JW, Shadrach JL, van Wijngaarden P, Rao TN, Wagers AJ, Franklin RJ.
Cell Stem Cell. 2012 Jan 6;10(1):96-103.

Abstract

Remyelination is a regenerative process in the central nervous system (CNS) that produces new myelin sheaths from adult stem cells. The decline in remyelination that occurs with advancing age poses a significant barrier to therapy in the CNS, particularly for long-term demyelinating diseases such as multiple sclerosis (MS). Here we show that remyelination of experimentally induced demyelination is enhanced in old mice exposed to a youthful systemic milieu through heterochronic parabiosis. Restored remyelination in old animals involves recruitment to the repairing lesions of blood-derived monocytes from the young parabiotic partner, and preventing this recruitment partially inhibits rejuvenation of remyelination. These data suggest that enhanced remyelinating activity requires both youthful monocytes and other factors, and that remyelination-enhancing therapies targeting endogenous cells can be effective throughout life.

Significance

Clearly, if adding back systemic factors from young animals can reverse aging or disease relevant deficits then it should be possible to isolate those factors and develop novel therapeutic strategies for dementia, MS, AD and other diseases. Confirming that this parabiotic approach is indeed reproducible is a first step.

Key studies to try to reproduce

The key elements of this study we wish to reproduce are: (a) to ascertain the impact of exposure to youthful blood-borne factors on remyelination activity in aged partners, by comparing lesions at 14 dpl when new OPC-derived oligodendrocytes appear in heterochronic-old animals compared with isochronic-old controls (the numbers of proliferating OPCs will be identified by coexpression of the OPC transcription factor Nkx2.2 and the proliferation marker Ki67 and (b) to test whether the enhanced production of Olig2+/CC1+ mature oligodendrocytes in heterochronic-old lesions leads to increased remyelination, using histological analysis of semithin resin sections to assess differences in remyelination in all three groups at 21 dpl.

Parkinson's Disease

PD Project 1 (Paper ranking 5/50)

Direct generation of functional dopaminergic neurons from mouse and human fibroblasts. Caiazzo M, Dell'Anno MT, Dvoretskova E, Lazarevic D, Taverna S, Leo D, Sotnikova TD, Menegon A, Roncaglia P, Colciago G, Russo G, Carninci P, Pezzoli G, Gainetdinov RR, Gustincich S, Dityatev A, Broccoli V.
Nature. 476(7359):224-7 (2011)

Abstract

Transplantation of dopaminergic neurons can potentially improve the clinical outcome of Parkinson's disease, a neurological disorder resulting from degeneration of mesencephalic dopaminergic neurons. In particular, transplantation of embryonic-stem-cell-derived dopaminergic neurons has been shown to be efficient in restoring motor symptoms in conditions of dopamine deficiency. However, the use of pluripotent-derived cells might lead to the development of tumours if not properly controlled. Here we identified a minimal set of three transcription factors--Mash1 (also known as Ascl1), Nurr1 (also known as Nr4a2) and Lmx1a--that are able to generate directly functional dopaminergic neurons from mouse and human fibroblasts without reverting to a progenitor cell stage. Induced dopaminergic (iDA) cells release dopamine and show spontaneous electrical activity organized in regular spikes consistent with the pacemaker activity featured by brain dopaminergic neurons. The three factors were able to elicit dopaminergic neuronal conversion in prenatal and adult fibroblasts from healthy donors and Parkinson's disease patients. Direct generation of iDA cells from somatic cells might have significant implications for understanding critical processes for neuronal development, in vitro disease modelling and cell replacement therapies.

Significance

Clearly, being able to generate dopaminergic neurons from human fibroblasts in particular would be a significant breakthrough for drug discovery in Parkinson's disease. The idea of personalised medicine where potential treatments could be tested in neurons derived from individual patients, irrespective of the cause of the disease would be brought a step closer if this approach is robust. Generating more uniform neuronal populations, more quickly and without having to go through iPSC, NSC proliferation and differentiation protocols has the potential to speed up the process and allow different genetic causes of PD to be tested for response to potential treatments more quickly.

Key studies to try to reproduce

The key elements of this study we wish to reproduce are:

a) to demonstrate human patient derived fibroblasts can be differentiated into neurons efficiently as claimed as assessed morphologically [Fig 4a-f]
b) to demonstrate that the transdifferentiated neurons are indeed functionally active and useful for testing potential therapeutics in [Fig 4j-o]

Appendix II: Exemplar publications from CRL in the reproducibility field

PLOS | ONE

A Monoclonal Antibody TrkB Receptor Agonist as a Potential Therapeutic for Huntington's Disease

Daniel Todd, Ian Gowers, Simon J. Dowler, Michael D. Wall, George McAllister, David F. Fischer, Sipke Dijkstra, Silvina A. Fratantoni, Rhea van de Bospoort, Jessica Veenman-Koepke, Geraldine Flynn, Jamshid Arjomand, Celia Dominguez, Ignacio Munoz-Sanjuan, John Wityak, Jonathan A. Bard

Abstract

Huntington's disease (HD) is a devastating, genetic neurodegenerative disease caused by a tri-nucleotide expansion in exon 1 of the huntingtin gene. HD is clinically characterized by chorea, emotional and psychiatric disturbances and cognitive deficits with later symptoms including rigidity and dementia. Pathologically, the cortico-striatal pathway is severely dysfunctional as reflected by striatal and cortical atrophy in late-stage disease. Brain-derived neurotrophic factor (BDNF) is a neuroprotective, secreted protein that binds with high affinity to the extracellular domain of the tropomyosin-receptor kinase B (TrkB) receptor promoting neuronal cell survival by activating the receptor and down-stream signaling proteins. Reduced cortical BDNF production and transport to the striatum have been implicated in HD pathogenesis; the ability to enhance TrkB signaling using a BDNF mimetic might be beneficial in disease progression, so we explored this as a therapeutic strategy for HD. Using recombinant and native assay formats, we report here the evaluation of TrkB antibodies and a panel of reported small molecule TrkB agonists, and identify the best candidate, from those tested, for *in vivo* proof of concept studies in transgenic HD models.

PLoS ONE 9(2): e87923 (2014)
http://www.plosone.org/article/info:doi/10.1371/journal.pone.0087923

Metabolism and pharmacokinetics of JM6 in mice: JM6 is not a prodrug for Ro-61-8048.

Beconi MG[1], Yates D, Lyons K, Matthews K, Clifton S, Mead T, Prime M, Winkler D, O'Connell C, Walter D, Toledo-Sherman L, Munoz-Sanjuan I, Dominguez C.

Abstract

Understanding whether regulation of tryptophan metabolites can ameliorate neurodegeneration is of high interest to investigators. A recent publication describes 3,4-dimethoxy-N-(4-(3-nitrophenyl)-5-(piperidin-1-ylmethyl)thiazol-2-yl)benzenesulfonamide (JM6) as a novel prodrug for the kynurenine 3-monooxygenase (KMO) inhibitor 3,4-dimethoxy-N-(4-(3-nitrophenyl)thiazol-2-yl)benzenesulfonamide (Ro-61-8048) that elicits therapeutic effects in mouse models of Huntington's and Alzheimer's diseases (Cell 145:863-874, 2011). Our evaluation of the metabolism and pharmacokinetics of JM6 and Ro-61-8048 indicate instead that Ro-61-8048 concentrations in mouse plasma after JM6 administration originate from a Ro-61-8048 impurity (<0.1%) in JM6. After a 0.05 mg/kg Ro-61-8048 oral dose alone or

coadministered with 10 mg/kg JM6 to mice, the Ro-61-8048 areas under the concentration-time curves (AUCs) from 0 to infinity were similar (4300 and 4900 nM × h, respectively), indicating no detectable contributions of JM6 metabolism to the Ro-61-8048 AUCs. JM6 was stable in incubations under acidic conditions and Ro-61-8048 was not a product of JM6 metabolism in vitro (plasma, blood, or hepatic models). Species differences in the quantitative rate of oxidative metabolism indicate that major circulating JM6 metabolite(s) in mice are unlikely to be major in humans: JM6 is rapidly metabolized via the piperidyl moiety in mouse (forming an iminium ion reactive intermediate) but is slowly metabolized in human (in vitro), primarily via O-dealkylation at the phenyl ring. Our data indicate that JM6 is not a prodrug for Ro-61-8048 and is not a potent KMO inhibitor.

Drug Metab Dispos. 2012 Dec; 40(12):2297-30663
http://www.ncbi.nlm.nih.gov/pubmed/22942319

Coalition for Evidence-Based Policy
A NONPROFIT, NONPARTISAN ORGANIZATION

President

Jon Baron
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[redacted]

1725 I Street NW, Suite 300
Washington, DC 20006
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September 23, 2014

To: Office of Science and Technology Policy (OSTP)
National Economic Council (NEC)

Re: Comments on *Strategy for American Innovation*, regarding the problem that many published scientific findings are not reproducible (question #11)

The Coalition for Evidence-Based Policy – a nonprofit, nonpartisan organization – offers the following input in response to question 11 in the July 29 Notice of Request for Information regarding the *Strategy for American Innovation.*

Question 11: ***Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?***

We agree that irreproducibility of published research findings is a major problem across scientific disciplines. Our organization focuses mainly on social policy research; thus, our comments below discuss the problem, and potential solutions, in that area of science.

Problem: Successful replication trials are a critical missing piece of the evidence base in most areas of social policy, greatly limiting the reliability of what is "known" to work.

A. **Progress in science (and, by extension, evidence-based policy) depends on the replication of positive findings.** Across diverse fields of science and research, it is widely recognized that until positive research findings are replicated, there is always a question about whether they are valid, and whether they can be generalized beyond the initial study conditions.

B. **Indeed, in medicine, social policy, and other fields, research shows that, too often, positive initial study findings are not reproduced in large replication trials.** Reviews in different areas of medicine have found that 50-80% of positive results in phase II studies (mostly small randomized trials, or quasi-experimental studies) are overturned in larger, more definitive replication trials (i.e., phase III).[1] Similarly, in education policy, programs such as the Cognitive Tutor, Project CRISS, and LETRS teacher professional development – whose initial research findings were promising (e.g., met What Works Clearinghouse standards) – have unfortunately not been able to reproduce those findings in large replication trials sponsored by the Institute of Education Sciences.[2,3,4] In employment and training policy, positive initial findings for the Quantum Opportunity Program, and Center for Employment Training – programs once widely viewed as evidence based – have not been reproduced in large replication trials sponsored by the Department of Labor.[5,6]

C. **Some social programs have had successful, rigorous replications that provide high confidence of impact (e.g., Nurse-Family Partnership, LifeSkills Training)[7], but they are exceptions among programs widely viewed or rated as evidence based.** Most such programs have evidence from a single randomized trial, or multiple trials with limitations such as only short-term follow-up.

What's Needed: Strategic government investment in large replication trials, to determine which promising programs can reproduce important positive impacts on people's lives.

A. **Government investment in large replication trials is essential, as researchers and program providers have few incentives to initiate such studies on their own.** The lack of incentives for replication trials is a well-known and often lamented feature of academic research. University of Virginia psychologist Brian Nosek, a leading voice for replication studies, concisely summarizes the problem: "Scientists have strong incentives to introduce new ideas, but weak ones to confirm the validity of old ideas. Innovative findings produce rewards of publication, employment, and tenure. Replicated findings produce a shrug." In other words, "We're not rewarded for redoing what someone else does. The main reward is for doing something novel."[8] This problem – the lack of a replication culture in most disciplines – is the subject of excellent recent articles on National Public Radio and in Protomag.

   Similarly, providers of evidence-based programs have few incentives to initiate a large replication trial of their program, as an adverse finding (which as noted above is a real risk in such studies) may jeopardize not only the program's evidence rating but also its funding support.

B. **Such government effort should focus strategically on programs with the strongest signal of positive impact from prior research, to help avoid the frequent pattern of disappointing replications.** In cancer research, this was the central motivating principle for recent guidance issued by the American Society of Clinical Oncology on the development of definitive, randomized phase III trials: "It is necessary to observe extremely strong signals in phase II studies if we are to expect clinically meaningful outcomes to be achieved in subsequent phase III studies. Although this statement may be obvious, we sometimes are more optimistic about results from phase II trials than is warranted."[9]

   Similarly, an expert panel that we recently convened for the Department of Labor's Employment and Training Administration recommended that: "In selecting interventions to evaluate in a given area … [the agency] strategically search the existing evaluation literature to identify the strongest candidates – i.e., those most likely to produce sizable positive impacts. We recommend this approach because … the clear pattern in past experimental evaluations in workforce development is that most interventions produce weak or no positive impacts compared to services-as-usual."[10]

Proposed Next Step: Within each of several targeted fields of policy (e.g., education, workforce development, crime prevention), we suggest that OSTP and NEC –

A. **Convene meetings with federal agency officials and leading researchers, to identify high priority program areas for replication trials.** These would be program areas that (i) the OSTP, NEC, and agency officials identify as being of high policy interest; and/or (ii) the researchers identify as having a fecund evidence base of promising programs that may be good candidates for replication trials. (As an illustrative example, one such area might be employment programs for disadvantaged youth.)

B. **Once a high-priority program area is chosen, convene researchers from leading evidence-review efforts (e.g., clearinghouses of evidence-based programs) to develop:**

   1. **Recommendations of especially promising programs for replication trials** – i.e., programs whose prior evidence provides a very strong signal of positive impact; and

   2. **Suggested features of such trials needed to generate definitive evidence on each program's impact** (e.g., types of sites, key outcome measures, length of follow-up).

C. **Convene a final meeting, in which the above evidence-review group would present its report to federal officials, and participants would jointly explore policy steps to move the trials forward –** e.g., potential funding sources and/or grantmaking incentives for such trials, possible use of administrative data to facilitate low-cost replication trials, and so on.

<u>Conclusion</u>: The above process, carried out sequentially across different fields of social policy, would help build the key missing evidence in most evidence-based programs: reproducibility of important impacts on people's lives.

Thank you for opportunity to comment on the *Strategy for American Innovation.* We hope this input is helpful, and would be pleased to answer any questions or provide additional information.

Sincerely,

Jon Baron, President
Coalition for Evidence-Based Policy

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[6] Miller, Cynthia, Johannes M. Bos, Kristin E. Porter, Fannie M. Tseng, and Yasuyo Abe, *The Challenge of Repeating Success in a Changing World: Final Report on the Center for Employment Training Replication Sites*. Submitted by MDRC to the U.S. Department of Labor's Employment and Training Administration, September 2005.

[7] Based on their strong, replicated evidence, the Nurse-Family Partnership and LifeSkills Training both receive the highest evidence rating on the main "what works" websites, such as the Top Tier Evidence initiative, Blueprints for Healthy Youth Development, CrimeSolutions.gov, and the National Registry of Evidence-based Programs and Practices.

[8] Quoted in Linda Keslar, "The Problem of Replication," *Protomag*, a publication of Massachusetts General Hospital, Winter 2014; and Shankar Vedantam, "Why Reporting On Scientific Research May Warp Findings," National Public Radio, May 19, 2014.

[9] Lee M. Ellis, et. al., "American Society of Clinical Oncology Perspective: Raising the Bar for Clinical Trials by Defining Clinically Meaningful Outcomes," *Journal of Clinical Oncology*, vol. 32, no. 12, April 20, 2014, pp. 1277-80.

[10] Rebecca Maynard, Larry Orr, and Jon Baron, *Increasing the Success of Evaluation Studies in Building a Body of Effective, Evidence-Based Programs: Recommendations of a Peer-Review Panel*, prepared for the Employment and Training Administration of the U.S. Department of Labor, June 2013, linked here.

September 23, 2014

Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave NW
Washington, DC 20504

Via Electronic Mail (innovationstrategy@ostp.gov)

Re: *Strategy for American Innovation*

Dear Mr. Correa:

In response to the notice of inquiry published by the Office of Science and Technology Policy (OSTP) and the National Economic Council (NEC) in the Federal Register at 79 Fed. Reg. 44,064 (July 29, 2014), the Computer & Communications Industry Association (CCIA) submits comments concerning the strategy for American innovation. CCIA is a global trade association representing a leading cross section of computer, communications and Internet firms, which together generate annual revenues in excess of $465 billion. For over 40 years, CCIA has been promoting innovation, and preserving full, fair and open competition throughout our industry. Our commitment to vigorous competition, freedom of expression and openness comes from understanding past successes and the factors that can help our industry thrive in the future.

Technology companies generally ask little from the U.S. Government other than a playing field that enables next generation innovations to reach the marketplace. We support greater competition in the broadband market, open network protections, balanced intellectual property, and trade agreements that reflect the best of U.S. laws and policies ranging from balanced copyright rules to discouragement of Internet censorship.

I. Background

Innovation is critical to promoting productivity and economic growth, as well as solving social and environmental problems. Yet the U.S. Government has had difficulty implementing a coherent institutional framework for addressing the increasingly diverse, volatile, complex, and globally distributed nature of technology-enabled change. Congress abandoned its Office of Technology Assessment (OTA) twenty years ago; it eliminated the Technology Administration in the Department of Commerce in 2007. Meanwhile, a misdirected and misused patent system has imposed heavy costs and uncertainty on large segments of the economy, and efforts at reform now pit ordinary businesses against universities, while exposing division within universities between scholars and licensing offices.

Innovation is an increasingly rich and complex process that extends far beyond technological novelty. The case for government intervention in support of innovation varies greatly. At its worst, it can be reflexive, misapplied, and damaging to competition.

The RFI identifies varieties of innovation that do not fit the resource-intensive linear model and the policies associated with it. These include user innovation, combinatorial innovation, open innovation, Internet-enabled innovation, data-driven innovation, and institutional innovation. Although each has its champions, these models are not well-defined. In part they represent different aspects or phases of innovation and are not directly comparable as alternatives.

Nonetheless, the RFI raises an important question that reveals the lack of a policy or institutional framework for understanding these differences and their implications. There is considerable OECD work in this area where the U.S. Government should provide thought leadership – but has not done so. In terms of national models, the U.S. would do well to consider the UK's Department of Business, Innovation & Skills (BIS) which has funded rigorous research on innovation (much through the Intellectual Property Office) and taken an aggressive, integrated approach to policy. *See BIS research strategy 2014 to 2015* (Sept. 2014), *available at* https://www.gov.uk/government/publications/bis-research-strategy-2014-to-2015.

The general-purpose technology of our time, information technology, enables innovation throughout the economy, in other technologies, business practice, government, social life, and culture – often at a very low cost. Yet judicial decisions favoring abstract and trivial patents (such as do-it-on-the-Internet patents) have imposed high costs of acquiring, enforcing, and defending against patents across vast expanses of the economy where patents were unknown 30 years ago. Innovators have been plagued with expense and uncertainty, and the patent system has been wracked with controversy because this radical expansion was undertaken without foresight, planning, or accountability.

Conventional, siloed thinking persists in part because there is no effective focal point for institutionalized expertise within the federal government. OSTP is identified with the Administration in power, and its limited staff and priorities change as administrations change. At the other extreme, there is the Science and Innovation Policy Program (SciSIP) at the National Science Foundation (NSF), which sponsors academic research. There is little in between. In principle, SciSIP should contribute to sound, evidence-based policy. However, since it was initiated in 2005, it has only held one public event – a principal investigator's conference at the National Academies in 2012.

II. Principles for Innovation Policy

Questions 4, 5, and 6 of the RFI go directly to fundamentals of how innovation policies and national strategy should be managed within the government in light of the changing nature of innovation. CCIA suggests these guiding principles:

A. Dynamism

A national strategy must monitor and respond to change as a regular process that is incorporated into statistics collection, generation of reports, and ongoing dialog within the policy community. Innovation policies and national strategy should be innovative, not fixed for all times and technologies.

In stark contrast, a dominant ideology within the patent system has been to adapt by swallowing all forms of innovation (including organizational innovation) and confining them in a one-size-fits-all straightjacket. Worse, this rigid perspective is sometimes represented as being locked in to the WTO charter as a legal commitment that precludes tailoring the patent system to produce economically desirable results.

The need for dynamism is also illustrated by the new forms of IT-enabled asset-sharing such as Airbnb and Uber, which face opposition from locally regulated incumbents. Policy lock-in and capture by incumbents – the analog to Clayton Christensen's "innovator's dilemma" – is well known in Washington, although rarely acknowledged in formal policy development. Future innovators are simply not represented in the political process, and this tends to favor past success over present and future innovation.

Academics and journalists help monitor change in an ad hoc manner, but the government is uniquely capable of collecting reliable statistics on a regular basis – and it must do a better job of this on innovation. The 2008 NSF Business R&D and Innovation Survey remains a one-off effort. The U.S. does not follow the OECD Oslo Manual on the measurement of innovation, and has allowed Europe to provide intellectual leadership at an international level. U.S. participation in the OECD Committee on Industry, Innovation and Entrepreneurship has been conspicuously weak.

The political climate in the U.S. may be intolerant of failure, but an effective national innovation strategy must be agile, responsive, and prepared to experiment and take risks without locking agencies into programs that do not produce results . DARPA remains the paradigmatic experimental program; DARPA benefits from its national security mission, but it, too, has suffered from political constraints that demand narrow focus on short-term results and lethal weapons. Most programs operate under some form of peer review, which may inhibit risk taking.

B. Coherence and Continuity

Innovation programs and agencies are not immune from the siloed thinking that afflicts government agencies and results in stovepiping, inertia, and uncoordinated overlap. This sometimes results from a narrow mandate imposed by Congress, but it can be debilitating and wasteful when the nature of innovation demands multidisciplinary approaches, coordination among multiple players, pooling of resources, and need for scaling and commercialization.

Insular agency cultures are a major obstacle to coherent government-wide policy. For example, the PTO, long the centerpiece of innovation policy in the U.S., secured an unusual degree of autonomy for its operations when it became fee-funded in 1990, yet it remained charged with providing broad policy advice to the President. Although the agency launched an Office of Chief Economist in 2010, it has avoided addressing the hard problems that have resulted in deep political divisions and perpetual battle over patent reform. Instead, it has engaged in self-promoting or self-justifying studies and promulgated a fee structure that perpetuates the patent quality problem through a billion-dollar front-end subsidy of patent applications. This subsidy can only be made up from renewal fees, creating a magnet for low-quality applications as well as an incentive for the office to grant patents since its processing costs can only be recovered from issued patents.

At present there is little guidance for how patents resulting from federally funded research are to be licensed. Although universities may not assign such patents, they sell exclusive licenses to whoever is willing to pay. This feeds opportunities for patent assertion entities (PAEs) who are not commercializing the technology. While this may arguably be an option for privately funded research, it is inappropriate for publicly funded research and induces universities to oppose patent reform in the interest of maximizing revenue.

Another problem has been uncovered by OECD/G20 work on profit-shifting for tax purposes, an area we and others are likely to be looking at more in the future. By moving ownership of intangible assets among affiliates abroad, companies can eliminate or minimize tax on licensing income, and when this is done using patents that have benefited from the research and experimentation tax credit, this can amount to an effective subsidy greater than 100%. This disadvantages small firms who must pay full taxes because they lack foreign affiliates to which profits can be shifted.

In the absence of an institutionalized home outside the White House, innovation policy has lacked the continuity needed for sustained role in national economic policy. *See* Brian Kahin & Christopher T. Hill, *United States: The Need for Continuity* (Issues in Science & Technology, Spring 2010), *available at* http://www.ccianet.org/wp-content/uploads/library/Kahin-Hill.pdf. This is unfortunate because a "national strategy" implies a responsive mix of policies – at least if they form a coherent whole. Without continuity and coherence, innovation strategy may be seen as a partisan or special interest agenda that is ad hoc and opportunistic rather than strategic in the long-term interests of the nation. If a home for innovation policy is not feasible in Commerce, consideration should be given to expanding the SciSIP program to include outreach components as a resource for agencies, states, Congress, and the public. It might also be possible to encourage interagency coordination through an innovation policy subcommittee of the NSTC Technology Committee (there is already an interagency working group on "science of science policy" under the Social, Behavioral and Economic Research Subcommittee of NSTC Committee on Science).

C. Accountability

Accountability, like continuity, is essential to ensure that innovation policy and strategy is seen as a credible, evidence-backed function of the U.S. Government. Beneficiaries of federal policy and programs should be obligated to report and disclose how a subsidy or award worked, or not, in practice – with the understanding that failure in innovation is expected and acceptable but should be a source of learning.

It is easy to focus on benefits accrued by the intended beneficiary. The burden imposed on others (especially small users) in terms of risk, uncertainty, and costs is often not easy to acknowledge and harder still to quantify, especially when there are long lag times. For example, PAEs do not file suit until an average of eight years after the patent issues. Conversely, the high costs of enforcing patents, especially for startups facing deep-pocketed defendants, may virtually eliminate their deterrent effects and their value to small patent holders. Accounting for the real costs and practical effects is essential to developing realistic policy for patents, just as cost-benefit analysis should inform other kinds of intervention.

Accountability also demands taking consistent, principled positions that can be defended internationally. However, trade agreements are negotiated in secret and then approved with limited scrutiny and amendment. Invariably some interests, typically those with the most at stake, are closer to the negotiations than others. This leads to the kind of favoritism associated with "industrial policy" – which is amplified when simplistic one-size-fits-all policies are locked into treaties as "international obligations." The WTO provision on technological nondiscrimination noted above is a consequence of favoring the interests of the pharmaceutical industry without attention to the long-term economic consequences for high tech. This problem has become especially critical in the context of international debate over state espionage, where the U.S. has justified espionage in the context of trade negotiations – as long as it is not in the interests of individual companies.

III. Response to Questions

While most of CCIA's recommendations are summarized in Question 1, answers to Questions 4, 6, 8, 17, 21 and 22 follow:

Question #1

In its next Strategy for American Innovation, the Administration should:

1. Adopt guidelines for maintaining Internet freedom;
2. Address threats to the openness of the Internet;
3. Ensure balanced refinement of copyright law and trade agreements that fully reflect domestic law and policy;
4. Reform the patent system, the misuse of which has become a major threat to U.S. innovation;
5. Continue efforts for immigration reform;
6. Increase basic research, especially high stakes research that may result in breakthrough innovations; and
7. Enhance the domestic labor pool through education, especially STEM education.

A. Trade

Innovation, particularly in the increasingly robust and intertwined commercial Internet ecosystem, requires trade policy that supports an open global Internet. Indeed, the development of the Internet has led to a revolution in the way we conduct international commerce and trade. Unfortunately, digital barriers persist, limiting innovation in Internet communications and services.

U.S. trade policy constructed an enduring legacy of free trade beginning with the General Agreement on Tariffs and Trade (GATT) more than 60 years ago. Today, service industries employ 95 million of America's 110 million private-sector workers, and exporting service industries employ more people than work in factories, farms, and mines combined. This shift to services is increasingly true of other economies, yet discrimination against the services persists. Given the importance of the Internet to innovation and the international trade in services, there is a need to further encourage Internet-enabled trade.

With that in mind, U.S. innovation policy should promote the following trade principles:

1. Cross-border data flows

The modern networked economy, and international commerce generally, depends upon data flowing freely without impediment -- and this must not be undermined by other policies. Exceptions to the "free flow" of cross-border information should be narrowly tailored to legitimate ends.

2. Balanced intellectual property

U.S. policy should endeavor to strike the same intellectual property balance internationally as we have struck domestically. Therefore, important limitations and exceptions to IP protection that have allowed the Internet economy to thrive (such as fair use and the first-sale doctrine) should be as important to our trade negotiators as the protections themselves.

3. Full market access for digital products

U.S. trade agreements should include a strong e-commerce chapter that ensures that digital products, regardless of their classification, are not discriminated against merely because they are provided and consumed digitally.

4. Avoid forced localization

Trade agreements should oblige signatories not to take actions that affect the choices of commercial actors in physical provision of hardware, software, or services that might impact network performance, resiliency, security, and/or costs of deployment or operations. Many countries are tempted to require that certain types of hardware or software integral to the operation of the network be physically sited within their national boundaries. There are many reasons why these choices are made, but mandates of this kind generally frustrate efforts to ensure the best performance for the largest number of Internet users at the lowest cost, and there are better and more sustainable ways to encourage local investment in the ICT sector than through these kinds of mandates.

5. Reasonable liability rules regarding third-party activity

Unbounded liability rules constitute a major barrier to international Internet commerce and communications. Due to the extraordinary quantity of data transiting communications networks, these businesses could be extremely vulnerable to strict liability for the misdeeds of users. Congress responded to this problem in 1996 with Section 230 of the Communications Decency Act, providing categorical immunity from liability for user misconduct, thus allowing Internet companies to combat undesirable or potentially illegal activity without fear of additional liability for editing user content. Section 230 states that "no provider or user of an interactive computer service shall be treated as the publisher of any information provided by another information content provider."

Section 230 has been a boon to the Internet industry and directly paved the way for the exponential growth of the domestic U.S. Internet industry. Unfortunately, the same robust protections for intermediaries are not universal and this has directly hampered U.S. Internet companies overseas. *See* Ali Sternburg & Matt Schruers, *Modernizing Liability Rules to Promote Internet Trade*, CCIA Research Paper (Sept. 2013), *available at* http://www.ccianet.org/wp-content/uploads/2013/09/CCIA-Liability-Rules-Paper.pdf. Given the relative saturation of the U.S. market, U.S. Internet companies must focus on expanding beyond U.S. borders. In order to maintain the same robust pace of growth and innovation, national and international trade law must reflect the same principles that fostered growth in the U.S.

B. Copyright

The economic significance of balanced copyright to the U.S. economy cannot be understated. A 2011 economic study commissioned by CCIA concluded that industries depending upon fair use and related limitations to copyright generated revenue averaging $4.6 trillion, contributed $2.4 trillion in added value to the U.S. economy (roughly one-sixth of total U.S. current dollar GDP) and employed approximately 1 in 8 U.S. workers. *See* Thomas Rogers & Andrew Szamosszegi, *Fair Use in the U.S. Economy* at 26-27 (2011), *available at* http://www.ccianet.org/wp-content/uploads/library/CCIA-FairUseintheUSEconomy-2011.pdf

U.S. domestic innovation policy and international trade policy should therefore aim to ensure a proper balance in copyright law. The balance should provide proper protection for strategically important and constitutionally-rooted principles like fair use. A robust first-sale doctrine should guarantee that IP rights do not limit the movement of lawfully-purchased goods. Business certainty is needed for industries that may not provide content but are nevertheless heavily regulated by copyright law. This certainty can be achieved through imposing rational limits on copyright's statutory damages system, strengthening the DMCA safe harbors for online services, deterring misuse of copyright, and reestablishing the customary corporate veil to copyright. Statutory damages are a significant and measurable deterrent to innovation; these chilling effects could be mitigated by reforming disproportionate statutory damages to provide greater predictability and re-examining whether statutory awards should be permitted to aggregate infinitely.

Copyright compliance has a great impact on early-stage investment, and, consequently, innovation as well as the economy. Interviews with hundreds of angel investors and venture capitalists found them to be overwhelmingly wary of new regulations and desiring an unambiguous copyright regime. In particular, increasing user or website liability would negatively affect innovation by driving early investors into other areas. A recent study found that such risks could have the effect of reducing the pool of interested angel investors by 81%, and that increased exposure for users would likely reduce the pool of interested angel investors by 48%. In general, 80% of investors polled reported being uncomfortable investing in business models in which the regulatory framework is ambiguous. *See* Matthew Le Merle *et al.*, *The Impact of U.S. Internet Copyright Regulations on Early-Stage Investment: A Quantitative Study* (Booz & Company 2011), *available at* http://www.booz.com/media/file/BoozCo-Impact-US-Internet-Copyright-Regulations-Early-Stage-Investment.pdf.

Changes in copyright law and policy that provide more certainty for intermediaries, such as the Second Circuit's decision in *Cartoon Network, LP v. CSC Holdings, Inc.* ("*Cablevision*"), positively impact venture capital investment in cloud computing. The *Cablevision* decision led to additional incremental investment in U.S. cloud computing firms that ranged from $728 million to approximately $1.3 billion over the two-and-a-half years after the decision, the approximate equivalent of $2 to $5 billion in traditional R&D investment; after *Cablevision*, the average quarterly investment in cloud computing in the United States increased by approximately 41 percent. *See* Josh Lerner, *The Impact of Copyright Policy Changes on Venture Capital Investment in Cloud Computing Companies* (Analysis Group 2011), *available at* http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/Lerner_Fall2011_Copyright_Policy_VC_Investments.pdf

C. Patents

Strong patent rights are not appropriate for every type of innovation. For example, in an industry or field where developments are made incrementally with lots of small improvements, patents are problematic because a single patent on a small improvement can block anything that tries to build on that improvement. The tech industry (especially software) is a classic example of this type of field. With few exceptions, there are no giant leaps forward. Rather, a long series of small steps produce software improvements. The current patent system is a better fit for industries where each product stands on its own, like pharmaceutical. A new compound generally is not blocked by a patent for an old compound.

The Administration's 2013 *Patent Assertion and U.S. Innovation* report concludes by calling for improvement in three areas:

- clearer patents with a high standard of novelty and non-obviousness,
- reduced disparity of litigation costs between patent owners and technology users, and
- greater adaptability of the innovation system to challenges posed by new technologies and new business models.

We agree. While the White House and the House of Representatives have made some progress in addressing reform, more needs to be done. Beyond the reforms supported by the President and the House of Representatives, we suggest:

1. Integrate patents and other means of appropriating returns into a coherent innovation policy grounded in realistic assessment of costs, risks, and benefits.
2. Address the persistent quality problem by elevating the standard of obviousness from "person having ordinary skill" to peer review ("recognized skill"), and independently monitor allowance rates and evaluate causes (and consequences) of change.
3. Monitor and assess real benefits and costs of the patent system; require reporting of assignments, licenses, settlements, contractual demands for indemnification,

and costs associated with global coverage and litigation; and require timely registration of assignments, licenses, notice/demand letters, litigation, and settlements.

4. In line with the WTO panel decision in Canada - Pharmaceuticals (2000), clarify that TRIPS proscription of discrimination does not apply to rational differentiation. Confirm that economic outcomes should be the goal of the patent system, and that any discrimination should be measured in terms of outcomes.
5. Provide expanded licensing guidelines for government-owned and government-funded inventions (prizes, grants, cooperative agreements, or contracts) to reflect economic considerations, including the contribution of public funding, the difference between combinatorial and discrete-product innovations, and the appropriateness of alternative means of achieving returns from innovation. Limit university participation in speculative/secondary markets by requiring meaningful steps toward commercialization within five years and requiring full reporting of licensing revenues.
6. Broaden the Patent Public Advisory Commission beyond "user" and practitioner communities too predisposed to expanding the volume and scope of the system, and include economists and technology experts capable of evaluating the functioning and effectiveness of the system.
7. Redesign the fee structure to eliminate the front-end subsidy (and internal incentive to allow marginal patents) except for small and micro entities as provided by Congress. Require owners of invalidated patents to reimburse fees paid by successful challengers (but allow patent owners an opportunity to abandon patents prior to administrative proceedings upon presentation of prior art or other invalidating evidence).

D. Internet Openness, Trust, and Freedom

Internet freedom is critical to vibrant communication and information exchange to foster innovation and help drive our economy. The U.S. Government should lead by example to ensure Internet freedom. This means fighting Internet censorship in all its forms and making sure Internet users can access content freely, Internet services and other online businesses can reach customers, and that innovators do not need permission from Internet access providers.

Internet access connections are now part of our critical infrastructure for economic growth. Open, interconnected networks are essential for permissionless innovation and launching new businesses. The adoption of enforceable Open Internet rules under Title II by the FCC is important to existing U.S. businesses that might otherwise face commercial discrimination by duopoly network operators selling their own affiliated content, but also for the next generation of online innovators.

High quality broadband network infrastructure is critical for supporting innovation in the 21st century, but is characterized by minimal competition. Excessive rates and anticompetitive terms and conditions for business broadband (or special access) must be dealt with by the FCC. The FCC must legally safeguard open Internet access for all consumers, students, start-ups, small businesses and nonprofits. The federal government should encourage additional private build out of fiber access networks, and the repurposing and sharing of underutilized federal government spectrum.

To maintain both a platform for innovation and a key tool for Americans to reach all available resources on the Internet, the federal government should facilitate upgrades of physical digital network infrastructure by:

1. Pursuing spectrum policies that promote innovation using both licensed and unlicensed spectrum blocks, and repurposing or enabling sharing of underutilized federal government spectrum;
2. Advocating for cybersecurity legislation that will secure critical telecom network infrastructure from cyberattacks;
3. Adopting and enforcing strong new FCC open Internet rules that will ensure continued access to critical network infrastructure for market-based innovation without permission online; and
4. Adopting and enforcing policies that enable access competition with the dominant incumbent telecom networks, both landline and wireless, and preventing anticompetitive rates, terms and conditions for essential business broadband services.

E. Privacy, Surveillance and Internet governance

The government should also help support, or at least not undermine, the trust of Internet users with its policies on privacy, surveillance, security and Internet Governance by:

1. Encouraging Congress to update the Electronic Communications Privacy Act and pass the USA Freedom Act with measures to prevent bulk metadata collection;
2. Ensuring that government agencies from the State Department to USTR denounce government censorship;
3. Promoting multi-stakeholder Internet governance at global conferences;
4. Ensuring that any consideration of new regulations related to commercial "big" data use are crafted in collaboration with private sector stakeholders so they do not stifle innovation nor hinder legitimate business practices and responsible uses of big data; and
5. Promoting opportunities for industry self-regulation as to data management and protection, and supporting safe harbors for participating companies.

Question #4

Many policies can affect the ability of research-intensive companies to innovate and compete in the marketplace, but the impact of future policy choices on innovation is often not well understood in advance. For example, telecommunications spectrum policies that facilitate innovative business models may enable significant productivity growth in the mobile communications sector. Improved Federal capacity for analysis of such impacts would help inform policy development to support innovation.

Question #6

The nature of innovation is more complex than when some policies were enacted. For example, the patent system tends to be geared toward the needs of more traditional forms of innovation – such as a biotech company patenting a new drug. In the technology sector, innovation happens in more incremental steps and has numerous components that depend on interoperability. The iPhone, for example, has thousands of different patents, and one in six U.S. patents involve Smartphones, according to CCIA's calculations based on numbers from patent aggregator RPX. *See* Daniel O'Connor, *One in Six Active U.S. Patents Pertain to the Smartphone*, Disruptive Competition Project, Oct. 17, 2012, *at* http://www.project-disco.org/intellectual-property/one-in-six-active-u-s-patents-pertain-to-the-smartphone/. According to numbers from the National Science Foundation, 40 percent of patents issued fall under the ICT sector. Policies such as those for granting patents need to consider the nature of an industry and find ways to balance the patent system so that incumbents can no longer misuse patent law to block new innovation and new market entrants.

Question #8

Agencies lacking a traditional focus on research and development nonetheless pursue critical missions that could benefit from innovation. Given these agencies' more modest capacity to support research, development and other avenues to innovation, there is potentially underinvestment in science, technology and innovation to address key national problems such as education, workforce development and poverty alleviation.

Question #17

Over the past two decades, the cost of starting and scaling an IT-based company has plummeted due to a combination of cheap, scalable cloud computing, open source software, and other similar trends. Extending these or similar developments to more capital-intensive sectors, where costs remain a significant barrier, would yield significant benefits.

Question #21

Technology innovation has always been and will increasingly be collaborative and dependent on interoperability. The challenge will be to continue to allow new innovation to come to market by watching that incumbent companies are not using intellectual property or the standard setting process in anticompetitive ways. The FTC is investigating current problems of IP being used anti-competitively as part of its 6(b) study.

Question #22

Law or regulations to rein in abuse and misuse of the patent system will have large economic benefits both for the companies not having engineering and financial resources drained, and for the innovative contributions from start ups that are not put out of business by patent assertion entities. One prominent study estimated that PAEs cost the U.S. economy over $29 billion a year. *See* James Bessen & Michael Meurer, *The*

Direct Costs from NPE Disputes (Boston Univ. Sch. of Law Working Paper No. 12-34 June 28, 2012), *available at* https://www.bu.edu/law/faculty/scholarship/workingpapers/documents/BessenJ_MeurerM062512rev062812.pdf. A recent study showed a strong link between increased PAE litigation and reduced venture capital investment. *See* Catherine Tucker, *The Effect of Patent Litigation and Patent Assertion Entities on Entrepreneurial Activity* (June 2014), *available at* http://www.ccianet.org/wp-content/uploads/2014/06/Tucker-Report.pdf.

Further, we have seen that when it comes to copyright, a more is better approach to enforcement can stifle legitimate innovation. Intellectual property law must be balanced to protect both existing and future innovators. A CCIA-commissioned economic study based on publicly available government data and WIPO methodology, cited *supra*, found that industries that depend on fair use and exemptions to copyright law make up one sixth of the GDP and employ one of every eight U.S. workers. The government must consult with all stakeholders — not just so-called IP-intensive industries — when developing copyright policies.

*   *   *

In conclusion, CCIA urges OSTP and NEC to consider the innovation policy suggestions described herein.

Respectfully submitted,

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[redacted]

Strategy for American Innovation - Response

Dr. Gregory Hager, on behalf of the Computing Community Consortium
Professor and Chair, Department of Computer Science, Johns Hopkins University
Chair, Computing Community Consortium

September 23, 2014

(3) What specific actions can the Federal Government take to build and sustain U.S. strengths including its entrepreneurial culture, flexible labor markets, world-class research universities, strong regional innovation ecosystems, and large share of global venture capital investment?

The United State as a long history of high-risk high-reward research and development, starting with basic research funding and expanding through translation research and into venture funding. In particular, basic research in computing and engineering fields has fueled significant growth of the economy. For example the 2012 PCAST NITRD report traces the impact of basic research over a period of decades and provides numerous examples that connect basic research to multi-billion dollar market sectors, most of which are populated by US-based companies. Computing will continue to play a central role in future innovations. Nearly every field of science and engineering is now impacted in some way by advances in fundamental computing research and access to advanced computing infrastructure, and the availability of trained computer scientists.

However, although still considered a world leader in IT innovation, the US lead in computing is at significant risk. It has lost its lead in patents filed, new businesses created, and has ceded many major industries (e.g. advanced robotics) overseas. There are many likely causes for this trend. The most obvious is that as a fraction of GDP, the United States provides less funding for basic research than many other developed nations such as Japan, Germany, or Korea. Due to a lack of funding growth, basic research funding to US researchers has become intensely competitive, with funding rates for research proposals at NSF or NIH sometimes falling into the single digits. This decline comes at a time when private-sector opportunities (e.g. employment at Google, Facebook, Amazon, Dropbox etc.) are tremendously attractive.

The impact of limited basic research and highly lucrative private opportunities is manifold. First, some of the most creative and brightest minds are being pulled away from basic research into more applied R&D. While this may have positive benefits for the short-term, the long-term basic discoveries that will fuel innovation in the coming decades will be steadily eroded. Conversely, within academia, funding limitations have led to a culture where a large fraction of time and energy is devoted to writing proposals that will not be funded. This situation promotes a trend toward more conservative, incremental (i.e. low risk) research endeavors, decreases the amount of time faculty are able to spend on research, and ultimately dilutes creativity and risk taking.

A second trend has been the loss of industrial research groups (e.g. Bell Labs) that formed the “glue” between academic basic research and industrial applied R&D. As a result, more and more of the burden of both innovation **and** translation falls on universities and their research staff. While many universities are now seeking to fill this gap by creating incubators and accelerators, these efforts again dilutes time and energy for basic research by spreading researchers across a wider spectrum of activities.

Finally, we note that new players, e.g. Google, have begun to create facilities that surpass anything available to University research groups. However, these facilities are not open to the basic research community, stifling the ability of university research to identify and address problems of direct relevance to rapidly evolving commercial IT businesses.

There are many steps the government should take to enhance the US IT R&D competitiveness:

1) Increase funding, as a fraction of GDP, to all areas of basic and translational IT research. It is indisputable that the US needs for skilled IT researchers and practitioners at all levels is limiting innovation and expansion of both start-up and established businesses. These much needed resources will allow Universities to train more students, to hire new faculty, and will provide, over the longer term, much needed capacity to drive translational as well as basic research.

2) Create new incentives for academic-private partnerships to support basic research, to provide exposure and training for students in areas relevant to the commercial IT R&D enterprise, and to ensure a vibrant flow of information between academic and private players. Possible actions include:

    a. Establish co-funded initiatives to provide testbeds for university research. For example, recent NSF funding has facilitated the development of experimental cloud-computing facilities (e.g. so-called "bare metal clouds") that can support basic IT research, but which can also be tested under realistic "real-world" loads.

    b. Create federally funded sabbatical opportunities that support university researchers to spend time participating in or developing a private endeavor, or conversely allow private-sector researchers to spend time in a university basic research laboratory.

3) Encourage high-risk high-reward science. There are several recommendations that would enhance the competitiveness of US science:

    a. Create more long-term funding opportunities. Most research grants last 3-4 years, yet the time to get a PhD is 5-6 years. Providing more funding programs that have 5-7 year time horizons would reduce both the disruption incurred when funding on a grant runs out and quite possibly would also reduce the number of proposals written/submitted.

    b. Provide mechanisms to leverage university investments to create internal funding pools that take advantage of unique local resources or capabilities that are not well matched to existing federal programs.

4) Educate the public and science policy leadership by investing in organizations and individuals that can educate the congress, US science policy leadership on the role and impact of basic research and its connection to translational R&D.

(6) How has the nature of the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?

For example, many cite the growing importance of open innovation, combinatorial innovation, and user innovation; the convergence of biology, the physical sciences, and engineering; and the emergence of human-centered design.

The evolution of data-intensive computing has had a tremendous impact in all areas of the economy, in the social sector, and in basic science and engineering. The US has a unique advantage as a leader in this important area, and has pioneered many of the major players that are active today. However, the resources to teach and (re)train in these important areas are failing. Computer Science departments around the country are unable to cope with the rapidly growing needs and demands for education, at all levels, in this area. Programs and funding that support the training and support of new teaching resources are essential to maintain our competitiveness in core computing.

Computing related to the physical world will follow "big data" as the next major disruptive trend. This is an area that could play a major role in the next wave of American innovation, but, like data-intensive computing, will require a new set of skills, will require cross-disciplinary thinking and research, and which will benefit from early forethought in the development of common frameworks and interface, open-source platforms, and new cyber-infrastructure. In particular, the combination of rapid prototyping/agile manufacturing and the internet is a game-changing disruption for the future economy, but also one that introduces a number of new risks requiring substantial forethought.

Human-centered computing is similarly a fertile cross-disciplinary area. In particular, human interaction with computing will play a major role in the shaping of society over the next decade and beyond. Pursuing these trends requires new partnerships between traditional cognitive, behavioral, and psychological sciences with computer science and mathematics.

Some recommended actions are:

1) Make substantial investments in programs that support advanced training on computing and on computational research. In particular, the need for training in "computational thinking" is enormous and spans the entire academic and private R&D enterprise. This should begin at the K-12 level and extend through post-graduate education. This should involve new investments, and should be a high-profile national initiative to give every citizen opportunities to become educated in computing.

2) Promote cross-disciplinary thinking e.g. by investing and rewarding agencies and programs that draw together multiple disciplines to attack major national needs or economic opportunities. Include in these efforts both technical and non-technical (regulatory, policy, legal, and social) aspects.

3) Design policies that promote the transfer of ideas from basic research to application. As noted in #3 above, this will require new ways to allow basic and applied R&D personnel to easily move across disciplines, roles and enterprises to enhance knowledge transfer and "mixing" of talents.

(7) What emerging areas of scientific and technological innovation merit greater Federal investment, and how can that investment be structured for maximum impact?

Complex systems that involve people, physical devices, and computation are rapidly emerging as the new frontier in research. Traditional boundaries of mechanical engineering, social or cognitive science, and computing are rapidly falling as the “internet of things” and modern social platforms begin to merge into an amalgam of information, action, and interaction. Smart homes, cars, neighborhood, and cities will have enormous impact on education, healthcare, and the aging society.

Just as the recent manufacturing efforts have led to funding for several regional innovation centers, the federal government should create regional “Innovative Institutes” that are designed to bring together creative thinking individuals from multiple disciplines to design and create new products and devices. The institutes would be endowed with core funding, but would be expected and required to develop deep ties to regional industries, universities, and to the surrounding ecosystem. Their measure of success would be two-fold: to develop new ideas that attract new thinking through follow-on research and other scientific measures, and economic impact by teaming with local and regional industries to (e.g. SMEs) to enhance their competitiveness and efficiency.

(9) What additional opportunities exist to develop high-impact platform technologies that reduce the time and cost associated with the "design, build, test" cycle for important classes of materials, products, and systems?

The explosion of additive manufacturing (aka 3D printing) may simply replace subtractive machines, such as milling machines, with additive ones. Of greater potential is a "design, fabricate, finish, inspect, test" suite of computer-controlled shop tools and software integrated as a "platform" for agile manufacturing. Especially important, due to materials limitations of many additive processes, will be mechanical testing to insure that a fabricated part will meet its strength requirements. One could imagine robotic-controlled probes that inspect and test parts of many different shapes and sizes. The entire suite of tools and software must be driven mostly by a part's design, and avoid manual design of jigs or test procedures. While such an integrated flow has been a dream for a long time, and has seen partial fulfillment, the new developments in 3D printing and robotics warrant a fresh approach.

(10) Where are there gaps in the Federal Government's science, technology, and innovation portfolios with respect to important national challenges, and what are the appropriate investment and R&D models through which these gaps might be addressed?

Innovative healthcare research remains stifled by the lack of funding mechanisms to rapidly develop, deploy, test, and iterate to a final design that can be rapidly translated into new products and services. This gap is particularly true for new mobile and personalized health technologies that require substantial engineering iteration and human-centered design, and thus do not fit that traditional "clinical trial" methodology. Mobile health and home health technologies have the potential to address many gaps and barriers in healthcare delivery from increasing patient engagement and adherence to treatment, to providing critical data to inform cost-effective treatment of chronic diseases. However the basic and translational research in these areas cannot follow traditional, pharma-based NIH timelines but instead must stay apace with innovation in consumer technologies.

Another example is the innovations needed to address the care of the US's aging population. Multi-disciplinary research and translational efforts are greatly needed to transform American homes into sites where people can "age in place." The goal here is to reduce the economic burden of institutional care while sustaining the quality of life and independence of older adults as they age. However "aging in place" approaches meet seemingly insurmountable barriers as these settings are too noisy for traditional NIH clinical studies, the underlying technologies require rapid iteration while staying current with consumer home and communication technologies, and most reimbursement policies do not favor tele- and home-based healthcare delivery.

In both of these cases, what is needed are multi-agency programs that combine basic "blue sky" science (NSF), tremendous healthcare expertise (NIH), key stakeholders (e.g. VA, HUD), regulatory agencies (e.g. CMS, FDA, FCC) and vital industry partners to invest in ground-breaking research programs that have the potential to transform many key sectors of healthcare delivery and combat the most-expensive and fastest growing segment of healthcare expenses.

The importance and potential impact of these needed innovations in healthcare have been well documented in multiple PCAST reports:

- "*Better Health Care and Lower Costs: Accelerating Improvement through Systems Engineering.*" (2014)
- "*Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward*." (2010)

as well as the Institute of Medicine Report Best Care at Lower Cost: The Path to Continuously Learning Health Care in America (2013). What is needed are the multi-agency research programs to meet these needs.

Committee on Equal Opportunities in Science and Engineering (CEOSE)

September 22, 2014

Dr. Dan Correa
Senior Advisor for Innovation Policy
White House Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

Dear Dr. Correa:

The Committee on Equal Opportunities in Science and Engineering (CEOSE) advises the National Science Foundation (NSF) on policies and programs to encourage full participation by persons from underrepresented racial and ethnic minority groups (African Americans, Hispanic Americans, and Native Americans), persons with disabilities, and women within all levels of America's science, technology, engineering, and mathematics (STEM) enterprise. The Committee is pleased to provide the following comments to help inform the upcoming update of the *Strategy for American Innovation.* Specifically, we address questions 1 and 24.

Question #1: What specific policies or initiatives should the Administration consider prioritizing in the next version of the *Strategy for American Innovation*?

The National Science Foundation (NSF) Committee on Equal Opportunity in Science and Engineering (CEOSE) 2011-2012 Biennial Report [1] to the NSF Director and to Congress focused on a single, bold recommendation for "a bold new initiative, focused on broadening participation of underrepresented groups in STEM [Science, Technology, Engineering and Mathematics]… that emphasizes institutional transformation and system change; collects and makes accessible longitudinal data; defines clear benchmarks for success; supports the translation, replication and expansion of successful broadening participation efforts; and provides significant financial support to individuals [women, underrepresented minorities, and persons with disabilities] who represent the very broadened participation that we seek."

The report furthermore suggested some concrete steps that could be taken toward realization of an initiative that must be of a size, scale, and scope to effect national change. For example, it "might include several multi-site, geographically based, national experiments of foundational and implementation research involving universities, schools, and communities, inclusive of all underrepresented populations."

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1. CEOSE 2011-2012 Biennial Report to Congress, http://www.nsf.gov/od/iia/activities/ceose/reports/Full_2011-2012_CEOSE_Report_to_Congress_Final_03-04-2014.pdf

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To advance this bold initiative in practice, we suggest a framework of five specific elements that provide a means for realizing the overarching grand challenge described above, which when realized will transform the STEM enterprise to fully engage all the nation's citizens—including women, underrepresented minorities, and persons with disabilities.

1. *Develop and implement an effective preK-20+ system of STEM pathways.*
   Parity in the STEM workforce can be achieved by developing partnerships among local schools, colleges and universities, government and industry across the nation that will educate, inspire, train, and retain individuals in STEM at all levels of engagement, from preK and into the STEM workforce. Such interactions should aim to open the STEM pipeline at its source and increase the seamless flow of individuals—especially women, underrepresented minorities, and persons with disabilities—at every stage in the pipeline. Integral to this will be to transform institutions of higher education into more inclusive institutions with the know-how and the capacity to help build these effective pathways.
2. *Provide stable and sufficient direct support for individuals.*
   It is vital to provide direct support for the individuals—students, postdocs, pre-professionals—progressing through the STEM pipeline who represent the very broadened participation that we ultimately seek. This direct support must be significant, consistent, and large scale—equal to the magnitude of the broadening participation challenge itself.
3. *Develop a science of broadening participation that is grounded in empirical research*.
   Develop and support a coherent body of scholarly work that, among other things, identifies models and approaches that are effective, increases understanding of why and how different approaches work, and leads to an emerging, implementation-based theory of broadening participation. This approach and the emerging implementation theory will provide a more informed basis for model identification, adaptation, and replication.
4. *Conduct field experiments to understand and mitigate the barriers to broadening participation.*
   Leverage the direct support for individuals and programs (see #2 and #3 above) as opportunities to conduct investigations that lead to a deep, systemic, scientific understanding of the factors that currently limit, filter out, and otherwise preclude the full engagement of individuals in STEM. Ensure that the outcomes of these experiments result in a more "open and frictionless" preK-20+ system of pathways (see #1, #2 and #3 above).
5. *Recognize the field specific nature of the broadening participation challenge.*
   Embed and engage the bold initiative within and across all NSF directorates and divisions, recognizing that different approaches will be required in different disciplines while optimally connecting and clustering activities between and among disciplines. Use the effort at NSF to guide collaboration with other federal agencies.

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The enormity of the grand challenge of broadening participation in STEM is such that cooperation and coordination beyond NSF is necessary. Indeed, the broadening participation challenge writ large is not NSF's challenge alone; it is the nation's challenge, and thus it is the nation's responsibility to solve. Yet, we believe that NSF must serve as the catalytic focus for coordinated, multiple agency, national action. It is NSF's responsibility to provide the intellectual and scientific leadership if we are to develop a truly inclusive STEM enterprise that fully and effectively engages all of our citizens.

Question #24: Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?

Broadening the participation of women, underrepresented minorities, and persons with disability must be a national priority if we are to fully utilize our most important natural resource—our people—to advance American innovation. Diversity—in the form of individuals with different perspectives, backgrounds, and experiences—is a key component of innovation. That diverse groups are better at solving problems is now widely recognized in business and industry, yet creativity, innovation and problem-solving are central to the STEM enterprise. Less diversity in STEM means slower progress in solving the scientific and technical challenges of the day, slower advancement of living standards, and more rapid erosion of American competitiveness and global leadership.

Best Regards,

Committee on Equal Opportunities in Science and Engineering

September 22, 2014

Mr. Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave NW
Washington, DC 20504

Via Email: *innovationstrategy@ostp.gov*

Docket Number 2014-17761

Dear Mr. Correa,

Thank you for the opportunity to comment on the Office of Science and Technology Policy and the National Economic Council's request for public comments to provide input into an upcoming update of the *Strategy for American Innovation.*

The Connected Learning Alliance is a network of organizations, projects & individuals helping spread & scale "connected learning," a model of learning geared to the networked, digital age and designed to address the urgent need to re-imagine learning and education. Similarly, the Badge Alliance is a network of organizations and individuals working together to build and support an open alternative credentialing ecosystem, through the use of digital badges, to recognize lifelong learning and connect it directly to jobs, admission and other learner goals.

We strongly support the focus on innovation and respectfully submit the following information "to gather valuable insight into promising opportunities to boost our innovation capacity in order to drive economic growth and competitiveness."

Question 1: What specific policies or initiatives should the Administration consider prioritizing in the next version of the Strategy for American Innovation?

We believe there are two areas that should be included in the next version of the *Strategy for American Innovation:* connected learning and digital badges. Connected learning is an educational approach that effectively prepares learners for an innovative workforce in the 21st century, and digital badges are tools to recognize and communicate learning across a connecting learning ecosystem.

Connected learning is seeks to make learning relevant to all populations in both everyday life and work, taking into consideration the opportunities and realities of the digital age. It incorporates learning that is (1) peer-supported, (2) interest-driven, and (3) academically-oriented. These three spheres of learning allow students to focus on learning pathways that interest them and to go deeper into content that ultimately shapes their understanding of potential educational and career opportunities with the support of peers and mentors. In addition, six principles define connected learning; connected learning environments need to be

(1) interest-powered, (2) openly networked, (3) production-centered, (4) academically-oriented, (5) peer-supported and (6) built around a shared purpose.

An extensive meta-analysis conducted by DuBois and associates of 73 independent studies of youth mentorship programs aligned with connected learning principles concluded that mentor matching based on shared interests doubled programs' effect size for academic, socio-emotional, attitudinal and health outcomes. The authors conclude: "our results suggest that the relatively straightforward strategy of prioritizing shared interests in this process has the potential to substantially improve program outcomes."

As a tool for creating connected learning environments, Open Badges work provides a flexible, granular, evidence-based and interoperable credential or micro-credential to recognize more learning of all kinds, including out-of-school experiences, on-the-job training and more. This allows learners to build more comprehensive portfolios of their skills and accomplishments that they can carry with them into job interviews, higher education applications, communities of practice and more.

Badges are connectors along career and learning pathways because they reveal granular steps toward mastering specific competencies that are sought out by employers and educational institutions. They can guide learners through these pathways as well as keep track of and showcase the 21st century skills they have achieved. Employers and recruiters can use badges to zero in on the specific skills they know will benefit their industry, communicate these skills to potential candidates, and draw from a more robust portfolio of applicants to find better matches.

Question 12. What novel mechanisms or models might facilitate matching skilled STEM workers with employers and helping individuals identify what additional skills they may need to transition successfully to new roles?

Today, it is clear that businesses are looking for more than just core academic knowledge when hiring for jobs. Businesses want their employees to be able to demonstrate skills that include, but are not limited to, creativity, collaboration, curiosity, and problem solving. It is important to realize that in order to attain these skills, students need to feel connected and engaged in their learning. In fact, a growing body of research shows evidence that these skills are best cultivated in the context of hands-on, real-world, and socially-connected projects and that classroom learning alone cannot deliver these outcomes.

According to a study published in the *International Journal of Science Education* by Dabney, Tai, et al. — whether it be through science clubs, camps, competitions, or reading and watching science fiction and nonfiction materials, middle school and high school students who engage in such out-of-school activities are more likely to have interests in STEM careers as college students. Students may not be developing a strong interest in science and mathematics simply because they have not been exposed to these disciplines in such a manner that engages and encourages their interests. It is becoming increasingly clear that outside-of-school-time science education plays a powerful role in a myriad of science education experiences of youth and that these experiences have an association with long-range outcomes.

Connected learning is also uniquely equipped to bring underrepresented groups into the talent pool for STEM and innovation. In order for young people to develop both interest and expertise in STEM areas, they need to engage in meaningful projects and have mentors with whom they identify. By meeting learners where they are in their communities and interests, connected learning brings young people into STEM subjects and careers who would not otherwise be interested or feel as if they belong. Mentorship and project-based learning approaches that are grounded in shared interests and identity are particularly important in bringing young people into new areas such as digital arts and STEM areas. For example, YOUMedia learning labs – where underrepresented youth work with mentors in areas of shared interest in the digital arts – have shown substantial promise in developing young people's interest in technology and creative production

Students must also be recognized for learning that occurs both in the classroom and outside of the classrooms, online and offline, and the inclusion of digital badges as part of the next version of the *Strategy for American Innovation* can highlight an effective mechanism for meeting this need. Students need more opportunities to earn, capture, and convey competency-based, industry-recognized, 21st century skills aligned with STEM fields. Traditional assessments, resumes, applications, certificates and grades typically do not have this capability. Open Badges provide credible indicators of skills earned by learners because of the data and evidence displayed by the badges digital platform that demonstrate students' achievements around standards defined by STEM employers and institutions themselves.

An example of badges used in the STEM field is a resource called BuzzMath – a website and mobile application that focuses on learning and practicing middle school mathematics. It leads students to obtaining mastery of concepts outlined in the Common Core State Math Standards. Along the way, students can acquire badges for content knowledge, process knowledge and achievement. They portray a comprehensive view of students' progress and accomplishments with math competencies.

Additionally, Chicago Summer of Learning – now Chicago City of Learning (also described below) – offers many different STEAM (science, technology, engineering, arts, and math)-related badges. It involves over 100 organizations that provide learning opportunities for youth and award badges to students during summer months. Each organization has different objectives for their engagement with Chicago youth and work with varying age groups. Some organizations focused on face-to-face activities, while others worked with youth online. Because of the STEAM theme of summer 2014, organizations had to base learning opportunities on STEAM skills, and all badges were mapped to these issue areas. There were also city-level sets of badges that were standardized and controlled, known as the City of Chicago Scientist, Technologist, Engineer, Artist and Mathematician badges.

Question 19. What partnerships or novel models for collaboration between the Federal Government and regions should the Administration consider in order to promote innovation and the development of regional innovation ecosystems?

Connected learning is, at its core, tied to local communities and grows out of the interests and needs of those communities. Badges then act as a way to formalize, encourage and communicate the learning that happens across the network. Examples of badge systems connected to local governments can be found in Cities of Learning, which grew out of the Chicago Summer of Learning first launched in 2013.

The Chicago Summer of Learning – now Chicago City of Learning – is a citywide effort to engage young people in hands-on learning experiences. Since taking office, Mayor Rahm Emanuel focused on expanding the school day, and to grow this initiative, he worked to tap into community resources to support student learning anytime and anywhere.
The Mayor reached out to the MacArthur Foundation and Mozilla Foundation to discuss how badges could help connect learning opportunities across the city. This began a public-private partnership that later encompassed other city officials and agencies as well as non-profit organizations and local cultural institutions. Through the Chicago Summer of Learning, youth were able to earn recognition for engaging in learning during the summer and help teachers track student learning the following fall.

The initiative began with three clear goals:

- Help every kid in Chicago, or even visiting Chicago, learn something and have evidence of that learning (i.e. obtain a badge)
- Provide pathways and encourage kids to learn more (i.e. discover and motivate more learning through the badges)
- Communicate the learning back to schools and local businesses in the fall (i.e. show the badges are worth something)

A goal for year two of this initiative included a focus on creating "pathways" for students. To do this, the city had to focus on employers' needs and the skill sets they seek. Then, the city had to create a badge system that "levels up," or builds, these skills. Year two also focused on increasing transparency so students understand what can be attained through different pathways. Processes established this past two summers enable interest-based career exploration starting at an early age that connect youth to mentors and, ultimately, to employment.

The work done by Chicago Summer of Learning received significant attention across the country, and additional cities have recently launched or are planning to launch their badge systems as a part of the national Cities of Learning. These cities include: Dallas, Pittsburgh, Los Angeles, District of Columbia, Boise and Columbus. Each will adapt the Chicago Summer of Learning model to fit the needs and resources of the local community. They will all establish a citywide network of free or low-cost learning opportunities at parks, museums, libraries, and other local institutions, as well as opportunities to learn online. All participants will be able to earn digital badges for the new knowledge and skills they acquire.

The Administration should consider playing a supportive role in models like Cities of Learning that infuse the principles of connected learning and the tools digital badges. Providing resources for these efforts and highlighting case studies across the country will forward learning networks that yield a more innovative workforce.

Thank you for allowing us the opportunity to comment on the next version of the *Strategy for American Innovation.*

Sincerely,

Mimi Ito
Director of Connected Learning Alliance
Cultural Anthropologist

Erin Knight
Executive Director, Badge Alliance

Jessica Lindl
General Manager, GlassLab

Below please find the Consumer Electronics Association's (CEA)® response to the Office of Science and Technology Policy and the National Economic Council's request for input into an upcoming update of the *Strategy for American Innovation.*

CEA is the trade association representing the consumer technology industry. Our more than 2000 members range from large corporations to startups, and include the most innovative companies in the world.

CEA also is the owner and producer of the International CES®, the global trade show and gathering place for all who thrive on the business of consumer technologies, held every January in Las Vegas, Nevada.

We commend the administration for inviting input into America's innovation strategy. Around the world, we see our economic competitors restructuring their legal and regulatory systems to be more innovation-friendly. Capital leaps across borders with the touch of a button. Entrepreneurs go wherever they see opportunity, setting up shop anywhere with a high-speed internet connection.

America starts with many advantages: strong capital markets, a transparent and effective legal system, outstanding academic institutions, a culture of innovation and risk-taking. Yet many of our current government policies are industrial age legacies that inadvertently hamper innovation and economic progress, and jeopardize America's competitiveness.

In the modern global environment there is one way to succeed: work tirelessly and strategically to make the United States the single best place in the world to build a business. The following priorities, if effectively pursued by this administration, will allow entrepreneurs to prosper and ensure that America remains the globe's paramount innovation economy

Eliminate Unnecessary Regulation

Unnecessary regulation is the antithesis of innovation. It imposes costs and makes business less agile and competitive. Unfortunately, the regulatory burden on United States economy has grown well beyond what is needed to protect public health and safety: last year a remarkable 3,659 new rules were issued by 63 federal government departments, agencies and commissions.

Today, the government is considering new mandates on many of our most vibrant industries. The National Highway Traffic Safety Administration is debating the regulation of mobile technology devices, an area beyond their statutory jurisdiction. Vague and unclear Food and Drug Administration regulations stall investment in new mobile medical devices. The Federal Communications Commission is even considering extensive new regulations for Internet service providers, despite a flourishing Internet economy and no evidence of market failure.

All these mandates have a steep price: according to the Competitive Enterprise Institute, regulations cost the economy $1.863 trillion in 2013, the equivalent 11.1 percent of the U.S. gross domestic product (GDP). Regulation also limits an industry's ability to be nimble and take advantage of new market opportunities. It's no surprise that the Mercatus Center has found that heavily regulated industries grow at approximately half the rate of those less regulated.

Gratuitous regulation also causes entrepreneurs to "vote with their feet" and seek a pro-innovation environment. For example, Federal Aviation Administration now requires any commercial entity to secure a permit before flying unmanned aerial vehicles or drones, even if they are doing so in remote areas far from people or air traffic. Rather than awaiting US government permission, drone companies are increasingly moving abroad to test their cutting-edge flying machines and taking their high-skill jobs with them.

Exciting advances are on the horizon in areas such as sensors, 3D printers, and facial and voice recognition devices. All of these technologies are potentially transformative - and will invite hasty, ill-considered government mandates. Our regulatory posture toward these new products will determine whether the United States or one of our competitors will be the innovation hub of the future.

If we want to be the birthplace of tomorrow's new technologies, we must streamline our regulatory system and make it more innovation-friendly. The administration should immediately require rigorous cost-benefit tests prior to the adoption of any new federal regulatory mandates, including the public disclosure of all anticipated costs. More, the administration should proactively reduce outmoded government regulations. For example, the White House could create an independent and bi-partisan Regulatory Reduction Commission to identify unnecessary rules and present its findings to Congress.

We recognize that limited and targeted government regulation can provide many public benefits. But Industrial-age regulation is an anchor on a digital age economy. Refraining from creating new mandates - and aggressively removing those that no longer make sense - would be the equivalent of a major cost-free stimulus for American innovators and entrepreneurs.

Stop Patent Litigation Abuse

Our patent system was created to incentivize innovation and risk taking. For many years it drove progress and spurred economic growth. Unfortunately, today it is often used to suppress, not promote innovation. An entire industry has sprung up of patent law abusers: so-called "patent trolls" that make no product or service, but litigate questionable claims against those who do.

The facts are disturbing: frivolous patent claims cost US businesses over $80 billion per year. More, the problem goes far beyond the technology industry: consumers, retailers, main street companies and other end users are now being targeted. The primary victims are small businesses and startups, including many of America's most innovative and dynamic companies. This explosion of frivolous litigation stifles innovation, as companies must divert resources from creating new products and new jobs.

The administration has made serious efforts to address patent abuse. The President has spoken forcefully and highlighted the problem in his State of the Union address. Among other useful initiatives, the White House has encouraged the Patent and Trademark Office to require patent applicants to update patent ownership information, and sought to prevent patent examiners from approving overly broad claims.

While these steps have been helpful, a truly effective solution requires comprehensive legislation from Congress. Last year the Innovation Act (H.R 3309) passed the House of Representatives by an overwhelming and bipartisan margin with provisions that would halt large-scale patent abuse while protecting legitimate patent holders. We encourage the administration to urge Senate enactment of this approach, including "loser pays" provisions that would enable recovery of fees from frivolous plaintiffs. ith your continued support, we can fix our broken patent system and once again make it an engine of innovation.

Make America the Magnet for the World's Best and Brightest

America has thrived as the historic haven for the globe's most industrious and innovative. A recent study by the National Venture Capital Association found that immigrants founded or cofounded almost half of the top venture-backed companies in the United States. A list of immigrant-founded firms includes many American "crown jewel" companies including Intel, Google, Yahoo! and ebay.

Unfortunately, in the wake of the September 11 tragedy, it has become tougher for immigrants to add their ingenuity to our economy. High-skilled immigrants now find it difficult to work and stay in the United States. More, international students graduating from our world-class universities (with their education often subsidized by US taxpayers) are forced to leave our country rather than starting businesses and creating American jobs.

Meanwhile, our economic competitors seize initiative and opportunity. Countries ranging from Chile to China open their borders to students and engineers and entrepreneurs - some even providing economic inducements. Canada is putting up billboards in Silicon Valley encouraging immigrant engineers to move north. America is losing the battle for global brainpower.

The solutions are sensible and straightforward: Phase out family and "diversity" visas and move to a skill based immigration system, where prospective immigrants are prioritized based on their education and work experience. Expand permanent visas for engineers, scientists and computer programmers graduating from US universities.

Increase the available number of high-skilled visas based on demand, and create a "start-up visa" category for foreign entrepreneurs and investors.

Clearly, enabling innovative people to come and stay in the America is a national priority. Unfortunately, immigration reform has been stymied as both parties have been unable to move beyond highly rancorous and partisan debate. This politically-driven stalemate is harming our nation and our economic future.

If we are to continue as the world's most innovative nation, we must have the most innovative people. We urge the White House to work with Congress and enact immigration policies that will again make the United States a magnet for the world's best and brightest.

Ensure an Ample Supply of Wireless Broadband Spectrum

In the digital age, spectrum is the oxygen for innovation. The demand for mobile data from laptops, smartphones, tablets and other mobile data devices is growing exponentially: today's smartphones generate 22 times more data and a tablet 80 times more data than a basic feature phone. Spectrum demand is now pressing on the ceiling of our current spectrum holdings.

To alleviate this crunch, our spectrum policies must be updated to reflect our transition from the analog to the digital world. For example, while broadcast television was once the county's dominant platform for information transmission, less than ten percent of American households now rely on over-the-air broadcasts. This creates a horrendously inefficient resource allocation: huge portions of the valuable (and publicly-owned) broadcast spectrum lie unused, even as new and rapidly growing technologies face a spectrum shortfall.

The Federal Communications Commission is now proceeding toward an auction that will free-up broadcast spectrum that will be repurposed for wireless broadband and other innovative uses (unfortunately, the broadcast industry has filed a lawsuit to delay the auction). Critically, this auction also includes unlicensed spectrum, which allows startups and smaller companies to bring new products to market and contributes $62 billion annually to the US economy.

The White House should continue its strong support of broadcast spectrum auctions and do its utmost to ensure that the upcoming auction is successful and on schedule. The administration also should embrace additional repurposing of broadcast spectrum as wireless demand grows and over-the-air television viewership continues to drop.

While television broadcast spectrum auctions are helpful, the US government continues to hold the greatest amount of prime spectrum resources. Many government agencies hold spectrum far in excess of that needed to perform their actual duties.

We appreciate the White House's various initiatives directing government agencies to share or relinquish spectrum for commercial use. More, we recognize that these initiatives face resistance from agencies reluctant to give up or even accurately account for their spectrum holdings.

Ample access to wireless spectrum translates directly into new businesses, new technologies, new benefits for consumers and new jobs. Please continue your aggressive push to free up government spectrum and ensure that underused broadcast spectrum is reclaimed and used in a way that will benefit our nation.

Create a Pro-Innovation Tax System

In a competitive global economy, our outmoded tax structure increasingly discourages businesses from locating or bringing foreign-earned profits back to the United States.

According to the International Competitiveness Index recently published by the Tax Foundation, the US tax code ranked 32 out of 34 among countries in the Organization for Economic Cooperation and Development (OECD). This poor showing is caused by our OECD-high statutory corporate rate of 35 percent and because the United States is one of the few countries requiring corporations to pay taxes on their worldwide income, even if it was already taxed by foreign countries.

The results of our non-competitive tax structure are sadly predictable: companies are shifting their legal addresses abroad to more business-friendly jurisdictions and refusing to bring foreign-earned profits back into the United States.

We must change our tax code to encourage job creation. Rather than chastising companies who seek to reduce their tax burden under the current rules, the White House should support changes to our corporate our tax rate that make it more competitive with those of our economic rivals.

More, we must move to a territorial system that taxes only those profits earned within the United States, encouraging companies to bring home the estimated two trillion dollars currently held offshore for productive use in the US. To make it more politically attractive, the administration should work with Congress on creative solutions allowing companies to repatriate money at a lower tax rate if some portion of it is set aside for an agreed-upon use such as infrastructure development.

Fix Our Crumbling Infrastructure

From revolutionary-era canals to transcontinental rail road to the interstate highway system our economy has historically thrived because of our commitment to a world-leading infrastructure. Unfortunately, our infrastructure is now crumbling while our competitors invest in 21st century facilities.

The dire situation is obvious to anyone who has left from gleaming new international hub such as Beijing's BCIA and landed at New York's JFK or Los Angeles' LAX. Many of our roads, bridges, schools and waterways date from the middle of the last century. Our geriatric infrastructure has health and safety consequences: according to a recent report by Transportation for America, over 70,000 bridges in the United States were found to be "structurally deficient".

Government attempts to address this pressing issue have been entangled in partisan politics, with both parties attempting to advance their political interests rather than address the underlying problem. Meanwhile, our growing inability to move people, products, goods and services efficiently makes us less attractive as a global innovation center.

The Administration should make infrastructure investment a key part of its innovation strategy, and do so in a way that both parties can support. We suggest a process based on that used to select surplus military bases for closure: set up an independent commission to recommend specific projects using objective criteria, which would then be presented to Congress for an up-or-down vote. More, a requirement that federal funds be matched by state and local governments will help ensure that resources go to actual and pressing needs.

By prioritizing infrastructure development, subjecting decisions to objective rigorous standards, and de-politicizing the approval process, we can start building an infrastructure befitting a 21st century economy.

Restore America to a Sustainable Fiscal Path

Our massive federal debt - $17.9 trillion, according to the FY15 Federal Budget - has a crushing impact on our national economic health, innovation future and global competitiveness.

Unsustainable spending creates a climate of uncertainty for innovators and investors. Federal interest payments crowd out investment in good and necessary programs. We are forced to rely on the financing of foreign nations, whose lender position may allow them to impact American fiscal and monetary policies.

Much of this spending is driven by our burgeoning entitlement burden: promised benefits grow, and more people are using them as the baby boomer generation reaches retirement. Meanwhile, the federal government continues to provide its full time employees with generous defined-benefit pension plans. The federal retirement program alone supports more than 2.5 million annuitants.

Our current fiscal path is incompatible with a strong and stable economy. he solutions are not complex: All new federal employees should be shifted from defined-benefit to defined contribution plans. All government outlays must be prioritized by whether they promote the well-being of our children, or respond to a high priority like infrastructure investment or national defense. More, spending programs should include measurements to determine whether they are working, and triggers to discontinue them if they are not.

Many of these suggestions are included in the President's Deficit Commission Report released by Co-Chairs Erskine Bowles and Alan Simpson and endorsed by CEA. This bipartisan, shared-sacrifice approach would effectively address our national debt and unfunded liabilities. We urge the White House to put its full support behind this plan and its enactment into law.

By taming runaway deficits and shifting our spending from entitlements to strategic investments, we can promote innovation and restore confidence in our economic future.

Open New Markets to American Exporters

Trade expands opportunities for American innovators, giving them access to new markets and consumers. Trade lowers prices and gives our citizens access to affordable goods and services. Strong trade relationships build bonds among nations and promote a more stable and peaceful world.

The United States currently has more than 20 trade agreements currently in force. Unfortunately, in recent years the pace of finalizing trade agreements has slowed to a near stop. Progress on trade agreements with Europe (the Transatlantic Trade and Investment Partnership) and Asia (the Trans-Pacific Partnership) have stalled. Congress cannot agree to extend Trade Promotion Authority (TPA), harming our ability to negotiate effectively. Meanwhile, other nations move forward, forming free-trade blocs that disadvantage American goods.

The White House must redouble its efforts to complete these outstanding trade deals, and aggressively seek more worldwide trade negotiations and agreements. More, we need to ensure that the terms accurately reflect our digital economy, and do not contain the kinds of intermediary liability and other extreme intellectual property provisions that have previously been rejected by Congress.

We also encourage the administration to continue its advocacy in favor of an expanded Information Technology Agreement (ITA). Updating the ITA to include new generation multi-function products could increase US exports of information technology products by $2.8 billion.

Trade should not only be free, it must also be fair. CEA applauds the administration for its successful World Trade Organization case against China for restricting the export of rare earth elements and other metals essential to manufacturing. We encourage the administration to continue its vigilance and ensure American companies are not the victims of unfair market practices.

Embrace Startups and Disruptive Innovators

Innovation is in our national DNA. Americans have always taken risks and labored to improve the status quo. We see change as inevitable, and ultimately beneficial. Today, American start-ups are coming out of nowhere and transforming entire markets and businesses sectors. Entrepreneurial incubators are no longer the sole province of Silicon Valley or Cambridge. They are blossoming across the nation. Founders are starting companies and creating jobs anywhere with access to a broadband internet connection.

The economic impact of these disruptive innovators is profound. For example, “sharing economy” services are allowing Americans to be micro-entrepreneurs using their own automobiles or extra rooms in their houses. One company alone - the ride sharing service Uber - recently disclosed that it was creating 50,000 jobs per month.

In contrast to America, some our economic competitors regard innovation and change with suspicion. Looking abroad, we see the European Union imposing new regulations on search engines, and Germany banning new ride-sharing services. By visibly choosing the status quo over innovation, these countries provide the United States with a tremendous leadership opportunity.

Disruptive innovators are often challenged by powerful well-established industries who ask the government to block new market-changing technologies. In cities across the country, we see start-ups such as Uber, Lyft and Airbnb fighting attempts to limit their market access. A recent national example was the advocacy by large content companies of legislation (“SOPA” and “PIPA”) that would have imposed new legal liabilities on internet-based businesses. We commend the administration for standing against SOPA and PIPA, and recognizing the importance of the Internet as a critical platform for business, innovation and free expression. The administration should continue to ensure that new innovators have full access to markets, and are not blocked by those defending legacy business models.

Limited access to capital presents another obstacle facing startupsi. In 2012, Congress passed and the President signed the JOBS Act, which allowed small companies to access new revenue by “crowd funding” public offerings. Over two years later, the Securities and Exchange Commission (SEC) has failed to pass rules to enable crowd funding. The resulting uncertainty harms the startup community and inhibits funding. The President should direct the SEC to immediately conclude its rule making and enable startups to more easily reach out to investors.

By publicly championing and ensuring that our government supports startups and disruptive entrepreneurs, the administration will make a strong statement: in the United States, innovators are free to challenge and change and transform our society for the better.

Thank you for the opportunity to provide these comments. We look forward to working with you and are pleased to provide any additional information.

OFFICE OF SCIENCE AND TECHNOLOGY POLICY (OSTP)

AND NATIONAL ECONOMIC COUNCIL

REQUEST FOR INFORMATION

CONCERNING

UPDATE OF THE *STRATEGY FOR AMERICAN INNOVATION*

Published at 79 Fed. Reg. 44064 (July 29, 2014)

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WRITTEN COMMENTS OF

COPYRIGHT CLEARANCE CENTER, INC.

September 23, 2014

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INTRODUCTION

Copyright Clearance Center, Inc. ("CCC"), submits these written comments in response to the request for information of the Office of Science and Technology Policy (OSTP) and the National Economic Council (NEC) set forth in their Notice published at 79 Fed. Reg. 44064 in connection with their upcoming update of the Administration's *Strategy for American Innovation*.

CCC has been engaged for more than 35 years as a centralized licensing hub for text-based copyrighted materials, enabling the issuance of licenses on behalf of rightsholders to users of all kinds, including academic, business, government and non-profit organizations. We regularly assist parties in facilitating licensing between users and holders of copyright rights in text works and, to a lesser extent, other media types, and we offer a host of pay-per-use and repertory licensing services. We enjoy long-standing and close relationships with tens of thousands of publishers, authors, other rightsholders, and individuals, institutions and associations that represent rightsholders; and today our licenses cover thousands of business and academic organizations representing approximately 30 million employees and over a million college and university students.

Because CCC operates at the intersection of content creation, technological delivery and public consumption, we believe we are in a unique position to comment specifically on Question 21 of the OSTP/NEC RFI:

Intellectual Property/Antitrust

(21) What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation (including, e.g., through the growing use of open innovation, combinatorial innovation, user innovation, internet-enabled innovation, and big data-driven innovation)?

SOUND INTELLECTUAL PROPERTY AND INNOVATION POLICY MUST REFLECT THE BALANCE EMBODIED IN THE CONSTITUTION

When the government undertakes to evaluate policy choices, and especially policy choices that have deep historical and jurisprudential roots, it is appropriate for the government to begin at the beginning, in this case with Section 8 of Article I of the Constitution. There among the powers granted to Congress is clause 8:

> To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries[.]

It has long been appreciated by Congress and the Courts that this clause (referred to as "the Copyright and Patent Clause") embodies within it a direction by the Founders that any intellectual property environment created by Congress needs to reflect an exquisite balance between the public good ("to promote the Progress of Science and useful Arts") and the private good of the creators of intellectual property (by providing an "exclusive Right"). And it is this balance that allows our very successful economic system to nurture innovation (again, "the Progress of Science and useful Arts"), which is inevitably the result of the use of yesterday's creations by today's and tomorrow's further creators. In our current parlance, users of others' intellectual property will often focus on the need "to promote science and the arts" as a justification for whatever acts they take, while rightsholders will typically focus on the "exclusive right" as a justification for their choices in how to manage their intellectual property. But neither the public nor the private good are to be given first place because, as the Founders recognized in the formulation of that Clause, they inevitably work together; the government is charged with managing the balance.

It is as true in 2014 as it was 225 years ago that maintaining a balance between rightsholders' and users' interests is important, and it is also as true now as then that those interests will inevitably pull the government and its policy-making apparatus hard in their respective directions. Throughout American history, the power of each interest has waxed and waned and, as a result, American intellectual property policy has swung between them. Today appears to present the unexpected circumstance of the pendulum having swung "too far" <u>both ways</u> simultaneously: in the Internet environment, (i) "user advocates" allege that rightsholders have too great power to protect and enforce their rights, thereby impeding "the progress of science and the arts", while (ii) rightsholders argue that users, harnessing the power of the Internet, to disseminate multiple copies at no cost, leave them with many infringers and no way to benefit from their "exclusive rights." However, good intellectual property policy should avoid the trap of fostering polarization among creators, users, distributors, and consumers. Maintaining a working balance among these parties in the public interest should therefore rank high among the goals of any policy update.

LICENSING MECHANISMS ARE UNIQUELY SUITED TO ACHIEVING BALANCE BETWEEN THE INTERESTS OF CREATORS AND USERS OF INTELLECTUAL PROPERTY IN THE FACE OF AN INCREASING DIVERSITY OF MODELS OF INNOVATION

Because it is also true that most intellectual property rightsholders are users of others' rights, the private sector in its communal self-interest long ago developed a relatively efficient mechanism for trying to balance the rights of each. That form of private ordering is called licensing. CCC believes that a balanced approach to intellectual property policy and innovation policy must include the ability of private parties to enter into licenses. Government should foster conditions that enable stakeholders – who know their needs and markets better than governments – to enter into private licensing arrangements. Our experience as rights licensing experts, over more than 35 years in business, reinforces this belief.

The vast majority of CCC's business involves individual and collective licensing that is elaborated at length at our website (www.copyright.com) and is addressed in the literature.[1] Building on our relationships with both sides, CCC has gradually developed working licensing models that help millions of users ensure that they respect the copyrights of others and that contribute royalties to rightsholders' bottom lines in an effort to help them make content creation a viable business. In essence, we look at our responsibility – and, we respectfully submit, we think that the government has a like responsibility – to "make copyright work" and to accomplish that through the private ordering of licensing.

INNOVATION THROUGH TEXT AND DATA MINING OFFERS A PRIME EXAMPLE OF HOW LICENSING MARRIES IP AND INNOVATION

Regretfully, we acknowledge that it is sometimes fashionable to look past yesterday's successes (such as our licensing services) and view "new technologies" as requiring new paradigms. We submit, however, that not only does licensing remain viable as new technologies, made possible by more powerful computer processing and larger collections of searchable information, enter the field of copyrighted text materials, but that it offers solutions that are every bit as dynamic and evolutionary as the new technologies themselves. CCC was founded in part as a result of the disruption caused by the photocopy machine, and CCC's experience with text and data mining ("TDM"), while still nascent, provides a good example of how licensing can still support disruptive and exciting innovation.

[1] *See, e.g.*, American Geophysical Union v. Texaco Inc., 60 F.3d 913 (2d Cir. 1994), *cert. dismissed*, 116 S. Ct. 592 (1995); Princeton University Press v. Michigan Document Svcs., Inc., 99 F.3d 1381 (6th Cir.) (*en banc*), *cert. denied*, 117 S. Ct. 1336 (1997); 6 Nimmer on Copyright § 26.06 (2014).

TDM is one of the great opportunities to use published content in order to drive innovation through data and combinatorial technologies, and intellectual property licensing regimes are well suited to help drive such innovation. Text mining is the data analysis of natural language works, while data mining is the data analysis of data works. For example, in text mining a researcher might want to mine a large body of scientific journals to track whether a particular genome has ever been correlated with a particular disease. Similarly, data mining can look at large amounts of data to determine the correlations of a specific medicine with a disease with which it has not previously been correlated. Together, they hold promise for improving care and solving many vital medical, scientific and social challenges.

After extensive discussion in the UK in 2011-12 on the issues and opportunities raised by text and data mining,[2] there was a lot of sound and fury as to whether copyright was "good" or "bad" with respect to TDM. While this debate was heated, it was not particularly illuminating. As a result, CCC brought users, companies that provide TDM technologies, and copyright rightsholders (primarily publishers) together and asked basic questions about how TDM could be enabled. These efforts led to key findings as follows:

From TDM users we learned:

1. Users wanted to mine both content to which they already have lawful access (such as through subscriptions or purchases) and other content as well.
2. Regardless of how much content users subscribe to, users named the ability to obtain standardized content from multiple publishers through a single mechanism as the greatest need in their TDM research workflow.
3. Those users who wished to mine across unsubscribed content saw especially high value in obtaining this additional content, and were willing to pay rightsholders for the right to obtain such content and pay a fee to download the structured full-text.
4. Users expressed efficiency concerns; namely that downloading, standardizing, storing, and maintaining ongoing feeds of content from multiple publishers in XML format, and negotiating the necessary terms for mining would be costly and time consuming.
5. Although some users wished to text and data mine for drug discovery and similar research purposes, text and data mining for marketing purposes was also highly desired.

From publishers we learned:

1. Publishers were uniformly interested in allowing some form of text and data mining of their content so long as they were reasonably compensated, especially for full-text delivery in formats most amenable to TDM (which are not formats that permit easy readability by humans).
2. Publishers viewed allowing text and data mining of subscribed content as helping to establish the value in the subscriptions.
3. Publishers viewed allowing text and data mining of unsubscribed content as a way of driving subscription and article sales.

[2] *See, e.g.*, "Value and benefits of text mining" (JISC, 2012). Accessed at http://www.jisc.ac.uk/reports/value-and-benefits-of-text-mining

4. Publishers expressed concerns about website performance if multiple users using varying tools crawl or mine their sites. They also wanted to ensure that users who download content for mining act responsibly with the content – for example, not redistribute it in competition with lawful channels, not create unauthorized derivative works, and not otherwise replace the need for subscriptions and content purchases, all ways in which the "copyright balance" can be unfairly upset.
5. Publishers also expressed efficiency concerns, such as the fact that setting up feeds for multiple users, managing authentication, and negotiating terms for mining would be time consuming.
6. Publishers wanted to ensure that additional costs incurred to provide minable content are recovered.

With these findings, CCC created a pilot licensing and article access program to enable researchers to gain quick access to full-text content for mining in a centralized manner with a common interface, while allowing each user to use its own choice of TDM tools. The pilot was successful and we are now signing publishers and larger users into a full commercial service for launch within the next year. The service will enable researchers to, *inter alia*:

- Download from one place full-text XML content obtained directly from multiple publishers;
- Create article *corpora* of subscribed and unsubscribed content from publishers to obtain the broadest possible set of TDM results;
- Obtain a common set of terms and conditions across publishers, thus eliminating the need for multiple negotiations;
- Obtain a common format of metadata for easy integration with TDM tools; and
- Integrate content into user workflows.

The lesson of this joint effort is that viable solutions to the challenges presented by new models of innovation are more likely to arise from multistakeholder collaborations than from blunt policy instruments which favor one faction or the other. Open innovation, combinatorial innovation, user innovation, Internet-enabled innovation, and Big Data-driven innovation are best developed through collaboration between rights owners and users. Those collaborations themselves are forms of innovation deserving of respect and encouragement. We encourage OSTP and NEC to look for and endorse, not the divisive policies often promoted by some, but collaborative opportunities and in particular those that rely on familiar and available licensing mechanisms.

CONCLUSION

CCC looks forward to further public discussion of OSTP/NEC's upcoming policy update. The balanced approach we recommend here to "innovation policy issues" like text and data mining of works protected by copyright is consistent with CCC's practice and experience. As OSTP and NEC evaluate the recommendations that they will make, we sincerely believe that pursuing a Constitutionally-guided balance of the rights and needs of rightsholders and users – including encouragement of licensing as a reasonable and long-familiar mechanism for private ordering and intermediaries – is most likely to best serve both private and public interests and to do so in a time-honored and successful manner.

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ELECTRONIC FRONTIER FOUNDATION

COMMENTS OF THE ELECTRONIC FRONTIER FOUNDATION REGARDING THE STRATEGY FOR AMERICAN INNOVATION

The Electronic Frontier Foundation (EFF) is grateful for this opportunity to respond to the request by the Office of Science and Technology Policy (OSTP) and the National Economic Council for comments regarding an upcoming update of the *Strategy for American Innovation*. EFF is a nonprofit civil liberties organization that has worked for more than 20 years to protect consumer interests, innovation, and free expression in the digital world. EFF and its more than 27,000 dues-paying members have a strong interest in helping courts and policy-makers strike the appropriate balance between intellectual property and the public interest.

I. Introduction

In this submission, EFF discusses three innovation issues: patents, open access to scientific research, and the "anti-circumvention" provisions of the Digital Millennium Copyright Act (DMCA). For each of these topics, an overly restrictive legal regime threatens innovation by limiting the ability of creators and inventors to build upon the work of others. The Administration has already taken some positive steps (particularly to improve the patent system and promote open access), but more remains to be done. We urge the Administration to lead the movement to improve patent quality, reduce the harm caused by patent trolls, open access to federally funded scientific research, and to support legislative reform to undo the harm caused by Section 1201 of the DMCA.

II. Patents

EFF urges the Administration to take a balanced approach to patent policy, mindful of the costs as well as the benefits of the patent system. Patents can harm innovation in two ways. First, low-quality patents provide an unjustified government monopoly. Such patents limit competition but provide no benefit. Second, patents can be abused as litigation weapons. Some patent assertion entities (PAEs, known colloquially as "patent tolls") use the extraordinary cost of defending a patent suit to extort settlements. In recent years, patent trolls have filed thousands of cases against small businesses and startups. Most of these cases have involved low-quality software patents.

EFF supports the Administration's goal of promoting market-based innovation. For the software industry, this goal can only be achieved by addressing patent abuse. Below, we describe the problem with software patents in more detail and propose some actions the Administration can take.

A. Low-Quality Software Patents Harm Innovation.

Software patents are a relatively new phenomenon; the software industry grew from nothing into a mature business without any need for patent protection. For decades, the Patent and Trademark Office (PTO) was generally reluctant to issue patents that covered software. But in 1994, the Federal Circuit opened the floodgates for software patents after it held that an algorithm implemented in a general-purpose computer could be patentable.[1] By 2012, the PTO

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[1] *See In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994).

was issuing about 40,000 software patents a year, but unfortunately, the quality of these patents has tended to be very low.[2]

There are many reasons why software-related patents tend to be of low quality. First, software patents tend to have fuzzy boundaries. This means that "they have unpredictable claim interpretation and unclear scope . . . [giving] rise to many situations where technology firms inadvertently infringe."[3] Due to their fuzzy boundaries, software patents are not easily searchable, which leads to the issuing of invalid patents and unintended infringement, and means that software patents do not serve as a resource of knowledge or teaching.[4]

Patent examiners are not able to adequately search the prior art for software claims. For software-related applications, the most relevant prior art will likely include numerous sources—such as open source software code—that are not easily located and searched. Patent examiners spend an average of only 19 hours reviewing each application. With only some of this time available for prior art searching, this is not nearly enough time for a thorough review.[5]

Low-quality software patents feed directly into the PAE business model. Specifically, "there is a business opportunity based on acquiring patents that can be arguably read to cover existing technologies and asserting those patents, litigating if necessary in order to obtain a

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[2] *See* Christina Mulligan & Timothy Lee, *Scaling the Patent System* (March 6, 2012), NYU Annual Survey of American Law, Vol. 68, p. 289, 2012, http://ssrn.com/abstract=2016968.

[3] James E. Bessen, Michael J. Meurer, & Jennifer Laurissa, *The Private and Social Costs of Patent Trolls* (September 19, 2011). Boston Univ. School of Law, Law and Economics Research Paper No. 11-45, http://ssrn.com/abstract=1930272.

[4] *See generally* Shaun Miller and Alex Tabarrok, *Ill-Conceived, Even If Competently Administered: Software Patents, Litigation, and Innovation*, Econ Journal Watch 11(1) January 2014: 37-4513, http://mercatus.org/sites/default/files/Dourado_PerspectivesonIP_v2.pdf.

[5] *See* Michael D. Frakes & Mellissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application*, NBER Working Paper No. 20337 (July 2014), http://www.nber.org/papers/w20337.

licensing agreement."[6] One study found that between 2007 and 2011, 46 percent of patent lawsuits involved software patents, accounting for 89 percent of the increase in the number of patent defendants during this timeframe.[7]

Unsurprisingly, since software patents tend to be of low quality, the software industry itself (in contrast to PAEs) treats patent protection as a very low priority. A recent study by the National Science Foundation is informative.[8] In the information sector (which includes software, Internet, and data processing) only 10 percent of companies found patents either "very" or even "somewhat" important. *Id.* at 3. Those companies rely instead on copyright, trademark, and trade secret protection. *Id.* From 1994-2004, only 20 percent of software startup companies even applied for a patent.[9] The evidence shows that actual innovators—the companies trying to bring new products and services to the marketplace—do not rely on software patents. Rather, these patents tend to be the tools of patent trolls seeking to tax innovation.

B. Abusive Patent Litigation Harms Innovation.

The increase in software patents has fed an explosion of software patent litigation. As the Administration noted in a recent report, much of this litigation involves patent cases brought by

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[6] Bessen, Meurer, & Laurissa at 24.

[7] *See* United States Government Accountability Office, *Assessing Factors That Affect Patent Infringement Litigation Could Help Improve Patent Quality*, 22 (2013), http://www.gao.gov/assets/660/657103.pdf.

[8] *See* John E. Jankowski, *Business Use of Intellectual Property Protection Documented in NSF Survey*, National Science Foundation InfoBrief (February 2012), http://www.nsf.gov/statistics/infbrief/nsf12307/.

[9] *See* James Bessen, *A Generation of Software Patents*, Boston University School of Law Working Paper No. 11-31 (June 21, 2011) at 6, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1868979

PAEs.[10] This explosion of litigation has been costly. PAE activity cost defendants and licensees $29 billion in 2011, a 400 percent increase over $7 billion in 2005.[11] These losses are mostly deadweight, with less than 25 percent flowing to innovation and at least that much going towards legal fees.[12]

The litigation explosion particularly burdens small companies, which often find themselves the targets of these suits.[13] Litigation-based legal expenses can kill small startups entirely, and the mere threat of those expenses can chill innovation. In a small company, key management and engineers must deal with a PAE claim. Thus, small cash-poor companies become vulnerable targets that lack leverage to deal with a PAE lawsuit, leaving them stuck paying nuisance settlements regardless of the merits of the underlying claim. With small- and medium-sized companies making up so many defendants in PAE suits, such nuisance settlements are widespread. The Administration's innovation policy should include measures to reduce this kind of abusive litigation.

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[10] *See* Executive Office of the President, *Patent Assertion and U.S. Innovation*, 5 (2013), http://www.whitehouse.gov/sites/default/files/docs/patent_report.pdf.

[11] Brian T. Yeh, *An Overview of the "Patent Trolls" Debate*, Cong. Research Serv., R42668, at Summary and 2 (2012), https://www.eff.org/sites/default/files/R42668_0.pdf

[12] *See id.*

[13] One study found that nearly 75 percent of venture capitalists have had their portfolios impacted by litigation from a patent troll. Colleen Chien, *Patent Assertion and Startup Innovation*, New America Foundation (Sept. 2013) at 11, available at: http://www.newamerica.net/sites/newamerica.net/files/policydocs/Patent%20Assertion%20and%20Startup%20Innovation_updated.pdf. More than half of the defendants involved in litigation brought by patent NPEs are companies with annual revenues of $10 million or less. Colleen Chien, *Startups and Patent Trolls* (Santa Clara Univ. School of Law, Legal Studies Research Paper Series, Accepted Paper No. 09-12, 2012) at 3, available at: http://ssrn.com/abstract=2146251.

C. The Administration Should Take Further Action on Patent Reform.

This Administration has already been a leader on patent reform. In February of this year, the President announced a series of Executive Actions aimed at improving the patent system.[14] More remains to be done. EFF urges the Administration to support needed legislative reform to improve patent quality and reduce abusive litigation.

In particular, EFF urges the Administration to support the Innovation Act, H.R. 3309, which passed the House with an overwhelming bipartisan vote in December 2013. While this bill did not address every problem with the patent system, it included a powerful set of proposed reforms that—taken together—will significantly reduce the threat of abusive PAEs. We also urge the Administration to support the expansion of post-grant trial proceedings at the PTO (such as covered business method review) that have proven to be efficient means of removing low-quality patents from the system. Legislative patent reform stalled in the Senate in May. But Congress is likely to take up the issue again soon. The Administration should be a leader in that process.

III. Open Access

Our innovative future relies upon understanding the knowledge of the past and present. Unfortunately, scholarly papers are often locked up behind expensive paywalls, strict copyright regimes, and unusable formats. For this reason, EFF urges the Administration to not only follow through with its agenda to provide public access to taxpayer-funded research, but also to make sure future policies allow for truly open access, reuse, and innovation.

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[14] *See* Press Release, Off. of Press Sec'y, *Fact Sheet - Executive Actions: Answering the President's Call to Strengthen Our Patent System and Foster Innovation* (Feb. 20, 2014), *http://www.whitehouse.gov/the-press-office/2014/02/20/fact-sheet-executive-actions-answering-president-s-call-strengthen-our-p*.

In February of 2013, the Director of the OSTP, Dr. John Holdren, issued a public access memorandum,[15] requiring each federal agency with a research budget of $100 million or more—22 agencies in total—to put in place a public access policy that allows for free access to and reuse of federally funded scholarly research within 12 months of original publication. This policy builds off the similar, highly successful policy of the National Institutes of Health, instituted in 2008.

While each agency has submitted its respective proposal to the OSTP, only one—the Department of Energy's (DOE) public access plan—has been publicly announced.[16] The DOE plan creates a repository, PAGES, that hosts metadata about research funded by the agency, and links to scholarly articles on original journal publishers' websites. If the paper is not available on a publisher's site, PAGES will host the full article after a 12-month embargo. While each agency and the OSTP are free to explore public-private initiatives like this, the results—as seen with the DOE's plan—are far from ideal.

First, the storage of articles in multiple repositories makes it difficult to run important computational analysis or text mining on such research—a task that would be far more productive if the full-text, searchable articles were in one central repository. Digital publishing opens up a host of potential beyond the reported research itself, allowing the exploration of research on a broader, comparative level. This sort of innovation is stifled through disjointed approaches like the DOE's.

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[15] Available at: *http://www.whitehouse.gov/blog/2013/02/22/expanding-public-access-results-federally-funded-research*

[16] Available at: *http://www.energy.gov/downloads/doe-public-access-plan*

Second, under the DOE plan, publishers retain full copyright over the articles; there is no open licensing policy to encourage and allow for downstream reuse. We recommend urging agencies to mandate publicly funded research to be licensed in a way that allows for maximum flexibility—for example, using a Creative Commons Attribution license—which ensures that the paper's authors get the credit they deserve, while also fostering the free flow of information upon which truly collaborative and innovative science relies.

Third, a 12-month embargo period has become the norm, as per the National Institutes of Health's policy, but is not the ideal. We encourage the Administration to push for shorter embargo periods, knowing that the public benefits most from quicker—preferably immediate—availability.

Access is only one of many goals of a public access policy. While efforts to make scholarly papers publicly available should be applauded, the full realization of open access can only come if such work is organized, searchable, and reusable, with as few technical and copyright barriers as possible.

IV. DMCA Section 1201

As counsel and as friends of the court, we have been involved in most of the leading court cases interpreting the "anti-circumvention" provisions of the Digital Millennium Copyright Act, 17 U.S.C. § 1201. Today, we regularly counsel security researchers, innovators, and ordinary Internet users regarding Section 1201. We also have extensive experience with the 1201 exemption process.

Based on this experience, we have seen that Section 1201 has not been used as Congress envisioned. Section 1201 of the DMCA was ostensibly intended to stop copyright infringers from defeating anti-piracy protections added to copyrighted works. In practice, however, the anti-circumvention provisions have been used to stifle a wide array of legitimate activities.[17] Here are just a few examples.

A. Section 1201 Impedes Competition and Innovation.

Traditionally, once a consumer has purchased a product, she has been free to use it however she sees fit. Legitimate consumers of electronic goods have been free to customize their products to better fit their needs, and to choose competitive add-on or alternative technologies that interoperate with the goods they buy, because innovators were able to develop and distribute such technologies. Section 1201 threatens those freedoms.[18]

The anti-competitive effect of Section 1201 became evident early on with respect to DVDs. Despite early lawsuits, easy-to-use DVD copying software has been available for free from many online sources for many years. Yet movie studios continued to embrace encryption, using it on every commercial DVD release. Why? We believe that one reason is that the movie studios (acting through their agent, the DVD Copy Control Association (DVD-CCA)) could force innovators to sign a license agreement for that encryption software before they built anything that can decrypt a DVD movie.

This gave the movie studios unprecedented power to influence the pace and nature of innovation in the world of DVDs. Any new feature (like copying to a hard drive) must first pass muster in the three-way "inter-industry" negotiation (movie studios, incumbent consumer electronic companies, and big computer companies) that is DVD-CCA. In other words, you must get permission (from your adversaries and competitors!) before you innovate in the DVD space.

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[17] *See* https://www.eff.org/pages/unintended-consequences

[18] *See* Dan L. Burk, *Anticircumvention Misuse*, 50 UCLA L. REV. 1095, 1139 (2003)

If these had been the rules in the past, there would never have been a Betamax, much less an iPod.

But the problem does not stop with DVD technologies. Most modern durable goods—including household appliances, power tools, calculators, cameras, stereos, printer cartridges, garage door openers, as well as video game controllers, headsets, and memory cards—contain some element of copyrightable software code.[19] In order for replacement parts and compatible accessories to function, they must "access" the code inside. If unauthorized access amounts to circumvention of a Technological Protection Measure (TPM) and is therefore prohibited, the manufacturer can use the DMCA to assert exclusive control over the market for those goods and accessories.

The detrimental effects on consumers are well documented. For instance, cell phone manufacturers sell phones equipped with technological protection measures that lock consumers to a particular service provider, forcing them to pay artificially inflated service charges and crippling the market for used phones.[20] According to the claims of major U.S. wireless carriers, unlocking a phone without your carrier's permission violates the DMCA. But a prohibition on unlocking has nothing to do with preventing infringement. Camera makers have similarly installed technological protection measures that render pictures unreadable in competitors'

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[19] See, e.g., David Chartier, *Microsoft's New Vision: A Computer in Every . . . Coffee Maker?,* Ars Technica, Jan. 12, 2009, http://arstechnica.com/microsoft/news/2009/01/microsofts-new-vision-a-computer-in-every-coffee-maker.ar.

[20] David Kravitz, *Apple v. EFF: The iPhone Jailbreaking Showdown*, Wired, May 2, 2009, http://www.wired.com/threatlevel/2009/05/apple-v-eff-the-iphone-jailbreaking-showdown/.

photo-editing programs, preventing consumers from editing their own pictures with their preferred software.[21]

Similarly, Apple has relied on the DMCA to "lock" iPhone owners into purchasing software exclusively from Apple's own App Store.[22] Apple uses technical measures backed by the DMCA to try to lock iPhone owners into obtaining software ("apps") exclusively from Apple's own iTunes App Store, where Apple must approve every app and retains 30% of revenues generated by app sales. This business practice has had significant consequences for both competition and speech, as Apple regularly rejects apps that might compete with Apple's own offerings or that are deemed "potentially offensive."[23]

Despite Apple's efforts, millions of iPhone owners took steps to "jailbreak" their iPhones to use the carriers and apps of their choice. They did so under a legal cloud, however; Apple contended that these activities violated the DMCA. Responding to intensive efforts, the Librarian of Congress granted an exemption for jailbreaking, but that exemption is both narrow and temporary.

And that's just the beginning: the DMCA has been used to block aftermarket competition in laser printer toner cartridges, garage door openers, videogame console accessories, and computer maintenance services. The infamous Lexmark litigation is case in point. Lexmark, the

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[21] Declan McCullagh, *Nikon's Photo Encryption Reported Broken*, CNET, Apr. 21, 2005, http://news.cnet.com/Nikons-photo-encryption-reported-broken/2100-1030_3-5679848.html.

[22] David Kravets, *Apple v. EFF: The iPhone Jailbreaking Showdown*, Wired, May 2, 2009, http://www.wired.com/threatlevel/2009/05/apple-v-eff-the-iphone-jailbreaking-showdown/.

[23] See e.g., Jason Kincaid, *Apple is Growing Rotten to the Core: Official Google Voice App. Blocked from App Store*, TechCrunch, Jul. 27, 2009), http://techcrunch.com/2009/07/27/apple-is-growing-rotten-to-the-core-and-its-likely-atts-fault/; Fred von Lohmann, *Another iPhone App Banned: Apple Deems South Park App 'Potentially Offensive*,' EFF Deep Links, Feb. 17, 2009, http://www.eff.org/deeplinks/2009/02/south-park-iphone-app-denied.

second-largest laser printer maker in the U.S., added authentication routines between its printers and cartridges explicitly to hinder aftermarket toner vendors. Static Control Components (SCC) reverse-engineered these measures and sold "Smartek" chips that enabled refilled cartridges to work in Lexmark printers. Lexmark then used the DMCA to obtain an injunction banning SCC from selling its chips to cartridge remanufacturers. SCC ultimately succeeded in getting the injunction overturned on appeal, but only after 19 months of expensive litigation while its product was held off the market. The litigation alone sent a chilling message to those in the secondary market for Lexmark cartridges.[24]

More recently, Microsoft used the DMCA to try to shut down competition for gaming accessories. Datel, Inc. produces third-party accessories for every major videogame console, including Microsoft's Xbox 360.[25] As with all third-party manufacturers, Datel must engineer its accessories so that they will be compatible with the chosen first-party console; this frequently requires reverse-engineering or other work-arounds. In 2009, Microsoft issued a mandatory firmware update for all Xbox 360 consoles connected to the Internet; this update had no effect on Microsoft's own memory cards, but rendered Datel's less expensive memory cards completely unusable. When Datel sued Microsoft for antitrust violations, Microsoft counterclaimed by accusing Datel of violating the DMCA. In a nutshell, Microsoft forced consumers to purchase its own memory cards and then used the DMCA to attack legitimate competitors.

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[24] Declan McCullagh, *Lexmark Invokes DMCA in Toner Suit*, CNET News (Jan. 8, 2003), http://news.com.com/2100-1023-979791.html; Lexmark v. Static Control Components, 387 F.3d 522 (6th Cir. 2004).

[25] Mike Masnick, *Microsoft Still Claiming That It Can Use The DMCA To Block Competing Xbox Accessories*, TechDirt (Jun. 21, 2011), http://www.techdirt.com/articles/20110620/10505614766/microsoft-still-claiming-that-it-can-use-dmca-to-block-competing-xbox-accessories.shtml.

Moreover, manufacturers of ordinary consumer products have sought to extend the DMCA to police consumer behaviors and innovations that happen to be contrary to the manufacturers' preferences. For example, calculator manufacturers have brought circumvention claims against hobbyists who reverse-engineered their personal graphing calculators to develop alternative operating systems for personal use.[26]

B. Section 1201 Jeopardizes Fair Use.

To make a fair use of a copyrighted work, a person must be able to access that work. Today, many forms of digital content—including e-books and video—are "copy-protected" and otherwise restricted by technological means. Whether the public will continue to be able to make legitimate fair uses of these works will depend upon the availability of tools to bypass these digital locks, and the legal right to use those tools. By banning all acts of circumvention, and all technologies and tools that can be used for circumvention, the DMCA grants to copyright owners the power to unilaterally eliminate many fair use rights, stifling in turn the innovative new products that rely upon those rights.

The DMCA, however, prohibits the creation or distribution of such tools, even if they are needed to enable innovative fair uses. As a result, fair uses have been whittled away by digital locks allegedly intended to "prevent piracy." Equally importantly, the DMCA prevents the law from developing to encompass new technologies. Future fair uses may not be developed for restricted content, because courts will never have the opportunity to rule on them. Fair users will be found liable for "picking the lock" and thereby violating the DMCA, whatever the merits of their fair use defense.

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[26] Dan Goodin, *Texas Instruments Aims Lawyers at Calculator Hackers*, The Register, Sept. 23, 2009, http://www.theregister.co.uk/2009/09/23/texas_instruments_calculator_hacking.

For example, e-books often include Digital Rights Management (DRM) technology that prevents people who are blind or visually impaired from running books that they have lawfully purchased through a text-to-speech converter. Similarly, Internet-distributed video, DVD, and Blu-ray discs include DRM features that inhibit development of advanced closed captioning and video description technologies that make movies and television shows accessible.[27] Technologies for bypassing these technologies are available and clearly serve a valuable and non-infringing purpose. Nonetheless, using them may be unlawful under the DMCA except where disability rights advocates have managed to obtain a temporary exemption. Moreover, as discussed below, because the exemption process does not apply to the distribution of tools, companies and individuals who develop these technologies remain under threat.

DMCA lawsuits have hampered many other legitimate fair uses. Once a video is copied to a computer—an act that may require circumvention—video creators can remix movie clips into original YouTube videos, frequent travelers can load movies into their laptops, and DVD owners can skip the otherwise “unskippable” commercials that preface certain films. Unfortunately, DMCA lawsuits targeting makers of DVD copying tools hampered these and other fair uses, such as format-shifting. For example, RealNetworks was forced to stop sales of its RealDVD software, which allowed users to copy a DVD and store it on their hard drive. This format-shifting by RealDVD would have enabled DVD owners to create backups, organize a movie collection digitally, and watch a DVD at any time without being tied to a physical disc—all valuable personal uses. Nor did RealDVD represent a “piracy” threat: RealDVD preserved the DVD’s Content Scramble System (CSS) copy-protection system and added numerous additional

[27] Blake Reid, *The Digital Millennium Copyright Act Is Even Worse Than You Think*, Slate, Mar. 20, 2013, http://www.slate.com/articles/technology/future_tense/2013/03/dmca_copyright_reform_u_s_law_makes_digital_media_inaccessible.html

control measures. Nevertheless, a federal court ruled in August 2009 that, even if the uses enabled by RealDVD were lawful fair uses, the DMCA forbids the distribution of tools like RealDVD.[28] The same anti-innovation tactics have also been applied to streaming.[29]

C. The Costs of Section 1201 Do Not Outweigh the Benefits.

These costs might be tolerable if they were outweighed by real benefits, i.e., if our anti-circumvention rules and the technologies they are supposed to backstop actually deterred infringement. Sadly, they do not.[30] Individuals and companies that engage in large-scale copyright infringement are not deterred by Section 1201. After all, chances are they are *already* on the hook for substantial copyright damages.

Moreover, despite widespread infringing activity, legitimate media sources manage—year after year—not only to stay afloat, but also to flourish. iTunes, Amazon, Magnatune and dozens of other sites sell huge volumes of music without the need for DRM. Streaming services like Netflix and Spotify have succeeded because they are more convenient than unauthorized alternatives, not because DRM does anything to enhance their economics. Indeed, just a few months ago, Frank Gibeau, the president of Electronic Arts, declared DRM to be a "failed dead-end strategy."[31]

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[28] *Real Networks, Inc. v. DVD Copy Control Ass'n*, 641 F. Supp. 2d 913, 942 (N.D. Cal., 2009).

[29] *RealNetworks, Inc. v. Streambox, Inc*., No. C99-2070P, 2000 WL 127311 (W.D. Wash. Jan. 18, 2000).

[30] This likelihood was spotted early on. *See, e.g.,* Stuart Haber, Bill Horne, Joe Pato, Tomas Sander, Robert Endre Tarjan, "If Piracy is the Problem, is DRM the Answer?" http://www.hpl.hp.com/techreports/2003/HPL-2003-110.pdf

[31] Andras Neltz, EA Labels President Calls DRM a "Failed, Dead-End Strategy." http://kotaku.com/ea-labels-president-calls-drm-a-failed-dead-end-strat-461313335

D. The Exemption Process Does Not Save Matters.

The DMCA triennial rulemaking was meant as a "fail-safe" to prevent DRM from encroaching on the public's ability to engage in activities that would otherwise be perfectly legal under copyright law. Unfortunately, the rulemaking has not served its purpose. The exemptions created by the Copyright Office can be helpful, but they are too narrow and too brief. And however well-intentioned and dedicated the Copyright Office and the Library of Congress may be, it does not make sense to task a small group of overburdened copyright lawyers and librarians with making decisions that can shape the future of technology markets.

The process does not apply to tools. The DMCA provides that the Librarian of Congress can only grant exemptions from the DMCA's prohibition on *acts* of circumvention; exemptions from the DMCA's prohibition on distributing *tools* of circumvention are not within the scope of the rulemaking. As a result, exemptions granted can only be exercised by persons who have the technical know-how to fashion their own tools. Thus, the rulemaking proceeding holds out, at best, an empty promise to consumers: a legal right to circumvent, without access to the tools necessary to make that right a reality.

The process is complex and burdensome. Any person interested in participating meaningfully in the DMCA rulemaking process must first decipher a bewildering array of legal arcana and independently gather considerable evidence. Without expert assistance, individuals cannot reasonably gather the evidence and devote the time necessary to participate successfully in the DMCA rulemaking process. And even if they do succeed, they must be prepared to make the case again, three years later.

The exemptions that are granted continue to be unnecessarily narrow. For example, security researchers had sought a DMCA exemption in 2003 in order to facilitate research on dangerous DRM systems.[32] In 2006, the Librarian granted an exemption to the DMCA for researchers examining copy protection software on compact discs.[33] However, this exemption did not protect researchers studying other DRM systems. In 2009, security researchers again sought a DMCA exemption for computer security research relating to DRM systems, including the protection mechanisms used on the Electronic Arts videogame, *Spore*, which has been the subject of class action lawsuits alleging security vulnerabilities.[34] A narrow version of this exemption was granted in 2010. However, the exemption was not renewed in 2012, leaving this research vulnerable to legal action.[35]

E. What Can the Administration Do to "Fix" Section 1201?

Much of the action needed to remedy the harms of Section 1201 must take place in Congress. We believe the best outcome would be for Congress to overturn Section 1201 altogether. Short of that, the law should be scaled back to ensure that its applicability is limited to the situations it was intended to target. In particular, using or distributing tools for circumvention should not be a violation unless the use or distribution is intended to facilitate copyright infringement. We strongly support the Unlocking Technology Act, introduced last year by Representative Zoe Lofgren and a bipartisan group of sponsors. We believe the Administration should join us.

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[32] Recommendation of the Register of Copyrights in RM 2002-4, Oct. 27, 2003, 87-89, http://www.copyright.gov/1201/docs/registers-recommendation.pdf.

[33] Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 71 Fed. Reg. 68,472, 68,477 (Nov. 27, 2006), http://www.copyright.gov/fedreg/2006/71fr68472.pdf.

[34] Comments of Prof. J. Alex Halderman, http://www.copyright.gov/1201/2008/comments/halderman-reid.pdf.

[35] *See* Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 77 Fed. Reg. 208 (Oct. 26, 2012) (to be codified at 37 C.F.R. pt. 201), http://www.copyright.gov/fedreg/2012/77fr65260.pdf.

A much less preferable alternative would be to urge Congress to reform the DMCA so as to authorize the Copyright Office to craft exemptions that would include the distribution of circumvention tools. As noted above, consumers must have access to circumvention tools if they are to be able to take advantage of any DMCA exemptions granted in the rulemaking.

In the meantime, the Administration should urge the Librarian of Congress to reform the triennial rulemaking process. Such reforms should include:

• *Independent Fact-Finding.* As part of the triennial rulemaking, the Copyright Office should actively solicit input from users and undertake independent fact-finding to determine whether lawful uses of copyrighted works are being impaired by DRM technologies.

• *Reduce Complexity and Re-assign Burdens of Proof.* The complexity and burden now imposed on consumers should be replaced with a regime that imposes the burden of proof on those best positioned to shoulder it. Accordingly, once a petitioner comes forward with a concern regarding a lawful use that appears to be impaired by DRM restrictions, the burden should then shift to the copyright owner to (1) describe how the technology functions and how widely it is deployed; and (2) demonstrate by a preponderance of the evidence that continuing DMCA protection is necessary to the market viability of the work.

• *Leave Fair Use to the Courts*. Where a petitioner comes forward with a use, otherwise impeded by DRM restrictions, that might plausibly be viewed by a court as a fair use, the Copyright Office should presume that the use in question is a fair use for purposes of considering whether an exemption should be granted.

V. Conclusion

EFF again thanks the Office of Science and Technology Policy and the National Economic Council for the opportunity to comment regarding the upcoming update of the *Strategy for American Innovation*.

Respectfully submitted,

Electronic Frontier Foundation
Corynne McSherry
Intellectual Property Director
Daniel Nazer
Staff Attorney and Mark Cuban Chair to Eliminate Stupid Patents.
Adi Kamdar
Activist

September 23, 2014

ENDOCRINE SOCIETY
Hormone Science to Health

September 23, 2014

Attn: Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Buliding
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Washington, DC 20504

Dear Dr. Holdren and Members of the National Economic Council,

The Endocrine Society would like to thank you for the opportunity to provide input into the development of an updated *Strategy for American Innovation*. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. The Society's membership of over 17,000 includes scientists who drive breakthrough innovation from fundamental biological insight through clinical research. Many of our member scientists are supported by research grants from federal agencies, in particular the National Institutes of Health (NIH). We are therefore encouraged by the recognition of the "critical role of government in supporting our innovation system" in the Request for Information (RFI).

While we acknowledge the importance of each of the questions within the RFI to the national innovation ecosystem, we would like to focus our comments and suggestions to a few categories. Specifically, our membership is uniquely positioned to provide input on overarching questions, innovation trends, science and research priorities, and national priorities. Our comments specifically address biological sciences and medicine; however, the same principles are broadly applicable to fostering continued innovation in all areas of science, technology, and engineering. We are confident that addressing these comments will increase the Nation's capacity for innovation, and provide additional incentives to "drive economic growth and competitiveness."

Overarching Questions

Biomedical Research Funding. One of the biggest and most fundamental challenges to the American innovation ecosystem is the inability of the annual federal budget process to provide a steady, sustainable trajectory of predictable funding increases for research funding agencies. While the doubling of the NIH budget in the late 1990's and early 2000's dramatically increased the research capacity of the nation, since 2003 the NIH budget has failed to keep pace with inflation. Consequently, the inflation-adjusted budget of the NIH has fallen to pre-2003 levels, and the likelihood of a scientist with a highly-regarded grant application successfully being awarded a grant has dropped from 31.5% in 2000 to an historic low of 16.8% in 2013[1].

[1] Salley Rockey, "FY2013 By The Numbers: Research Applications, Funding, and Awards," Rock Talk, January 10, 2014. http://nexus.od.nih.gov/all/2014/01/10/fy2013-by-the-numbers/ Accessed March 20, 2014.

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This cycle of boom-bust funding introduces inefficiencies that threaten to destabilize the biomedical research infrastructure[2]. The current funding situation is further threatened by austerity policies, such as sequestration. This has created an environment that reduces the ability of the United States to retain the excellent scientists that are trained by taxpayer funded grants. For example in 2013, the number of NIH supported scientists declined significantly, with nearly 1,000 NIH funded scientists dropping out of the workforce[3].

The Endocrine Society believes that one of the most effective actions for the Federal Government to take for sustaining U.S. strengths, including “entrepreneurial culture, world-class research universities, and strong regional innovation ecosystems”, would be to implement policies that create predictable, mandatory, long-term, sustainable budget increases for the NIH and other research funding agencies. For example, we strongly encourage the NEC and OSTP to create mechanisms that place the NIH on a sustainable path. One example is the American Cures Act, proposed by Senator Dick Durbin[4]. By creating long-term stability in the NIH budget, the federal government would allow the NIH to improve long-term planning efforts required for effective research projects and make more efficient use of taxpayer dollars.

Additionally, an examination of the history of innovation highlights the role of younger individuals whose thinking has not been shaped by existing dogmas and who are open to divergent and highly creative approaches. The NIH funding process for basic and clinical scientists has served as an impediment to this critical aspect of innovation. The average age of the first NIH grant to an independent investigator (i.e. RO1 grant) has increased from age 36 three decades ago to age 44-45 today. The curve of age related funding has continually shifted toward older individuals over this period of time and now 6% of RO1 grantees are over age 66. This distribution does not allow independent funding when investigators might be at their most creative. Attention to this issue and development of means to reverse this trend is critically needed.

Science and Technology Education. As an international scientific society, we also appreciate the need to learn from the practices adopted by other countries to promote scientific innovation. For example, our international members in countries such as India report being exposed to more practical research experience earlier in their education. Indeed, the impressive performance of the Indian economy in recent decades has occurred in parallel with a strong governmental emphasis of science and technology education[5]. An overarching goal should therefore be to prioritize scientific education as a fundamental

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[2] Richard Harris and Robert Benincasa, “U.S. Science Suffering From Booms and Busts in Funding September 09, 2014. http://www.npr.org/blogs/health/2014/09/09/340716091/u-s-science-suffering-from-booms-and-busts-in-funding Accessed September 09, 2014

[3] Jeremy Berg “The impact of the sequester: 1,000 fewer funded investigators.” ASBMB Today. March (2014). https://www.asbmb.org/asbmbtoday/201403/PresidentsMessage/ Accessed March 20, 2014.

[4] Endocrine Society Letter of Support for American Cures Act. March 10, 2014. Accessed September 13, 2014.

[5] http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SC/pdf/sc_usr10_india_EN.pdf. Accessed September 13, 2014.

aspect of learning, starting very early in the education system and increase public appreciation of the value of scientific education.

We strongly encourage the NEC and OSTP to emphasize the importance of public education in science and technology as a fundamental building block in the *Strategy for American Innovation*. Education in science and technology can help develop analytic skills and decision-making strategies. It will also raise awareness of the value of government funding for basic and clinical research. An enhanced public appreciation for scientific knowledge could also have add-on effects within the innovation cycle. For example, a critical barrier to the conduct of clinical trials is the enrollment of sufficient numbers of subjects, due in part to a lack of awareness among patients[6]. Increasing general public knowledge about the conduct of research could serve to incentivize participation in clinical trials and encourage patients to actively seek out opportunities to enroll.

Additionally, there exists a need for general educational materials separate from classroom settings that are broadly accessible, up to date, and developed by reputable sources. Increasingly, information is disseminated online and there is little knowledge about the extent to which evidence-based sources of information successfully compete with other interests. The Endocrine Society has developed compelling evidence based resources for lay audiences at www.hormone.org. A national effort to create an evaluation system for scientific and medical information would help ensure that patients and their families are able to make evidence-based decisions that impact their health. Critically, the educational and outreach efforts must ensure that all communities, especially underserved communities, have access to effective materials. We urge the OSTP and NEC to consider innovative methods being developed to improve access to healthcare prevention resources through community partnerships with research institutions, for example the Health Advocates in Reach and Research (HAIR) program[7]. We anticipate that educational and outreach efforts such as the HAIR program will be effective tools to address national priorities, such as the increasing burden of chronic diseases.

Innovation Trends

Personalized Medicine. One scientific area that is poised for breakthrough innovation is personalized medicine. Complex multi-genic, multifactorial diseases such as obesity, heart disease, and cancer are significant and increasing components of the economic disease burden in the United States and worldwide. A critical issue is the development of methodologies and strategies for analyzing the immense amounts of medical data being generated. It is widely understood that current technology can identify multiple mutations through comprehensive analyses of individual genomes. The critical aspect of this process is to determine which of these mutations are biologically relevant. Although underemphasized, data obtained from cell and animal model systems with engineered mutations provide a means to identify which mutations can cause specific organ dysfunction. These findings require the type of translational studies which lead to an understanding of abnormalities in individual patients and in

[6] Sandra Williams, "Clinical Trials Recruitment and Enrollment: Attitudes, Barriers, and Motivating Factors" http://cro.rbhs.rutgers.edu/documents/clinical_trials_recruitment_and_enrollment.pdf Accessed September 18, 2014.

[7] http://sph.umd.edu/community-partnerships/health-advocates-reach-and-research-hair. Accessed September 18, 2014.

populations with specific diseases. Organizations such as the Endocrine Society with its tripartite structure of basic- and clinical-scientists and clinicians-in- practice provide an example of the type of structure and interactions needed to fully understand genomic data and to apply this knowledge to the benefit of patients. In additional to these aspects, truly personalized medicine will require improvement in the numbers of validated assays for biomarkers, improved computing capacity, enhanced computer interfacing with electronic medical records and genetic data, development of algorithms that integrate multi-dimensional data, and support for drug development that focuses on small populations rather than one-size-fits-all.

Increased federal investment in personalized medicine can improve our understanding of genetic or epigenetic changes that result in protection against disease and introduce novel opportunities to prevent disease. A better understanding of the complex pathways through which genetics influence health can streamline the conventional drug development process by informing drug target selection and reducing the failure rate of clinical trials. To achieve maximum impact however, national and multi-national efforts will be required to create data repositories, analytic tools, and harmonized data standards. Projects at the NIH, such as the new type 2 diabetes genetics database[8], are effective uses of federal research dollars.

<u>Technology Transfer Infrastructure</u>. The road from basic research to applied science is a long and extremely challenging process that can be undermined at many stages. Scientists and entrepreneurs are in need of action by the Federal Government to support high-risk, high-reward projects with long horizons for the realization of returns. A more effective integration of scientific, business, and technology transfer expertise is needed to accelerate the application of scientific knowledge. Novel mechanisms and incentives to support public-private partnerships are required to ensure that appropriate expertise can be deployed when needed to address the complicated issues that arise when starting a new company or making critical decisions on, for example, when and if to patent a technology.

A large amount of university-owned intellectual property remains unlicensed and unused, implying that there are innovative products that are never developed due to the challenges faced by entrepreneurs in developing discovery research[9]. We ask the OSTP and NEC, in the *Strategy for American Innovation*, to encourage research on common bottlenecks in the process that undermine the successful transition of a promising discovery to application. We also encourage the Strategy to emphasize the role of the Federal Government in supporting entrepreneurship towards the application of discovery research. Creative efforts to incentivize entrepreneurship could include, for example, challenge competitions that provide seed funding for promising ideas in the pre-venture capital space.

Science, Technology and R&D Priorities

The Endocrine Society would like to emphasize that many items already mentioned in our comments are responsive to the questions asked in this section. Specifically, our comments on personalized medicine,

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[8] http://type2diabetesgenetics.org/login/auth Accessed September 18, 2014.

[9] Samuel Arbesman, "'Dark Intellectual Property': Why We Need a Kickstarter for Patents" July 25, 2013. http://www.wired.com/2013/07/dark-ip-why-we-need-a-kickstarter-for-patents/ Accessed September 18, 2014.

science and technology education, technology transfer, and biomedical research funding are synergistic with respect to science, technology, and R&D priorities. However, we provide additional comments addressing question 11 below.

Reproducibility of Research Findings. The Endocrine Society acknowledges that the value of biomedical science is dependent on the reproducibility of research results. While the Federal Government has an important role in ensuring that research results are reproducible, there is also a need for grassroots action by the biomedical research community to address this important issue. This will require a shift in culture from having the highest impact paper to having solid and accountable research output. Independent replication should be an acceptable practice, and considered as part of promotion and tenure processes, rather than being considered derivative. Manuscripts that dispute high-profile papers should not be discounted without scrutiny for the underlying cause of the discrepant findings. Education of new scientists in standards of rigor is necessary, and animal research should require validation of models and a focus on statistically appropriate sample sizes.

The role of the Federal Government should be to enable best practices by encouraging and rewarding mechanisms for supporting pure replication studies of clinically relevant or high-profile papers. Importantly, the *Strategy for American Innovation* should articulate how additional resources might be used to support independent replication studies, for example through administrative supplements or the establishment of methodological gold standards. The Endocrine Society emphasizes however, that efforts to enhance reproducibility will require additional funds to avoid compromising current research productivity.

National Priorities

Health Disparities. The Endocrine Society appreciates that the *Strategy for American Innovation* seeks to "address important challenges confronting U.S. security or living standards". A necessary component of achieving this goal is to ensure that the benefits of taxpayer-funded medical research are equitably distributed to the public. According to the National Institute on Minority Health and Health Disparities, many "populations in America, whether defined by race, ethnicity, immigrant status, disability, sex, gender, or geography, experience higher rates of certain diseases and greater morbidity and mortality from them compared with the general population[10]." It is important to design effective interventions to reduce health disparities to improve overall public health. We therefore encourage the OSTP and NEC to explicitly consider health disparities research a national priority.

Sex as a Critical Biological Variable. In addition to the reproducibility of basic research, the generalization of data requires that all stages of the biomedical research cycle include a consideration of sex differences in research subjects where appropriate. A significant component of the rigor and completeness in research is the investigation of sex specific effects. Despite decades of awareness of the issue, women are still inadequately represented in many clinical trials. Additionally, sex differences are still not routinely considered as a critical variable in basic biological studies. This critical inconsistency in the biomedical research pipeline can have serious consequences. For example, of the 10 drugs that

[10] http://www.nimhd.nih.gov/about.html Accessed September 18, 2014.

were withdrawn from January 1, 1997 through 2001, 8 posed greater health risks for women[11]. The Endocrine Society therefore recommends that the *Strategy for American Innovation* also support the consideration of sex as an important biological variable.

In Summary

The Endocrine Society appreciates the critical role of the *Strategy for American Innovation* in spurring innovation, promoting economic growth and competitiveness, and catalyzing breakthroughs in national priorities. To summarize our comments, we ask the OSTP and NEC to prioritize the following in the updated Strategy:

- The importance of steady, sustainable, and predictable increases for federal research funding agencies such as the NIH;
- Creation of processes to fund young investigators at the time of their most creative thinking
- Innovative methods to develop and deliver educational materials to the public at all stages of life;
- Nation-wide efforts to advance the adoption of personalized medicine;
- Creative efforts to improve the success of technology transfer and translation of research findings to applied science;
- Mechanisms to support replication studies of high-impact and clinically relevant research;
- Reducing health disparities; and
- Supporting the consideration of sex as a critical biological variable.

We appreciate the opportunity to comment on the *Strategy for American Innovation* and thank the OSTP and NEC for considering our comments. If we can be of any further assistance in your efforts, please do not hesitate to contact Joseph Laakso, Associate Director of Science Policy at the Endocrine Society, at [redacted]

Sincerely,

Richard J. Santen, MD
President, Endocrine Society

[11] http://www.gao.gov/new.items/d01286r.pdf Accessed May 20, 2014

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September 22, 2014

Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave NW
Washington, DC 20504

RE: Strategy for American Innovation
Document Number: 2014-17761
Federal Register: Vol. 79, No. 145, Tuesday, July 29, 2014, Page 44065

Dear Mr. Correa:

Please accept the following comments submitted on behalf of the Entomological Society of America (ESA) in response to the Request for Information on the upcoming update to the *Strategy for American Innovation*.

ESA is the largest organization in the world serving the professional and scientific needs of entomologists and individuals in related disciplines. Founded in 1889, ESA has almost 7,000 members affiliated with educational institutions, science agencies, private industry, and government.

Overarching Questions

(1) What specific policies or initiatives should the Administration consider prioritizing in the next version of the Strategy for American Innovation?

Increased investment in pollinator health research should be a stated priority in the next version of the *Strategy for American Innovation* because of the importance of pollinators to the nation's food security and economy. According to U.S. Department of Agriculture (USDA) estimates, pollination by managed honey bees is responsible for over $15 billion in increased crop value per year; the value increases to $29 billion per year when other pollinators are included. In recent years, pollinator populations have been declining in the U.S., but there remains an incomplete understanding of the diverse and complex factors that threaten the health of pollinators.

Earlier this year, the White House issued a Presidential Memorandum creating a federal strategy to promote the health of honey bees and other pollinators. As part of this initiative, the President directed the establishment of a Pollinator Health Task Force composed of representatives from several federal agencies. The Task Force was asked to develop a National Pollinator Health Strategy, including a Pollinator Research Action Plan.

We believe the recommendations of the forthcoming Research Action Plan should seek to incorporate input from the stakeholder community, including relevant professional scientific societies. The Research Action Plan should be considered a first step in the necessary national prioritization of pollinator health research; the next step should involve strategic, increased investment in this area across the appropriate federal agencies. The *Strategy for American*

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Innovation should highlight pollinator health research needs and begin to outline a plan to invest in and coordinate multi-agency efforts to address this challenge.

Innovation Trends

(7) What emerging areas of scientific and technological innovation merit greater Federal investment, and how can that investment be structured for maximum impact?

Over the past few decades, a resurgence of vector-borne infectious diseases, such as dengue, Chikungunya, West Nile Virus, and Lyme disease has become a growing threat to human health in the United States. In addition, new and emerging vector-borne diseases, including huanglongbing disease of citrus and leaf roll and red blotch disease of grapes, are also impacting the agricultural industry.

Greater federal investment is needed to support the development of innovative tools and strategies for combating vector-borne diseases. Specifically, support for new vector-borne research is needed to understand the global factors fostering emerging, resurgent, and new diseases; to develop scientifically based models to track and predict the spread of vectors and disease; to examine the biology and ecology of disease vectors; and to test new methods of prevention, control, and therapeutics.

For maximum impact, investing in an initiative to address vector-borne diseases across the federal government should establish greater partnering and coordination between federal health, agricultural, and environmental agencies.

Skilled Workforce Development

(13) What emerging areas of skills are needed in order to keep pace with emerging innovations or technologies? What are successful models for training workers with these skills to keep up with emerging innovations?

To keep pace with the growing need to address vector-borne diseases, a strong pipeline of scientists trained in medical entomology is required. The outbreak of West Nile virus in the late 1990's and early 2000's illustrated the importance of maintaining support for experienced medical entomologists at the federal, state, and local level, as well as the need for Centers for Disease Control and Prevention (CDC)-sponsored training programs. Federal investment by CDC and the National Institutes of Health should support training programs at institutions of higher education to attract and train medical entomologists.

Furthermore, as pest-related challenges become increasingly diverse and complex, workforce development for the next generation of Integrated Pest Management (IPM) scientists and practitioners is critical to ensure human health and environmental protection. Despite support from the industry and the IPM research and extension community, no specific IPM training plan or funding exists to address this need. As recommended by the October 2013 USDA National Road Map for Integrated Pest Management, there should be a Federal Agency IPM Training Program in order to develop this cadre of trained individuals with enhanced management skills. Furthermore, there

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should be federal support for IPM education programs in academia to train the next generation of IPM scientists and practitioners.

Entomologists with expertise in insect identification are needed to accurately recognize pests that pose potential threats to human health, agriculture, and the environment. This is critical not only for monitoring the appearance of insect vectors of disease, but also for detecting invasive species with the potential to devastate crops, rangelands, and forests, resulting in significant economic impacts. In addition to supporting training programs in this area, resources must be provided to maintain and provide trainees access to biological specimen collections.

National Priorities

(24) Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?

Broadly, the ability to secure a safe and nutritious food supply should be identified as a national priority. To meet this growing societal challenge, the federal government must invest in and coordinate multi-agency efforts 1) to protect pollinators that are critical to the economy and to the production of some of our most nutritious food crops, 2) to prevent and control the spread of invasive insect species and pathogens that can destroy food crops, and 3) to develop and implement advanced Integrated Pest Management and biologically-based control practices.

In addition, the need to track, predict, and address the threat of emerging infectious diseases – including those spread by insect vectors – should also rise to the level of "national priority." With an increasingly globalized world and a warming climate, infectious diseases cannot be treated as a problem only affecting other countries. To position the United States as a leader in providing innovative solutions to these diseases worldwide as well as to ensure the nation is properly prepared for natural and manmade threats to the homeland, a comprehensive federal strategy for multi-agency investment in emerging infectious diseases is required.

Sincerely,

Frank Zalom, Ph.D.

President, Entomological Society of America
Professor of Entomology, University of California, Davis

The Federal Circuit Bar Association

BENCH & BAR

Via Email (innovationstrategy@ostp.gov)

Mr. Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave NW
Washington, DC 20504

Subject: Strategy for American Innovation
Comments of the Federal Circuit Bar Association

Dear Mr. Correa:

We write on behalf of the Federal Circuit Bar Association. The Office of Science and Technology and the National Economic Council have published a "Notice of Request for Information" inviting input on the upcoming update of the "Strategy for American Innovation." 79 Fed. Reg. 44064 (July 29, 2014). Responses are due by September 23, 2014 and to be forwarded to the Office of Science and Technology Policy, at innovationstrategy@ostp.gov.

The Association has worked closely with intellectual property, trade, and government contract topics related to innovation since 1985. Its membership encompasses private and corporate practitioners in the United States Court of Appeals for the Federal Circuit, the district courts, and other tribunals reviewed by the Circuit. Our membership includes both national and international businesses, drawing from the most sophisticated and experienced intellectual property sectors in the world. Although we have government members, when we address government policy matters we do not speak on their behalf. They have not been involved in this topic. With these considerations in mind, we offer the following comments in response to the specifically enumerated "Notice" questions.

(4) How can the Federal Government augment its overall capacity for analysis of both the forces that determine the competitiveness of specific sectors and the impact of Federal policies—including, but not limited to, science, technology, and innovation policies—on sector-specific productivity and competitiveness? What are the most important outstanding questions about innovation policy and process and how might government promote systematic research and program evaluation in those areas?

One area of federal policy which impacts innovation is the federal government's policy with respect to intellectual property rights in federal procurement contracts. In recent years, the federal government has been taking a more aggressive approach to intellectual property used in connection with performance of government contracts, to the extent that contractors may risk having the government claim unlimited rights in intellectual property previously generated at purely private expense. The policy with respect to intellectual property in government contract situations impacts innovation. Specifically, an overly aggressive assertion of government rights to technical data or inventions developed at private expense creates disincentives for contractors' investment in R&D and innovation. Such a policy precludes contractors from reaping the competitive benefits of that innovation in the marketplace – thus avoiding the advancement sought to be encouraged by innovation policy.

(21) What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation (including, e.g., through the growing use of open innovation, combinatorial innovation, user innovation, internet-enabled innovation, and big data-driven innovation)?

With respect to open source technologies, and specifically as those relate to government contracting, a clear policy statement as to whether or not the government will embrace such technologies by purchasing products that include open-source source code and open-source licensing clauses would be very helpful. DFARS part 227 Rewrite, Section 815 of the National Defense Authorization Act, Better Buying Power 2.0, and the Open System Architecture Contract Guidebook for Program Managers, Version 1.1 Government all fail to address this issue, and if anything, point to a procurement framework that is less tolerant of commercial software products. Simultaneously, commercial software manufacturers are increasingly incorporating open source code into their products as the licensing schemes regarding these works are clarified and refined. A clear strategy on the part of government agencies would enable commercial software manufacturers to make better decisions about product development and whether and how they participate in the government marketplace. As innovation policy pertains to government procurement, improvements could foster competition and efficiency.

(22) What are specific areas where a greater capacity for experimentation in law, policy, and regulation at the Federal level is likely to have large benefits? Are there useful models of experimental platforms in the public or private sectors that the Federal Government can adopt? How might the Federal Government encourage state and local experimentation?

New technologies and business models often evolve more rapidly than law, policy, and regulation at the Federal, state, and local level. One approach to dealing with this challenge is to increase the capacity of governments at all levels to support experimentation. For example, the FCC recently reformed its experimental licensing rules to help researchers and manufacturers bring new products to market more rapidly. Analogous opportunities may exist in other areas. A second example of effective Government agency program innovation can be found in the details of the PTO Track 1 examination program at http://www.uspto.gov/patents/init_events/Track_One.jsp. That program reflects effective policy "experimentation" helping to bring new innovations (ones which the market determines to be of greater economic value) to the marketplace faster.

Protection of IP is pivotal. While the benefits of open innovation, open interfaces, and the like are significant, the Government must simultaneously ensure that strong intellectual property protections are maintained for innovations which are privately funded by commercial companies and contractors at all tiers. Reductions in IP protection, such as by Government agencies seeking greater rights in software or technical data from contractors and commercial vendors (above), will discourage private investment in innovation, discourage companies with valuable technology from doing business with the Government, or do both. Further, the Government should continue to focus on ways to reform and strengthen the US patent system which discourage needless patent litigation and, at the same time, maintain the strong patent rights necessary to support innovation.

Finally, US Government should consider increasing incentives for private industry to engage in R&D collaborations. One example is in direct US Government funding for R&D. Another tool encourages private industry ownership of IP. Some countries (such as Canada) pursue special government policies encouraging private companies to collaborate with universities on research. These policies allow, on one hand, for collaboration while permitting the sponsor company to own at least some resulting IP and/or, on the other hand, permit collaborators to work out their own fair and reasonable IP agreement, as long as the results are eventually used/exploited within the country providing the grant funds.

Thank you for the opportunity to provide these comments. We would be glad to discuss these matters further and to provide additional information. Please do not hesitate to contact us.

Sincerely,

James E. Brookshire
Executive Director
[redacted]

FIRST

September 22, 2014

RESPONSE: Notice of Request for Information
Input for an Update of the White House Strategy for American Innovation

Introduction

The United States Foundation for Inspiration and Recognition of Science and Technology (*FIRST*®) is a not-for-profit organization devoted to helping young people discover and develop a passion for science, technology, engineering and math (STEM) founded 25 years ago by inventor Dean Kamen. *FIRST's* mission is to inspire young people to become science and technology leaders by engaging them in exciting mentor-based programs that build STEM skills that inspire innovation and foster well-rounded life capabilities including self-confidence, communication, and leadership. *FIRST's* goal is to increase the likelihood of *FIRST* participants declaring a science- or technology- related major in college. The *FIRST* progression of robotics programs provide increasing challenges in the field of science, technology, and engineering by introducing elementary school students to Junior *FIRST*® LEGO® League, then *FIRST*® LEGO® League to middle school students, and finally, *FIRST*® Tech Challenge or *FIRST*® Robotics Competition to high-school students. It is through this K-12 sequence of project-based, experiential learning that *FIRST* creates a school-to-career pipeline through which young people are inspired to explore the STEM disciplines. Today *FIRST* programs are in approximately 80 countries and serve over 350,000 youth ages 6-18.[1]

FIRST submits this Response to share its experience in stimulating K-12 students to pursue careers in STEM. We would be delighted to continue this discussion with the Administration to help it shape policies to spread STEM engagement in order to produce the number of STEM professionals this country needs and improve the diversity of our STEM workforce.

The state of STEM in the United States is troubling. The U.S. is losing ground to many other countries in STEM areas, demonstrated by consistently lower math and science standardized test scores for U.S. students and lower selection rates of natural science and engineering degrees as primary areas of study for U.S. undergraduates.[2] At the same time, STEM-related occupations are projected to grow more than non-STEM occupations over the next few years,[3] and most of these jobs will require a bachelor's degree or more.[4] Many young

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[1] For more information about *FIRST* see, www.usfirst.org.

[2] National Science Board (May, 2010). Preparing the Next Generation of STEM Innovators: Identifying and Developing Our Nation's Human Capital. National Science Foundation. Available at http://www.nsf.gov/nsb/publications/2010/nsb1033.pdf.

[3] U.S. Department of Commerce (July, 2011). STEM: Good Jobs Now and for the Future. ESA Issue Brief #03-11. Available at http://files.eric.ed.gov/fulltext/ED522129.pdf.

Americans are not developing the skills necessary to secure those jobs and compete in the global marketplace.

STEM skills alone are not enough to prepare young Americans for a global workforce. Students need to develop and cultivate other attributes that will prepare them to work in a competitive, changing, and fast-paced environment. Skills such as team work, problem solving, time management, communication and other 21st century work-life skills are critical to preparing the next generation of scientists and engineers.

This update to the Strategy for American Innovation presents the best opportunity to meet the challenge set forth by the President's Council of Advisors on Science and Technology: produce one million additional STEM graduates by 2022. If the updated Strategy is to achieve its goals of promoting lasting economic growth and competitiveness through policies that support transformative American innovation, exposure to effective, energizing and engaging STEM programs cannot wait until college. It must begin early in a child's education and continue engaging the student through high school.

While many obstacles exist to achieving such a challenging goal, the success of any program hinges on delivering adequate resources to the people and environments best suited to use them. The Office of Science and Technology Policy and the National Economic Council should therefore look to successful private and state level programs (such as the Iowa and Michigan STEM programs) that have already achieved measurable success at spurring innovation and fueling future economic growth.

Comment on Question 1. What specific policies or initiatives should the Administration consider prioritizing in the next version of the Strategy for American Innovation?

Specific goals and rationale: The Administration should prioritize policies and initiatives that inspire students to pursue college majors in STEM fields. Children lose interest in STEM as they progress through school. Only 20% of students in eighth grade have an interest in STEM and only 4.5% will graduate with a STEM major at the undergraduate level.[5] Globally, U.S. students lag behind students from many other industrial countries such as China, the European Union, and South Korea in choosing natural science or engineering as a major.

The low percentage of graduates with STEM majors is most efficiently addressed by targeting students while they are still developing their career interests.[6] Increasing the proportion of primary and secondary students interested in STEM subjects will allow time for many

[4] Carnevale, AP., Smith, N., Melton, M. (October, 2011). Stem. Washington DC: Georgetown University, Center on Education and the Workforce. Available at https://georgetown.app.box.com/s/cyrrqbjyirjy64uw91f6.

[5] Stephens, R. Testimony to the House Science and Technology Committee, Subcommittee on Research and Science Education. February 4, 2010. Available at http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg54618/html/CHRG-111hhrg54618.htm.

[6] See supra note 4.

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children to discover their ability to excel at and enjoy science and math. Without these additional STEM graduates, many other science and math initiatives will not succeed. Therefore, one of the most important goals of the updated Strategy should be to fund and develop programs that inspire children to pursue STEM subjects and careers.

The updated Strategy should also support initiatives to incentivize upper-level educational institutions (from four-year universities to local community colleges) to produce more qualified secondary education STEM teachers. The presence of un- or under-certified STEM teachers in early education is a massive problem hampering effective STEM instruction. Ineffective instruction in middle and high school disrupts the critical learning stages of math and science, preventing many students from enjoying and pursuing STEM subjects later in college.[7] Support is needed for programs that provide opportunities for youth to apply academic learning to real life situations, and develop important STEM and 21st century work skills that will have direct application to future careers in STEM.

Finally, the updated Strategy should seek to increase the diversity of students pursuing STEM careers. Women and minorities are underrepresented in STEM fields when compared to the population at large. A state's STEM program can target underserved schools and help to improve diversity in the overall STEM professional population.

Actions the Administration should take: The most efficient way for the updated Strategy to achieve measurable results is to formulate a block grant program for state funding of project-based, hands-on in-school and after-school programs that have a measurable impact on STEM interest, 21st century work skills and education outcomes. Programs should incorporate STEM challenges and/or competitions outside of class, and real-world projects that stimulate learning and excitement for math and science. These comprehensive state-wide STEM programs are already used in states such as Iowa and Michigan to successfully develop entrepreneurial passion for math and science.

Funding should be modeled after these existing state STEM programs. These programs typically combine legislative grant funding with private-sector investment, cost-sharing initiatives, and corporate partnerships. An advisory council directs the capital and human resources to create and advance an array of curriculum and after-school hands-on opportunities for students to engage with real-world STEM projects. Students are encouraged to enroll in after-school programs, parts of which may or may not be extensions of the general school curriculum. For example, the Iowa STEM program combines a $5.2 million legislative apportionment with nearly $5 million in outside grants, private sector investment, and cost-sharing partners. From that strong foundation, a variety of programmed after-school STEM opportunities become possible for students in K-12. The after-school programs are an important compliment to STEM curriculum because they energize the subject matters covered in the classroom and provide an important reward for learning. State fairs, conferences, and festivals become a visible platform for students to display their skills and learn from one another. Students collaborate and positively

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[7] See supra note 4.

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compete with their fellow classmates, along the way absorbing important social skills and life lessons.

In addition to curriculum and other project-based activities, some funding must go to incentivize STEM teacher recruitment and retention, as well as ongoing training for enhanced instruction. In the Iowa program, for example, a number of host businesses and agencies provided real-world externships for teachers for professional development purposes.[8] Teachers trained in this way report that it is a valuable education device that surpasses other means of professional development.[9]

Benefits and costs: This type of funding would put the most resources possible into a system that has already been proven to encourage and inspire youth to pursue STEM for future study and employment. STEM programs that include mentorship and cooperative learning elements also enhance the academic material demonstrated to and practiced by students. Group learning and team building provides for leadership opportunities not otherwise available. Working on teams focused on a STEM challenge leads to the development of 21st century work skills, teaching students to communicate, negotiate, compromise and problem solve. Furthermore, as previously mentioned, a wide reaching state block grant program can include STEM exposure to previously underserved communities, directed at increasing the diversity of eventual STEM graduates.[10]

The economic and social benefits of a large-scale federal investment in STEM curriculum and after-school programs would be enormous. Producing highly intelligent, skilled, and productive members of society creates a ripple effect of prosperity. The nation will be able to meet the anticipated increased demand for more skilled STEM workers, and with more employment in higher-paying positions, the tax-base will grow. Students who might otherwise languish in underserved school districts or under stimulated classrooms will have a chance to put their knowledge into practice at an early age. Our country will also benefit from a higher percentage of math and science professionals because improved problem-solving and collaborative skills will translate to all aspects of life.

Program costs will likely include budgeting for learning programs, funding a regional network of STEM programs for competition and comparison, a public awareness campaign to foster an appreciation for the benefits of careers in STEM subject areas, STEM conferences and special events, and ongoing assessments of the program's progress. These programs and activities will require purchases of equipment and instructional materials, the rental of adequate space to conduct experiments and construct projects, and other associated expenditures. Cooperative partnerships and sponsorships with businesses and industry can help to defray some of these costs while simultaneously benefitting the businesses with positive community interactions.

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8 Heiden, Erin O. et al. Iowa STEM Monitoring Project, 2013-2014 Summary Report. Available at http://iowastem.gov/sites/default/files/Iowa_STEM_Year_in_Review_Monitoring_Report.pdf.

9 See supra note 7.

10 See supra note 4.

FOR INSPIRATION AND RECOGNITION OF SCIENCE AND TECHNOLOGY

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Roles of other stakeholders: Private sector involvement is a key component for STEM programs to have a pronounced and lasting impact on students. Involvement with companies and other organizations in STEM fields, that use and apply math and science every day, visibly demonstrates to students the potential rewards and opportunities available to them should they pursue a math, science, or technology career. Further, organizations and companies are a source of mentoring for students and teachers. This human resource is an important component of successful STEM programs. Other stakeholders, if effectively engaged, will provide unique access and resources for STEM students.

Comment on Question 2. What are the biggest challenges to and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?

A major challenge for developing an innovative workforce is the loss of interest in STEM among unengaged young Americans. Increased access to engaging and effective after-school STEM programs is needed for students to see the value of math and science, apply concepts learned in the classroom to real-life challenges, and envision their role in the STEM economy. If these programs are to expand successfully, block grants administered by states to established after-school STEM engagement programs are the best solution.

Innovation requires more than STEM knowledge, but also a workforce prepared to face the challenges of a changing, demanding and fast-paced industry. Innovation requires young Americans to think critically and creatively, to overcome failure and obstacles, and to work cooperatively in a demanding environment. STEM programs like *FIRST* provide the conditions that mirror an innovation-driven economy. They complement the education system by providing the application of classroom material to real life situations. They make learning science and math "real" for students. However, access to STEM programs is contingent on the resources of school districts to be able to afford and sustain the program. Supporting school districts through funding is critical to enable all schools to have access to effective programs like *FIRST*. Additionally, reducing the barriers to funding for STEM programs by relaxing Department of Education research study requirements attached to many existing grant programs would help spread resources to deserving organizations that cannot currently meet the rigorous research standards.

Comment on Question 3. What specific actions can the Federal Government take to build and sustain U.S. strengths including its entrepreneurial culture, flexible labor markets, world class research universities, strong regional innovation ecosystems, and large share of global venture capital investment?

The federal government can best build and sustain U.S. economic and academic strengths by providing funding for well-established STEM after-school programs and after-school challenge-based and/or competition-based STEM engagement programs that target young students and provide them with the resources necessary to permit a hands-on, engaging experience with science and math. Effective systems and programs already exist, but often lack the necessary funding or institutional impetus to be enjoyed broadly. The federal government

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can, at the primary and secondary education levels, provide block grants to states for use in STEM programs that solidify early student interest in STEM studies.

Comment on Question 5. What innovation practices and policies have been adopted at the state and local level that should be piloted by the Federal government?

Michigan's STEM Partnership supports an academic core curriculum that includes the Next Generation Science Standards as well as project-based learning in order to enhance student engagement with STEM material with a variety of tools. The state Partnership is guided by a governing board made up of employers and educators. The state has five regions that are individually directed by a leadership team that focuses on the individual needs and requirements of the region. An overall strategic plan is implemented by these regional leadership teams, and the regions are assessed annually. The Michigan Partnership programs focus on the development of problem-solving and collaborative skills through a project-based application of science and math topics.[11]

A similar STEM block grant program in Iowa has six regional hubs, and is currently broadening the reach of its STEM program to involve more students. The Iowa program targets increasing student interest and achievement through a series of Scale-Up academic programs and projects.[12] One example is the *FIRST®* Tech Challenge, a community involved robotics program that uses a robotics competition to teach important work ethic and collaborative values in addition to the science and engineering of robotics. Over the past several years, programs such as this have helped Iowa experience increased proficiency in mathematics and science, increased percentages of students meeting benchmarks for science on other standardized tests, an increased number of students taking Advanced Placement courses in STEM-related subjects, and an increase in high school interest in STEM majors and careers.[13]

Comment on Question 14. What mechanisms or programs can effectively increase the supply of workers with technical training, from industry-recognized credentials and postsecondary certificates to two- and four-year degrees?

As previously discussed in the comment to Question 5, individual programs with a track record for success are an invaluable compliment to any school STEM curriculum. The 2014-2015 listing of STEM programs for Iowa includes ten distinct projects or competitions that engage students outside the classroom in important and unique ways. These programs can effectively increase the supply of workers with technical training by capturing the imaginations and enthusiasm of students. These engagement programs help students learn to associate math and science with fun and rewards, and also allows students intellectual discovery through action, collaboration, and self-motivation. While post-graduate grants and incentives are an important part of any increase in the supply of workers with STEM training, instilling students with the

[11] Michigan STEM Partnership website, available at http://mistempartnership.com/about/.

[12] Iowa STEM Programs website, available at http://www.iowastem.gov/hubs/.

[13] See supra note 7.

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desire to pursue math and science from an early age increases the odds these students will finish college with a STEM degree.

Comment on Question 24. Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?

Because an innovation-driven economy is critical for sustained U.S. economic strength, nurturing a robust home-grown STEM workforce from elementary school and up is paramount. Providing access to effective, energizing and engaging STEM programs for *all* students in the United States should be identified as a national priority. STEM programs are needed to provide the connection of classroom material to real-life challenges. Making science real, local and personal is more likely to result in STEM interest and inspiration.[14] STEM learning opportunities for all youth are needed. Today, school districts that have resources are able to provide STEM programs to their students. We need to ensure that all students have access to STEM learning. Access needs to start in the primary grades and continue through high school, to ensure that students develop, maintain and intensify their interest and skills in STEM, preparing them for post-secondary education and training.

Teaching STEM subjects in schools is not enough to prepare young Americans for a demanding career in STEM. We must focus also on developing 21st century work skills so they have the ability to think creatively, work cooperatively, solve problems and communicate. STEM programs, like *FIRST*, that emphasize teamwork need to be available to all students.

[14] Maltese, A.V. & Tai, R.H. (2011). Pipeline persistence: Examining the association of educational experiences with earned degrees in STEM among U.S. students. *Science Education95*: p.900.

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September 22, 2014

Dr. Dan Correa
Senior Advisor for Innovation Policy White House Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

Dear Dr. Correa:

The Fisk-Vanderbilt Master's-to-PhD Bridge Program represents a collaboration between Fisk University, a venerated Historically Black University, and Vanderbilt University, a leading major research university, with the goal of ***significantly increasing the nation's capacity to produce STEM doctoral degrees to underrepresented minorities***. Through this initiative, Fisk has become the nation's leading producer of African American master's degrees in physics, and Vanderbilt has become the nation's leading producer of underrepresented minority PhDs in astronomy, physics, and materials science, currently three of the least diverse fields in STEM. Tracks in biology and chemistry have recently been added as well.

Based on our 10 years of experience in building and leading this national model initiative, we are pleased to provide the following comments to help inform the upcoming update of the *Strategy for American Innovation*. Specifically, we address questions 1 and 24. Finally, please note that Fisk-Vanderbilt Master's-to-PhD Bridge Program co-director, Dr. Keivan Stassun, presented expert witness testimony to the House Committee on Science & Technology's Hearing on Broadening Participation in STEM[1]. That testimony and supporting material[2] may prove useful in providing additional context, data, and references for the *Strategy for American Innovation*.

Question #1: What specific policies or initiatives should the Administration consider prioritizing in the next version of the *Strategy for American Innovation*?

We offer up ***the Fisk-Vanderbilt Master's-to-PhD Bridge Program as a model initiative*** whose strategies, mechanisms, and lessons learned can be incorporated into the Strategy for American Innovation in order to broaden participation of underrepresented minorities at the PhD level in science, technology, engineering, and mathematics (STEM) and thereby spur American innovation through the engagement of all American citizens in the leadership of the science and technology enterprise.

The Fisk-Vanderbilt Master's-to-PhD Bridge Program (FVBP), created in 2004, has as its primary mission the increase of underrepresented minorities (URMs) in STEM academe and workforce. To date we have enrolled 79 students, 83% of them are underrepresented minorities, 52% male and 48% female. Twelve students have completed the PhD phase, all with offers of employment in the STEM workforce prior to graduation. The program is on pace to produce 5-6 URM PhDs per year moving forward, making it a national leader in URM PhD production in astronomy, biology, chemistry, physics, and materials science.

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[1] http://science.house.gov/hearing/subcommittee-research-and-science-education-hearing-broadening-participation-stem
[2] http://science.house.gov/sites/republicans.science.house.gov/files/documents/hearings/031610_Stassun.pdf

Because research shows that URM students are 50% more likely than non-URM students to earn a terminal master's degree en route to a STEM PhD, and that over the past 20 years there has been a greater than 500% increase in the number of URM STEM master's degrees earned at minority-serving institutions (MSIs), we have designed the FVBP to specifically guide students through the ***crucial master's to PhD transition***. Students begin with a master's degree at Fisk, and are then prepared for PhD work through extensive research training, courses tailored to address any gaps in academic preparation, additional professional development, and multi-tiered mentoring. Students are then encouraged to apply to Vanderbilt PhD programs as well as other institutions that meet their research interests and professional goals. The program itself is built on the sense of community and students are part of the program and are assisted not only for the master's degree but the full PhD phase and beyond. Of the 50 students who have met the requirements of the program to maintain an adequate GPA and make satisfactory progress in research, ***100% have been accepted into PhD programs*****.** While the majority go to Vanderbilt, students have bridged to Yale University, University of Wisconsin-Madison, University of Texas-Austin, and Purdue University among others. The overall retention to the PhD for the FVBP is 82%, far greater than the national average of 50% as found by the Council of Graduate Schools.

Our program has taken an alternate approach to selecting and retaining URM students to the STEM PhD that has demonstrated success. We have focused on characteristics such as grit, leadership, and drive rather than standardized test scores in identifying students that have potential. Research shows that ***misuse of standardized test scores in graduate school admissions is a major cause of the ongoing low representation of women and URMs in STEM***[3]. Research furthermore supports our model of wrap-around mentoring as being particularly beneficial to a diverse student body.

We recommend these practices be more wide-spread in graduate education to increase the numbers of URMs attaining PhDs in STEM, addressing a critical need in America today in the drive for innovation.

1. *Provide adequate financial support for URM students at the MA and PHD phases.*
   Removing the financial barrier to entry into STEM programs at the Master's stage of education would greatly benefit URM students, the majority of whom use this pathway to PhD. The majority of master's STEM programs are unfunded, and rising student debt is a national concern. Reducing educational costs by providing stipend and tuition support particularly to master's programs at MSIs would increase diversity in the STEM workforce.
2. *Implement programs that encourage collaborations and seamless student transitions between MSIs and research universities and national laboratories.*
   It has been noted in our program that undergraduate mentors prefer to send students to an environment that they trust. By building collaboration between MSIs, research universities, and/or national labs, we create relationships between faculty and researchers that are supportive of students in the long-term. It generates joint research projects and creates better

[3] http://www.nature.com/naturejobs/science/articles/10.1038/nj7504-303a

transitions for students. In addition, adding in the national labs can build a pipeline for students to move from research experiences to jobs in the federal government system.

3. *Implement additional training for faculty mentorship of a diverse student body.*
   While educational research has made strides in understanding what practices are supportive of URM students and what practices may suppress student success, the translation of that information to the classroom and the lab has been slow. Support for faculty training that promotes best practices and generates greater awareness of the challenges faced by URM students would go a long way in improving campus climate and student outcomes. Further, student mentoring is not a part of standard STEM graduate or postdoctoral training. Implementing opportunities for more faculty, post-docs and students to have additional experience with and education on mentoring practices would be beneficial to all engaged in higher learning. Such improvements would result in increased URM student retention and advancement to the PhD.
4. *Promote metrics beyond standardized test scores for assessing potential student success.*
   Students in the FVBP are judged not on standardized test scores but rather their undergraduate academic preparation, research experiences, and a set of non-cognitive attributes shown to be associated with student success. These characteristics are derived from careful reading of essays and letters of recommendation as well as brief interviews. While this technique is more time consuming, it has surely contributed to our 82% retention rate and leading national production of URM PhDs. Reviewing test scores of different demographic groups with the same incoming GPA indicates test performance alone can lead to underrepresentation of women and minorities in STEM, as we recently reported in the journal Nature[4]. It is time to move past these dated standards to a more holistic approach when analyzing student potential. We recommend these practices be presented on a national level as beneficial to the long-term success and diversity of the STEM academe ad workforce. They need not replace but should be strongly encouraged to complement standardized test scores to strengthen the selection process. For example, the National Science Foundation Graduate Research Fellowship program no longer permits GRE scores to be reported in the selection of awardees.

Question #24: Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?

Diversity is one of our nation's greatest strengths and it must be promoted to ensure we continue to movie into the future as leaders in innovation. Different viewpoints creates better problem solving from which can arise new technologies, theories and ideas that drive science. Making changes in our higher

[4] http://www.nature.com/naturejobs/science/articles/10.1038/nj7504-303a

education system that maximize the use of resources to ensure student success and increase diversity can translate to a stronger and more competitive American workforce.

Please do not hesitate to contact us if we may be of further assistance in the development of the update to the *Strategy for American Innovation*.

Sincerely,

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GIPC Additional Comments on
The Strategy for American Innovation
to the Office of Science and Technology Policy
and
The National Economic Council
September 23, 2014

The U.S. Chamber of Commerce' Global Intellectual Property Center appreciates the opportunity to provide our comments on these important issues.

The U.S. Chamber of Commerce is the world's largest business organization representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations, and is dedicated to promoting, protecting, and defending America's free enterprise system.

The Global Intellectual Property Center (GIPC) was established in 2007 as an affiliate of the U.S. Chamber of Commerce. Today, the GIPC is leading a worldwide effort to champion intellectual property rights and safeguard U.S. leadership in cutting-edge technologies as vital to creating jobs, saving lives, advancing global economic growth, and generating breakthrough solutions to global challenges.

GIPC appreciates the opportunity to comment on the update to the Administration's Strategy for American Innovation. We write specifically to address the fundamental and foundational role of intellectual property in fostering innovation. The Notice of Inquiry (NOI) frames the matter as follows:

> *Intellectual Property/Antitrust*
>
> (21) What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation (including, e.g., through the growing use of open innovation, combinatorial innovation, user innovation, internet-enabled innovation, and big data-driven innovation)?[1]

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[1] 79 Fed. Reg. 44064, 44067 (July 29, 2014)(hereinafter "NOI").

It is well established that in the United States antitrust and intellectual property protection are aligned in their respective support for consumer welfare. Further, it has been agreed that that intellectual property rights do not confer market power.[2] GIPC urges that the Administration reaffirm these principles and consider the issues accordingly.

The Role of Intellectual Property in Innovation

The Administration's 2010 Joint Strategic Plan on Intellectual Property Enforcement[3] began, appropriately, with the following statement of President Obama:

> [W]e're going to aggressively protect our intellectual property. Our single greatest asset is the innovation and the ingenuity and creativity of the American people. It is essential to our prosperity and it will only become more so in this century.[4]

GIPC could not agree more. The President's statement rightly recognizes the Administration's agreement and understanding of the foundational role that intellectual property plays in fostering innovation. That understanding finds its roots in the U.S. Constitution itself, which famously authorized Congress to promote the progress of science and useful arts through the granting of exclusive intellectual property rights.[5]

Consistent with the President's statement, GIPC's mission is to promote intellectual property protection and enforcement, and thereby generate innovation that in turn

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[2] See "Antitrust Guidelines for the Licensing of Intellectual Property," U.S. Department of Justice and the Federal Trade Commission, §2.2 (April 6, 1995).
[3]http://www.whitehouse.gov/sites/default/files/omb/assets/intellectualproperty/intellectualproperty_strategic_plan.pdf
[4] *Id*. (Statement made on March 11, 2010).
[5] U.S. Const. Art. I, Sec. 8, Cl. 8.

creates jobs and economic growth. GIPC urges the Administration to remain true to this time-tested understanding and to adopt and implement policies that enhance intellectual property protection (and reject those that weaken it) so as to foster American innovation.

Open Innovation

The text of the question posed in the NOI focuses on "the increasing diversity of models of innovation" to the apparent exclusion of considering the new challenges and opportunities for traditional innovation models. No strategy or policy is complete if it fails to consider all the models of innovation, including "traditional" models that have generated 40 million American jobs, over $5 trillion in output, and more than 60 percent of U.S. exports.[6]

A growing number of models of innovation exist. What these models have in common is that they all rely on robust intellectual property to enable their success. For example, the popularity of open innovation relies on the use of open source licenses that permit reproduction, distribution, and adaptation, but only on certain conditions (including the further availability of the work). Copyright law enables these terms and conditions and renders open source licenses enforceable.

There are a number of factors, such as the specific technologies involved and market needs that influence how a business will choose to sell their goods and services. To stay competitive, we need to maintain a business-model independent intellectual property system. The U.S. will be best positioned if our innovators can choose the models that best suit their own circumstances and those of the market. Therefore, GIPC urges the Administration to reaffirm the foundational role of intellectual property across innovation models.

[6] See "Intellectual Property and the U.S. Economy: Industries in Focus," Economics and Statistics Administration and the U.S. Patent and Trademark Office (March 2012).

Some who find the non-proprietary approach appealing take that position to an illogical extreme, arguing against proprietary innovation models and even against intellectual property itself. These arguments are at best unsupported and at worst self-defeating. For example, critics of the availability of patents for software ignore the fact that today, software innovation is an indispensable aspect of advances in every field of technology and every sector of the economy. Software-based innovations power amazing technologies, from the modern smart-phone to advanced robotic manufacturing, artificial retinas, driverless cars, GPS, medical and diagnostic tools, and an endless list of other fields. Patent protection provides a critical incentive for innovators to pursue new inventions and proceed to market, and this incentive should be recognized and preserved.

Moreover, the need for proprietary-based innovation is often a reflection of the ease with which free riders may compete directly with the innovator. Common examples of this are commercial[7] copyrightable software, movies, and music, which can be reproduced and distributed at virtually no cost in the modern marketplace. Similarly, products utilizing patented art that are vulnerable to reverse engineering are poor candidates for non-proprietary innovation. And to the extent that almost any successful product and company is subject to the fraud of counterfeiting, they must and do rely on trademark law to address such unfair competition.

Innovators rely on both registered assets, as well as less formal rights like trade secrets. Trade secrets typically involve products, or more often services, that are difficult to replicate, such as a computer algorithm that drives a service.

[7] To be sure, there are many examples of open source software and user-generated content. And some of these produce economic returns. But the overwhelming majority of innovation in these fields has been generated by commercial entities that employ large numbers of people and require a proprietary model to operate successfully.

Unlike patents, trade secrets are, by definition, not shared outside the company. To the extent that intellectual property protection is weakened and/or enforcement is ineffective, innovators whose work might have been a better fit elsewhere will be forced to shoehorn their business into a trade secret model. Thus, open source advocates who seek to reduce intellectual property protection not only would undermine the framework of their own innovation model (and innovation, generally), they would drive others to be *less* open.

Of course, trade secrets do play an important role in supporting American innovation for companies that choose that route. Strong trade secret protection is critical to enabling the collaboration that accelerates technology development and enables market access. They are also relied upon extensively by smaller firms, which often cannot afford other types of IP protection.

Investing in innovation is not cheap and when innovators sense their hard-earned achievements are at risk, they will naturally limit what they share externally. The only protection available for this type of knowledge is self-help or trade secrets. And with trade secrets being one of the most underdeveloped areas of intellectual property law globally, many innovators may choose not to engage in critical opportunities that could improve U.S. competitiveness.

In February, 2013, the Administration issued its "Strategy on Mitigating the Theft of U.S. Trade Secrets."[8] GIPC applauded that document as an important step in the right direction. Congress is currently considering a federal civil trade secret bill that could vastly improve the landscape for American innovators. The proposed legislation would empower them to take action against theft of their confidential information, by both preventing devastating losses and providing a path to recovery when they do occur. GIPC urges the Administration to support that legislation.

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8 http://www.whitehouse.gov//sites/default/files/omb/IPEC/admin_strategy_on_mitigating_the_theft_of_u.s._trade_secrets.pdf

While protecting the information that supports our knowledge-based economy at home is critical, we need to look beyond our borders to protect our competitive edge. Outside the U.S., trade secret law varies dramatically and is often sub-standard. This lack of protection for innovation can prevent full engagement in the global market, which translates into fewer export-driven American jobs. Improving existing trade secret regimes through bilateral and multilateral negotiations like the Transatlantic Trade and Investment Partnership (TTIP) and Trans-Pacific Partnership (TPP) as well as through other diplomatic contacts is vital to our economic growth.

The 2011 Strategy for American Innovation

GIPC offers additional thoughts based on a contemporary look back at the 2011 Strategy for American Innovation (2011 Strategy) in light of what has happened in the three years since its issuance.

Data Protection for Biologics

In the 2011 Strategy, the Administration identified among its highest priorities to "accelerate biotechnology, nanotechnology, and advanced manufacturing." With regard to biotechnology specifically, the Administration has an opportunity through the Trans-Pacific Partnership negotiations to support advancement.

Research has shown that it takes between 12.9 and 16.2 years for innovators and investors to cover the tremendous costs of innovation in the biotechnology field.[9] Law in the United States recognizes this practical reality, and provides twelve years of data exclusivity for confidential clinical trial data related to biologic products.

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[9] See http://www.innovationfiles.org/the-healthcare-battle-you-dont-know-about-2/

In the context of the TPP negotiations, the Administration has the opportunity to obtain this same level of protection abroad with some of our most important trading partners. Unfortunately, rather than pursue this clear win, the Administration has repeatedly proposed *reducing* the needed protection in U.S. law and by delaying the introduction of the issue in the TPP negotiations for years.

GIPC urges the Administration to ensure that the final text of the TPP requires our trading partners to ensure a full twelve years of protection for biologics' data, just as U.S. law does.

Support the Intellectual Property Administrative Agencies

The 2011 Strategy mentions prominently the need for the U.S. Patent and Trademark Office to provide timely and quality service, particularly in regards to the review of patent applications. GIPC agrees wholeheartedly. It therefore urges the Administration to move forward with speed to nominate an experienced leader to serve as the new Director of the USPTO. That position has been filled on a temporary, acting basis for approximately a year and a half. The USPTO cannot be expected to do its best without proper leadership, and the continuing vacancy sends exactly the wrong signal about the importance of its role.

While permanent leadership plays a vital part in setting the tone for the USPTO's role to further American innovation, equally important is the agency's control over its own budget. While the USPTO is entirely funded by user fees, the agency does not automatically get to spend what it brings in. Historically funds have been withheld to the tune of nearly $1 billion since the early nineties, diverting them to unrelated government programs instead of enhancing U.S. competitiveness. Our innovators have a legitimate expectation that the precious dollars they pay to register their rights be used towards the examination of their assets and administration of the USPTO.

While the situation improved with recent legislation, the USPTO must go through the appropriations process annual to gain access to its own fees. The USPTO was also subjected sequestration last year, again despite having already brought in the funds to cover its operations. As a result of these challenges, the USPTO was forced to limit its activities, including by hiring fewer examiners, and limiting their training as well the tools that support the critical services they perform. This structure harms American innovators, slowing down the ability to issue essential IP and increasing uncertainty that makes it harder to invest in developing technology. The Strategy should shift this paradigm by pursing policies that would provide USPTO full control over the money it secures through the funds it collects.

GIPC also appreciates the leadership of the U.S. Copyright Office in its thoughtful consideration of copyright policy issues, and we support its efforts and desires for modernization so as to better serve businesses that produce valuable copyrighted works, businesses that help deliver those works to the public, and consumers who benefit from both. Just last week, the House Judiciary Committee held a Copyright Office oversight hearing.[10] During that hearing, there was bipartisan support for structural reforms and enhanced funding to allow the Copyright Office to do its job. GIPC urges the Administration to support these improvements and to work with Congress and the business community to advance them.

Conclusion

GIPC appreciates the opportunity to provide these comments on the role of intellectual property in fostering innovation. GIPC urges that the next update of the Strategy for American Innovation reflect the need for vibrant intellectual property systems, including vibrant intellectual property administrative agencies. GIPC stands ready to work with the Administration towards those goals.

[10] http://www.judiciary.house.gov/index.cfm/hearings?ID=95910560-FC9E-410D-BB95-C8C0A75DC5E9.

September 22, 2014

Response to Request for Information on Strategy for American Innovation from the Office of Science and Technology Policy and the National Economic Council

Submitters: Mike Rossner, Data Publication Lead; Chris Allan, Technical Lead; and Jason Swedlow, President, Glencoe Software, Inc., Seattle WA (http://glencoesoftware.com)

Background

The Open Microscopy Environment (OME) is an international consortium of biomedical research scientists that builds data management tools for multi-dimensional microscopy image data in the life sciences. All of these tools are open source and are available at http://openmicroscopy.org. In 2005, Glencoe Software, Inc. was founded as the commercialization arm of the OME to provide enterprise support for and customization of OME's resources.

We have chosen to respond to question 11 regarding the reproducibility of scientific findings. Our response reflects our conviction that this issue can be addressed in part by providing readers with access to the primary research data underlying publications, and it reflects our experience in providing this kind of access for biological image data.

Question 11: Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

The issue of the reproducibility of biomedical research has received heightened attention recently following the publication of studies by Bayer Healthcare (1) and Amgen (2) highlighting the irreproducibility of a high percentage of preclinical research reported in the peer-reviewed literature. These studies provided quantification of an issue that had long been discussed in research and publishing circles in abstract terms.

Bayer and Amgen reported on their efforts to replicate published pre-clinical research (primarily in the field of cancer biology) – the first step taken by a pharmaceutical or biotechnology company before initiating a project based on literature reports. The studies indicated that ~66% and 89%, respectively, of published studies could not be replicated.

This situation clearly represents an impediment to innovation at both the basic and applied level if researchers have to replicate ten studies to find one that might be worth pursuing. Various ways to address this problem have been discussed in the research community. Here we highlight three of them that we wholeheartedly endorse, and we believe that Federal policies can help to achieve them.

1. Improve experimental rigor. The key to promoting reproducibility is to train research students in the concepts of experimental rigor. These concepts include the use of effective controls, use of large sample sizes, replication of samples within experiments, repetition of experiments, awareness and understanding of selection bias, and the understanding and use of appropriate statistical analyses. Currently, many students are expected just to pick up these concepts from their supervisors and fellow lab members, however we believe that Federal training grants should require formal training in experimental rigor. Funds could be made available to develop standardized course materials on experimental rigor in various disciplines, and the use of these materials could be mandated to institutional recipients of Federal training grants.

2. Provide readers with access to the original data underlying publications. Access to primary research data is vital for the advancement of the scientific enterprise. In addition to promoting reproducibility by facilitating the validation of existing observations, it can provide the raw materials to build on those observations (3). In the life sciences, there are many examples of domain-specific repositories for data structured along strict, community-established guidelines, such as gene sequences, protein structural data, and gene and protein expression profiles. Federal funding was instrumental in the creation of these resources and continues to be essential for their maintenance. There are now also repositories (both not-for-profit and commercial) for unstructured data. The National Science Foundation provides vital support for the Dryad Digital Repository (http://datadryad.org), in which unstructured data can be uploaded and linked to a publication. We strongly support the continuation of Federal funding for these types of efforts.

Our expertise is in the specific domain of microscopy image data. We have worked with the scientific research community for 12 years to create a structured data format that preserves the pixel information in original image files along with all of the associated metadata about the acquisition and characteristics of images. Our database management engine allows for effective sharing of microscopy image data throughout their lifecycle of acquisition, processing, visualization, analysis, publication, and archiving.

In partnership with the *The Journal of Cell Biology* we built the JCB DataViewer (http://jcb-dataviewer.rupress.org), the first repository of original, multi-dimensional image data underlying published articles. Launched in 2008, the JCB DataViewer publishes images of gels, immunoblots, autoradiograms, and microscopy in their original formats, as they were captured by the acquisition systems. Highly complex image data can be hosted in the JCB DataViewer, such as high content screens containing up to a million images, 3D electron tomography, and very large (gigapixel) images. The JCB DataViewer is accessed by ~15,000 unique users in an average month, and user surveys indicate that the data are used for evaluating the conclusions of a specific article, generating new hypotheses for research related to a specific article, or obtaining images for educational purposes. An average of ~10 Gb of data are accessed on the site each month. (4)

Other publishers are currently developing this technology to use with their journals. Individual institutions, such as the Harvard University LINCS project (https://lincs.hms.harvard.edu/) and the Stowers Institute (http://odr.stowers.org/websimr/), use this technology to make original image data available to the public. At the Stowers Institute, the data are specifically linked to the related publication.

While these efforts are a promising start, they are currently piecemeal, and there is no centralized system for sharing multi-dimensional image data. To address this problem we support the creation of a central Federal Data Commons – a collective of data management applications for both unstructured data and structured, domain-specific data. Such a resource has already been proposed by Phil Bourne for data resulting from NIH-funded research and more broadly by Mike Stebbins of the OSTP for data resulting from funding by any Federal agency. The data in the Data Commons will be universally available to all research scientists to fuel innovation through data sharing.

3. Mandate public access to data underlying publications, and enforce those mandates. In the OSTP Public Access Memorandum from February, 2013, Federal agencies that fund research were asked to develop policies to provide "Public Access to Scientific Data in Digital Formats" (5). The types of data that should be publicly available were defined in the memo, which specifically mentioned "data sets used to support scholarly publications". We believe that such access should be mandated by each agency to every funding recipient. Failure to comply with these mandates should result in refusal to renew funding. Deposition can be monitored using unique identifiers (such as a Digital Object Identifiers) deposited in central databases to locate data deposited anywhere. The identifiers should be included in publications to directly link them to the deposited data.

Scientific journals (and the research communities they represent) often lead the way in requiring access to underlying data before funding agencies make the same requirement. Nearly 25 years ago, journals started requiring the deposition of gene and protein sequences and protein structures in publicly accessible databases. Recently, the Public Library of Science instituted a policy that "authors must make all data publicly available, without restriction, immediately upon publication of the article." (6) We hope the Federal agencies that fund research will follow suit shortly.

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GBSI Global Biological Standards Institute®

Advancing Life Science Standards®

September 22, 2014

Comments submitted via: *http://www.regulations.gov*
(Response to Federal Register Document Number 2014-17761)

To: Office of Science and Technology Policy (OSTP) and National Economic Council (NEC)

Subject: **Update to *Strategy for American Innovation***

The Global Biological Standards Institute (GBSI) is solely dedicated to enhancing the quality and reproducibility of biomedical research by advocating best practices and standards to accelerate the translation of preclinical research breakthroughs into life-saving therapies. GBSI, a non-profit organization, provides a global, independent forum for government, industry, academia and other stakeholders to increase awareness and use best practices and standards throughout the scientific research process. For more information about GBSI, please see www.gbsi.org.

A. Summary of GBSI Comments

GBSI appreciates the opportunity to provide information for an updated *Strategy for American Innovation*. GBSI's comments are limited to one question posed in the Request for Information: "(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?"

This question relates directly to GBSI's core mission of reducing wasteful irreproducibility in scientific research, which costs the U.S. billions of dollars per year.[1] On October 1, 2013, GBSI sponsored a conference with the Massachusetts Institute of Technology's Center for Biological Innovation to explore irreproducibility in life sciences research. http://www.gbsi.org/mit. In December 2013, GBSI published a comprehensive paper examining the problem specifically in the area of preclinical life sciences research. See http://www.gbsi.org/CaseForStandards. The report identified greater implementation of standards as the principal means for addressing the irreproducibility problem within the preclinical life science industry.

The Federal Government, in its capacity as funder of scientific research, can play a very substantial role in addressing the irreproducibility problem by doing at least two things:

- First, it should condition funding on use by grantees of commonly accepted standards; and,
- Second, it should promote greater education among scientific researchers on use of best practices and standards.

GBSI discusses both of these recommendations below in the context of preclinical life science research, an area with a substantial irreproducibility problem.

B. The Federal Government Should Condition Initial And Continued Receipt Of Grants On Use By Grantees of Voluntary Consensus Based Standards

Commonly agreed to best practices and consensus-based standards are used widely in many industries, for example, clinical stage life sciences research, food manufacturing, and

[1] Freedman, Gerstein, Rosenfield, Cockburn, and Simcoe,"The Economics of Reproducibility in Preclinical Research," (forthcoming GBSI publication).

communications technology. Formulation, implementation, and widespread use of commonly accepted standards create efficiencies.

In preclinical life sciences, greater use of standards will enable more efficient use of ever scarcer early stage research funding. It will also spur more rapid development of safe and effective drugs and other therapeutics to market, giving the industry a competitive advantage over others outside the U.S. that do not adhere to a comprehensive common set of research standards.

As relevant consensus-based standards are created and adopted, GBSI strongly recommends that the Federal Government, the largest single funder of preclinical life sciences research, condition use of such standards on initial and continued receipt of Federal Government funds. GBSI emphasizes that adoption of standards should, as the Federal Government recognizes, evolve primarily from practitioners who will use such standards.[2] In conditioning research funding, the Federal Government can utilize the concept of "voluntary consensus based standards" and other relevant guidelines from OMB's Circular A-119.

In the subsection that immediately follows, GBSI provides an example from the preclinical life sciences industry of a particular voluntary consensus based standard that may be utilized by the Federal Government in its role as funder. Thereafter, GBSI provides a case study

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[2] The Office of Management and Budget recently completed a request for comment on revisions to Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," 79 Fed. Reg. 8207 (Feb. 11, 2014). As directed in The National Technology Transfer and Advancement Act of 1995, Public Law 104-113, the Federal Government must "use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities," except if inconsistent with law or impractical. GBSI submitted comments to OMB to enhance the effectiveness of Circular A-119 in promoting development and adoption of voluntary consensus standards. GBSI, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," posted May 12, 2014 (OMB-2014-0001-0012), available at http://www.regulations.gov/#!documentDetail;D=OMB-2014-0001-0012.

from the non-profit charitable sector of a preclinical life sciences funder that has begun to condition award and re-award of grant funds on use by grantees of this standard.

1. Toward Comprehensive Standard Operating Procedures For Scientific Research

Comprehensive standard operating procedures (SOPs) will be the most effective way to remedy the irreproducibility problem. However, such research cycle SOPs will take a long period of time and the efforts of many to develop and implement. In the preclinical life sciences industry, such comprehensive SOPs, do not yet exist.[3]

In the interim, the Federal Government should leverage its role as funder to require grantees to utilize particular, available, widely accepted promulgated standards. One such standard in preclinical life sciences is ASN-0002, Authentication of Human Cell Lines: Standardization of STR Profiling. The standard, available through the American National Standards Institute (ANSI), was developed by the American Type Culture Collection (ATCC), a non-profit organization founded in 1925 to serve as a storage and distribution center for biological materials.[4] More information about this particular standard is available through review of "ATCC Releases American National Standard on Identification of Human Cell Lines Significant Benefits to key Areas of Biomedical Research Expected," published in ANSI News and Publications (June 5, 2012), available at http://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=3264,

[3] One significant example of a standard currently under development is the National Institute of Standards and Technology's effort to develop one or more assays, or tests, to measure development potential of stem cells. For more information, please see http://stemcellassays.com/2014/08/nist-set-quality-control-assays-standards-stem-cells/.
[4] ATCC is a parent organization of GBSI.

and Yvonne Reid et al., "Authentication of Human Cell Lines by STR DNA Profiling Analysis," published in Assay Guidance Manual (May 1, 2013), available at http://www.ncbi.nlm.nih.gov/books/NBK144066/.

This standard provides a means for identifying and authenticating human cell lines through DNA profiling. Human cancer cell lines originate from an individual person. The original cells are then cloned, reproduced, and transferred among scientific researchers. This process can result in contamination, misidentification, and other research vulnerabilities. Use of the ASN-0002 standard allows a researcher to ensure and document that the particular cell line received is an authentic and uncontaminated copy of the original.

2. Case Study: How The Prostate Cancer Foundation Leverages Its Role As Funder To Tackle Irreproducibility

In cancer research, human cancer cell lines are used to study the biology of cancer cells and to test cancer drugs and other therapeutics. Misidentified and contaminated cell lines present significant problems for early stage cancer research and are a well-known cause of irreproducibility. Misidentified cell lines are lines that have been contaminated and taken over by cells of other origin or species, or have simply been mistakenly characterized from the start. For example, cancer cell lines thought by researchers to be breast tumor in origin have, upon analysis, turned out to be lung cancer cells, or in many cases contain multiple cell origins. Contaminated cancer cell lines contain bacteria, viruses, or other substances that can create error or invalidate the conclusions drawn from research conducted with those contaminated cell lines. In either case, misidentified or contaminated cell lines may materially affect the results of research such that testing the efficacy of a particular drug or therapy using a misidentified or contaminated cancer cell line can lead to potentially erroneous results.

The Prostate Cancer Foundation (PCF), www.pcf.org, a non-profit organization that provides grants to prostate cancer researchers in furtherance of its mission, has undertaken a program to address the misidentification/contamination problem in prostate cancer cell lines. Through its Prostate Cancer Cell Line Authentication Initiative, PCF is funding STR (short-tandem repeat) profiling and testing using another technology called PCR (polymerase chain reaction) of all prostate cancer cell lines currently used by its scientific researcher grantees, and is requiring all grantees to use only cell lines that have been demonstrably authenticated for use in research using PCF grant funds. The goal of the PCF Initiative is to produce greater reproducibility among research results by eliminating the misidentification and contamination variables. For more information about the Initiative, please see http://www.pcf.org/site/c.leJRIROrEpH/b.8846593/k.2D20/20th_Annual_PCF_Scientific_Retreat__Cell_Line_Authentication.htm and http://www.pcf.org/site/c.leJRIROrEpH/b.8851951/k.BEB2/Howard_Soule_PhD_Best_Practices_in_Cell_Line_Authentication.htm. The GBSI Task Force on Cell Authentication and Standards will be issuing recommendations on this topic at the GBSI BioPolicy Summit on November 13, 2014 (For more information, please see http://www.gbsi.org/2014BiopolicySummit).

GBSI believes that the Federal Government should closely examine the example of the Prostate Cancer Foundation and use it as a model to develop its own initiatives requiring grantees to perform funded research according to particular consensus based standards. Federal Government agencies that fund scientific research should seek out this and similar standards, and condition grant funding (both initial and supplemental) on adherence by grantees to conduct funded research utilizing these standards. OSTP and NEC should recommend that Federal

Government funding agencies utilize their leverage to condition grants on adherence to such standards.

C. <u>The Federal Government Should Foster Best Practices Training And Credentialing Programs</u>

Education of the U.S. scientific workforce in best laboratory practices, including use of voluntary consensus based standards, also plays a central role in reducing irreproducibility. Currently, there is not a lot in terms of a standard curriculum for best preclinical laboratory research practices in the United States. Rather, such laboratory practices are typically learned by young researchers through employment or other affiliation with particular laboratories headed by more senior researchers.

National development of standardized curricula that teach best laboratory practices within industries should be a Federal Government funding priority. One very recent example of appropriate focus on education as a means for tackling the irreproducibility problem comes from the Federal Government itself. The National Institutes of Health Research Education Program has announced that it is initiating a program of grants to develop exportable training modules in areas of biomedical science that can benefit from enhanced data reproducibility. Such modules, to be developed around particular stages of the preclinical life sciences research process, are intended for wide dissemination to researchers. http://grants.nih.gov/grants/guide/rfa-files/RFA-GM-15-006.html.

GBSI strongly supports this effort and believes that more is needed in this area from the Federal Government. In the forthcoming iteration of *Strategy for American Innovation*, OSTP and NEC should call for greater focus on development of best practices training throughout scientific industries experiencing irreproducibility problems, and the Federal Government should fund development of training programs to implement use of voluntary consensus based standards and other best practices among scientific researchers in those industries.

D. <u>Conclusion</u>

So that the updated *Strategy for American Innovation* most effectively recommends ways in which the Federal Government in its role as funder of research can address the irreproducibility problem in scientific research, GBSI urges adoption of its recommendations set forth in this letter. GBSI would be happy to further discuss its recommendations with OSTP and NEC if such would be helpful.

Respectfully submitted,

GLOBAL BIOLOGICAL STANDARDS INSTITUTE

By: ______________________________________
Leonard Freedman, Ph. D., President

AAU *Association of American Universities*
APLU *Association of Public and Land-grant Universities*
ACE *American Council on Education*
AUTM *Association of University Technology Managers*
AAMC *Association of American Medical Colleges*
COGR *Council on Governmental Relations*

MEMORANDUM

September 23, 2014

TO: **Office of Science and Technology Policy**

FROM: **Association of American Universities**
Contact: Tobin Smith, [redacted] (202) [redacted]

Association of Public and Land-grant Universities
Contact: James Woodell, [redacted] (202) [redacted]

American Council on Education
Contact: Ada Meloy, [redacted] (202) [redacted]

Association of University Technology Managers
Contact: David Winwood, [redacted] (225) [redacted]

Association of American Medical Colleges
Contact: Steve Heinig, [redacted] (202) [redacted]

Council on Governmental Relations
Contact: Robert Hardy, [redacted] (202) [redacted]

On behalf of the research universities, affiliated research institutions, medical colleges, and the higher education community represented by our associations, we appreciate the opportunity to respond to the Office of Science and Technology Policy (OSTP) and National Economic Council, Notice of Request for Information (RFI) on the Administration's Strategy for American Innovation. Recognizing that innovation is a leading driver of economic and national security, we commend the Administration for continuing to advance and revise a Strategy on American Innovation. We also believe it is important to outline a macro strategy to help unite the efforts of the federal government, states, industry, and academia.

We support the Administration's Innovation Strategy and recognize the critical role of university research in the strategy. We share the goal of facilitating the commercialization of research performed at our universities to promote innovation and entrepreneurship. We appreciate the ongoing dialogue that we have had with the OSTP officials about these matters, and view the RFI as another step in the process.

Our associations previously submitted comments, as invited by the Department of Commerce, for the RFI on the Strategy for American Innovation in May 2010. We highlighted the importance of maintaining the Bayh-Dole Act; the challenges and barriers to commercialization, including finding resources to support commercialization by universities; our support for Administration initiatives underway; and additional specific policy and funding recommendations such as modifying the research and development tax credit and providing supplemental grants to support the translation of research with a high potential for commercialization. We are pleased to see the Administration incorporate some of the suggestions from our response in May 2010, and again are submitting comments to help address issues and questions raised in the RFI.

Our collective response to selected questions posed in the RFI is included in the attached.

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Joint Response to OSTP RFI for Strategy for American Innovation

Overarching Questions

1) ***What specific policies or initiatives should the Administration consider prioritizing in the next version of the Strategy for American Innovation?***
2) ***What are the biggest challenges to, and opportunities for, innovation in the United States?***
3) ***What specific actions can the Federal Government take to build and sustain U.S. strengths?***
4) ***How can the Federal Government augment its overall capacity for analysis of both the forces that determine the competitiveness of specific sectors and the impact of Federal policies?***
5) ***What innovation practices and policies have other countries adopted that deserve further consideration in the United States?***

The top priority for the next version of the American Innovation Strategy should be increasing the productivity of our national science and technology enterprise, including basic research conducted at universities. Innovation relies heavily on well-educated and trained people who are scientists, engineers, entrepreneurs, educators, creative thinkers, and leaders in universities, industry, and government, and leaders in their laboratories. This is critical if the United States is to compete successfully, prosper, and ensure its economic and national security in the 21st century. To meet that commitment, the Federal Government must set and meet investment targets that provide for steady and sustained real growth in funding for all of the major Federal research agencies that support basic research, including: NIH, NSF, the Departments of Agriculture, Defense and Energy, NASA, NIST, and NOAA.

Our many member organizations favor thinking positively and expansively about a research ecosystem that lends itself more easily to innovation. Unfortunately, the nation's ability to make sound and sustained investments in fundamental research has been hampered by sequestration and unrealistic caps on discretionary spending imposed by the Budget Control Act (BCA). Indeed, we view sequestration as the greatest threat to future U.S. innovation. As recently noted by the American Academy of Arts and Sciences, "there is a deficit between what America is investing and what it should be investing to remain competitive, not only in research but in innovation and job creation."[1] This growing "innovation deficit" undermines future U.S.

[1] American Academy of Arts and Sciences, 2014. *Restoring the Foundation: The Vital Role of Research in Preserving the American Dream*, p. 12.

economic growth and harms our nation's overall fiscal health, worsening long-term budget deficits and debt.

While federal research funding has stagnated due to our dysfunctional budget process, countries such as China, South Korea, and Singapore are far outpacing the U.S. in their annual percentage growth of research and development funding. And as nations around the world aggressively seek to prepare their citizens to take on the global workforce challenges of the 21st century, our nation is falling behind. To maintain our competitive edge, the U.S. must invest in research and offer access to higher education to all who seek it.[2]

Innovation Trends

6) How has the nature of the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?

The view that innovation occurs in a linear fashion—basic research leads to applied research, which leads to development—has always been overly simplistic and is no longer viewed as the model upon which U.S. science and innovation policy should be based. The innovation process is much more dynamic and interactive. New fundamental research needs are often driven and informed by later stages of research and development (the same bi-directional feedback is also true in medical research, as advances in clinical and population health research often contribute to discoveries in fundamental biomedical research). New government mechanisms are needed to encourage, incent and support university-industry collaborations. Programs such as the National Network for Manufacturing Innovation (NNMI) and the Semiconductor Technology Advanced Research network (STARnet) are important models that the administration should expand and try to replicate in other industrial sectors.

Unfortunately, there are some instances where recently implemented agency policies have increased administrative burdens on institutions and faculty without a proven commensurate benefit to the public or to the research enterprise. Such rules could discourage productive university-industry collaboration. One example is the Public Health Service's (PHS) financial conflict of interest (FCOI) rule. These regulations, which expanded previous rules in place since 1995, imposed new obligations on institutions and lowered the threshold for financial interests that must be disclosed to institutions by investigators. In response to these new requirements, institutions have made substantial modifications to their conflict of interest policies and processes. By increasing the amount of information reviewed by institutions, as opposed to focusing upon if and how universities are actually managing these conflicts to ensure the promotion of ethical and principled partnerships, the FCOI rule has added to faculty burden and cost universities significant resources to implement without knowing whether such increased burden would be justified by resulting in any noticeable increase in the number of problematic FCOI cases avoided or properly managed. We would encourage the Administration to closely reexamine the PHS FCOI rule to evaluate and assess both its effectiveness, costs and adverse

[2] See: http://www.innovationdeficit.org/.

impacts on entrepreneurial activities as has already been suggested by the National Science Board in its March 2014 report titled *Reducing Investigators' Administrative Workload for Federally Funded Research*.[3] We note that the AAMC is engaged in a 4-year data collection project to assess the financial impact of this specific regulation and has been in discussions with NIH about how this data could be useful to the PHS in conducting this type of review.[4]

It is also worth noting that industries' willingness to make investments in basic and applied research has been declining. More and more, industry R&D money is devoted to development work. The result is increasing pressure on university and Federal laboratories to undertake more applied research. Venture capitalists have also decreased their investments in high risk research. The government will have to promote policies and new funding mechanisms that support expanded fundamental research at universities, Federal laboratories, and private non-profit research institutes to fill the void.

8) What are important needs or opportunities for institutional innovation and what steps can the Federal Government take to support these innovations?

So that new ideas and technologies developed with Federal research funding can be translated into the marketplace and for public good, the Federal Government must work with universities, federal laboratories and non-profit research organizations to develop and support new and innovative translational research, technology transfer, and commercialization programs. While there has been significant interest in increasing such activities at universities, one of the major challenges is that funds often do not exist to support such activities. That said, we see innovative new Federal programs such as Innovation Corps (I-Corps), the i6 Challenge and the NIH Research Evaluation and Commercialization Hub (REACH) program as positive developments in this area. NIH and NSF should also be commended for their recent collaboration on I-Corps, and the NIH's willingness to base such a program, with credit, on the experience of a sister agency; the willingness of agencies to collaborate and learn from each other is in itself a valuable response to funding constraints. We would encourage further exploration of how Federal agency programs like these can help in accelerating innovation and technology transfer. In particular, proof of concept funding programs, as discussed further below (item #15), have the potential to vastly accelerate innovation and commercialization.

[3] National Science Board, 2014. *Reducing Investigator's Administrative Workload for Federally Funded Research*, pp. 14-15. Available online: http://www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf.

[4] For more information, see: https://www.aamc.org/metricsproject.

<u>Science, Technology, and R&D Priorities</u>

10) Where are there gaps in the Federal Government's science, technology, and innovation portfolios with respect to important national challenges and what are the appropriate investment and R&D models through which these gaps might be addressed?

While our associations do not emphasize any specific gaps in current funding for science and technology, we believe it is timely to reiterate the vital role that the social and behavioral sciences – anthropology, economics, political science, psychology, linguistics, sociology, among others – combined with advances in other areas of science will play in addressing the nation's most pressing challenges in areas such as national security, education, commerce, health, energy, crime and public safety, and transportation. We are concerned about actions indicating that some in Congress seek to relegate such research to a second-class status in federal research funding by imposing restrictions on it, or worse, barring federal funding of such research entirely. With this in mind, we encourage the Administration to continue to support these important fields of scientific research and to recognize the critical role that they must play if the Administration's National Innovation Strategy is to be successful.

11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

The science community, including NIH, NSF, and other funding agencies, is intensely focused on gauging the extent of this problem and developing measures to improve the reproducibility, quality, and reliability of experimental findings. The NIH has initiated a review at its highest level, and among other actions, convened a working group of scientific publishers who have agreed to take further responsibility for the reproducibility of findings published in their respective journals. The NIH has made significant progress in analyzing the problem, at least in the biomedical sciences. The NIH has concluded that the most problematic results lie with preclinical studies, particularly with animals, and much less with human subjects research, where experimental designs and procedures are more amply documented and reviewed. This conclusion resonates with the widely publicized concerns of the pharmaceutical industry. Problems also arise from the increasing sophistication and complexity of science, including the sensitivity of instrumentation, reliance on highly refined or specialized resources, such as genetically engineered animal models, and on new and variable capabilities in computer modeling, statistical analyses, and programming.

We believe the Federal Government currently has the complement of tools and policies to address these concerns effectively. These include a strong peer review and oversight apparatus at all key funding agencies, a broad diversity among institutions and scientists performing research, extensive training programs, and an ethos promoting independent inquiry and competition. In recent years, policies have also been strengthened to promote sharing of data within the scientific community, public access to published results of Federally sponsored research, and expedited translation of results into commercial application (a process in which findings are also rigorously examined). The community is also developing best practices for documenting the statistical and other programs used in analyzing complex datasets. We believe that we can strengthen the reliability and quality of research findings by further strengthening these processes, and by targeted efforts on areas, like enhanced training or review of research design in preclinical trials. Our associations are concerned that major regulation or legislation to address reproducibility would further stress the enterprise, while not being as effective in tailoring reforms to variations among disciplines or modes of research.

Skilled Workforce Development

12) What novel mechanisms or models might facilitate matching skilled STEM workers with employers and helping individuals identify what additional skills they may need to transition successfully to new roles?

The best mechanism for matching skilled STEM workers to employers is effective partnerships between universities and industry. New approaches to such partnerships are emerging and attracting the attention of business and higher education leaders alike. The Business-Higher Education Forum, for example, is working with the Association of Public and Land-grant Universities (APLU) and others to foster the development of strategic relationships between university and industry partners in a number of regions across the U.S., each partnership focused on a critical area of STEM workforce needs, such as cybersecurity, data analytics, or financial services. These partnerships are established based on clear and reliable labor market needs analyses. A complete, evidence-based understanding of labor market needs is an important starting point.

Universities and industry partners must go beyond such needs analyses, however, to design the most appropriate programs to engage students in learning about and connecting to career opportunities. While curricular approaches are often appropriate, some areas of STEM skills development are so rapidly changing that it is difficult to design curriculum to meet these needs. Universities—working in partnership with industry—can and should develop, design, and implement new kinds of agile programs to complement credit-bearing curricula.

The development of non-STEM-specific skills and capabilities is important to the success of STEM graduates in the labor force. University-industry partnerships must recognize the importance of creativity and innovation, critical thinking, communication, problem-solving and other "21st century skills"—and the link between these skills and non-STEM curriculum in the arts, humanities, and social sciences. Professional Science Master's (PSM) degree programs, currently being developed and implemented by many of our member institutions, are one example of an approach that includes both STEM curriculum and development of workplace skills. The service professions, for example in health care, social work, and environmental science, are similarly developing innovative educational degree programs and curricula amplifying on STEM skills and content.

14) What mechanisms or programs can effectively increase the supply of workers with technical training, from industry-recognized credentials and postsecondary certificates to two- and four-year degrees?

Community colleges are employing a number of approaches to supply industry with technically skilled workers. Many colleges are creating stackable credentials, which award students with industry-valued certificates on the way to earning a degree. This approach is central to career pathways, which provide workers with a structured sequence of courses and services that allow them to move seamlessly between work and further education and training, which is essential in rapidly evolving technical fields. Community colleges are working with businesses and industry associations to incorporate industry certifications directly into curricula, so that successful students will earn both a credential from their institution and one or more certifications during the course of their studies.

Many of these approaches are featured in the new Workforce Innovation and Opportunity Act, which reauthorizes several of the key Federal job training programs. For the last decade, the Federal Government has directly supported the expansion of innovative job training programs at community colleges, first through the Community-Based Job Training Grants and subsequently through the Trade Adjustment Assistance Community College to Career Training (TAACCCT) grants. 2014 marks the final year of the TAACCCT grant program. Continued, dedicated support for community college workforce development programs, as proposed by the administration in the Community College to Career Fund, is vital to producing skilled workers. The Carl D. Perkins Career and Technical Education Act also remains a vital source of support for these programs.

Congress and the administration should continue to explore ways to modify the student aid programs so that they are not impediments to providing workers with the training they need. Competency-based programs, shorter-term certificate programs, and aid for current baccalaureate degree holders seeking additional training are some of the areas where targeted innovations would likely yield positive results. It would also be beneficiation to increase focus on quantitative and scientific literacy, plus the basic skills businesses say they need that can be enhanced in academic programs: communication skills, problem solving, and teamwork. Promoting defined career ladders in emerging technologies with outreach to middle and high schools would supplement the outreach made for the STEM fields. Expansion of the apprenticeship model to more industries, and support for internships allowing practical experience, would also be mechanisms to increase the supply of qualified workers, ready to produce from day one.

Manufacturing and Entrepreneurship

15) What new or existing investment models should be explored to support entrepreneurship in new geographies, as well as in technologies and sectors that are capital-intensive, relatively high-risk and require sustained investment over long periods of time?

Public policy and public expectations have increasingly emphasized the need to move university basic research discoveries into the commercial marketplace. Bridging this gap, often referred to as the "valley of death," is a critical need. To tackle this problem, Federal research agencies have focused on developing new translational research programs. While such programs can play a supporting role in transferring research into the marketplace, effective tech transfer and commercialization require more than translational research. A central barrier to effective transfer and commercialization is the fact that researchers and universities do not have resources available to support the proof of concept work, market analysis, and mentoring needed to translate these ideas from the university laboratory into commercial products.

Our associations encourage the administration to support the creation of a new multi-agency program focused on funding earlier stage proof of concept research across research agencies and scientific disciplines. One might think of such a program as a SBIR "phase zero" program. A program like this would help more projects cross the "valley of death," and also aid in enhancing the infrastructure (e.g., expertise, personnel) and facilitating the cultural change necessary for universities to better support this kind of transfer. The NIH has recently developed the Research Evaluation and Commercialization Hub (REACH, noted above) program to address this need. We are hopeful that this program model can be expanded at NIH and adopted by other federal research agencies in the future. Another non-federal program we would point towards as a successful model is the Wallace H. Coulter Foundation Translational Research Partnerships awards in Biomedical Engineering.[5]

18) What investments, strategies, or technological advancements, across both the public and private sectors, are needed to rebuild the U.S. ''industrial commons'' and ensure the latest technologies can be produced here?

A number of promising initiatives for rebuilding the U.S. industrial commons are already underway. The Administration's vision for a set of regional manufacturing innovation institutes holds the promise to help close the divide between research and commercial application of advanced manufacturing technologies by bringing researchers and industry personnel together at these institutes. The Revitalize American Manufacturing Innovation (RAMI) Act, currently being considered by the Congress, supports the establishment of the Administration's proposal to create a national network for manufacturing innovation (NNMI). Approval and of this legislation and subsequent Congressional appropriations are critically important to scale NNMI to the level which has been proposed by the Administration. A piecemeal approach will not move quickly enough to ensure the rapid technological advancements necessary to sustain the competitiveness of the U.S. manufacturing industry.

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[5] See: www.whcf.org/partnership-award/overview.

It is important that the Administration continue to support the Hollings Manufacturing Extension Partnership as well. This program provides important technical assistance to manufacturers as they adapt to the new technologies and business models of advanced manufacturing. The program is important for small- and medium-sized manufacturers, which employ a significant portion of the American manufacturing workforce.

Regional Innovation Ecosystems

19) What partnerships or novel models for collaboration between the Federal Government and regions should the Administration consider in order to promote innovation and the development of regional innovation ecosystems?

The i6 Challenge from the Economic Development Administration (EDA) is a good example of how the Federal Government can foster regional innovation ecosystems. The program is modeled after successful university strategies—specifically the MIT Deshpande Center for Technological Innovation and the von Liebig Center at the University of California San Diego—that focus on proof of concept work as central to success in regional innovation and entrepreneurship. Other sections of this response address the critical need for support of proof of concept programs. Programs supported by i6 increase and deepen partnerships between institutions of higher education, industry partners, and economic developers, helping to establish the innovation networks that form the backbone of regional innovation ecosystems.

Universities and other higher education institutions frequently play a convening role for such networks. They bring core assets and innovation economy infrastructure—from labs to classrooms—and help to build connections between and among other innovation network nodes. One example of this dynamic comes in the form of what the National Governors Association has called "institutes for collaboration"—facilities that house assets from multiple universities and industry partners in the same physical space and have a catalytic effect on not only technology development but also stimulation of innovation networks. Examples of such institutes for collaboration include the Commonwealth Center for Advanced Manufacturing (C-CAM) in Virginia, Clemson University International Center for Automotive Research (CU-ICAR) in South Carolina, California Institute for Quantitative Biosciences (QB3) in California, and Oregon Nanosciences and Microtechnologies Institute (ONAMI) in Oregon. The Administration's vision for manufacturing institutes is essentially an "institutes for collaboration" strategy, and this approach can and should be extended across industry sectors and beyond manufacturing.

20) How should the Federal Government promote the development of metropolitan ''innovation districts,'' where large research institutions, companies, start-ups, and business accelerators congregate to facilitate the knowledge flows that sustain innovation?

As described in the recent Brookings report, *The Rise of Innovation Districts*, regional innovation ecosystems are "synergistic relationship[s] between people, firms, and place (the physical geography of the district) that facilitates idea generation and commercialization." The report further points out that while economic and physical assets are important, networking assets are at least as critical, and that an important step in creating innovation districts is to build a collaborative leadership network. The Federal Government should consider policy models focused on fostering the leadership networks without which the other critical elements cannot and will not fall into place.

Policy models that support institutes for collaboration, as described above, could be central to innovation district strategies. Programs that require collaboration between universities and industry, and involvement of economic developers, could help. Policy strategies to promote innovation districts and measure their success should include the extent to which a network has been established and whether the network has undertaken new efforts. If policies focus only on the intended outputs and outcomes of such networks and do not also value the networks and interactions themselves as important inputs needed to reach intended outcomes, it will be difficult to achieve success in policy implementation.

Intellectual Property/Antitrust

21) What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation?

New models of innovation will directly impact business transactions in the commercial sector. Universities will contribute substantially to some of these models, such as open innovation, through the production and dissemination of new knowledge. This university contribution will be enhanced by the ongoing implementation of the thoughtful OSTP public access policy promulgated in OSTP Director Holdren's February 22, 2013 memorandum.

As previously noted, a critical component of university contributions to the nation's innovative capacity is the continuation of a strong patent system. Since the passage of the Bayh-Dole Act in 1980, there has been a remarkable increase in patents and licenses resulting from university research in a wide range of fields. University associations agree that the current legal framework for university technology commercialization, as set forth by the Bayh-Dole Act of 1980 and implementing regulations, continues to be effective and needs to be maintained. Patents play a key role in the transfer of inventions resulting from university research into the marketplace for development

Unfortunately, in recent years, legitimate patent holders across the spectrum, including universities and their licensees, have been victimized by abusive practices that impair the ability of the U.S. patent system to foster innovation and economic competitiveness. We caution, however, that any proposals targeting abusive practices must be structured so that they curb abuses without undermining the ability of legitimate patent holders to enforce their patents and, by extension, diminishing the value of patents.

Another critical component of the U.S. patent system facilitating university contributions to the nation's innovative capacity has been an effective grace period. The grace period in effect prior to the enactment of the America Invents Act (AIA) supported the university mission of early, broad dissemination of research results, providing up to one year after the disclosure of an invention to file for a patent on that invention. Unfortunately, the AIA grace period is fatally flawed, discouraging early disclosure of patentable discoveries. A statutory fix to the AIA grace period will encourage early, broad disclosure of research results, benefiting innovation in a manner comparable to OSTP's public access policy noted above.

Finally, the *Guidance Memorandum for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products* http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf issued by the Patent and Trademark Office (PTO) in March has led to serious concerns in the patent community about PTO's very broad interpretation of recent Supreme Court precedents. This could have a substantial adverse effect on innovation. We believe that far more public input and deliberation is necessary before the promulgation of final guidance that significantly reduces the ability to patent discoveries and inventions related to natural products.

Novel Governmental Tools For Promoting Innovation

22) What are specific areas where a greater capacity for experimentation in law, policy, and regulation at the Federal level is likely to have large benefits?

We urge the administration to closely consider how Federal regulations and reporting pertaining to the research can be streamlined, harmonized and in some instances, outright eliminated to improve the efficiency with which innovation occurs by reducing investigator administrative burden, decreasing costs yet still ensuring adequate accountability. AAU, COGR and APLU have recently worked together to develop a listing of major research regulations and reporting requirements that should be targeted for reform. Many of our recommendations are similar to those released in March of this year by the National Science Board.[6] Even after two previous presidential orders calling for regulatory reforms, we have seen little action by the Administration to reform research related regulations. In fact, many would argue that the development of recent agency policies—such as the PHS FCOI—have further burdened the research enterprise by levying additional requirements and costs on both researchers and research institutions.[7]

We therefore call upon OSTP to establish an ongoing process for reviewing and assessing regulations that could be streamlined, harmonized or eliminated.

[6] National Science Board, 2014. *Reducing Investigator's Administrative Workload for Federally Funded Research*. Available online: http://www.nsf.gov/pubs/2014/nsb1418/nsb1418.pdf

[7] Smith, T. L., Trapani, J., DeCrappeo, A., & Kennedy, D., 2011. Reforming Regulation of Research Universities. Issues in Science and Technology, 27:4. Available online: http://issues.org/27-4/smith-5/

23) ***Beyond current Federal efforts to promote open data and open application programming interfaces (APIs), what other opportunities exist to open up access to Federal assets (such as data, tools, equipment, facilities, and intellectual property from Federally funded research) in order to spark private sector innovation?***

As noted in the response to question #21, the Administration's public access policy and new open innovation models will facilitate private sector innovation through greater access to Federal assets and the results of Federally funded research.

Another opportunity to facilitate greater access is to enhance the functionality and usability of Federal databases such as the invention data reported in the *i*-Edison system maintained by the National Institutes of Health. This database currently has limited access and searchability, and the reporting requirement tends to be viewed as a compliance obligation rather than marketing opportunity. The database also has limited dedicated resources. Uniform search tools that can interface with multiple technology databases both Federal and elsewhere such as the Association of University Technology Managers (AUTM) Global Technology Portal and Licensing Survey are lacking, and there is no common taxonomy of search terms. Development of tools that can link potential users with a wide range of Federal and non-Federal data and information and allocation of more resources to develop and maintain such capabilities would enhance access and private sector utilization.

Additional opportunities to broaden access might be possible through the modification of the current rules and policies that govern access to Federally funded property and equipment. Current and prospective rules discourage use of Federally funded property and equipment for non-Federal purposes (2CFR215.32; OMB Uniform Guidance 200.313(c)). They also prohibit use of equipment to provide services at less than commercial rates for equivalent services (2CFR215.34(b); Uniform Guidance 200.313(c)(3)). While not an unreasonable requirement, implementation has proved contentious, leading to confusion and disputes. Greater clarity and less prohibitive rules would encourage greater use of and access to these assets.

Similarly, the IRS "private business use" rules (Rev. Proc. 2007—47) that govern use of facilities financed by tax exempt bonds have led to considerable misunderstanding, and have had a negative impact on the ability of universities to enter into research agreements with the private sector. Of most concern is the requirement that commercial use of resulting technology by the industry sponsor is permitted only on the same terms as non-sponsors (i.e. at competitive prices), and the price must be determined at the time the technology is available for use or license. An additional impediment is created by the 1986 Tax Code requirement that limits private business use to 10% of bond-financed facilities for public institutions, and 5% for private 501(c)(3) institutions. These rules restrict the ability of the private sector to collaborate and form partnerships with Federally funded research institutions.

National Priorities

24) Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?

We believe that the Federal investment in basic research is the most important national priority to include in the American Innovation Strategy due to the unique role the Federal Government plays as the primary sponsor of basic research. Industry, philanthropic gifts, and university funded basic research are not a substitute for the Federal investment. The need for near-term technological advances, along with aversion to assuming significant investment risks for unforeseen outcomes, will continue to prevent substantial industry investments in basic research. While philanthropic gifts and university funding directed at basic research have increased in recent years, they are typically targeted for specific purposes and the investments remain relatively small. As such, they cannot make up for the Federal Government's investment. The Federal Government is the primary funder of basic research because such investment serves the public good and the short- and long-term interests of our nation. Only the Federal Government can make such large-scale investments with long time horizons and uncertain returns.

The American Innovation Strategy should support basic research funding increases. Increased investments should be made without the offsets that would force detrimental tradeoffs between one field of science and another. To ensure our national competitiveness, we need to maintain a strong foundation of basic research across all scientific disciplines, from the physical, mathematical, and life sciences, to engineering and the social, economic and behavioral sciences. Additionally, within the context of strong Federal investments in basic research, it is important to ensure that Federal scientific agencies, guided by their scientific advisory committees and boards, continue to set priorities for funding within and among the full range of scientific disciplines. This principle has served the nation well for decades.

Human Factors and Ergonomics Society

September 23, 2014

Human Factors and Ergonomics Society Response to *Strategy for American Innovation*

The Human Factors and Ergonomics Society (HFES) supports the Administration's effort to solicit stakeholder input in updating the *Strategy for American Innovation*. The Society thanks the Office of Science and Technology Policy (OSTP) and National Economic Council (NEC) for the opportunity to comment. HFES is a multidisciplinary professional association with 4,500 individual members worldwide, including psychologists and other scientists, engineers, and designers, all with a common interest in creating safe and effective products, equipment, and systems that maximize and are adapted to human capabilities.

In response to OSTP and NEC's overarching question as to which policies or initiatives should be considered in the next version of the *Strategy for American Innovation*, HFES recommends the Administration encourage the inclusion of human factors and ergonomics (HF/E) experts in manufacturing processes, technology development, and research and development priorities, as well as in cultivating the HF/E workforce.

The field of HF/E works to develop safe, effective, and practical human use of technology, by developing scientific approaches for understanding the ways in which humans interact with complex systems, known as "human-systems integration." HF/E cuts across many different research and development fields and provides a foundation for the development of sound, innovative technologies. The 21st century economy will require workers trained in HF/E to keep pace with emerging technologies and innovations.

With increasing reliance by federal agencies and the private sector on technology-aided decision-making, HF/E plays a critical role in developing and evaluating innovative technologies and in conducting research that can lead to new fundamental discoveries. Federal research for HF/E is embedded in agency missions, most prominently at the Department of Defense, the Federal Aviation Administration, the Department of Labor, the National Aeronautics and Space Administration, and the Food and Drug Administration.

HF/E also contributes to advancing fundamental scientific understanding of the interface between human decision-making, engineering, design, technology, and the world around us through research funded by the National Science Foundation and the National Institutes of Health. The reach of HF/E is profound, touching nearly all aspects of human life from the health care sector, to the ways we travel, to the hand-held devices we use every day. HF/E applies to fields as diverse as transportation, architecture, environmental design, consumer products, electronics/computers, energy systems, medical devices, manufacturing, office automation, organizational design and management, aging, farming, health, sports and recreation, oil field operations, mining, forensics, and education. Given this fact, HF/E must be embedded across the federal R&D portfolio to ensure the new technologies that are developed are safe, effective, and adapted to human capabilities.

Thank you for the opportunity to provide comments. Please do not hesitate to contact HFES should you require additional information.

*The **Human Factors and Ergonomics Society (HFES)** is a multidisciplinary professional association with 4,500 individual members worldwide, including psychologists and other scientists, engineers, and designers, all with a common interest in creating safe and effective products, equipment, and systems that maximize and are adapted to human capabilities.*

IEEE-USA
Comments for the
Office of Science and Technology Policy

Submitted September 23, 2014

Input for OSTP's Strategy for American Innovation

Challenges for the progress of the US in the world economy

We appreciate the opportunity to comment on the update of the "Strategy for American Innovation" by the Office of Science and Technology Policy and the National Economic Council. Our comments represent a summary of the inputs of IEEE members in the United States, and in particular members that own or work in Small to Medium size Technology Enterprises (SMTEs) or technology startups. Our members contribute to American innovation and exports by starting, owning or working for technology companies.

Our findings indicate that government activities, policies, initiatives have a major impact on the formation and growth of small to medium technology companies. Therefore, we applaud the effort by the Office of Science and Technology Policy and the National Economic Council to identify ways in which the government can change its behavior to improve innovation in the United States. We hope that our comments will help in shaping those changes.

Small to Medium size Enterprises (SMEs) and SMTEs in the United States are major contributors to employment and innovation in our country. Some statistics:

1. In 2011, according to the US Census Bureau, SMEs in the United States made up 99.7% of employer firms.
2. In 2008, SME produced 46% of the private nonfarm GDP.
3. From 1993 to 2013, 63% of new job creation in the US came from SME according to the SBA.
4. According to the SBA, SMTEs produce 16 times more patents per employee than large patenting firms.
5. In 2011, SMEs were responsible for 33% of exported products, according to the International Trade Administration.

However, changes in the economic climate and US Law make the path to founding and growing technology enterprises more difficult. Other issues such as government funding, regulations, and export incentives have not been addressed adequately in the past and they have the potential to significantly increase the performance of SMTEs as innovators, job creators, and exporters.

Funding

Currently, more so than in the past, entrepreneurs have difficulty finding the capital they need to fund start-ups and to raise additional capital for healthy growth. Since the 2008 financial crisis banks have been even more reluctant to loan money to startups and small enterprises. One of the difficulties banks cite in evaluating the risk of a loan to a technology company is the bank's inability to accurately assess the value of intellectual property. A recent IEEE Survey of Members who are STMEs reported the vast majority, 74%, of their company's pre-revenue dollars were

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acquired through bootstrap financing. While the Government has tried to open up funding, the IEEE-USA report revealed only 2.2% of pre-revenue funding came from government agencies. R&D investments also tend to favor large corporation rather than SMTEs.

Even after SMTEs start to grow and earn a profit, the majority of funding (52.2%) still comes from bootstrap sources. Angels and VC's make up less than one percent (1%) of the funding for mature SMTEs, while government programs come in at less than 2%. Exporting by SMTEs is greatly hampered by the difficultly these businesses have obtaining trade credit insurance, working capital loans guarantees, and delivering products to other countries because of weak shipping infrastructure and difficulty understanding export restrictions. The inability to export can block SMTEs from some 95% of their potential markets, according to the Department of Commerce.

Health Care

Healthcare costs are a major burden to growth and job creation as smaller enterprises see higher healthcare costs absorb more and more of their profits as they become larger. The new healthcare laws, while possibly intended to help small enterprises, have in fact created uncertainties and bureaucracies that are difficult to navigate for companies that do not have staff dedicated to human resources and employees' healthcare.

Intellectual Property

IEEE-USA's latest survey indicates that intellectual property is important to 32.1% of small businesses run by IEEE members. For many, their innovative ideas represent the majority of their assets. Small business owners must not only have innovative ideas, but also be able to legally protect those ideas if they are to turn their ideas into growth and revenue. This process involves two distinct, but equally important steps:

1. Small businesses must be able to secure copyrights, trademarks and patents for their ideas and inventions quickly and inexpensively. In many fields, technology becomes obsolete within a few years, making a three-year patent application process less than optimal.
2. Once acquired, intellectual property protection must be easily enforceable. Given how precious cash is to small companies, it cannot be wasted on expensive, lengthy legal battles.

Recent and ongoing changes to IP laws may have a negative effect on U.S. leadership in innovation as they progressively make it more difficult to obtain and protect patents, particularly for small entities that cannot afford costlier patents nor enforcement actions against infringers. Recent changes and proposed changes include:

1. Loss of a clear grace period (American Invent Act of 2011)
2. Inability to enforce patents and get injunctions for clear cases of infringement (Innovation Act of 2013)
3. Primacy of filing date (American Invent Act of 2011)
4. Discounting ability to rely on provisional patent applications (American Invent Act of 2011)
5. Lack of clarity on patenting of secret commercial use and commercial exploitation (American Invent Act of 2011)

Regulations

38.1% of IEEE entrepreneurs report being hindered by standards and regulations in their effort to innovate and grow. Their main complaints are the high cost of product certification, multiple standards, conflict between national and international standards, and the complexity of navigating multiple inconsistent requirements for compliance with standards and certification by the government branches.

One example is 49 FR 8326. On March 6, 1984, the Occupational Safety and Health Administration proposed a comprehensive overhaul of its regulatory procedures related to OSHA's requirements for safety testing or certification of certain workplace equipment and materials (49 FR 8326). The goals of the proposal were to:

1. Ensure that products certified and marked as meeting a safety standard in fact were consistently tested to all the requirements of the standard through an accreditation process, and
2. Encourage the creation of more testing entities, Nationally Recognized Testing Laboratories (NRTLs), and through competition reduce the costs and speed of testing and certification. Delays in the ability to sell a product because of testing and testing costs affect innovation and growth, particularly for SMTEs and entrepreneurs relying on timely ROI from their R&D and cash flow.

A number of NRTLs now exist, all capable of testing products and certifying that standards are met. The issue of certification delays and high cost remains as each NRTL has its individual mark. Buyers can require that products be certified by a specific NRTL (perhaps an older better known one), thus limiting competition. With limited competitive pressure, costs and performance, particularly response times, have not improved. While all NRTLs are accredited, they are not equal.

The second issue manifests itself when more than one standard can be used to certify safety of a product by a NRTL. Currently the standard used by the better known or better connected NRTL will become the de-facto standard

Exporting

The International Trade Administration reports that Small Entities (up to 50 employees, a much lower number than that used by other agencies) were responsible for 24% of goods exports in 2011, and that small enterprises could sharply boost exports by entering new markets. Overall, SMEs were responsible for 33% of goods exports in 2011. Most of this was without meaningful support from the Export-Import Bank or other government agency. With support, SMEs could be exporting far more than they already are.

Doing Business with the Government

54% of respondents to our recent survey said that encouraging the government and government contractors to buy more products from small businesses was the best way to create additional market opportunities for small technology companies. 28.2% of respondents said “Insufficient opportunities to sell products or services from small businesses” was one of the top obstacles to their growth.

Availability of Talent

33% of IEEE members in our survey said they were having difficulty finding qualified people, especially technical/professional talent, with 16% saying “lack of talent” was the biggest challenge they face bringing a new product to market. Technology companies are uniquely dependent on a skilled workforce, since their products are ideas more than physical things. Without skilled workers to develop and produce their products, small technology companies cannot exist.

The United States produces, through our universities, the majority of the world’s top engineering and technical talent. The problem is, much of that talent lacks American citizenship.

But international students who earn degrees from our universities are usually off-limits to small technology companies because our immigration system is so expensive, complicated and slow. Large corporations have experts to navigate this system, the patience to wait for it to function, and the finances to afford to pay for it.

Small companies do not.

As a consequence, some of the most innovative companies in our economy are effectively cut-off from many of the most innovative students graduating from our universities. This same immigration system makes it inordinately difficult for international graduates to start companies on their own, depriving the United States of one of the world's best sources of successful entrepreneurs.

Recommendations

Data Collection

Currently, different government agencies classify SMTEs in different way, sometimes including enterprises of up to 1,500 employees. Other agencies limit companies to less than 50 employees. Consistent classification of the data collected by the Census and other government agencies when dealing with the private sector and the economy would allow government agencies to tailor their services, activities, initiatives, and funds to those entities that most contribute to the American economy, worldwide competition, innovation, and standard of living.

We suggest that the government adopt a version of the following classification structure: Companies with up to 5 employees, 5 to 15 employees, 15 to 50 employees, 50 to 100 employees and 100 to 500 employees. The government should also distinguish between small to medium-size entities (SMEs) and small to medium size technology entities (SMTEs), as well as exporting and non-exporting entities.

Funding

Address the issue of funding startups and SMTEs by various government and private sources:

1. Identify the issues that discourage commercial lenders from extending loans to SMTEs and modify or create new initiatives to help identify, quantify, and review risks to those lenders, including:
    a. Create a system for valuing intellectual property tied to technological innovations for the purpose of helping small technology companies secure loans. This system could either be run by the SBA or privately run with SBA support and oversight. Some entities such as the Licensing Executives Society already evaluate IP for royalties, acquisitions etc. Evaluating IP (patents specifically) will require:
        i. Feasibility of the invention from a technical prospective
        ii. Strength of the patent from a legal prospective
        iii. Marketability of the product/service derived from the invention
    b. Prioritize SMTEs (representing the entities most likely to grow by innovation, to create high-quality jobs, and to export), in programs including SBA loan guarantees, SBIR, and DARPA.
    c. Create incentives through tax exemptions (such as the Section 179 deduction), loan guarantees, etc. for SMTEs and support the private sector sources of capital such as Angels, venture capitalist, and crowd funding entities to focus their effort on SMTEs.

Health Care

Lower the cost of healthcare to SMTEs by simplifying the current system and providing easy ways for SMTEs to become part of larger risk groups. Our small business members would benefit from simpler and clearer regulations associated with the process of obtaining healthcare.

Intellectual property

Help small businesses protect their intellectual property by facilitating the acquisition of patents, trademarks and copyrights and by helping to ensure that the rights conferred by these protections can be enforced by small companies. Review the impact of the American Invent Act of 2011, and the proposed Innovation Act of 2013 as well as some recent Supreme Court decisions such as Alice Corporation v. CLS Bank International on the availability of intellectual property protection and enforcement to all American innovators, and particularly SMTEs and writers of innovative software.

The USPTO can mitigate the chilling effect of these new developments on American innovation and the ability of innovators to obtain funds to start and grow new enterprises. Legislative efforts will eventually be required to correct some of the unexpected consequences of the recent legislation and Supreme Court decisions.

Regulations

Enable OSHA to oversee NRTLs and assure that all products tested and certified safe by accredited NRTLs are not discriminated against on the safety issue alone. This flaw in the current safety assurance process (standards and testing) is hurting SMTE that do not have the resources to get certification from multiple NRTLs or from a specific NRTL in a non-competitive testing environment.

A relatively simple solution would be to allow testing to multiple safety standards and then requiring a Collective Mark be used to indicate product certification regardless of which NRTL performed the product testing. Buyers and insuring agencies then should not be concerned about accepting only products tested and certified by a specific NRTL. Having more choices of testing entities will reduce testing costs and delays. It will also alleviate the difficulties caused by different NRTLs using more than one standard.

Exporting

Congress should enact the following reforms to help the Export-Import Bank be more useful to small and new businesses.

1. Require the Bank to treat all applications from small businesses, including micro businesses, equally. Companies should not be placed at a disadvantage because they only need a small amount of assistance.
2. Require the Bank to devote more of its resources to its Small Business Group, and increase the visibility and authority of that group. The Small Business Group ought to operate as an advocate for small businesses within the Bank and should be instructed to focus most of its efforts on the smallest and newest companies.
3. Require the bank to devote a larger percentage of its resources to contracts worth less than $5 million to encourage companies that do not currently export to begin to do so.

IEEE-USA believes that, with these reforms, the Export-Import Bank will be able to play an even more constructive role in promoting American exports and creating American jobs than it already does.

Doing Business with the Government

Small companies want to do more business with the federal government and its contractors, but doing so will require more than statements of support from the government. One relatively easy way to help facilitate commerce between the two would be to establish an organization within the government that would help small businesses navigate and interact with government agencies.

This office's mandate ought to extend beyond just offering advice into actively facilitating commerce between companies and the government. Specific activities should include:

1. Helping small companies provide information to multiple agencies. For example, when companies have to provide patent information to multiple departments, the forms required differ by department – but the patent information is the same. The office could take the patent information from a small business once, and then distribute it to all necessary agencies on the company's behalf.
2. Explaining reporting requirements. Different agencies require different paperwork before completing a contract. It is not always clear what these requirements are, nor how similarly sounding requirements differ from one agency to the next. Small businesses should have a central place they can go to get accurate information on what forms need to be submitted to which offices.
3. Advocating for inter-government standardization. If the DOD, DOE and DOS all require companies to prove they pay fair wages before buying from a company, the form used to prove this should be the same. In fact, demonstrating basic information about a business ought to only require one form, which can be shared with all relevant agencies. This new office ought to be tasked with leading efforts to enact these simple, but enormously important endeavors.

Availability of Talent

The best and easiest way to provide all businesses with access to the talented students graduating from American universities is to expand the EB green card system so that every international student who earns a Masters or PhD in a STEM field to get a green card within one year of graduating. Students can already use OPT status for that year. Such a proposal is part of the Senate's comprehensive immigration reform bill and was passed by the House of Representatives in 2012.

It is important to note that expanding the H-1B temporary visa program will not help small businesses. H-1B visas are temporary, whereas small businesses need permanent access to skilled workers. H-1B visas are expensive, difficult and time consuming to acquire and demand on-going paperwork and fees to maintain. While many small businesses have ideas to spare, few have extra money, time or energy. Lastly, H-1B visas may not be used by entrepreneurs to start companies, making them completely useless to international students who want to found their own businesses.

Expanding the politically popular and much more useful EB program would give small technology companies access to the talent graduating from our universities.

Small technology companies have been, and remain, the source of a disproportionate amount technological innovation in the American economy. We believe that, by taking the steps outlined above, the government can help our small technology companies succeed and thrive – creating jobs and economic growth for all Americans in the process.

Industrial
PhD & Postdoc
Association

September 23, 2014

Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave NW.,
Washington, DC 20504

Re: Strategy for American Innovation

Dear Mr. Correa:

Thank you for your Request for Information and the opportunity to provide input into the development of an updated *Strategy for American Innovation*. Herein, we will give a very specific recommendation to the Science and Technology Policy Office followed by some insights about the Danish Industrial PhD and PostDoc programs as well as its alumni organization the Danish Industrial PhD & PostDoc Association.

Recommendation:

US innovation policy should encourage joint PhD and PostDoc projects between universities and companies

Based on the experiences from the Danish way of conducting research/education/innovation in university-industry partnerships, we encourage US innovation policy makers to get inspired by this model. We believe that this type of collaboration could also work in the US and would benefit all participating parties (universities, industry, students, government, and society) thereby contributing significantly to American innovation.

Background:

The Danish Industrial PhD Program is a partnership between the government, universities, businesses and PhD students in Denmark to undertake investigations of both academic and commercial value to improve the economic and social future of the country. The program was launched over 40 years ago and has funded thousands of PhD student and projects. In recent years programs to support innovation in the public sector as well as a PostDoc program have also been added.

The Danish Industrial PhD and PostDoc programs are associated with higher patent applications, increased gross profit, increased overall employment, and increased total factor productivity for the participating companies than traditional PhD programs. Participants in the programs experience an increased salary and higher corporate leadership roles compared to conventional PhD students and ordinary graduates.

The IPhD or IPostDoc is hired by the company and enrolled by the university at the same time. These projects are driven by the widely-accepted notion that companies and universities should work together to create commercially-actionable and research-based knowledge that further the goals of the Danish society. The students and postdocs under the guidance of project leaders at their universities and companies undertake the research. Specifically universities ensure that projects have value from an academic perspective, something measured by publication in high impact journals and international peer review. Companies undertake the project to deliver business goals, such as improving industrial production or creating new products and services. The Innovation Fund (InnovationsFonden – Denmark) ensures that projects conform to the program's requirements.

The success of the program can be largely attributed to each of the partners in the program and the equal weight placed on the academic and commercial aspects of the program. In American terms, all the parties—the Innovation Fund (part of the Ministry of Higher Education and Science, the government agency overseeing the program), the university, the company, and the PhD student—have skin in the game. That is to say, each party makes a significant contribution, whether financial, professional, or academic. The program also requires that projects deliver both academic and commercial value.

As for the financial requirements of the program, the company pays at least 50% of the students/postdoc's salary and expenses (which could also include lab equipment). Up to 50% of the salary as well as tuition at the university and a travel grant is funded by the Innovation Fund. The IPhD or IPostDoc divides her time equally between the university and the company, but works only on the project. Many IPhD or IPostDoc also have a 3rd party collaborator – often a university abroad. The IPhD student finishes the three-year project by writing up a PhD thesis and defending it on the same terms as ordinary academic PhDs.

The program has had an impact in both small/medium as well as a large companies, though the dynamics of each firm may be different. Moreover universities having frequently worked in an "academic bubble" find that the industrial PhD and PostDoc programs are ways to make academic research actionable and improve their collaboration with industry in general.

For your information, there are a number of American companies that participate in the program through their Danish affiliates including IBM Denmark, DuPont Nutrition Biosciences, Intel Mobile Communications, KPMG, PWC, Thermo Fisher Scientific, and others. We welcome a dialogue with you about how the US can take advantage of learning and how our postdocs could contribute to American innovation efforts with partnerships with Danish and American companies and universities.

The Danish Industrial PhD program was the first of its kind, but there are also other programs. One notable program is the EU-funded Marie Curie European Industrial Doctorate (EID). The conditions are slightly different than the Danish Industrial PhD Program.

Industrial PhD & Postdoc Association

To support prospective and current students as well as alumni, the Danish Industrial PhD and PostDoc Association provides helpful and valuable source of professional networking. We offer a series of events, a LinkedIn group page, and a website to facilitate exchange and information about the program.
For more information about the Danish Industrial PhD and PostDoc, please check out the links below:

What the U.S. Can Learn From Denmark's Industrial PhD Program
http://www.innovationfiles.org/what-the-u-s-can-learn-from-denmarks-industrial-phd-program/

Ministry of Higher Education and Science – The Industrial PhD Program
http://ufm.dk/en/research-and-innovation/funding-programmes-for-research-and-innovation/find-danish-funding-programmes/postgraduates-in-the-private-sector/industrial-phd/the-industrial-phd-programme

Thank you for the opportunity to comment. Please don't hesitate to be in touch if you have further questions about the Danish Industrial PhD and PostDoc programs.

Sincerely,

Kjartan Frisch Herrik
Scientist, Industrial PhD
Lundbeck
President, Danish Industrial PhD and Postdoc Association

Roslyn Layton
PhD Fellow
Aalborg University
Strand Consult

ITIF
The Information Technology & Innovation Foundation

itif.org

Information Technology and Innovation Foundation

Comments to Notice of Request for Information on:

The Strategy for American Innovation

September 23, 2014

The Information Technology and Innovation Foundation commends the Administration for seeking public comment as it begins to articulate the second *Strategy for American Innovation (SAI).* A successful strategy for American innovation must promote both technological-based and non-technological-based (i.e. institutional and organizational) innovation throughout all layers and parties in an economy, including the private sector, government agencies, and non-profit organizations. In other words, the strategy should not only address innovation in government; rather, its chief aim should be to fundamentally change private sector activity and behaviors to spur greater levels of innovation.

Q1: *What specific policies or initiatives should the Administration prioritize in the next SAI?*

As part of the next *SAI*, the Administration should direct each federal agency to develop its own specific innovation strategy/agenda in which each agency takes the lead in undertaking a study evaluating how it can spur greater levels of innovation in the economic sectors they touch, including an assessment of how regulatory policy/regulations may preclude or limit innovation in each sector. The core challenge is that federal agencies currently work to advance their own particular missions and have not been charged with coordinating with other agencies or taking into account the impact of their actions on America's innovation competitiveness. Take medical devices: the Food and Drug Administration (FDA) reviews the safety and effectiveness of medical devices, the Department of Health and Human Services (HHS) sets reimbursement schedules, and the Department of Defense (DoD) and the Veteran's Administration (VA) procure such devices. But there is little or no coordination across agencies to develop a unified strategy that would orient government policies to support the competitiveness of the U.S. medical device industry. To address this, the *SAI* should task each agency with developing strategic roadmaps and guide inter-departmental collaboration to ensure that the regulatory policies and activities of disparate government agencies, are, wherever possible, aligned to promote the global competitiveness and productive capacity of strategic sectors of the U.S. economy.[i] Furthermore, each agency should analyze how to improve productivity in key services sectors (i.e., construction, higher education, transportation, health, finance, etc.). Thus, the Department of Transportation (DoT) would lead in spurring the national deployment of intelligent transportation systems; HHS in health IT; the Federal Communications Commission (FCC) in mobile payments, etc.

Pursuant to this, each federal agency should create an innovation fund (of at least 3 percent of the agency's budget) for pilot programs seeking to identify innovative ways of using technology to drive high-impact, transformational change. For instance, DoT should repurpose money away from concrete to cost-effective solutions that increase mobility, such as computerized adaptive traffic signal lights and parking meters, real-time traffic information, and intelligent vehicles and infrastructure. Further here, each agency should develop an Internet of Things (IOT) strategy (e.g. HHS examines how to use IOT in the housing system, DoE and FERC in the utilities sector, etc.). It should be institutionalized as part of each agency's charter that driving innovation across the economy and society is part of its core mission and agencies should be charged with authoring an innovation strategy every five years.

Q2: ***What are the biggest challenges to and opportunities for innovation in the United States?***

The biggest challenges are underinvestment in research and development (R&D) and innovation, the erosion of America's industrial commons, and an increasingly mercantilist global trade system that threatens America's innovative industries.[ii] Federal R&D plays a key role in driving U.S. innovation, productivity, and overall economic growth, but the federal government's investment in R&D has faltered both in historical terms and relative to competitors.[iii] In fact, to restore federal support for research as a share of GDP to 1987 levels, America would have to increase federal support for R&D by almost $110 billion—per year.[iv] If current trends hold, Battelle estimates that China will surpass America in federal investment in R&D within a decade.[v] The impact of declining federal investment has been felt particularly in the life sciences sector, where funding for the National Institutes of Health (NIH) has declined by 22 percent in real terms since 2003.[vi]

Yet the private sector is also to blame for underinvestment in R&D. As ITIF writes in *Innovation Economics*, the United States has been the only leading industrial economy over the past two decades in which companies overwhelmingly shifted their research portfolios from basic and applied R&D to development. In fact, from 1991 to 2008, basic research as a share of corporate R&D conducted in the United States fell by 3.6 percent, while applied research fell by roughly the same amount, 3.5 percent. In contrast, development's share increased by 7.1 percent.[vii] This corporate short-termism is also evident in underinvestment in workforce development training (which has been cut by U.S. enterprises 38 percent over the past decade) and as business investment in capital goods such as equipment, software and structures grew just 0.5 percent annually in the 2000s, a fraction of growth in previous decades.[viii] This sustained underinvestment and short-termism have led to serious erosion in America's industrial commons that has left us unable to manufacture a range of advanced high-technology products from fabless semiconductor chips to LCD screens and lithium polymer batteries.[ix]

To tackle this short-termism, the Administration should organize a Commission on Short-termism in U.S. Capitalism, a joint task force bringing together Treasury, the Securities and Exchange Commission (SEC), the Department of Commerce, the National Economic Council, OSTP, and other agencies to better identify the sources and causes of risk aversion and short-termism in America's financial capital markets. The Commission would also include CEOs, innovation gurus, and capital market experts, etc., and ask questions such as how to get American enterprises to invest more in R&D, capital equipment, workforce training, and to take a longer term time horizon. As part of this, the SEC should think about crafting a reform agenda for a corporate governance structure that will help better drive long-term, breakthrough investments in innovation. A White House summit on this topic could be framed as a pro-growth collaboration with American industry.

America's greatest opportunities in innovation are in sectors such as advanced manufacturing, robotics, life sciences, aerospace, information and communications technology (ICT) manufacturing, and Internet and digital services. An increasing challenge, however, is designing a regulatory environment in which innovation in these sectors can flourish.

Q4: ***How can the federal government augment its capacity for innovation and competitiveness analysis?***

Ideally, the Administration should create a new traded sector analysis unit within the federal government. The entity, which might be positioned within the National Institute of Standards and Technology (NIST) Innovation and Industry Services division, would regularly assess important aspects of overall U.S. traded sector competitiveness (e.g., trends in FDI, growth of traded sector jobs and output, changes in global market share of U.S. traded sectors, unfair foreign trade practices affecting these sectors, etc.). The entity would also coordinate, improve, and maximize the impact of the various federal agency innovation and productivity strategies described in Q1 above. The Administration should also increase funding for key federal statistical agencies assessing America's traded sector competitiveness (and even contemplate creating a national statistical agency). Here, the Administration should look as a template to *The High-Tech Strategy of Germany*, which undertakes a comprehensive SWOT (strengths, weaknesses, opportunities, threats) analysis of Germany's major industries and platform technologies.[x]

Yet because all-too-often federal agencies propose regulations with little consideration given to their effect on innovation, the Administration should create within the Office of Management and Budget (OMB) an Office of Innovation Review (OIR) that would have the specific mission of being the "innovation champion" within agency rule-making processes.[xi] OIR would have authority to push agencies to either affirmatively promote innovation or achieve a particular regulatory objective in a manner least damaging to innovation. OIR would be authorized both to propose new agency action and to respond to existing agency action. OIR could also incorporate a "competitiveness screen" in its review of federal regulations.

Q5: *What innovation practices and policies have other countries adopted that deserve consideration in the United States?*

There are many, including applied R&D institutes, innovation vouchers, collaborative R&D tax credits, patent boxes, design assistance programs, and service innovation strategies. ITIF applauds the Administration's efforts to create a National Network for Manufacturing Innovation (NNMI) focused on promoting industrially relevant R&D and innovation in advanced manufacturing product and process technologies, but the United States now has four of these, compared to Germany's 69 Fraunhofer Institutes.[xii] Continued build-out of America's NNMI is needed.

At least a dozen nations have established collaborative R&D tax credits designed to incentivize industry investment in collaborative research, often including universities, enrolling multiple partners.[xiii] Accordingly, the Administration should push Congress to establish a 30 percent collaborative R&D tax credit for industry research undertaken in conjunction with universities, research institutes, national laboratories, or multi-firm consortia. But while R&D tax credits spur research, at least eight nations have adopted (and the United States should consider) tax incentives to spur the commercialization of that R&D through "patent boxes" that allow corporate income from the sale of patented products to be taxed at a lower rate than other income.[xiv] Most competitor nations have also sought to make their R&D tax credits more generous and expansive (such as Norway's extending R&D tax credits to services sectors and making it clear that process R&D qualifies for the R&D tax credit), while the U.S. R&D tax credit languishes and has fallen to just the world's 27th most generous.[xv]

Many countries seek to increase their R&D efficiency by using existing funding for scientific research to incent universities to focus more on technology commercialization. For example, in Sweden, 10 percent of regular research funds allocated by the national government to universities are now distributed using performance indicators. Finland also allocates 25 percent of the research and research training budgets of Finnish universities based on "quality and efficacy," including the quality of scientific and international publications and the university's ability to attract research investment from businesses.[xvi] Accordingly, the federal government should allocate a share of federal university R&D funding based on performance.[xvii] To make universities more accountable for results, the amount of industry-funded university research should be the first variable used to make allocation decisions, which could be achieved by requiring the inclusion of this factor in the evaluation of all National Science Foundation

(NSF) research grants. Further, to encourage the commercialization potential of federally funded research, all NSF-awarded private investigator grants should require the grantee to include at least a one-page description of the commercialization potential of the research being undertaken through the grant. The Administration should also create a knowledge bank (e.g., an online database) that makes all ideas generated from federally funded research publicly available to entrepreneurs and other researchers.

Several nations have introduced programs to help SME manufacturers understand the importance and role of design methods and principles.[xviii] For example, the UK's Designing Demand program is a mentoring and support service helps businesses make strategic design decisions and set up and manage design projects. Likewise, Ontario's Design Industry Advisory Committee (DIAC) has launched the Design Advisory Service, a design support program to help manufacturers and other growth-oriented SMEs improve their innovation outcomes.[xix] The United States should add a similar charge to the Manufacturing Extension Partnership (MEP) program and also launch an education and training program to help U.S. traded-sector services SMEs with services design and services innovation. Further to this, several countries, including Finland and Taiwan, have developed national services innovation strategies. The United States should undertake a Services Innovation research project that examines how ICT-based tools, functions, and platforms can promote innovation and productivity improvement in key services sectors and study what policies other nations have implemented to spur service innovation.

Q6: ***How has the nature of the innovation process changed?***

The modern innovation process is far more collaborative than ever before, explaining why two-thirds of R&D Magazine R&D 100-award winning innovations now stem from collaborative efforts (whereas in the 1970s most came from corporations acting on their own), demonstrating the importance of public policies that spur and incent collaborative industry-university R&D activities.[xx] Another major change has been the advent of rampant global innovation mercantilism, specifically competitor country policies such as localization barriers to trade that attempt to force the transfer of technology and/or intellectual property or location of productive activity (e.g., manufacturing) as a condition of market access. As ITIF writes in *Designing a Global Trading System to Maximize Innovation*, by introducing market balkanization, enabling excess competition, or compromising American intellectual property, innovation mercantilism constitutes a fundamental threat to the success of America's innovation-based industries.[xxi] As such, trade policy—including both trade enforcement and market opening initiatives—must be viewed as a key enabler of American innovation, particularly in the traded sectors of America's economy.[xxii]

Q7: ***What emerging areas of scientific and technological innovation merit greater federal investment?***

The core strength of America's national innovation system has long been science-based innovation, whereas its core weakness has been engineering-based innovation. That approach worked well when few nations had the capacity to leverage U.S. scientific discoveries for their competitive advantage. But now U.S. federal R&D dollars for basic science generate knowledge that is essentially a non-rival, non-appropriable public good that can be quickly picked up and leveraged by foreign competitors. Today, competitors often rely on the basic research discoveries coming out of U.S. universities and national laboratories, which allows them to concentrate their efforts on turning U.S. scientific discoveries into their own innovative technologies and products which they sell to other nations. That's why science-based discoveries aren't sufficient anymore. The United States must also be able to make things here. And that requires engineering-based innovation, an appropriable activity through which U.S. establishments can add and capture value. And this requires the United States getting better at generating pathways that turn science into U.S.-made high-technology products.[xxiii]

Unfortunately, the United States invests significantly more in scientific research than it does in engineering. Of the total federal research investments in science and engineering in 2008, approximately 1/7th was allocated to engineering development and 6/7th to the various scientific fields.[xxiv] NSF invests roughly 1/10th the amount on engineering education as it does on science and mathematics education.

Therefore, it's time to raise the profile of engineering within our national innovation system, starting with significant increases in funding for NSF engineering activities, including raising funding for NSF's Industry/University Cooperative Research Centers (I/UCRCs) to at least $50 million per year while doubling Engineering Research Centers (ERC) funding to at least $110 million. But the Administration could go much further. But because NSF's primary mission is funding scientific research—not promoting engineering-based innovation—the Administration should request that Congress create a National Engineering and Innovation Foundation as a separate entity operating alongside NSF and fund it with $300 million annually.

More broadly, it's time to recognize that certain research programs NSF supports are much more important to our country's economic well-being and competitiveness than others and explicitly take this into account when making budgetary allocation decisions. Therefore, the Administration should look to reallocate NSF resources toward the kinds of science that has direct economic and industrial benefits for the United States. In particular, this means increasing NSF budgets for four key directorates: 1) math and physical sciences; 2) engineering; 3) computer and information sciences and engineering (CISE); and 4) biological sciences, while permitting research budgets for the geosciences and social sciences to shrink.[xxv] Alongside this, the Administration should develop outcome-based innovation metrics assessing the effectiveness of federal research institutions (e.g., new companies created from research dollars) in addition to current output metrics (e.g., patents)

Q8: ***How can the federal government support institutional innovation?***

As noted in Q7, the United States needs new institutions to support innovation. This needs to occur across both the government, private, and educational sectors. The Administration should seek from Congress $50 million a year over the next five years, to be matched with funding from states and local school districts and industry, to invest in both the creation of new and the expansion of existing math and science high schools. The Administration could also offer planning grants for regions wishing to create alternative types of science, technology, engineering, and math (STEM) high schools or universities.

Another new type of institution needed are U.S. manufacturing universities that revamp their engineering programs to focus much more on manufacturing engineering and skills that is more relevant to industry. This would include more joint industry-university research projects, more student training that incorporates manufacturing experiences through co-ops or other programs, and a PhD education program focused on turning out more engineering graduates who work in industry.[xxvi] For inspiration, the Olin College of Engineering in Massachusetts is a good model for how the United States can transform its colleges into entrepreneurial factories while encouraging the development of completely new schools based on the needs of the current workforce.[xxvii]

U.S. federal agencies also need institutional innovation. Each agency should come up with the Top 5 institutional innovations they could undertake—for example, project-based learning and massively open online courses (MOOCs) at the Department of Education and public-private partnerships around ITS and tolling at the DoT. The Nuclear Regulatory Commission and America's network of National Laboratories are also sorely in need of institutional innovation.[xxviii] America could transform the National Labs into 21st century engines of innovation by adopting a flexible lab-management model that strengthens the labs' ability to address national needs and produce a consistent flow of innovative ideas and technologies. One component of this should be prioritizing the technology transfer activities of the National Laboratories, in part by adding more weight to technology transfer measures in DOE's National Laboratories Performance and Evaluation Measurement Plans.

Q9: ***What additional opportunities exist to develop high-impact platform technologies?***

A number of emerging technologies and manufacturing processes represent “platforms” for innovation that will touch innovation across all sectors of the economy. These should be the focus of elevated federal investment in basic and applied scientific research and the subject of public-private partnerships such as the Institutes for Manufacturing Excellence. Today’s transformative platform technologies include: big data, (contactless) mobile payment systems, next-generation wireless technologies, driverless (autonomous) vehicles, quantum computing, cyber-physical systems, nanotechnology, additive manufacturing, adaptive materials, integrated computational materials, biomanufacturing, synthetic biology, genetic engineering, robotics, and renewable energy technologies.

Q10: ***What are the gaps in the federal government’s science, technology, and innovation portfolios with respect to national challenges?***

The biggest current gap in America’s innovation system revolves around more consistently bridging the gap to transform basic scientific discoveries into useful technologies and on into commercializable products that can be manufactured at scale in the United States. In other words, our gap pertains to other countries’ industrial-oriented research and their manufacturing focus. For example, as a share of GDP, Germany invests seven times more than the United States into industrial production research. And while Germany has a strong science and research base, what it really excels at is applying that science base to engineering and manufacturing excellence.[xxix]

Part of the problem is that the current federal system for funding research pays too little attention to commercialization of technology, and is still based on the linear model of research that assumes that basic research gets easily translated into commercial activity. Accordingly, the Administration should propose creation of a Spurring Commercialization of Our Nation’s Research program to support university, state, and federal laboratory technology commercialization initiatives. In particular, the Administration should promote creation of a set-aside program for federal agency budgets that invests 0.15 percent to a technology commercialization fund to fund university, federal laboratory, and state government technology commercialization. Section 8 of the draft Startup America Act 3.0 proposes this through an “Accelerating Commercialization of Taxpayer Funded Research,” program, but the *SAI* should invest particular focus in promoting this concept and redoubled efforts to promote technology commercialization.[xxx]

Q12: *What novel mechanisms or models might facilitate matching skilled STEM workers with employers?*

The Administration should work to increase credentialing for the manufacturing and the closely related logistics industry workforce members by expanding the use of standards-based, nationally portable, industry-recognized certifications specifically designed for a variety of manufacturing and industrial sectors, such as those developed by the Manufacturing Skill Standards Council (MSSC). In other words, we need to move toward a system of skills/capabilities (e.g., where employers could specify they need employees with a 7+ on computer science skills and they could feed that into a database that automatically matches skills needs with candidate's capabilities). To further this, the Secretaries of Labor and Education should ensure that industry-approved certification standards are established and available nationwide.[xxxi]

Q15: *How to spur greater levels of entrepreneurship in the United States?*

Universities should define an entrepreneurial leave policy for undergraduate and graduate students in which students could retain full-time student status for one to two years while launching their own company. Likewise, universities should allow faculty members to suspend their tenure so that they may pursue commercialization opportunities. NSF should also collect better data regarding new business starts and spin-offs of new companies by faculty from universities. NSF could use this data to reward universities that do a better job; for example, by giving bonus points on research grant proposals they receive from private investigators at certain universities.

The Administration should reform the Small Business Innovation Research (SBIR) program, in part by combatting rumor mills, accelerating the disbursement of funds, and allocating a greater share of SBIR investments toward translational stage research. The Administration should also reform the Small Business Investment Company (SBIC) program by devoting a greater share of funds (at least 25 percent) to smaller, riskier deals (perhaps less than $2 million), not just smaller companies.

Q18: What investments, strategies, or technological advancements are needed to restore the industrial commons?

The Administration should advocate for the creation of a unified Innovation and Investment Tax Credit (IITC) that provides a credit of 45 percent of expenditures in R&D and skills training above 75 percent of base-period expenditures and a credit of 25 percent on capital expenditures made in excess of 75 percent of their base-period expenditures.

The United Kingdom has recently set up "industry growth councils" for every major sector of its economy. For example, the Industry-Government Automotive Council was set up in 2009 to develop a strategic, continuous and collaborative conversation between government and the automotive industry in the UK. The councils develop industry technology roadmaps, undertake industrial supply chain mapping initiatives, and develop overseas networks for trade promotion.

Another idea would be to repurpose Fannie Mae into an industrial support organization, not a housing finance organization. The new Fannie Mae (perhaps called the Federal National Industrial Mortgage Association) would buy loans made to traded sector firms from banks and other lenders and sell them on the secondary market.[xxxii]

Q19: ***How can the federal government promote the creation of regional "innovation ecosystems?"***

The Economic Development Administration operates a regional innovation cluster program that identifies and supports regional innovation clusters, but EDA's efforts are underfunded. Federal efforts should focus on providing matching funding for regional and state technology commercialization, R&D, and workforce training programs. For instance, the Administration should champion Congressional passage of S. 4047, Senate legislation which would create a Federal Acceleration of State Technologies Deployment Program, or "FAST," a federal funding strategy for accelerating the local commercialization of newly developed technologies by matching cash-poor state programs.[xxxiii]

Q20: ***How should the federal government promote the creation of metropolitan "innovation districts"?***

The regional innovation hubs spurred by DoE through the stimulus were great case studies, but they need additional support to reach sustainable funding. One way to do this is to provide a regional commercialization angle to some R&D grants/Lab programs so that these entities are engaged more in the R&D phase of tech development. Further, as ITIF and Brookings write in *Going Local: Connecting the National Labs to their Regions for Innovation and Growth Task*, DoE should task the labs with a regional economic development mission, including opening the labs to small- and medium-sized businesses and increasing their relevance to regional and metropolitan clusters, for example by creating off-campus "microlabs" to provide a "front door" to the labs.[xxxiv]

Q24: ***What new areas should be identified as "national priorities"?***

On this question, the Administration should ask "what would be the top five to ten technologies that, if we could develop them, would have the greatest impact on U.S. productivity and standard of living?" Part of the answer would certainly include cures for Alzheimer's, other chronic diseases, and forms of cancer. Recognizing that a 1 percent reduction in mortality from cancer would deliver roughly $500 billion in net present benefits, while a cure would deliver $50 trillion in present and future benefits, the Administration should insist that Congress maintain NIH funding at a level commensurate with at least one quarter of one percent (0.25 percent) of national GDP or higher.[xxxv] In the energy sector, this should include batteries; cheap, high-energy-conversion solar materials; drop-in, low-carbon fuels, and inexpensive methods for pulling carbon dioxide out of the atmosphere. Robotics and materials that last forever or that possess self-healing properties should also be treated as national priorities.

Still, productivity increases remain the principal way that economies grow. Accordingly, the United States should develop an American Productivity Commission modeled after Australia's Productivity Commission, whose mission is to promote productivity-enhancing public policies, initiate research on industry and productivity issues, hold public inquiries, and promote public understanding of matters related to industry and productivity.[xxxvi]

Q25: What federal policies could unleash additional corporate and philanthropic investment?

Better federal policies can help here—for example, a more generous R&D tax credit that also allows start-ups to take it could spur more corporate R&D. Also, more energy R&D programs requiring private/philanthropy matching could get more non-public skin in the game. The Administration should expand the use of prizes and grand challenges matched by corporate and philanthropic donors.

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September 23, 2014

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The Internet Association[1] appreciates the opportunity to submit written comments in response to the White House Office of Science and Technology Policy and the National Economic Council's request for information to update the Administration's *Strategy for American Innovation* (Strategy). We hope our comments will serve as a guide for the Administration in prioritizing specific policies critical to promoting the Internet economy and ultimately American innovation.

We commend the Administration's recognition that continued innovation is essential for increased economic growth and global competitiveness. In the 2011 Strategy report, President Obama is quoted as stating "the key to our success … will be to compete by developing new products, by generating new industries, [and] by maintaining our role as the world's engine for scientific discovery and technological innovation."[2] The report further explains, "the American economy is built on an enduring capacity for idea creation and diffusion."[3] These observations capture the very essence of the Internet. Often described as a decentralized, participatory platform for innovation, trade, and commerce, the Internet sparks creativity, cultivates ingenuity, amplifies speech, and encourages communication among its nearly 3 billion users.

[1] The Internet Association, represents the interests of the leading Internet companies including Airbnb, Amazon, AOL, Auction.com, eBay, Etsy, Expedia, Facebook, Gilt, Google, Groupon, IAC, LinkedIn, Lyft, Monster Worldwide, Netflix, Practice Fusion, Rackspace, reddit, Salesforce.com, SurveyMonkey, TripAdvisor, Twitter, Uber Technologies, Inc., Yelp, Yahoo!, and Zynga. We are dedicated to advancing public policy solutions to strengthen and protect Internet freedom, foster innovation and economic growth, and empower users.
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The Internet truly has transformed the U.S. and global economies: The numbers are astounding. In the past few years, the Internet accounted for 21% of GDP growth in advanced economies. It facilitates about $8 trillion in e-commerce annually across the globe, with the U.S. capturing more than 30% of global Internet revenues and more than 40% of net income. In a recent study, we found that Internet enabled part-time businesses contributed $141 billion to the U.S. economy and employed 6.6 million people in 2011 alone.[4] Given the Internet's expansive growth and its impact on all sectors of our economy, these numbers are just the tip of the iceberg.

The U.S. has well-established laws and policies that allowed the Internet to develop into the revolutionary platform that it is today. As the digital economy continues to bolster the U.S. economy, it is vital that the U.S. government support policies that ensure an open Internet for continued innovation and economic growth. In particular, our industry urges the Administration to continue efforts in making government data open and readily available while also allocating resources to research & development to support data-driven innovation. The Internet Association supports the Administration's prioritization of policies related to data innovation, intellectual property (IP), and trade.

I. INVEST IN THE BUILDING BLOCKS OF AMERICAN INNOVATION

Supporting Data-driven Innovation. Though the 2011 Strategy report committed to "building a data-driven government," this reference focused specifically on IP.[5] In just three years, both the private and public sectors have come to better appreciate the benefits of data-driven innovation. For instance, President Obama allocated $14 million for a data-driven innovation fund in his 2014 fiscal budget.[6] It is clear that the Administration understands that data analytics increase efficiencies and effectiveness of commercial and government services. In "Big Data: Seizing Opportunities, Preserving Values," the Administration acknowledged that data analytics

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[4] THE INTERNET ASSOCIATION, INTERNET ENABLED PART-TIME SMALL BUSINESSES BOLSTER U.S. ECONOMY (Oct. 2013), *available at* http://internetassociation.org/wpcontent/uploads/2013/10/InternetAssociationExecutiveSummary-InternetEnabledPartTimeSmallBusinessesBolsterEconomypdf.pdf.
[5] *2011 Strategy Report* at 44.
[6] EXECUTIVE OFFICE OF THE PRESIDENT, *Federal Funds,* http://www.whitehouse.gov/sites/default/files/omb/budget/fy2014/assets/eop.html (last visited Sept. 22, 2014).

"boost[s] economic productivity, drive[s] improved and government services, thwart[s] terrorists, and save[s] lives."[7]

Making Government Data Readily Available. The Administration has demonstrated its commitment to data analytics through various channels. Its launch of the Open Data Initiative is a strong step towards unleashing government data to fuel scientific discovery and spur growth. This initiative has already successfully released troves of high-priority datasets to address the needs of the public and private sector. For example, the Administration's recent launch of the National Oceanic and Atmospheric Administration (NOAA) open data website will support these goals by making datasets containing valuable and otherwise unavailable environmental data publicly accessible. However, critical national, state, and city-wide emergency response and public safety alerts remain in proprietary data formats. The Administration should work to identify and use open data formats that address the growing need for open datasets in these "mission critical" areas. Additionally, technologies used for translating alerts from legacy systems to open data formats should be piloted within the First Network Responder Authority initiatives. Therefore, we encourage the Administration to further its efforts to make more government data readily available, as this could create significant societal and economic benefits, including job creation.

Reaffirming the Strength of the U.S. Privacy Regime. As the Administration seeks to promote data-driven innovation, particularly with government programs, there is an ongoing, parallel policy conversation regarding data analytics and its impact on consumers. This conversation has focused on responsible uses of data, distinguishing between uses that offer consumers beneficial services and uses that may result in concrete harm to consumers. Recent discussion has raised the concern that it could promote unfair practices or exclude certain communities. At its very core, the Internet's decentralized model thrives on inclusiveness, and Internet companies leverage data analytics to provide helpful innovations and services for all users – including (and often especially) underserved or oppressed communities. The U.S.'s flexible and multi-layered privacy framework provides robust protections against privacy violations and permits industry players who conduct business within these guidelines to freely innovate. Rather than taking efforts to revamp the current U.S. privacy framework and policies, which could potentially disrupt innovative advances and limit opportunities created by data use, we urge the

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[7] EXECUTIVE OFFICE OF THE PRESIDENT, BIG DATA: SEIZING OPPORTUNITIES, PRESERVING VALUES 5 (2014), *available at* http://www.whitehouse.gov/sites/default/files/docs/big_data_privacy_report_may_1_2014.pdf.

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Administration to reaffirm the strength of our nation's existing privacy regime and commit to support privacy regimes that support responsible and fair data innovation. Moreover, we urge the Administration to focus on harmful uses of data rather than mere data collection, which will ensure that data continues to reveal new pathways for innovation.

Promoting Research and Development for Privacy-Enhancing Technologies and Digital Literacy. Rather than pursuing a new legal framework for data analytics, the Administration should dedicate resources to research and development on privacy-enhancing technologies, such as de-identification, to ensure that data-driven innovation continues to spur economic growth and trigger important societal changes, to the benefit of all American consumers. Additionally, we support the Administration's continued efforts with its Digital Literacy Initiative intended to assist Americans in increasing their online skills.[8] The Administration should also devote resources to developing digital literacy resources and curricula to be used in schools and communities nationwide. Populations that are starting to gain exposure to the Internet ecosystem—students, young adults, seniors, and low-income communities—would benefit immensely from effective training on how to manage their information online and take advantage of digital tools that will enhance their educational, professional, and social endeavors.

II. PROMOTE MARKET-BASED INNOVATION

Patent Reform. The 2011 Strategy report supported comprehensive patent reform efforts that ultimately led to passage of the America Invents Act (AIA). Since then, President Obama has acknowledged that although the AIA solved some problems with the U.S. patent system, others remain. In particular, levels of abusive patent litigation continue to grow, largely due to patent assertion entities (commonly known as patent trolls). Patent legislation is needed to stop patent trolls from "hijacking somebody else's idea"[9] by taking advantage of the high volume of poor quality patents combined with an inefficient and expensive litigation system to extort settlement payments from defendants. The harm to innovation is significant. In 2011, patent trolls cost defendants $29 billion in direct costs - resources that could be better used to advance innovative technologies. And, the cost to the U.S. economy is exponential - a $320 billion loss in the last four years alone.

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[8] OFFICE OF SCI. & TECH. POLICY, *Digital Literacy Initiative Aims to Help Americans Build Online Skills,* http://www.whitehouse.gov/blog/2011/05/13/digital-literacy-initiative-aims-help-americans-build-online-skills (May 13, 2011).
[9] The White House, *President Obama Participates in a Fireside Hangout on Google+,* YOUTUBE (Feb. 14, 2013), https://www.youtube.com/watch?v=kp_zigxMS-Y#t=16m04s.

Legislation that promotes efficient litigation and high quality patents will increase certainty for inventors and encourage investment. We call on the Administration to support legislation that will raise pleading standards in patent cases, achieve early determination of the meaning and scope of a patent, deter superfluous and burdensome discovery requests, and deter frivolous cases through fee shifting.

Balance in Copyright Law. In addition to patent policy, copyright policy is essential to our industry and as well as to American innovation overall. Presently, the U.S. House Judiciary IP Subcommittee is conducting a comprehensive review of the U.S. copyright system, and the United States Patent and Trademark Office has launched its multi-stakeholder process on the Digital Copyright Millennium Act (DMCA), a law that played a key role in the growth of the Internet. While our industry is engaged in these processes, we believe that the current U.S. copyright system works as intended even in the face of incredible innovation and changes relating to technology and content delivery platforms, which have promoted increased user innovation in online content. Balanced copyright law is the linchpin of the Internet's seamless operation, and today's marketplace shows that the current system achieves the appropriate balance between incentivizing creators, while at the same time permitting the public to enjoy their works. Additionally, court decisions taken into consideration alongside voluntary industry agreements, development of systems that identify rightsholders' works and create opportunities for rightsholders to monetize distribution, and the increase of legitimate digital services ensure that rightsholders may adequately protect these works while allowing users to access and build on their works through extensive exceptions and limitations such as fair use and the first sale doctrine.

The Internet Association encourages the Administration to recognize the importance of the intermediary liability protections afforded through the DMCA, which allows innovators to invest time, money, and talent to continuously create new services. A 2013 National Research Council study, *Copyright in the Digital Era: Building Evidence for Polic*y, revealed that assumptions that the digital era undermines copyright protection are "poorly informed by objective data and independent empirical research."[10] Therefore, we caution the Administration

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[10] NATIONAL ACADEMY OF SCIENCES, COPYRIGHT IN THE DIGITAL ERA: BUILDING EVIDENCE FOR POLICY 1 (2013) *available at* http://www.ip-watch.org/weblog/wp-content/uploads/2013/05/NRC-Copyright-in-the-Digital-Era-FINAL-Apr-2013.pdf.

against these assumptions and inflexible copyright policies, which are likely to harm investment and weaken the economy.

Facilitating Digital Trade. U.S. innovation policy should work to promote a pro-innovation, pro-Internet environment globally. Unfortunately, many countries have adopted or are considering restrictive approaches to Internet regulation that deviate substantially from the U.S. This will hurt both U.S. Internet firms as well as the entire cross section of U.S. industry that relies on the Internet to engage in the global economy.

The U.S. is a net exporter of Internet-related services and products because it has the most Internet-friendly policies in the world. Those Internet-friendly policies should be reflected in U.S. trade policy. As Congress works to renew Trade Promotion Authority to reflect the current digital economy, and as the United State Trade Representative negotiates high-stake trade agreements with Asia Pacific nations and the European Union, we encourage the government to revamp its trade IP template to reflect the full balance of U.S. copyright law. Outside of the IP context, Section 230 of the Communications Decency Act, which enables Internet platforms to host content without being considered the speaker of that content, has been another critical element in the Internet's economic and societal success. Promoting such a policy in U.S. trade policy will only further promote exports of Internet-related services. Furthermore, we support any future efforts by the U.S. government in revisiting trade policy related to services, customs, and financial services arenas to reflect innovations taking place in these sectors due to the Internet. Lastly, we encourage the Administration to prioritize policies to ensure facilitation of the global free flow of information.

III. CONCLUSION

The Internet industry has made significant contributions to American innovation, and we encourage the Administration to prioritize policies related to data, IP, and trade to advance the economic opportunities and societal benefits made possible by this evolving platform. Additionally, we believe that the Administration's dedication of resources to research and development, particularly as it relates to privacy enhancing technologies such as de-identification, will solidify the U.S.'s position as a global leader in the innovation economy.

Respectfully Submitted,

/s/Michael Beckerman
Michael Beckerman
President & CEO
The Internet Association

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JNCL-NCLIS

Foreign Languages & Innovation

Comment on the *Strategy for American Innovation* from the National Council for Languages and International Studies

September 2014

Overarching Questions

(2) What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?
The United States stands to derive a tremendous benefit in economic growth, productivity, leadership and entrepreneurship by investing in language education and promotion for its citizens. Economic growth and productivity can be facilitated by expanding the portion of Americans that can competently operate in cross-cultural settings in business as well as research. Specifically in the category of research and innovation, it is imperative that Americans in those fields possess the intercultural knowledge and language ability to converse and collaborate with their peers as they explore and innovate. To an ever-increasing degree, English is no longer the sole or dominant language of exploration and research, and our sector leaders will be cut off from valuable developments around the world if they are unable to communicate and understand their global counterparts, resulting in declining competitiveness as well as cooperation. Lastly, studies have demonstrated that language learning and bilingualism include cognitive benefits such as improved problem solving and creativity, skills essential for entrepreneurs and innovators.

(5) What innovation practices and policies have other countries adopted that deserve further consideration in the United States? What innovation practices and policies have been adopted at the state or local level that should be piloted by the Federal Government?
Governments around the world are investing in language education to give their students and workers an edge in the global market place and to fuel competition and development. English instruction is standard across the globe, but study is not limited to English. Our monolingual partners Australia and the Great Britain are outpacing the United States in investment in the languages of their trade partners and innovation competitors. Great Britain, after dropping language requirements a decade ago has reinvested, making language compulsory for all students up to the fifth grade. Similarly, the Australian government has recently opted to pilot pre-school foreign language programs, and is promoting study of other Southeast Asian languages in order to secure its influence in the region. The Irish government has invested in the Centre for Next Generation Localisation and the Localisation Research Centre, spending several million Euros per year. Similarly, the EU continues to invest in R&D and training for the

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language industry, with a EU Master's in Translation as well as research programs for computational linguistics, machine translation, and standards for translation and localization.

Skilled Workforce Development

(13) What emerging areas of skills are needed in order to keep pace with emerging innovations or technologies? What are successful models for training workers with these skills to keep up with emerging innovations?
There is a critical need to harness the technological capabilities to facilitate the acquisition of languages. Gone are the days that textbooks are the medium through which languages are learned. There are innovative approaches to language acquisition, such as DuoLingo and WeSpeke, that should be replicated for use in the classroom in order to engage American students in the language learning process.

(14) What mechanisms or programs can effectively increase the supply of workers with technical training, from industry-recognized credentials and postsecondary certificates to two- and four-year degrees?
The federal government might create an industry-recognized level of language proficiency for specific technical jobs needed by the U.S. Government and by specific industry sectors. This would motivate Americans to pursue language learning specific ways to measure language outcomes. Until the federal government steps in to encourage Americans to learn languages other than English, we will continue to fall behind in the ability to engage with others around the world to pursue innovations in a wide variety of sectors. Additionally, federal investment in programs for translation, interpreting, and language engineering/localization should be made. These areas are critically under-resourced in terms of federal funding, and the US faces a significant gap in skilled workers in these areas.

National Priorities

(24) Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?
In an increasingly interconnected and interdependent world where American jobs and exports are more dependent than ever on foreign markets; where Americans are engaged diplomatically and militarily around the globe as never before; and where issues such as the environment, health and disease, poverty, development, and government instability are increasingly defined as global problems that require international understanding and cooperation, the ability to communicate in languages and with cultures other than one's own has never been more vital. Even within our nation's own borders, a growing foreign-born population has far-ranging implications on the need for employees with linguistic and intercultural skills.

Yet Americans remain glaringly deficient in language skills. Although the United States is a nation of immigrants, only 9% of Americans speak a foreign language while just 18% of K–12 students and 8% of college students study a foreign language. Moreover, a decreasing number of schools are teaching languages and only 10 states require a foreign language for graduation. Monolingual Americans are graduating into a global marketplace where 22 out of 25 industrialized nations begin language studies in Grades K–5 and where 22 European Union countries mandate that students have had a minimum of 9 years of at least one foreign language. As Leon Panetta, Former Secretary of Defense, stated in 2000, "The United States may be the only nation in the world where it is possible to complete secondary and postsecondary education without any foreign language study whatsoever."

Presidential commissions as well as politicians, business leaders, and educators have been decrying the poor state of our foreign language competence for decades. In 1979, the President's Commission on Foreign Language and International studies found that "Americans' incompetence in foreign languages is nothing short of scandalous." Thirty-five years later, the state of our nation's language competence has not improved.

Therefore, we need a national priority to expand language learning at all levels of education, to train language workers, and to support the R&D required to keep the US at the cutting edge of this 21st century skill.

Appendices include responses that contributed to this submission from member organization of the National Council for Language and International Studies, as well as papers detailing the intersection of language and technology that were prepared at the request of OSTP in 2013 and 2014.

Appendix A: Response from Parents for a Global Education Association (PANGEA)
Appendix B: Response from the American Council on the Teaching of Foreign Language
Appendix C: Response from the Texas Foreign Language Association
Appendix D: Foreign Languages and STEM
Appendix E: World Languages and Technology

Appendix A

Response to the Office of Science and Technology Policy's Request for Information from PANGEA

The mission of PANGEA (Parents for a Global Education Association) is to prepare our children to be successful and productive citizens in a globalized world by supporting and promoting language immersion education.

PANGEA started its activities in the Cambridge Public School District and is now active on the Massachusetts state level where we are part of a coalition pushing for legislation that would support language immersion education for all children.

As parents, we are preoccupied by the future and focused on preparing our children to succeed and achieve happiness in that uncertain future. Our children – and their ability to lead and innovate on the global stage - will determine the future of this country. Because of this, and the role we play in choosing and providing for our children's education, it is imperative that the voices of parents be heard in any discussion of how best to enable innovation in the US.

It is our belief that language learning and, in particular, immersion language education are critical ingredients of future innovation in the United States. We speak as parents not experts but we have come to this conclusion for reasons that are based on solid evidence and research.

Knowing more than one language means knowing more than one culture which, in turn, opens up the ability to understand different perspectives and compare and contrast between cultures. The MIT data scientist Alex "Sandy" Pentland puts it this way: "We are used to emphasizing individual creativity, but we've found that creativity is mostly just the connecting of ideas that already exist. This is the source of innovation."

To be entrepreneurial and innovative in today's interconnected world one needs the skill set to spot opportunities in the global context and to assess the challenges posed by developments in other countries. Key ingredients of this skill set are speaking multiple languages and understanding multiple cultures. It is no coincidence that Chinese kindergartners are learning English and that Chinese high school students are studying American history. We as a country will be left behind if we are not able to understand our competition better.

Our public education system is in crisis. In a variety of different tests we compare badly with other countries. What is more the so-called "achievement gap" in public education is growing. Language immersion education offers a solution and hope. Research shows that the cognitive benefits of learning in two languages simultaneously can help level the playing field for children from lower socio-economic backgrounds. Research also shows that two-way language immersion programs serve English Language Learners (ELL) better than mono-lingual schools thus taking advantage of the huge resource that this country has with its myriad non English speaking communities.

There are a number of initiatives currently under way in the US that support language immersion teaching but they are piecemeal. The state of Utah is leading the way in elementary school education with its language immersion office and is providing support and advice to other states. The Asia Society is beating the drum for more widespread immersion teaching across the country. The DOD's National Security Education Program supports advanced language learning at the undergraduate level. It is time for the Federal Government to make language learning a priority and to provide sustained and integrated support for language immersion education *for all children* – fluency in more than one language can make a significant contribution to boosting innovative thinking in the United States.

Maria Balinska and Jane Chiang
Co-coordinators, PANGEA (www.pangeacambridge.com)
[redacted]
August 30, 2014

Appendix B

Response to the Office of Science and Technology Policy's Request for Information from the American Council on the Teaching of Foreign Language (ACTFL)

Skilled Workforce Development

What emerging areas of skills are needed in order to keep pace with emerging innovations or technologies? What are successful models for training workers with these skills to keep up with emerging innovations?
There is a critical need to harness the technological capabilities to facilitate the acquisition of languages. Gone are the days that textbooks are the medium through which languages are learned. There are innovative approaches to language acquisition, such as Duolingo and WeSpeke, that should be replicated for use in the classroom in order to engage American students in the language learning process.

(14) What mechanisms or programs can effectively increase the supply of workers with technical training, from industry-recognized credentials and postsecondary certificates to two- and four-year degrees?
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National Priorities

Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?
In an increasingly interconnected and interdependent world where American jobs and exports are more dependent than ever on foreign markets; where Americans are engaged diplomatically and militarily around the globe as never before; and where issues such as the environment, health and disease, poverty, development, and government instability are increasingly defined as global problems that require international understanding and cooperation, the ability to communicate in languages and with cultures other than one's own has never been more vital. Even within our nation's own borders, a growing foreign-born population has far-ranging implications on the need for employees with linguistic and intercultural skills.

Yet Americans remain glaringly deficient in language skills. Although the United States is a nation of immigrants, only 9% of Americans speak a foreign language while just 18% of K–12 students and 8% of college students study a foreign language. Moreover, a decreasing number of schools are teaching *languages and only 10 states require a foreign language for graduation. Monolingual Americans are graduating into a global marketplace where 22 out of 25 industrialized nations begin language studies in Grades K–5 and where 22 European Union countries mandate that students have had a minimum of 9 years of at least one foreign language. As Leon Panetta, Former Secretary of Defense, stated in 2000, "The United States may be the only nation in the world where it is possible to complete secondary and postsecondary education without any foreign language study whatsoever."*

Presidential commissions as well as politicians, business leaders, and educators have been decrying the poor state of our foreign language competence for decades. In 1979, the President's Commission on Foreign Language and International studies found that "Americans' incompetence in foreign languages is nothing short of scandalous." Thirty-five years later, the state of our nation's language competence has not improved.

Appendix C

Response to the Office of Science and Technology Policy's Request for Information from the Texas Foreign Language Association (TFLA)

Dear Sirs:

Please consider that languages are essential to a well-rounded education and global citizenship. The process of learning another language allows students to approach the world from different perspectives not reflected in their culture at home. It allows them to process information outside the confines of the society in which they live. It helps them understand that their opinions are not the only opinions, and not always the right ones. The study of languages breaks down barriers between people and countries by allowing them to appreciate differences in perspectives and opinions that could help them develop diplomatic and business relationships that can lead to peace and profitable business relationships. Beyond diplomacy and business, science and technology can benefit from the improved communication between scientists and technologists from various countries. The contributions from various sources aided by an improved ability to communicate in more than one language can lead to the development of vaccines and medicines, for example, in a more timely fashion. It can also lead to great leaps in technology that could benefit the human race.

If this is not enough to convince one of the necessity of learning a second or third language, consider how important it is to national security. Without the ability to understand what is being said by another person, one must rely on a third party to translate. Depending on that person's intentions, many things can be lost in translation. How much better it would be to be able to communicate directly with the person, or at least be able to understand what the interpreter is saying, instead of simply trusting that what is said in one language, is what is being communicated in the other.

In order to make that happen, we must start educating our students at a much younger age for a much longer sequence of study. Language proficiency does not occur overnight and requires a sizeable investment of effort on the part of the student and the teacher. Not only does it require class time, but study abroad. Obviously, the latter requires money to cover the expenses of travel, lodging, and tuition. The money for salaries for teachers for the younger students needs to be made available, as well as scholarships for study abroad for older students and teachers. Since language evolves over time, refresher courses are a must for teachers so they can remain current in the latest terminology in that particular country.

Appendix D

Foreign Languages and STEM
June 4, 2013

Overview: This paper provides a rationale to recognize Foreign Languages (FL) as an integral element of the Nation's STEM efforts. Beyond its role as a skill vital to the 21st century, FL has long been an element of the federal STEM portfolio. The work performed by the $15b US language industry is highly technologized. Finally, US STEM industries depend on the language industry to reach overseas markets worth $1.5 trillion.

Language has long been a STEM research subject: The Federal Government has funded R&D in a wide range of language fields for more than 50 years. These fields include theoretical and applied linguistics, sociolinguistics, the sociology of language, computational linguistics, first and second language acquisition, human language technology, translation and interpreting studies, machine translation, and many more. Funding derives from the NSF, DARPA, IARPA, NIH, OSD, and the IC, among others.

Language is a highly technologized STEM industry: The language industry is inextricably linked with technology, which now forms the core of nearly all work in the language sector. Localization is entirely digital, relying on workflow systems, translation management systems, translation memories, terminology and data mining, complex desktop publishing, content management systems, and machine translation, among other technologies. Translation and localization firms of any significant size have full IT teams to manage the required operating systems, interfaces, networks, and databases. Other language work, such as interpreting and teaching, relies increasingly on the information economy for the delivery of services. Finally, the language industry drives innovative R&D that cut across STEM, the social sciences, and the humanities.

America's STEM industries depend on the language industry: The work of traditional STEM enterprises is now inevitably global; advances hardly occur in one country or market. Multilingual communication is intrinsic to today's scientific progress, which means the language industry is fundamental to furthering every aspect of STEM professions and business. STEM companies in numerous sectors depend on the language industry to access more than $1.5 trillion in domestic and overseas markets.

Recommendation: As the U.S. supports and promotes STEM, it is vital that the language enterprise be included in the policy and planning for STEM. Specifically: languages should to be included in STEM educational policy; FL and linguistics research should be highlighted within the STEM accounts; and STEM-related policies on immigration reform, small businesses, and other areas should include FL.

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Appendix E

World Languages and Technology

The past decade has seen a revolution in how languages work. Technology is now considered an essential component of every language-related area – learning, translation, interpreting, and more. Machine translation, automated speech recognition, network analytics, and other technologies have been fused with well-known increases in computing power, storage capacity, and bandwidth. Applications unforeseen as little as 10 years ago, in particular in social media and cloud computing, have generated whole new fields of activity for language. Below are some key ways language and technology now intersect.

Translation and localization have been completely transformed by technology. Translation work now relies on Translation Memories (TM), Content Management Systems (CMS), Machine Translation (MT), and Translation Management Systems (TMS) to connect and manage globally distributed teams. Today's technologized translation industry is able to process an unprecedented volume, velocity, and variety of languages with greater consistency and reuse than ever before. Language technology has generated new categories of skills and jobs, and the opportunities for language work are exponentially greater.

Interpretation, still largely a face-to-face or in-person service, is increasingly being provided remotely on demand and for scheduled meetings. New forms of remote interpreting are emerging to meet increased demand in different settings. These platforms make use of wireless Internet, VoIP, video and web conferencing and other technologies to expand access while reducing costs associated with traditional service.

Second Language learning and teaching: Technology affords many advantages, among which are:
- Access to language instruction at a distance, including remote communities (Middlebury Interactive);
- Access to pedagogically appropriate authentic materials in almost any language via the web (SCOLA)
- Access to native speakers for conversation practice through language learning social media sites (WeSpeke)
- Tailoring curricula to optimize classroom time and homework (Transparent Languages)

Taken together, learning technology is transforming language education in the US, allowing students to interact with authentic language sources, communicate directly with speakers of other languages, and work individually, with classmates, or with groups in the country of the language being studied. Technology enables flipped classrooms and facilitates teachers' ability to meet the Common Core standards. Effective use of blended learning technologies has resulted in higher language proficiency outcomes, lower costs, lower attrition, and greater learner motivation at multiple US Government and academic language programs. Technology is also helping to level the playing field for certain students, including the non-traditional student, working students, students with families, and students with disabilities.

Preservation of languages of lesser diffusion and endangered languages is now possible because of digital recording technology, web-based access, and the ability to create new character sets. As a result, some languages have been rescued from the brink of extinction, and more than 1,000 languages are now active and commercially viable online.

ACKNOWLEDGEMENTS: JNCL-NCLIS thanks its members who contributed to this report: the Computer Assisted Language Instruction Consortium, the International Association for Language Learning Technology, the American Council on the Teaching of Foreign Languages, American Councils for International Education, the American Translators Association, Interpret-America, the Defense Language Institute Foundation, the Center for Applied Linguistics, the Center for the Advanced Study of Language, the Linguistic Society of America, the Council of Language Resource Center Directors, Monterey Institute of International Studies, Kent State University Institute of Applied Linguistics, Middlebury Interactive Languages, SCOLA, WeSpeke, Transparent Language, Global Professional Search.

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Comments of KEI regarding the White House OSTP call for comments on its *Strategy for American Innovation*

Attn: Dan Correa, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Ave NW., Washington, DC 20504.

Email: innovationstrategy@ostp.gov.

Re: *Strategy for American Innovation*

Date: September 23, 2014

Knowledge Ecology International is a non-profit organization. Information about KEI is available from our web page at http://keionline.org. Our comments follow:

1. The USPTO Office of the Chief Economist has yet to address some obvious questions about patent and copyright policy.

Many persons thought government policy makers needed to use more economic analysis to address controversial questions such as the costs and benefits of extended copyright or patent terms, or whether or not patents should be granted for software or business methods. So far, the Office of the Chief Economist (OCE) at the USPTO is best known for the widely ridiculed March 2012 report: *Intellectual Property and the U.S. Economy: Industries in Focus,* which used jobs in grocery stores and cut rate clothing stores to create the easily anticipated impression that millions of jobs depend upon every expanding intellectual property rights. This report, quoted endlessly by the former head of the USPTO David Kappos and hundreds of right holder public relations agents, came at a time when the United States needed to ask hard questions about copyright and patent policies. With the rise of a dynamic technology sector that dominates the global economy, the USPTO might have asked, do software patents create or hurt job growth? Does copyright fair use expand US jobs, or shrink US jobs? Instead, we have a report that makes no attempt to make any useful conclusions about the real challenges facing policy makers, and a government report that appears to have been designed largely as propaganda for a handful of right holders, including an increasingly strident motion picture industry that uses the report to justify 95 year copyright terms, and pharmaceutical companies that excel in raising prices for life saving drugs to an aging population.

KEI recommends the USPTO OCE adopt a work program that begins to explain why we grant patents for certain activities, and attempts to evaluate the appropriate term of protection and the balance of rights and exceptions that enhance our wealth and social welfare.

2. Federal agencies that fund or subsidize clinical trials for new drugs and vaccines should publish accessible data on the costs of those trials. *Sui generis* intellectual property rights for medical inventions should be conditioned upon the disclosure of data on the economics of drug development.

Nearly all significant debates about the appropriate pricing and intellectual property rights for drugs and vaccines are influenced by highly selective and sometimes self serving studies of drug development costs, based upon closely held and/or secret industry data sets. At the same time, the United States government spends billions of dollars on clinical trials. If the public and government policy makers want to have better evidence of drug development costs, they could begin by looking at the costs of the trials that they are already funding. This would include trials subsidized or funded by the NIH, the CDC, the Department of Defense, Homeland Security, the Department of Veterans Affairs, or other federal agencies.

When KEI contacted the NIH asking for information on the costs of vaccine trials, we were told that the NIH does not collect that information in any formats remotely accessible or useable for studying the economics of vaccine development. If true, this is a troubling omission.

KEI has been unable to get GAVI to respond to requests for information on vaccine trial costs.

The Gates Foundation has not expressed a willingness to share information with the public on the costs of vaccine trials.

Among the countless government and donor funded public/private partnerships involved in drug development, there have been only a few episodic efforts to provide evidence of the costs of the trials for the public's use.

There are many extraordinary public benefits and subsidies given to drug developers, such as the Orphan Drug Tax Credit, which covers 50 percent of qualifying trial costs, the seven years of Orphan Drug market exclusivity, the six months of exclusivity for pediatric testing, FDA test data exclusivity for pharmaceutical drugs (3 and 5 years) and biologic products (12 years), and FDA and USPTO patent extensions. These benefits are worth billions of dollars to drug developers, and cost consumers and other taxpayers billions of dollars. There are no current obligation on the companies enjoying these benefits to share any data with the public on the actual economics of drug development, or the sales generated by these products.

Does anyone honestly believe the public interest is served by policies that maintain deliberate ignorance of drug development costs?

3. Information on the licensing of federally funded inventions is not well organized, or accessible.

The federal government should require that all licenses for patented inventions that have benefited from federal subsidies be made public, with minimal and time limited redactions. This should extend not only to NIH funded inventions, but to all federal agencies and to anyone who receives federal funding, including researchers associated with universities and businesses.

The NIH should end its practice of redacting the royalty rates on NIH owned patent licenses, and it should report all royalty income from specific licenses, if not immediately, after a reasonable delay.

4. Open Source Dividend programs can better align private incentives with public interests.

At present, there are strong private incentives to restrict access to research, by patenting research, or keeping information private, in order obtain the commercial benefits associating with the licensing of the knowledge, materials or technology. This often makes sense for individuals, but not necessarily for society.

Sir John Sulston was awarded the 2002 Nobel Prize in Physiology or Medicine. Sir John Sulston also played a key role in pushing for sufficient funding to ensure that the core data from the Human Genome Project entered the public domain. (See, Sulston and Ferry, The Common Thread, 2002).

In one interview, Sulston speculated that medical research in the public domain is worth nine times as much as medical research that is held privately by pharmaceutical companies, because opennesses accelerates scientific progress.

Innovation inducement prizes also present special issues. If an innovation inducement prize can be obtained without patents, drug developers may have incentives to rely even more on trade secrets, and issue address by several academic researchers.

The open source dividend is designed to create an economic incentive to share knowledge, materials and technology. As proposed in federal legislative proposals by Senator Sanders (see, for example, S.627, 113th Congress), a portion of innovation inducement prize could be allocated to persons who openly shared knowledge, material and technology, that were deemed useful in the development of the prize winning products.

See: James Love and Tim Hubbard, "Prizes for Innovation of New Medicines and Vaccines," Annals of Health Law, Vol. 18, No 2, pages 155-186, Summer 2009.

The open source dividend does not rely upon the use of innovation inducement prizes. Indeed, one could simply require that a percent of all drug sales (or drug sales reimbursed by Medicare and Medicaid) go into a fund to be allocated to the open source dividend. The allocation could be managed through a jury system, that would accept nominations for open sourced research that would earn a share of the open source dividend.

Drug developers would both pay and benefit from this system. They would pay by sharing the revenue from the product sales or rewards. They would benefit by the expanded access to royalty free knowledge, materials and data, and fewer transaction costs.

5. Fund the request by the National Academies to study the feasibility of delinkage in drug development.

It is now fairly obvious that there will be no serious reform of drug pricing or innovation incentives without full delinkage of R&D costs from drug prices. The National Academies has proposed a study of the feasibility of delinkage strategies, including end prizes, open source dividends and upstream prizes managed by competitive intermediaries. This should move forward.

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Comments in Response to *Request for Information re: Strategy for American Innovation*

by

Stuart Buck
Vice President of Research Integrity, Laura and John Arnold Foundation
September 23, 2014

I. Introduction

The Laura and John Arnold Foundation (LJAF) submits these comments in response to the Request for Information by the White House Office of Science and Technology Policy and the National Economic Council. In particular, we intend to address the following question: "Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?"

Our foundation is a leading advocate for open science and improved research standards across various disciplines. Among other things, LJAF is the primary funder of the Meta-Research Innovation Center at Stanford University, an organization focused on improving the quality of medical research; and the Center for Open Science, an organization that works to promote transparency in scientific research and that has sponsored replication projects in both psychology and cancer cell biology.

By now, everyone has heard that many highly cited lab experiments on drug targets cannot be reproduced, even with the cooperation of the original investigators.[1] But this is just the tip of the iceberg. Publication bias and questionable research practices have been identified in virtually every field imaginable, such as clinical trials in medicine,[2] antibiotic resistance,[3] high-throughput bioinformatics,[4] neuroimaging,[5] ecology and evolution,[6] cognitive

[1] F. Prinz, T. Schlange, & K. Asadullah, "Believe it or not: how much can we rely on published data on potential drug targets?," *Nature Reviews Drug Discovery* 10 (Sept. 2011): 712.

[2] S. Hopewell et al., "Publication bias in clinical trials due to statistical significance or direction of trial results," Cochrane Database of Systematic Reviews 1 (2009).

[3] J. Caryl, "My published negative result," *The Gene Gym* (11 Oct. 2012). Available at http://www.scilogs.com/the_gene_gym/my-published-negative-result/.

[4] K. A. Baggerly & K. R. Coombes, "Deriving Chemosensitivity from Cell Lines: Forensic Bioinformatics and Reproducible Research in High-Throughput Biology," *Annals of Applied Statistics* 3 (2009): 1309-1334.

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science,[7] public health and epidemiological research,[8] genetic research on fruit flies,[9] animal research on potential stroke treatments,[10] parenting programs,[11] economics,[12] political science,[13] psychology,[14] psychiatry and psychotherapy,[15]

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[5] "Repeat after me: Replication in clinical neuroimaging is critical," available at http://www.sciencedirect.com/science/article/pii/S2213158213000090; J. Carp, "Better living through transparency: Improving the reproducibility of fMRI results through comprehensive methods reporting," *Cognitive, Affective & Behavioral Neuroscience* 13 (Sept. 2013): 660-66; R. G. Jennings & J. D. Van Horn, "Publication bias in neuroimaging research: implications for metaanalyses," *Neuroinformatics* 10 (2012): 67–80.

[6] M.D. Jennions & A. P. Møller, "Publication bias in ecology and evolution: an empirical assessment using the 'trim and fill' method," *Biological Reviews of the Cambridge Philosophical Society* 77 (2002): 211–222.

[7] J. Ioannidis et al., "Publication and other reporting biases in cognitive sciences: detection, prevalence, and prevention," *Trends in Cognitive Sciences* 18 (2014): 235–241.

[8] S. Young & A. Karr, "Deming, data and observational studies: A process out of control and needing fixing," *Significance* (2011): 116-120; T. Churches, "The benefits of reproducible research: a public health example," available at https://github.com/timchurches/meta-analyses/tree/master/benefits-of-reproducible-research.

[9] D. L. Stern, "Reported *Drosophila* courtship song rhythms are artifacts of data analysis," *BMC Biology* 12 (2014): 38.

[10] J. A. Hirst et al., "The Need for Randomization in Animal Trials: An Overview of Systematic Reviews," *PLoS ONE* (June 6, 2014), DOI: 10.1371/journal.pone.0098856; E.S. Sena et al., "Factors affecting the apparent efficacy and safety of tissue plasminogen activator in thrombotic occlusion models of stroke: systematic review and meta-analysis," Journal of Cerebral Blood Flow and Metabolism 30 (2010): 1905–1913.

[11] P. Wilson et al., "How evidence-based is an 'evidence-based parenting program'? A PRISMA systematic review and meta-analysis of Triple P," *BMC Medicine* 10 (2012): 130.

[12] D. S. Hamermesh, "Replication in Economics," *Canadian Journal of Economics* 40 (2006): 715-33; J. Ioannidis & C, Doucouliagos, "What's to know about the credibility of empirical economics?," *Journal of Economic Surveys* 27 (2013): [redacted] S. Necker, "Scientific misbehavior in economics," *Research Policy* (18 June 2014), doi: 10.1016/j.respol.2014.05.002.

[13] J. Esarey & A. Wu, "The Fault in our Stars: Measuring and Mitigating 'Significance Bias' in Published Work," working paper (11 Nov. 2013), available at http://jee3.web.rice.edu/significance-bias.pdf/.

[14] C. J. Ferguson & M. Heene, "A vast graveyard of undead theories publication bias and psychological science's aversion to the null," *Perspectives on Psychological Science* 7 (2012): 555–561; J. P. Simmons, L. D. Nelson, & U. Simonsohn, "False-positive psychology: undisclosed flexibility in data collection and analysis allows presenting anything as significant," *Psychological Science* 22 (2011): 1359–1366.

[15] E. Turner, "Publication Bias, with a Focus on Psychiatry: Causes and Solutions," *CNS Drugs* 27 (2013): 457-68; J. Coyne, "Salvaging psychotherapy research: a manifesto," (10 June 2014),

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education,[16] sociology,[17] computer science,[18] nanochemistry,[19] computational astronomy,[20] and physics.[21]

We therefore applaud the White House's interest in scientific reproducibility. **This issue should be a major agenda and budgetary item for every federal agency that funds research, without exception.**

II. Possible Solutions

While space does not permit a thorough discussion of every possible remedy for every scientific field,[22] a few broad ideas would improve almost all of science.

A. *Mandate Greater Use of Pre-Registration*

At the outset of any experiment or observational study that aims to confirm any particular hypothesis, scholars should specify and publicly pre-register as much of their research design as is possible.

Pre-registration is the standard practice in clinical trials, particularly since the Food and Drug Administration (FDA) Amendments Act of 2007, and is

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available at http://blogs.plos.org/mindthebrain/2014/06/10/salvaging-psychotherapy-research-manifesto/.

[16] T. D. Pigott et al., "Outcome-Reporting Bias in Education Research," *Educational Researcher* 42 (3 Oct. 2013): 424-32.

[17] A. S. Gerber & N. Malhotra, "Publication bias in empirical sociological research: Do arbitrary significance levels distort published results?," *Sociological Methods & Research* 37 (2008): 3–30.

[18] "Examining 'Reproducibility in Computer Science,'" http://cs.brown.edu/~sk/Memos/Examining-Reproducibility/.

[19] G. Ozin, "Nanochemistry Reproducibility" (19 Sept. 2013), http://www.materialsviews.com/nanochemistry-reproducibility/.

[20] L. Shamir et al., "Practices in source code sharing in astrophysics," *Astronomy and Computing* 1 (Feb. 2013): 54-58.

[21] E. Gross & O. Vitells, "Trial factors for the look elsewhere effect in high energy physics,"*The European Physical Journal C - Particles and Fields* 70 (2010): 525–530; J. R. Klein & A. Roodman, "Blind analysis in nuclear and particle physics," *Annual Reviews of Nuclear and Particle Science* 55 (2005): 141–163.

[22] Many other ideas should be considered, such as uniquely identifying and validating reagents used in biomedical experiments. See N. A. Vasilevsky, "On the reproducibility of science: unique identification of research resources in the biomedical literature," *PeerJ* 1 (2013): e148, http://dx.doi.org/10.7717/peerj.148.

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becoming more common in social science as well.[23] The rationale both in clinical trials and elsewhere is that studies are much more informative and reliable if the following are specified ahead of time: the main and supporting hypotheses, primary outcomes, statistical methods, sample size, subgroup analyses (if any), exclusion criteria, statistical power analysis, and more.[24]

Without such pre-specification, researchers have free rein to engage in ad hoc data mining, which is rarely reliable or reproducible because its results are more likely to be spurious positives. Federally mandated pre-registration could increase the reliability of many research fields.

B. Mandate improved experimental design and reporting standards.

Many problems of reproducibility arise from poor experimental design and poor reporting standards. Each federal agency that sponsors research should make improvements along the following lines.

First, the actual design of an experiment can be the difference between science that is reproducible or not. For example, one set of scholars argues that most pre-clinical animal research is so bad that it should "not be allowed to constitute part of the rationale for human trials," as it lacks such crucial elements as "randomization, allocation concealment, and blind outcome assessment."[25] In that field, then, federal agencies should mandate that researchers randomize animals to the different treatments or conditions that they are studying, blind the analysts to which animals were in each treatment group, and calculate sample size in advance so as to increase statistical power to a minimum of 80 percent. Beyond animal research, federal agencies should convene expert statisticians and subject matter experts to set minimum standards on how experiments must be designed whenever federal funding is used.

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[23] Examples can be seen on https://www.socialscienceregistry.org/ or https://osf.io/hxeza/.

[24] E. Miguel et al., "Promoting Transparency in Social Science Research," *Science* 343 (3 Jan. 2014): 30-31. Available at http://www.sciencemag.org/content/343/6166/30.full.pdf?keytype=ref&siteid=sci&ijkey=TMhxM94eiQUc2; M. Humphreys, R. S. de la Sierra, & P. Windt, "Fishing," working paper (8 May 2012), available at http://www.columbia.edu/~mh2245/papers1/PA_2012b.pdf.

[25] J. A. Hirst et al., "The Need for Randomization in Animal Trials: An Overview of Systematic Reviews," *PLoS ONE* (6 June 2014), doi: 10.1371/journal.pone.0098856. See also Malcolm R. Macleod, "Preclinical research: Design animal studies better," *Nature* 510 (5 June 2014): 35.

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Second, reporting standards can be improved dramatically. The CONSORT guidelines for clinical trial reporting[26] and the MIAME guidelines for microarray experiments[27] are widely applauded for standardizing the information that is collected and reported in those research areas, making it much easier for other scholars to understand the experimental procedure and to do meta-analyses on the results. Federal agencies could adopt similar standards for other fields, e.g., the ARRIVE guidelines for pre-clinical animal research.[28]

Finally, as Dartmouth's Brendan Nyhan has recently argued,[29] federal agencies should reward (through proposal scoring or supplemental grant awards) scholars who publish via the new "Registered Report" format. In this publication format, a scholar submits the experimental design to a journal prior to running the experiment and collecting results. Peer review occurs on the basis of how rigorous the experimental design is, rather than on whether the experiment shows "positive" results. As Nyhan says, "This procedure encourages authors and reviewers to develop the strongest possible designs — including those that replicate previously published studies — and eliminates perverse incentives to find or emphasize significant results after the fact." This procedure is already in use at several psychology and neuroscience journals, and should be extended much more broadly via federal incentives.[30]

C. *Mandate the Sharing of Data and Code*

A central principle of scientific advancement is the sharing of data so that other scientists can more easily build upon previous work. As *Science* has said, "Making data widely available is an essential element of scientific research."[31] Sharing data has led to many scientific advances, particularly in genetics. Since 2007 alone, the National Institutes of Health (NIH) database of Genotypes and Phenotypes has allowed "2,221 investigators access to 304 studies, resulting in 924

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[26] http://www.consort-statement.org/.

[27] http://www.ncbi.nlm.nih.gov/geo/info/MIAME.html.

[28] https://www.nc3rs.org.uk/arrive-guidelines.

[29] B. Nyhan, "To Get more Out of Science, Show the Rejected Research," *New York Times' The Upshot* (18 Sept. 2014), available at http://www.nytimes.com/2014/09/19/upshot/to-get-more-out-of-science-show-the-rejected-research.html?src=twr&abt=0002&abg=1.

[30] See https://osf.io/8mpji/wiki/faqs for a much more detailed explanation of how the new publication format works.

[31] B. Hanson, A. Sugden, & B. Alberts, "Making Data Maximally Available," *Science* 331 (11 Feb. 2011): 649.

publications and significant scientific advances."[32] For example, a recent reanalysis of data made significant advances in our understanding of which genetic loci are associated with esophageal cancer.[33]

By contrast, failure to share data can halt scientific progress. Recently, for example, researchers tried to do a meta-analysis of techniques for treating newborn infants who have trouble regulating their breathing, reflexes, etc., in the hopes of developing a prognostic tool for doctors to use. They found the meta-analysis impossible to carry out: over 60 percent of the data was unavailable because researchers either ignored the request or outright refused to share.[34]

Unfortunately, current data-sharing policy for federally funded research is far too narrow and easy to circumvent. The NIH, for example, currently requires that grants funded at $500,000 or more in direct costs per year must have a data management plan. But many grants whose data would be extremely valuable to the progress of science are funded at less than $500,000 per year. Worse, because data-sharing is not mandatory by default, investigators often get away with a data management plan that declines to share data or that shares only under such narrow circumstances that it is virtually worthless. To cap things off, even where the investigator theoretically agrees to share data, that is no guarantee that sharing will actually occur. People in multiple disciplines say that they have requested data from an NIH-funded grant and were unsuccessful even though the investigator had purported to be willing to share data on request.

Such a narrow and toothless rule should be tightened up considerably. **That is, the default rule for all research should be that the raw data created pursuant to any federal grant must be shared, along with the computer code used to transform and analyze it.**[35] The only exception should be for rare situations where the raw data is too voluminous (e.g., the Large Hadron Collider or certain astronomy projects); in these cases, the researchers should be mandated to share the processed or sampled data that they themselves use for any analytic purposes.

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[32] D. N. Paltoo et al., "Data use under the NIH GWAS Data Sharing Policy and future directions," *Nature Genetics* 46 (27 Aug. 2014): 934-38, doi:10.1038/ng.3062.

[33] C. Wu et al., "Joint analysis of three genome-wide association studies of esophageal squamous cell carcinoma in Chinese populations," *Nature Genetics* 46 (2014): 1001-06. Available at http://www.nature.com/ng/journal/v46/n9/full/ng.3064.html.

[34] G. J. Jaspers & P. LJ Degraeuwe, "A failed attempt to conduct an individual patient data meta-analysis," *Systematic Review* 3 (4 Sept. 2014): 97.

[35] When journals make data sharing mandatory as opposed to optional, the result is a 1,000-fold difference in the availability of data. See T. H. Vines et al., "Mandated data archiving greatly improves access to research data," *FASEB* Journal 27 (April 2013): 1304-08. Available at http://www.fasebj.org/content/27/4/1304.

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Likewise, computer code used to process and analyze data should routinely be made public in case anyone else is interested in reviewing it for correctness.[36] A good example can be found in the reproducibility policy for the journal *Biostatistics*, which requires authors to "submit all the necessary materials" so that an editor "can execute the code on analytic data sets and produce output similar to that obtained by the author."[37] Even prestigious scholars have been tripped up by coding errors,[38] and making code available allows independent researchers the chance to exercise oversight over poorly written code. The very possibility that other researchers might examine an investigator's code will incentivize that investigator from the outset to be meticulous about testing and writing careful comments.

Moreover, to the greatest extent possible, the entire scientific workflow should be preserved in an open manner. For example, in all fields where lab notebooks are used, government-funded research projects should require the use of open electronic notebooks, so that other researchers will be much better informed about how to replicate and extend the findings.[39] In many disciplines, an open software tool like the Open Science Framework would make it possible to preserve every document, dataset, and code script associated with a research project, along with every change made to each file during the project's lifespan.

These same rules on sharing data and code should apply to clinical trials in medicine. Clinical trials are often thought to be more reproducible than other research fields because they use the rigorous method of randomized trials and are usually conducted under the watchful oversight of the FDA. Even so, misinformation about pharmaceutical effectiveness abounds, because many trials, including trials funded by federal tax dollars, are never published in the medical literature.[40] Worse, even the trials that are published can be misleading, because a

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[36] Z. Merali, ". . . Error . . . why scientific programming does not compute," *Nature* 467 (14 Oct. 2010): 775-77.

[37] See http://biostatistics.oxfordjournals.org/content/10/3/405.full.

[38] G. Miller et al, "A Scientist's Nightmare: Software Problem Leads to Five Retractions," *Science* 314 (22 Dec. 2006): 1856-57.

[39] A. Mascarelli, "Jump off the page," *Nature* 507 (2014): 523-25.

[40] Ross et al. (2009) found that only 40% of industry-funded trials and 47% of NIH-funded trials are published. J. Ross et al., "Trial Publication after Registration in ClinicalTrials.Gov: A Cross-Sectional Analysis," *PLoS Medicine* (8 Sept. 2009), at http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000144. A subsequent study found that a third of NIH-funded trials remained unpublished even after a median 51 months since the trials were completed. Ross et al., "Publication of NIH funded trials registered in ClinicalTrials.gov: cross sectional analysis," *BMJ* 344 (3 Jan. 2012), at http://www.bmj.com/content/344/bmj.d7292.

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published article will be selectively written so as to highlight a desired finding.[41] Even government agencies, including the Centers for Disease Control, have published incorrect information when they had nothing to go on but the cherry-picked clinical trial results that make it into the published literature.[42] Due to inaccurate and incomplete information caused by a lack of transparency, patients and doctors are misled into using the wrong treatments.

Data from NIH-funded clinical trials should be made available to all reasonable requests from qualified analysts who agree to the appropriate confidentiality protections.[43] This would be the "gold standard" for turning clinical trials into reproducible research,[44] and an Institute of Medicine committee is currently considering guidelines on how best to release such data.[45] This is not a novel idea, however: since 2012, the *BMJ* (formerly *British Medical Journal*) has had this requirement for any clinical trials that it publishes.[46] Even with "failed" clinical trials, datasets can be examined to look for genetic and other characteristics of so-called super-responders, i.e., people in the treatment group who had surprising recoveries from a terminal disease.[47] As a distinctly second-best alternative, NIH-funded trials should at least make clinical study reports available; such reports

[41] Dwan et al., "Evidence for the Selective Reporting of Analyses and Discrepancies in Clinical Trials: A Systematic Review of Cohort Studies of Clinical Trials," *PLoS Medicine* (24 June 2014), at http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001666.

[42] To this day, the CDC's website claims that Tamiflu can prevent flu and decrease the risk of death (see http://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm), even though a full review of the evidence indicates that those claims are overstated. Jefferson et al., "Oseltamivir for influenza in adults and children: systematic review of clinical study reports and summary of regulatory comments," *BMJ* 348 (9 April 2014), at http://www.bmj.com/content/348/bmj.g2545.

[43] A. J. Vickers, "Whose data set is it anyway? Sharing raw data from randomized trials," *Trials* 7 (2006): 15; M. A. Rodwin & J. D. Abramson, "Clinical Trial Data as a Public Good," *JAMA* 308 (5 Sept. 2012): 871-72.

[44] P. C Gøtzsche, "Why we need easy access to all data from all clinical trials and how to accomplish it," *Trials* 12 no. 249 (2011), at http://www.trialsjournal.com/content/12/1/249.

[45] See http://www.iom.edu/Activities/Research/SharingClinicalTrialData.aspx.

[46] K. Thomas, "Medical Journal to Require More Details on Drug Trials," *New York Times* (31 Oct. 2012), available at http://www.nytimes.com/2012/11/01/business/british-medical-journal-to-require-detailed-clinical-trial-data.html?_r=1&.

[47] H. Ledford, "Cancer researchers revisit 'failed' clinical trials," *Nature News & Comment* (18 April 2013).

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provide information on the outcomes and side effects in clinical trials that are left out of the main published literature.[48]

One objection is that patient-level data are subject to privacy protections under the Health Insurance Portability and Accountability Act (HIPAA).[49] Nonetheless, it is possible to de-identify and further statistically anonymize datasets and then to make them available to other researchers subject to a confidentiality agreement. Indeed, several drug companies, such as GlaxoSmithKline, are voluntarily making some of their clinical trial datasets available to outside researchers. NIH-funded clinical trials should do no less.

D. Fund More Replications

Government agencies should fund many more replication experiments, particularly in areas like cancer cell biology or pre-clinical animal research. Even if initial studies have a high risk of being false positives, well-designed replication experiments can sharply reduce the overall false positive rate.[50]

LJAF has funded large replication projects in psychology and cancer cell biology that are the first of their kind in each field. But those projects are a drop in the bucket compared to what the NIH and the National Science Foundation (NSF) could fund *every year* if they devoted even *one percent* of their funding to replication experiments. Agencies should run systematic audits to decide on important experimental results that deserve replication, and fund such replication experiments either via contracts or as a condition for grant renewal.

Agencies should also fund re-analyses of existing datasets, particularly for expensive clinical trials where it is important that the findings' robustness be checked by independent investigators. This is rarely done at present; a recent team of researchers could find only 37 such re-analyses published in the past 35 years, 13 of which led to conclusions that were different from the original publication.[51]

E. Strengthen Monitoring and Enforcement Power

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[48] B. Wieseler et al., "Completeness of Reporting of Patient-Relevant Clinical Trial Outcomes: Comparison of Unpublished Clinical Study Reports with Publicly Available Data," *PLoS Medicine* (8 Oct. 2013), doi:10.1371/journal.pmed.1001526.

[49] For a good discussion of the risks, see M. Mello et al., "Preparing for Responsible Sharing of Clinical Trial Data," *New England Journal of Medicine* 369 (2013): 1651-1658, at http://www.nejm.org/doi/full/10.1056/NEJMhle1309073.

[50] R. Moonesinghe et al., "Most Published Research Findings Are False – But a Little Replication Goes a Long Way," *PLoS Medicine* (27 Feb. 2007), doi: 10.1371/journal.pmed.0040028.

[51] Ebrahim et al., "Reanalyses of Randomized Clinical Trial Data," *JAMA* 312 (2014): 213, doi:10.1001/jama.2014.9646.

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For any solution that is adopted, federal enforcement power should be strengthened. Government funders should be empowered to undertake audits of researchers (R01 grants in particular) to make sure that all policies related to reproducibility are being followed. There should be serious statutory penalties (such as funding freezes or even restitution) if researchers are wilfully falling short on their commitments. This stick should be joined by a carrot as well: agency reviewers who score grant proposals could give *substantial* credit to researchers who have pre-registered previous experiments and shared data and code, as well as to researchers whose main contribution was writing software or creating a dataset in and of itself.

III. Conclusion

LJAF strongly encourages the White House to make scientific reproducibility a key part of its innovation agenda. We have outlined several possible solutions and look forward to being part of the discussion that emerges over the next few years.

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September 23, 2014

<u>Via Electronic mail (InnovationStrategy@ostp.gov)</u>

Office of Science and Technology Policy
Attn: Dan Correa
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, D.C. 20504

Re: Mobile Future Comments on Strategy for American Innovation

COMMENTS OF MOBILE FUTURE

I. Introduction

Mobile Future[1] submits the following comments in response to the Office of Science and Technology Policy and National Economic Council's Request for Information as it seeks to revise the Administration's Strategy for American Innovation. Wireless innovation is at the forefront of the U.S. information economy. It also propels transformational advancements and opportunities in virtually every sector of our economy and corner of our lives.

As noted in last year's White House report, "Four Years of Broadband Growth," from its earliest days, this Administration has made clear its commitment to advancing the many opportunities that wireless is making possible for our nation's citizens and

[1] Mobile Future is an association of businesses, non-profit organizations and individuals interested in and dedicated to advocating for an environment in which innovation and investment in wireless technology and services are enabled and encouraged.

economy by pursuing an agenda that includes "freeing up spectrum for mobile broadband" and embracing "a light-touch, multi-stakeholder approach to regulation that has fostered both innovation in applications and deployment of infrastructure."[2]

From his clear attachment to his wireless device on the campaign trail to his 2011 State of the Union Address, where he established a moon-shot goal that "within the next five years, we'll make it possible for businesses to deploy the next generation of high-speed wireless coverage to 98 percent of all Americans,"[3] to boldly calling for a doubling of the amount of spectrum available to expand mobile broadband services,[4] to signing legislation that makes possible the upcoming incentive auctions,[5] President Obama and his Administration have consistently connected their agenda to advancing mobile innovation, maximizing its potential to enhance our economy and our lives.

This constructive, pro-innovation approach has propelled our nation's wireless success story and has allowed consumers—through their choices in a competitive marketplace—and innovators—through their ability to bring new ideas and breakthroughs to market—to guide the pace, direction, scope and sheer magnitude of the mobile revolution's broad contributions to our nation. It is this combination of regulatory restraint and billions of dollars in profound private sector capital investment in both mobile infrastructure and innovation that have combined to make the U.S. wireless sector the envy of the world.

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[2] Office of Science and Technology Policy & The National Economic Council, "Four Years of Broadband Growth," (June 2013), *available at* http://www.whitehouse.gov/sites/default/files/broadband_report_final.pdf ("Broadband Growth Report")
[3] President Obama, State of the Union Address, (Jan. 25, 2011).
[4] White House, "President Obama Details Plan to Win the Future through Expanded Wireless Access," (Feb. 10, 2012) *available at* http://www.whitehouse.gov/the-press-office/2011/02/10/president-obama-details-plan-win-future-through-expanded-wireless-access.
[5] *See* Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. No. 112-96), (Feb. 22, 2012) ("Spectrum Act").

The White House is to be commended for its Strategy for American Innovation. First established in 2009,[6] it correctly made the link between U.S. innovation and constructive progress in support of pro-investment, pro-innovation wireless policy approaches. When White House was further revised the policy in 2011, it correctly called for an additional 500 MHz of spectrum for wireless services.[7]

Important work remains to achieve the admirable objectives this Administration has established in the wireless space. America's mobile consumers currently reap the many benefits of record investment and growth in a wireless marketplace that is advancing at lightning speed. Consumers deserve the many positive benefits of a continued, constructive policy approach. The Administration should continue its successful, light-touch and pro-innovation approach in order to sustain, and even accelerate, the momentum mobile is delivering throughout our economy and to virtually all Americans.

II. Question 6: Changing Innovation – Increased Reliance on Wireless: Tremendous Mobile Data Traffic Growth and Network Evolution Since Original 2009 Strategy Debuted

Since the Administration first introduced its Strategy, wireless technologies have played a defining role in American innovation. And, as is typical with technology, much has changed and progressed in the last five years:

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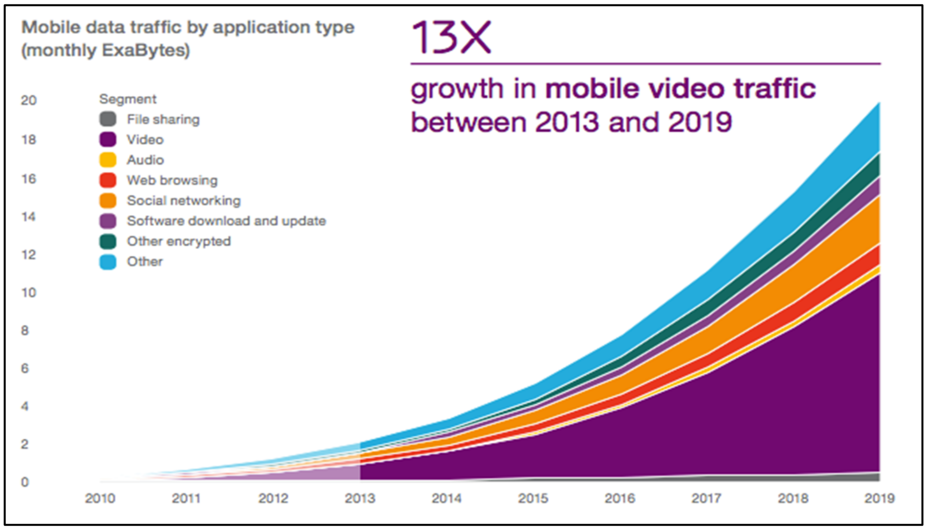
[6] Executive Office of the President, National Economic Council, and Office of Science and Technology Policy, "A Strategy for American Innovation: Driving Towards Sustainable Growth and Quality Jobs," (Sept. 2009) *available at* *http://www.whitehouse.gov/assets/documents/SEPT_20__Innovation_Whitepaper_FINAL.pdf ("2009 Innovation Strategy").*

[7] National Economic Council, Council of Economic Advisers, and Office of Science and Technology Policy, "A Strategy for American Innovation: Securing Our Economic Growth and Prosperity," (Feb. 2011) available at http://www.slideshare.net/whitehouse/a-strategy-for-american-innovation ("2011 Innovation Strategy").

- In 2009, there were 50 million smartphones used by Americans.[8] Today, nearly two-thirds of American consumers use a smartphone.[9]
- In 2009, there were 20,000 apps available in Google's Android Market[10] and 100,000 in Apple's App Store.[11] Today, there are 1.3 million apps available in Apple's App Store[12] and 1.3 million in Google Play (formerly Android Market).[13]
- In 2013, U.S. mobile data traffic reached 3.23 trillion megabytes, a 732% increase in just three years.[14]
- Nearly 30 percent of U.S. wireless connections were on LTE networks year-end 2013, allowing almost one-third of us to use the most dynamic wireless connections possible.[15] In contrast, worldwide, just 2.9 percent of mobile connections are 4G.[16]
- In 2009, just 15 million Americans watched video on their mobile devices.[17] Today, 101 million people are watching video on their smartphones.[18] During the second

[8] Brian Dolan, "CTIA: 50 Million Smartphones in U.S.," (March 24, 2010), *available at* http://mobihealthnews.com/7052/ctia-50-million-smartphones-in-us/.
[9] Jon Fingas, "Two-Thirds of Americans Now Have Smartphones," Engadget, (Feb. 11, 2014), *available at* http://www.engadget.com/2014/02/11/two-thirds-of-americans-now-have-smartphones/.
[10] Robin Wauters, "Android Market grows up, hits 20,000 apps milestone," Tech Crunch, (Dec. 15, 2009), *available at* http://techcrunch.com/2009/12/15/android-market-20000-apps/.
[11] "Apple Announces Over 100,000 Apps Now Available on the App Store," Apple, (Nov. 4, 2009), *available at* http://www.apple.com/pr/library/2009/11/04Apple-Announces-Over-100-000-Apps-Now-Available-on-the-App-Store.html.
[12] Sarah Perez, "iTunes App Store Reaches 1.3 Million Mobile Applications*,"* Mashable, (Sept. 10, 2014), available at http://techcrunch.com/2014/09/09/itunes-app-store-reaches-1-3-million-mobile-applications/
[13] *Number of Android Applications*, AppBrain Stats, (Sept. 12, 2014), *available at* http://www.appbrain.com/stats/number-of-android-apps.
[14] CTIA-The Wireless Association, Annual Wireless Survey, (June 17, 2014), *available at* http://www.ctia.org/your-wireless-life/how-wireless-works/annual-wireless-industry-survey ("2014 CTIA Survey").
[15] CTIA-The Wireless Association, "U.S. Investment in Wireless Leads the World," *available at* http://www.ctia.org/docs/default-source/default-document-library/031014-wireless-value-and-contributions.pdf.
[16] Cisco, "Visual Networking Index: Global Mobile Data Traffic Forecast Update, 2013–2018," (Feb. 5, 2014), *available at* http://www.cisco.com/c/en/us/solutions/collateral/service-provider/visual-networking-index-vni/white_paper_c11-520862.html ("Cisco VNI").
[17] Chris Harnick, "Mobile video consumption on the rise: Nielsen," Mobile Marketer, (Sept. 3, 2009), *available at* http://www.mobilemarketer.com/cms/news/research/4095.html.

quarter of 2014, 27 percent of all online video was watched on a mobile device or tablet.[19] Ericsson has estimated that mobile video data traffic will be 13 times what it was in 2013 by 2019.[20]



Source: Ericsson Consumer Lab (2013)

The growth of 4G connections and the expansion of more sophisticated and bandwidth-intensive devices will continue the ongoing explosion in mobile data traffic on America's wireless networks. By 2017, a 4G connection will generate eight times more traffic on average than a non-4G connection.[21] One example: consider that with every new generation of iPhone, iPhone data traffic doubles.[22] With the introduction of next generation of the Apple iPhone, Samsung Galaxy and other competing devices—massive,

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[18] Mark Walsh, "Mobile Video Audience Tops 100 Million In Q4, More Time On Mobile Web," Mobile Marketing, (March 5, 2014), *available at* http://www.mediapost.com/publications/article/220759/mobile-video-audience-tops-100-million-in-q4-more.html.
[19] Ooyala, "Mobile and Tablet Viewership Rises to 27 Percent of All Online Video, Report Investigates How Consumer Viewing Habits Change With the Weather," (Sept. 15, 2014), *available at* http://www.marketwatch.com/story/ooyalas-q2-global-video-index-highlights-revenue-building-opportunities-with-multiscreen-video-2014-09-15.
[20] Ericsson Mobility Report, (June 2014), *available at* http://www.ericsson.com/res/docs/2014/ericsson-mobility-report-june-2014.pdf.
[21] CTIA-The Wireless Association, Spectrum, Tower Siting and Antennas, *available at* http://www.ctia.org/policy-initiatives/policy-topics/spectrum-tower-siting-and-antennas.
[22] Chetan Sharma, "If You Buy An 'iPhone 6,' Expect Your Phone Bill To Go Up," Huffington Post, (Sept. 5, 2014), *available at* http://www.huffingtonpost.com/2014/09/05/iphone-6-data_n_5768428.html.

continued wireless infrastructure investment is an essential ingredient for ongoing innovation. Since 2009, $134.5 billion has been invested in the nation's wireless infrastructure.[23] Last year alone, carriers invested $33 billion in our nation's networks—four times as much per subscriber as the carriers in the rest of the world invest.[24]

III. Question 2: Opportunities for Innovation – Supporting Mobile Innovation as it Transforms Our Economy, Lives

From conservation to healthcare, education to economic opportunities, mobile has changed nearly every aspect of our modern lives. The White House report "Four Years of Broadband Growth" called the App Economy "one of America's most dynamic and growing sectors."[25] Today, this one sector of the mobile ecosystem accounts for 750,000 jobs.[26] Jason Furman, Chairman of the Council of Economic Advisors, has said "I think investments in wired and wireless broadband have been part of the reason for that total factor productivity rise from its level in the late '70s and early '80s; and I think that will continue to be important."[27]

Mobile is so important to future economic growth, that the 2014 Economic Report of the President highlighted the sector, stating that wireless infrastructure "is at the center of a vibrant ecosystem that includes smartphone design, mobile applications development, and the use of these technologies to effect broader changes in the economy and society—all of it centered in the United States."[28] In fact, among nonfinancial U.S.

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[23] CTIA-The Wireless Association, Annual Wireless Survey, 2009-2013.
[24] 2014 CTIA Survey.
[25] Broadband Growth Report.
[26] CTIA – The Wireless Association, Response To House Energy And Commerce White Paper on Modernizing U.S. Spectrum Policy, (April 1, 2014).
[27] Jason Furman, *Keynote address to the Economists for Peace and Security*, Jobs, Investment and Rebuilding America Symposium, (April 2014), *available at* http://www.epsusa.org/publications/newsletter/2014/apr14/keynote.html.
[28] Economic Report of the President at 33 (March 2014) *available at* http://www.whitehouse.gov/sites/default/files/docs/full_2014_economic_report_of_the_president.pdf.

companies, AT&T and Verizon are the top two capital investors further establishing the importance of the wireless industry to future economic growth.[29]

a. Impact on Government

Mobile services must be at the forefront of government planning and outreach in order to meet our nation's citizens where they spend so much of their time—in the wireless environment. The Administration should be commended for its "Digital Government: Building a 21st Century Platform to Better Serve the American People," a strategy designed to assist agencies in creating a more mobile government. Efforts also are underway to make mobile apps the default for government, allowing the government to keep up with its citizens' technology.[30] Jacob Parcell, manager of mobile programs at the General Services Administration's Digital Services Innovation Center has stated that as citizens use a wider array of devices, the presentation of government content needs to adapt to those varied platforms.[31]

The Department of Defense is just one example of an agency embracing mobile. According to former Defense Department Chief Information Officer Teri Takai, "This is not simply about embracing the newest technology…It is about keeping the Department's workforce relevant in an era when information accessibility and cybersecurity play a critical role in mission success."[32] Additionally, Takai stated military personnel are increasingly reliant on mobile technology "as a key capability enabler for joint force

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[29] Progressive Policy Institute, U.S. Investment Heroes of 2014: Investing at Home in a Connected World, (Sept. 10, 2014), *available at* http://www.progressivepolicy.org/issues/economy/u-s-investment-heroes-2014-investing-home-connected-world/.
[30] Kenneth Corbin, "Mobile Apps Becoming Default for Government Digital Content," CIO, (May 9, 2014), *available at* http://www.cio.com/article/2376399/government-use-of-it/mobile-apps-becoming-default-for-government-digital-content.html.
[31] Id.
[32] J. Nicholas Hoover, "Pentagon Unveils Secure Mobile Device Plan," InformationWeek, (Feb. 26, 2014), *available at* http://www.informationweek.com/mobile/pentagon-unveils-secure-mobile-device-plan/d/d-id/1108826?.

combat operations."[33] Since all Americans are so reliant on wireless connectivity, achieving the goal of dramatically enhancing the availability of government information and services in the wireless environment would advance the government's ability to inform, engage, and serve its citizens.

b. Impact on Consumers – The Internet of Things is the Next Quantum Leap

Despite everything that mobile is already doing to make daily life more efficient, enjoyable and safe, we've barely scratched the surface of what wireless innovation makes possible. The "Internet of Things" as we know it is making our appliances, vehicles and countless other physical tools sentient, connected and able to anticipate our needs.

From wireless sensors that help conserve energy and water, to connected glucose monitors that allow people living with diabetes to better manage their blood sugar, to the fact that watches—once nearly obliterated from the wrists of smart-phone wielding consumers—are back and smarter than ever, it is self-evident in our daily lives just how transformative the ongoing mobile revolution has been.

If our past and present are smartphones and tablets, the future is so much more. Machine-to-machine (M2M) data traffic is projected to grow 10 times between 2013-2018.[34] By 2018, almost 20 percent of all wireless connections will be from machines.[35] The Internet of Things ultimately will connect 99 percent of the objects around us—from cars to clothes, home appliances to hotel rooms.

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[33] Id.
[34] Cisco VNI.
[35] Id at 7.

This revolution promises untold innovation. Take energy: Buildings consume more than 70 percent of U.S. electricity.[36] Already, using today's technologies, smart buildings armed with wireless sensors that manage temperature, light and water are generating energy savings of up to 15 percent annually.[37] On the home front, simply programming your thermostat properly via your mobile device can save 20 percent in heating and cooling costs.[38] Clearly a wave of the near future, smart buildings will be home to more than 100 million wireless sensors by 2019.[39]

On a broader scale, smart grids nationwide are adopting mobile technologies to improve the efficiency, reliability and security of electricity distribution. Just a four percent reduction in electricity usage thanks to smart grids can save U.S. consumers and businesses $20.4 billion by 2030.[40] Meanwhile, if every one of the 117 million U.S. households[41] used smart grid capabilities, carbon emissions would be reduced by the equivalent of forgoing 117 million tanks of gas for a full-size truck each year.[42]

Mobile innovation is also improving our nation's health and wellness. Savvy smartphones are becoming the assisted living device of choice for many Americans. A contact lens that can read your blood sugar or a wireless app that can help visually-

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[36] IBM, A Smarter Planet, *available at* http://www.ibm.com/smarterplanet/us/en/green_buildings/overview/index.html,

[37] Carbon War Room, Raising The Roof: How To Create Climate Wealth Through Efficient Buildings, (July 2013), *available at* http://www.carbonwarroom.com/sites/default/files/reports/CWR13_Energy_Efficiency_Report_Raising_the_Roof--How_to_Create_Climate_Wealth_through_Efficient_Buildings.pdf.

[38] Nest Labs, "Nest Learning Thermostat Efficiency Simulation: Update Using Data from First Three Months," (Apr. 2012) *available at* http://downloads.nest.com/efficiency_simulation_white_paper.pdf.

[39] 100 Million Smart Building Wireless Sensor Network Devices by 2019, (Mar. 24, 2014), *available at* http://onworld.com/news/100-Million-Smart-Building-WSN-Devices-by-2019.html.

[40] Lisa Kling, "Biggest Changes Facing a Business," Houston Chronicle, *available at* http://smallbusiness.chron.com/biggest-changes-facing-business-45234.html.

[41] Linda A. Jacobsen, Mark Mather, and Genevieve Dupuis, "Household Change in the United States," (Sept. 2012), *available at* http://www.prb.org/Publications/Reports/2012/us-household-change.aspx.

[42] EPA, *Greenhouse Equivalencies Calculator*, accessed 3/18/2014, *available at* http://www.epa.gov/cleanenergy/energy-resources/calculator.html#results.

impaired people read everything from grocery store labels to prescription bottles, these are no longer the stuff of science fiction. And, in the near future, your car may have sensors implanted into its seats and seatbelts that monitor respiration and heart rate to alert a driver if they are too tired to drive.

Health care providers are adopting wireless devices and applications in record numbers—from the first interaction with a patient, to administering treatment, to managing follow-up care. And these tiny tools have big impacts. When patients released from the hospital receive text messages, for example, medication adherence goes up.[43] Those same reminders more than double the quit rate for smokers.[44] By 2018, remote patient monitoring using mobile devices is forecast to save the U.S. $36 billion in health care costs.[45]

Americans also are increasingly using their wireless devices to maintain a healthier lifestyle. Healthcare apps have been downloaded by 247 million Americans.[46] And, last year 95 million used mobile phones as health tools.[47]

As the Internet of Things continues to expand to accommodate consumers' desire for more mobile offerings, it will be critical that both industry and government alike stay one step ahead of the game. This can be achieved by prioritizing the need for more wireless spectrum to be made available to keep pace with the demands of consumers and

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[43] Jonah Comstock, "RCT: Text message-based program boosts adherence to appointments, medication," MobiHealth News, (July 10, 2014), *available at* http://mobihealthnews.com/34749/rct-text-message-based-program-boosts-adherence-to-appointments-medication/.
[44] Lorien C. Abroms, ScD, MA, George Washington University School of Public Health, "Text Messaging Program Helps Smokers Fight the Urge to Light Up," (June 6, 2014), *available at* http://publichealth.gwu.edu/content/text-messaging-program-helps-smokers-fight-urge-light#sthash.OBTuL9iL.dpuf.
[45] Jonah Comstock, "RCT: Text message-based program boosts adherence to appointments, medication."
[46] Sam Laird, "How Smartphones Are Changing Health Care," Mashable, (Sept. 26, 2012), *available at* http://mashable.com/2012/09/26/smartphones-health-care-infographic/.
[47] Jonah Comstock, "95M Americans used mobile for health in 2013," MobiHealth News, (Oct. 29, 2013), *available at* http://mobihealthnews.com/26821/95m-americans-used-mobile-for-health-in-2013/.

our economy. And, if the government continues to favor a light-touch regulatory framework when it comes to managing the substantial wireless data traffic growth we have witnessed to date and fully expect to continue in the coming years, a whole new wave of mobile innovation will be unleashed.

IV. Question 1: Policy Priorities - Mobile Holds Untapped Potential, So Long as We Maintain a Light-Touch Policy Approach that Encourages Investment and Innovation

Continuing the Administration's light-touch, multi-stakeholder approach is essential to ensuring both government agencies and U.S. consumers are able to take full advantage of the promise that mobile innovation can deliver. To realize these important objectives, there is much work to be done to make more spectrum available to expand mobile broadband and further take advantage of the wireless ecosystem, including the fast-emerging Internet of Things. Without question, the converse also is true: Reversing course on the Administration's successful light-touch approach will undermine the vital goals the President has embraced and the U.S. economy needs.

a. Keep Government Out of the Business of Network Management

Nowhere more so than in the intricate details of wireless network architecture is the importance of continuing the Administration's light-touch approach more compelling. Wireless providers investing enormous capital each year to expand and upgrade the nation's mobile infrastructure. Nevertheless, wireless networks remain inherently capacity-constrained when compared to fixed broadband networks. As an example, all usable commercial wireless spectrum, across thousands of licensees, has less than 10 percent of the capacity of a single fiber-optic cable.[48]

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[48] Peter Rysavy, How Wireless is Different: Considerations for the Open Internet Rulemaking, (Sept. 12, 2014), *available at* http://mobilefuture.org/resources/how-wireless-is-different/ ("Rysavy Paper").

With its constructive policies, the Administration has contributed to the current pro-investment, pro-innovation climate. It is important that the Administration embrace this progress and stand firm on an approach that has helped sustain the U.S. wireless sector become such a vibrant engine of economic growth, particularly when the President's goal of extending high-speed mobile broadband to 98 percent of Americans is within reach.

To maintain the forward momentum, U.S. innovation policy should continue to keep network engineers, rather than policymakers, at the forefront of the complex and technical challenges of keeping U.S. wireless capacity a step ahead of rapidly rising demand for mobile connectivity. Innovation evolves in the blink of an eye, regulations do not. Network engineers need to make real-time decisions and utilize a variety of tools to help ensure wireless network traffic is optimally managed. To illustrate the scale of the challenge, Mobile Future Chairman Jonathan Spalter recently noted at an FCC event that when asked how network management has changed since 2010, one senior network engineer at a wireless carrier said that in the 3G world of 2010, engineers would update the network's configuration about once a day.[49] Today, given the volume and complexity of demands on the network, those updates now occur up to six times each minute.[50]

Reasonable network management should continue to include room for the innovation we have yet to envision. Some prioritization would clearly be in the public benefit. For example, consider this comment from Cisco: "Think of new apps in the Internet of Things, like remote healthcare monitoring," said Jeff Campbell, Cisco's VP of public policy in the Americas. "What that tells us is that not all bits are created equal.

[49] Remarks of Jonathan Spalter, FCC Roundtable: Mobile Broadband and the Open Internet, September 16, 2014.
[50] Id.

Some of them really do need to be there at a very specific point in time with a very specific level of accuracy…The networks can't just be one big empty dumb pipe."[51]

The unique operational constraints of mobile broadband networks require engineers to have maximum flexibility to manage network congestion, keep pace with rapid cycles of innovation, and adapt business models to best meet consumers' wants and needs. When you consider that just a handful of mobile users streaming YouTube can cause a traffic jam for all customers using that same cell tower,[52] practical decisions need to be made—in real-time.

Subjecting wireless broadband networks to rules that dictate how wired networks are designed and operated would be a mistake. Government agencies do not always know where the next life-changing innovation will come or how network engineers will need to adapt to help make this progress possible and sustainable. Do we truly believe we can codify into regulation the blueprint for doing so?

It is imperative that the FCC keep this urgent demand-versus-capacity challenge in mind as it considers adding new net neutrality rules to the books. Everyone supports an open Internet. That's why—despite the call for more regulation—not a single formal net neutrality complaint has been filed with the Federal Communications Commission since the adoption of its 2010 Open Internet Order.

The success of the current light-touch approach and clear commitment of wireless companies to the core principles of an open Internet argue forcefully for resisting calls to subject the entire mobile ecosystem to Title II regulations written to micromanage the businesses of local telephone monopolies. One can hardly envision a more anti-

[51] Politico Morning Tech, "First Look: 'Enormous' Growth In Traffic, IoT Use, Report Shows," (June 10, 2014).
[52] Rysavy Paper.

innovation approach, and the Administration should flatly and publicly reject these extreme calls.

b. Maintain Focus on Freeing Substantially More Spectrum to Expand Mobile Broadband

If the Administration could leave just one legacy for the future of mobile-fueled innovation, freeing additional spectrum resources would likely have the broadest and most transformational impact across our economy and society.

When the Innovation Strategy was revised in 2011, the very first item was a call to make an additional 500 MHz of spectrum available to expand wireless broadband in order to keep pace with the fast-rising demand of American consumers for mobile connectivity.[53] We continue to make progress on these efforts. The H-Block auction, which took place in February of 2014, released 10 MHz of spectrum for mobile. The AWS-3 auction, scheduled to begin this November, will bring 65 MHz of spectrum to market. And next year, the FCC will conduct the historic incentive auction of the 600 MHz broadcast TV band that could yield up to 120 MHz of usable spectrum for wireless services.

Congress proposed, and the President signed into law, The Middle Class Tax Relief and Job Creation Act of 2012, which included provisions making possible the incentive auction process.[54] It is essential that the Administration see this process through to successful pro-consumer, pro-innovation outcomes that ensure adequate spectrum is available to meeting fast-growing demand for mobile broadband and to continue to enable our citizens and our economy to reap the many benefits of ongoing and fast-evolving wireless innovation.

[53] 2011 Innovation Strategy.
[54] *See* Spectrum Act.

The Administration also can make more spectrum available by making more efficient use of currently held government spectrum assets. The Administration should double down on efforts to free underused government-held spectrum for commercial use in order to creating a lasting legacy of making possible the profound waves of mobile innovation that lie yet ahead.

c. Advancing STEM Education and Focusing on the Talent Pipeline

Helping to safeguard the next generation of our American economy, we must keep pace with the international community to ensure that American students are adequately prepared for their future careers in our information economy. Mobile has the ability to bring every student, no matter his or her location or life situation, a first-class education. These opportunities can be formative at the earliest levels of schooling through adoption and use of mobile technology in the classroom as a curriculum tool and as an accelerator of parent-school-community engagement.

Right now, 81 percent of teachers believe mobile devices enrich classroom education.[55] Similarly, 90 percent of students who are tablet owners say that these devices are valuable for educational purposes.[56] E -Textbooks can also open new doors, allowing schools to bring the most up-to-date materials to their students while saving $250-$1,000 a student per year over traditional textbooks.[57]

Science, Technology, Engineering and Mathematics (STEM) education for all American students, including coding skills, should be a national priority. Mobile Future

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[55] Gayle Bennett, "Tablets rewrite the classroom rules," USA Today, (June 23, 2014), *available at* http://www.usatoday.com/story/sponsor-story/dell/2014/04/28/dell-tablets-in-education/8420627/.
[56] Pearson Foundation, Survey on Students and Tablets 2012, http://pearsonfoundation.org/downloads/PF_Tablet_Survey_Summary_2012.pdf.
[57] "Should Tablets Replace Textbooks in K-12 Schools?," ProCon.org, *available at* http://tablets-textbooks.procon.org/.

members understand the importance of the next generation of tech-savvy graduates and are actively working to support STEM learning.

AT&T and the AT&T Foundation have given nearly $87 million to support STEM initiatives since 1995.[58] These initiatives include STEM scholarship programs, science and math- focused summer camps for at-risk youth, and hands-on technology labs and elite robotics competitions at the nation's leading universities.[59]

Verizon, through its Foundation, uses mobile technology to increase student achievement and interest in STEM subjects. For the past two years, the Verizon Innovative App Challenge has provided middle and high school students with the opportunity to design and code real mobile apps with the help of MIT engineers. As a result, 60 percent of winners were more likely to pursue a STEM career. [60] Verizon also works directly with teachers, providing comprehensive, in-depth training and resources to help better integrate mobile technology into the classroom and improve student outcomes in STEM.[61]

Mobile Future member Cisco supports STEM through its networking academy, providing coursework for technology skills to schools,[62] and Alcatel-Lucent supports the "Mindbender Academy," a STEM camp targeting middle-school students.[63]

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[58] AT&T Corporate Citizenship, Supporting science, technology, engineering and mathematics (STEM) education, *available at* http://www.att.com/gen/corporate-citizenship?pid=17922.
[59] Id.
[60] http://www.verizon.com/about/responsibility/engaging-students/
[61] http://www.verizon.com/about/responsibility/empowering-educators/
[62] Technology Studies for the "T" and More, Cisco, *available at* http://www.cisco.com/web/learning/netacad/us-can/docs/Put-the-T-in-Your-STEM-Education-Program-with-Cisco-Networking-Academy.pdf.
[63] 2014 Mindbender Academy STEM Camp – Gaining STEaM, Alcatel-Lucent, *available at* http://www2.alcatel-lucent.com/foundation/newstories/2014-mindbender-academy-stem-camp-gaining-steam.php#sthash.bhlJ6Unf.oDZ08sxu.dpuf.

A number of community-based organizations are emerging to help fill the knowledge gap by connecting underserved Americans to these opportunities. As an example, Mobile Future member Black Founders is an organization dedicated to diversity in the tech industry.[64] They work with coders to stimulate entrepreneurship and foster economic growth in their community. Additional groups such as Digitalundivided, Code Now, Code.org and Black Girls Code also work to foster entrepreneurship, coding skills and mobile tech expertise.

Given the central role of mobile technology in our economy today—a role that will only grow in the future—ensuring all of our citizens have the skills needed to participate in the economic opportunities mobile innovation makes possible can play a central role in building the "ladders of opportunity" the President has envisioned.

d. Additional Policy Considerations

There are several other policy considerations that the Administration should keep in mind in working to advance U.S. wireless innovation. These include:

- Fostering infrastructure investment through accelerated tower siting processes, market-based policies, and continued development of advanced services;
- Ensuring U.S. tax policies are fair and non-regressive, so they do not deter consumer access to wireless services and help maintain U.S. competitiveness;
- Continuing current Administration efforts to ensure U.S. leadership in global markets through advancement of trade policies and treaties that encourage an open Internet, free markets and the lowest possible trade barriers;

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[64] *See* www.blackfounders.com.

- Ensuring any new privacy and cybersecurity policies are appropriately balanced to achieve their objectives while not unnecessarily impeding mobile innovation and/or degrading the wireless consumer experience; and,
- Continuing diplomatic focus on ensuring Internet governance can remain multi-stakeholder and is not Balkanized or held hostage to multilateral organizations.

V. Conclusion

We applaud the Administration for once again focusing its attention on constructive ways that government can further stoke the flames of American innovation. With its core mobile objectives, this Administration has set a bold course for American wireless innovation—from connecting virtually all U.S. consumers to mobile broadband, to doubling the amount of spectrum available for commercial wireless services, to successfully seeing through historic incentive auctions and working to see both government agencies and consumers take full advantage of the ongoing wireless revolution. On all fronts, there remains important work to be done. Thus, it has never been more important that the Administration continue to embrace its light-touch, multi-stakeholder approach. It has well-served the nation these past six years, and it continues to be the right path for American innovation, our nation's more than 300 million mobile consumers and our collective mobile future.

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Comments of the National Association of Manufacturers
on
Updating the *Strategy for American Innovation*

Submitted September 22, 2014 via email to innovationstrategy@ostp.gov

1. Introduction

The National Association of Manufacturers (NAM) is the largest industrial trade association in the United States representing 12,000 manufacturers from every single industry segment and in all 50 states. The NAM supports policies that will make the United States the best place in the world to manufacture, invest, grow a workforce, and innovate. We request the Office of Science and Technology Policy and the National Economic Council to consider the following comments in updating the *Strategy for American Innovation (*the *Strategy).*

2. Background

The Role of Manufacturing in the U.S. Economy

In 2013, manufacturers contributed $2.08 trillion to the U.S. economy. Taken alone, U.S. manufacturing would be the 8th largest economy in the world. This economic engine accounts for 12.5 percent of the U.S. Gross Domestic Product (GDP).

Manufacturing in the United States also has the highest multiplier effect of any economic sector. For every $1.00 spent in manufacturing, another $1.32 is added to the economy. There are 12 million men and women working in manufacturing today, equaling nine percent of the workforce in this country. Manufacturing supports an estimated 17.4 million U.S. jobs – 1 in 6 of all private sector jobs.

The manufacturing workforce is a high-skilled, high-paid workforce. The average annual pay of a manufacturing employee is $77,505. In contrast, the average worker in all other U.S. industries earns $62,063 annually.

3. Updating the *Strategy for American Innovation*

Sound Innovation Policy Will Help Grow U.S. Manufacturing

The NAM supports national technology policies that will continue to drive economic growth, productivity gains and job creation. These policies should be developed in close cooperation with industry, government and academia, be based on their needs and priorities and proceed with their knowledge and support. These policies should create an overall environment that ensures the leadership of the United States in technology and industrial competitiveness. To this end, the NAM recommends that the *Strategy* focus on raising awareness of the importance of sustained technological development.

Specifically, it is critically important for the *Strategy* to educate policymakers and the general public on the importance of technology and innovation to manufacturing and our nation's economic competitiveness. In particular, we must work together to raise the level of national public awareness of the vital role played by manufacturers in leveraging science, technology, engineering and mathematics (STEM) disciplines to increase U.S. competitiveness.

The government should support this effort by adequately funding and staffing existing institutions responsible for technology, science, intellectual property and research and development (R&D) programs. Federal agencies in turn need to make the most efficient use of their resources and coordinate their science and technology programs with industry to focus on meeting national needs and priorities.

Support for Research and Development (R&D) is Key

R&D is fundamental to the health and vitality of our nation's industrial and economic progress. It is important for the *Strategy* to support private sector R&D, especially in the applied sciences and process technologies. The federal government's major role in initiating and funding R&D should be to provide support for science, engineering and infrastructure. In general, this support should be directed toward solving national problems beyond the capabilities of the private sector, or when the federal government is the primary beneficiary of such research.

Much of the basic research directed at expanding our science and engineering knowledge base is conducted in universities. This work requires significant government support and the level of support should be continued and regularly reviewed. Furthermore, in the interests of establishing funding stability for longer-term research projects, multi-year authorizations should be established wherever feasible. Support for basic research is integral to our nation's continued competitiveness and the future of our innovation economy. In addition, sound and permanent tax policies that incentivize research and development should be part of the *Strategy*.

Improving Technology Transfer Programs Is Important

The federal laboratory system of the United States is one of our most prized technology resources, yet its potential has yet to be fully tapped. For too long, the innovations developed in these laboratories were unavailable to, or unused by, industry.

Generic manufacturing R&D efforts, focused on base-building technologies and processes, should be promoted. As noted above, declassification and transfer of government-developed technologies to the private sector should be expedited whenever possible. The federal government should also assist state and local governments in their efforts to promote local technology development.

The NAM is highly supportive of programs that provide incentives for U.S. businesses, schools and laboratories to expedite the transfer of technology into the commercial sector, as improved mechanisms for technology transfer and cooperative partnerships between industry, government and academia will benefit all three sectors and the country as a whole.

Protecting and Enforcing Intellectual Property Rights Are Critical

Intellectual property rights incentivize innovation, enable collaboration and promote the commercialization of new technologies. The protection and enforcement of those rights at home and abroad assures manufacturers that their inventions will be secure as they create jobs and build industries around them. For this reason, it is important for the *Strategy* to support policies that nurture the creation and application of technology and vigorously protect intellectual property, as the creation of technology is the creation of intellectual property. Without strong protection and enforcement, the incentives for future innovation-directed R&D will be diminished.

The NAM supports a coordinated policy that strengthens the protection and enforcement of intellectual property rights afforded by both domestic laws and international agreements and includes strong coordination and oversight by the governmental agencies charged with safeguarding our nation's intellectual property. U.S. policy should reflect the vital importance of intellectual property rights for U.S. industrial competitiveness.

Policymakers should be strongly committed to supporting the rights of innovators to exploit their own inventions and should continually review the adequacy of our laws in the face of fast-paced scientific and technological change and new and emerging threats. In particular, the NAM believes the *Strategy* should:

- Increase national awareness of the inseparable link between innovation, the protection and enforcement of intellectual property rights, improved trade performance, sound economic growth and strong national security;

- Recognize that effective intellectual property rights promote open innovation and other collaborative models by incentivizing disclosure and enabling the transfer of knowledge and technology among firms;

- Communicate that intellectual property is an important currency and a tool for creation and management of business relationships and innovation processes in almost all forms of collaborative innovation;

- Strengthen U.S. intellectual property laws, including through improved procedures to safeguard confidential business information and trade secrets, which account for a significant and growing share of the knowledge portfolios of many innovative manufacturers;

- Include steps to improve trade secret regimes globally in appropriate bilateral, regional, and multilateral trade discussions as well as through other diplomatic contacts;

- Protect the health, safety and welfare of American consumers by recognizing the harmful effect of counterfeit and pirated products on the public and on our economy.

Enforcement policies, both public and private, and strong interagency coordination and public education should be strengthened to help eliminate this threat;

- Ensure the continued improvement of U.S. intellectual property laws, procedures and penalties to increase the effectiveness and efficiency of the system;

- Recognize that the centerpiece of an effective intellectual property protection regime is an adequately staffed, efficiently operated and fully funded United States Patent and Trademark Office that will process patent and trademark applications in a high-quality and expeditious fashion; and

- Support policies that continue to eliminate unnecessary cost, complexity and uncertainty in the U.S. patent system.

4. Conclusion

For manufacturing to continue to be the bedrock of this nation, a long-term strategy is needed that incentivizes investment in research and development, supports a legal system that protects intellectual property, and grows a skilled workforce that will drive innovation. The National Association of Manufacturers is committed on behalf of the 12 million men and women working in manufacturing today to working with you to ensure the *Strategy* makes the United States the best place in the world for manufacturers to innovate.

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Response to Request for Information on the *Strategy for American Innovation* Report

From the National Health Council September 23, 2014

The National Health Council (NHC) appreciates the opportunity to submit the following comments to the Office of Science and Technology Policy and the National Economic Council's request for public input for an update of the *Strategy for American Innovation* report. The NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes the nation's leading patient advocacy groups, which control its governance. Other members include professional societies and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, biotechnology, and health insurance companies.

In response to question number 1 – What specific policies or initiatives should the Administration consider prioritizing in the next version of the *Strategy for American Innovation* – we detail here three policy issues that we believe should be prioritized by the Administration: (1) the gap in incentives to spur innovation in new drugs to treat unmet medical needs; (2) the lack of clarity and predictability in how our pharmaceutical and biopharma industry should conduct and rely on patient engagement in drug development; and (3) the conflict between patient data sharing to accelerate research and the Privacy Rule. Addressing these issues will alleviate barriers to getting promising new medicines to patients, ensure the patient perspective is heard and its value realized to enhance drug development, and guarantee that health research is not impeded by privacy laws that contravene patient preferences.

Issue 1: Bridging the Incentives Gap to Bring Promising New Medicines to Patients

- **Lack of adequate patent protection causes many promising medicines to be abandoned**

More than 133 million Americans – over 40% of the U.S. population – live with a chronic disease or disability.[1] But for many people there are no treatments, and existing treatments work for only 50-75% of the patients who currently use them.[2] There are limited treatment options for too many diseases and disabilities, including mental health aliments, neurological, autoimmune and many rare diseases, or for the prevention of various diseases and disabilities.

[1] CDC Website, available at: http://www.cdc.gov/chronicdisease/pdf/2009-power-of-prevention.pdf (last accessed September 22, 2014).

[2] Spear et al. Clinical application of pharmacogenetics, *Trends Mol Med* (2001) 7(5):201-4.

Roughly 30,000 drugs were abandoned by the pharmaceutical industry over the past 30 years.[3] Unfortunately, many promising drug candidates are abandoned not based on an assessment of their potential to benefit patients, but because manufacturers anticipate that they will not have enough patent protection when they enter the market to re-coup the company's investment. Without sufficient patent protection, manufacturers simply will not continue developing these drug candidates, despite their potential to treat unmet medical needs and benefit patients.

Two shortcomings of our patent system contribute to a lack of sufficient patent protection to ensure the development of many promising drug candidates. First, somewhat counterintuitively, the best new medicines do not automatically qualify for a patent. Only new and nonobvious inventions are patentable and while these standards are designed to encourage ingenuity, they have also created barriers to innovation in the drug development process.[4] For example, the novelty standard can bar a best new medicine in the situation where a promising new drug candidate is one in a family of related compounds described but not claimed in (and therefore not be protected by) a patent application. When that application publishes, the promising new drug candidate is disclosed to the public; it is no longer new and now ineligible for patent protection.[5] In other situations, a promising new drug candidate cannot obtain patent protection because its beneficial therapeutic properties could have been reasonably anticipated from what was known about drug design when the compound was invented, rendering the new drug candidate "obvious." The unfortunate reality is that "drugs that initially look most likely to be effective are often the least likely to be patentable. The standard withholds patented protection from drugs based on the scientific advances that allowed researchers to identify them as ones that are likely to be effective."[6] As science progresses and we continue to learn more about how drugs work, the scope of this problem caused by the nonobviousness standard is likely to expand, rendering more and more promising drug candidates "obvious" and unpatentable.

Second, because medicines are required to obtain Food and Drug Administration (FDA) approval or licensure before they can enter the market, the term of many patents claiming a promising drug candidate expires before any value in protecting the medicine from generic competition can be realized.

[3] Wadman, Meredith, New Cures Sought from Old Drugs, Nature 490, 15, October 4, 2012.

[4] See in general, Roin, Benjamin N., Unpatentable Drugs and the Standards of Patentability (February 2009). *Texas Law Review*, Vol. 87, pp. 503-570, 2009. Available at SSRN: http://ssrn.com/abstract=1127742.; see also Armitage, The Hatch-Waxman Act: A Patch Forward for Making it More Modern, William Mitchell Law Review. Accessible at: http://www.wmitchell.edu/lawreview/Volume40/documents/2.Armitage.pdf (last accessed June 15, 2014).

[5] Roin, Benjamin N., Unpatentable Drugs and the Standards of Patentability (February 2009). *Texas Law Review*, Vol. 87, pp. 503-570, 2009. Available at SSRN: http://ssrn.com/abstract=1127742 ("a drug cannot be patented if it was previously disclosed to the public; no exception is made for when the disclosed drug has not yet been tested in clinical trials and thus has not been approved by the FDA." Current law allows seemingly insignificant disclosures to undermine the novelty of drugs, which makes it easy for researchers to unwittingly disclose their discoveries. Companies [file] overly broad patent applications to establish priority over large numbers of potential new drugs. As their research advances, the companies typically disclaim most of those compounds from their applications, leaving only the prior disclosure of the drugs. Practices such as these have created a significant body of potentially valuable drugs that cannot be patented.").

[6] Roin, Benjamin N., Unpatentable Drugs and the Standards of Patentability (February 2009). *Texas Law Review*, Vol. 87, pp. 503-570, 2009. Available at SSRN: http://ssrn.com/abstract=1127742.

Developing a new drug is a long and expensive process, taking up to 15 years to bring a compound to market. Because manufacturers must apply for patents very early in the research and development process, and patent terms extend 20 years from the date of patent application (not the date the patent is issued or the date the drug enters the market), life of patents covering medicines (unlike those for non-regulated products) dwindle while the medicine works its way through the development and FDA approval processes. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, provides for patent term extensions for pharmaceutical patents to help offset regulatory delays in obtaining FDA approval to market the drug.[7] However, these extensions only partially compensate for lost patent life because they can only add a maximum of five years of patent term and cannot extend a patent term to last more than 14 years.[8] Therefore, even with maximum patent term extensions, little or no patent life may be left when the medicine finally comes to market. This is especially problematic for medicines with long development times, such as those being developed for Alzheimer's or Parkinson's.

Because of this fact, our current system encourages the fastest, least expensive innovation – not necessarily the treatments that are most important to society or to individual patients. This results in increased research and development in the later disease stages at the expense of the enormous public health benefit of studying medicines to prevent diseases, treat early-stage diseases, or treat diseases that have never had any treatments, are not well understood, or progress slowly, like Alzheimer's.[9]

Finally, incentives are also needed to develop companion diagnostics for drugs that predict which patients will benefit (or not) from a medicine. Many people take drugs that don't work for them, unnecessarily increasing patient and societal costs and exposing patients to the risk of side effects of the drug. Companion diagnostics can tailor treatments to each patient, radically improving how we deal with many diseases.

- **The MODDERN Cures Act addresses these patent protection barriers**

To address these patent protection barriers, patient advocacy organizations crafted a bill titled H.R. 3116, the Modernizing Our Drug & Diagnostics Evaluation and Regulatory Network Cures Act of 2013, or the MODDERN Cures Act. The bill was introduced in the House in September 2013 by Representative Leonard Lance and is currently cosponsored by a bipartisan group of 76 Members of Congress.

The MODDERN Cures Act aligns incentives with the needs of patients by setting a term of regulatory exclusivity for new medicines intended to treat unmet medical needs. The

[7] Pharmaceutical Patent Term Extensions: A Brief Explanation. CRS Report for Congress. January 2002. Accessed at: https://opencrs.com/document/RS21129/

[8] Roin, B. Dormant Therapies. National Health Council's Briefing on the MODDERN Cures Act. February 2012. Accessed at: http://www.nationalhealthcouncil.org/NHC_Files/Pdf_Files/NHCMODDERNCuresActBriefing.pdf

[9] Budish et al. National Bureau of Economic Research. Do fixed patent terms distort innovation? Evidence from cancer clinical trials. September 5, 2013. Available at: http://www.nber.org/papers/w19430.pdf. (last accessed June 9, 2014).

MODDERN Cures Act aims to ensure that the most promising therapies for unmet medical needs are not abandoned due to uncertain patent protection. Removing this uncertainty frees up manufacturers to decide a medicine's fate not by whether enough patent protection may exist at an unknown date in the future, but by the drug's potential to benefit patients and enhance the public's health.

Furthermore, the MODDERN Cures Act removes the disincentive for companies to pursue medicines with long development timelines. As such, we anticipate that passage of the Act will result in increased research and development into medicines with the potential to prevent disease or disability, treat early-stage conditions, and others with long development timelines, transforming the way we treat many diseases and disabilities.

Under the MODDERN Cures Act, a new medicine that is being studied to treat an unmet medical need can be designated as a "dormant therapy." A designated dormant therapy can receive regulatory exclusivity, which protects the medicine from generic or biosimilar competition for 15 years after FDA approval. This allows manufacturers to pursue medicines that have the greatest potential to meet an unmet medical need, even if the treatment has no patent protection. The dormant therapy designation is only available when requested and only for new drugs that treat an unmet medical need as defined by FDA. This designation does not automatically apply to all drugs or even all new drugs. [10]

The MODDERN Cures Act also creates a predictable timeline for generic or biosimilars manufacturers to bring (and patients to expect) these lower-cost products to market. In fact, the Act contains the strongest "anti-evergreening" protections ever included in legislation. The MODDERN Cures Act accomplishes this by requiring owners of relevant patents (those that protect the dormant therapy) to waive their rights to enforce these patents against generics/biosimilars after the 15-year regulatory exclusivity period ends. This ensures that lower-cost generics and biosimilars are not prevented from entering the market at the end of the regulatory exclusivity term granted to dormant therapies.[11]

In addition, the MODDERN Cures Act is anticipated to decrease industry reliance on the use of trade secrets to protect their products, ultimately benefiting patients by allowing enhanced data transparency and accelerating research. Because a dormant therapy enjoys a set term of regulatory exclusivity during which FDA cannot approve a generic or biosimilar, public sharing of information about a medicine's development no longer presents a risk that a generic or biosimilar can use that information to gain entry into the market by "free-riding" on the innovator's work. Enhanced sharing of clinical trial data is anticipated to benefit patients by (1) decreasing the number of unnecessary and costly duplicate clinical studies conducted, (2) allowing other researchers to confirm or challenge study conclusions to learn more about the

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[10] Designation as a dormant therapy is optional. Manufacturers will still able to use the existing provisions in the Hatch-Waxman Act if they choose.

[11] Based on patent protection or regulatory exclusivity of the reference product; does not address other factors that may prevent generics/biosimilars from coming to market.

safety, efficacy, and use of current medicines, and (3) help patients make treatment decisions – all accelerating research and leading to better outcomes for patients.

The MODDERN Cures Act would also remove the need for any patent litigation between innovator and generic companies. Because the patents cannot be enforced against generics or biosimilars after the regulatory exclusivity period ends, and FDA cannot approve a generic or biosimilar before the regulatory exclusivity period ends, neither party benefits from patent litigation. A successful patent challenge or settlement will not affect the date that generic competitors may enter the market. As such, both parties save significant legal costs by avoiding patent litigation, allowing innovator companies to reinvest legal costs in research and development.

Finally, the MODDERN Cures Act also promotes personalized medicine by encouraging the development of companion diagnostics that predict the safe, effective, and efficient use of medicines. It does this by extending the time generics or biosimilars are barred from entering the market by either 12 months (for a medicine with a diagnostic that was developed at the same time) or 6 months (for a medicine with a diagnostic that was developed before or after the medicine).

Issue 2: Incorporating the Patient Perspective into Drug Development to Enhance Innovation

- **A lack of clarity and predictability thwarts meaningful patient engagement during drug development**

Today, there is broad recognition among stakeholders that the patient perspective needs to be incorporated into the development and approval of medicines. Patients can and should have important roles in the drug development process beyond participating in clinical trials as research subjects. For example, the Patient-Centered Outcomes Research Institute, created in 2010 by the Affordable Care Act, is demonstrating that patient engagement can generate research data that is more useful for decision makers. In addition, FDA, through its Patient-Focused Drug Development initiative, is currently conducting disease-specific meetings to collect information on patient and caregiver perspectives about select diseases and, where applicable, current treatments.

We must move beyond transient involvement of patients in research to harness the full value of patient engagement across a medicine's full life cycle. However, identifying a practical framework in which patients and their perspectives are continuously integrated throughout the continuum of research processes, including drug research, development, and regulatory approval, has proven challenging. Specifically, a need exists for clarity and predictability for manufacturers of medicines concerning how to engage patients during drug development.

Currently, no agreed-upon definition of meaningful patient engagement exists, and a standard, useable framework for conducting patient engagement during drug development has yet to be developed. In addition, it is unclear how information obtained from a manufacturer's engagement with patients can or should be incorporated into the medicine’s marketing application or otherwise be used with FDA. Further, manufacturers do not know how the Agency will receive and use that information in its approval (or licensure) determinations.

Separate from the uncertainty described above, another troubling barrier to meaningful patient engagement in drug development involves FDA's restrictions on pre-approval communications from manufacturers regarding unapproved medical products. Manufacturers frequently struggle with how best to discuss the value of investigational products to patients in a manner that is consistent with FDA's policies prohibiting pre-approval promotion. Because manufacturers are prohibited from marketing unapproved medical products, companies can be reluctant to discuss medicines that have not been approved by FDA for fear of facing enforcement action and fines by FDA or the Federal Trade Commission. As a result, manufacturers often forgo invaluable input from patients to inform earlier-stage research decisions, such as determining endpoints that patients find most impactful and clinical trial design. Many companies conduct trials only to learn after their drug is approved that the outcomes they chose to study are of no value or interest to the patients who will take the drug. A more rational approach would be to allow manufacturers to appropriately engage patients to inform their research and development decision-making processes and to ensure their products will best meet the needs of patients.

Efficient and patient-centered drug development is essential to accelerate innovation and bring medicines and treatments to the clinical setting that reflect what patients want and need. In addition, meaningful patient engagement allows manufacturers to answer patient-perspective questions earlier and more quickly abandon drugs that will not benefit patients, which in turn will save resources and result in more efficient studies that only look at outcomes that patients care about (rather than capture all data points imaginable). This is likely to enhance participation in clinical trials, as patients are more likely to enroll in studies that look at outcomes important to them and follow study designs that accommodate their perspective, challenges, and needs. However, without an agreed-upon framework for manufacturers to rely upon, the current barriers to meaningful patient engagement will continue to block progress and separate patients from the design, development, and approval of their medicines.

- **FDA should issue guidance on meaningful patient engagement during drug development**

A robust process for engagement must continuously solicit and integrate patient input throughout research and development. FDA can play an important role in encouraging sponsors to incorporate patient input, which we believe will ultimately enrich the FDA regulatory review and approval process and accelerate patient access to new treatments.

To remedy the lack of clarity and predictability, FDA should issue guidance on patient engagement in drug development that includes the following:

- *Defining the patient community.* The patient voice is represented by a wide range of individuals and organizations. Often, the terminology used to describe the individuals and organizations of “the patient community” is inconsistent or fails to capture the distinctions among them. For example, patients, patient advocates, and consumers are sometimes used interchangeably or are grouped together, and caregivers are often excluded altogether.

- *Describing meaningful engagement.* Patient engagement can represent a range of activities, from passive engagement such as clinical trial participation to more active participation in research and development. Across this spectrum of activities, the elements that constitute or can help achieve meaningful engagement have yet to be clearly defined.
- *Developing a framework and methods for engaging patients*. A framework would offer a structure and process for patient engagement, as well as define the expected outcomes of that engagement. Guidance on appropriate methods is crucial to implementing a process for involving patients and developing a framework that manufacturers can rely upon.
- *Addressing the conflict between the prohibition of off-label promotion and meaningful patient engagement.* This may include provisions that explain how adherence to the FDA guidance and/or specific actions will safeguard manufacturers from or minimize the risk of penalties for violating off-label promotion laws.

Finally, by utilizing guidance to address these issues, interested stakeholders, including patients, patient advocacy groups, and manufacturers, have the opportunity to have their opinions heard by submitting public comments to the guidance docket. Docket comments inform the development of the final guidance and will assist FDA in defining meaningful patient engagement, crafting an optimal patient engagement framework, and promoting its use.

Once meaningful patient engagement has been defined through guidance, companies should be assured that engaging with patients in a fashion that is in accordance with such guidance will not subject them to fines related to marketing unapproved medicines.

Issue 3: Addressing the Conflict between Data Sharing to Accelerate Research and the Privacy Rule

- **HIPAA is unjustifiably blocking sharing of patient data for use in research**

The federal health Privacy Rule adopted by Health and Human Services under the Health Insurance Portability and Accountability Act (HIPAA), prohibits the use of personal health data for research unless: (1) it is radically de-identified, (2) the individual gave consent, or (3) an Institutional Review Board (IRB) gave substituted consent. While well-intentioned to protect the privacy of personal information used in health research, the unfortunate reality is that the Privacy Rule impedes research while failing to adequately protect data privacy in the research context. Each one of these conditions that allows use of personal health data for research is problematic – radically de-identifying data renders it useless for the majority of health research questions; individual consent is expensive, burdens patients, and is ethically questionable; and IRB consent introduces delay and inconsistency into the research process.

The Institute of Medicine explored this issue in 2009, held a meeting to discuss these challenges to health research, and in its report, *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research*, concluded that:

> [T]he HIPAA Privacy Rule does not protect privacy as well as it should, and that, as currently implemented, the Privacy Rule impedes important health research. The committee found that the Privacy Rule (1) is not uniformly applicable to all health research, (2) overstates the ability of informed consent to protect privacy rather than incorporating comprehensive privacy protection, (3) conflicts with other federal regulations governing health research, (4) is interpreted differently across institutions, and (5) creates barriers to research and leads to biased research samples, which generate invalid conclusions.[12]

Unfortunately, a majority of patients are unaware that HIPAA is blocking the use of their personal data in health research. When informed of this reality, many report that they want their data to be used to contribute to research essential to advance the discovery of better treatments and cures.[13] But, without a practical way to "opt-in" to allow their patient data to be shared for health research, this is nearly impossible. The Privacy Rule, therefore, both impedes health research and contravenes patient preferences without effectively protecting the privacy of information used in research. Opportunities to use patient data to accelerate research and innovation are lost.

A need exists for new policies to address this conflict and misalignment between HIPAA and patient preferences, and enhance sharing of patient data to accelerate research and drive innovation to benefit patients and society.

- **Improve researcher access to patient data to accelerate research**

The goals of any policy to remedy this situation must be to enhance the use of patient data in health research and accelerate research by improving researcher access to patient data, while respecting patient preferences and ensuring patient privacy. Whatever the model, patient engagement in developing and implementing the policy is key.

One option may be to make it easier for patients to "opt-in" and allow their patient data to be used for all future health research without contravening the Privacy Rule. Patients routinely express the desire to "opt-out" of HIPAA to allow their data to be used, but the current system makes it essentially impossible for them to do so.

[12] IOM, Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research (2009).

[13] National Health Council. HIPAA Privacy Rule: Exploration of Patient & Caregiver Perspectives (2012).

National Photonics Initiative

White House Strategy for American Innovation 2014

INTRODUCTION

Crucial breakthroughs in the fields of optics and photonics have led to technologies that help form the infrastructure of many US industries and provide essential technologies for national defense and security. Photonics – the study and use of light – enable nearly every commercial sector, from advanced manufacturing to information technology and energy to medicine. Historically, the United States has been the world pioneer in transitioning photonics research to commercial markets; however, increased global competition has put at risk our nation's leadership position, threatening national security, economic growth and the pipeline of US jobs. Photonics is a platform technology, an enabling technology, and it must be part of any innovation strategy developed in the 21st century.

To maintain US competitiveness and retain American jobs in a number of dramatically growing commercial- and defense-related areas, the National Photonics Initiative (NPI), a collaborative alliance of industry, academia and government experts, has identified critical technology challenges and made recommendations for strategic investments in infrastructure to the US government. On behalf of the optics and photonics community, the NPI hopes our Response for Information highlights areas for public and private sector investment and support that best address the White House's Strategy for American Innovation.

OVERARCHING QUESTIONS

Response to Question 1

1.1 Fabrication and prototyping centers (Institutes for Manufacturing Innovation model)

The NPI advises the US government to consider an end-user-driven approach to identifying competitive photonics technologies and developing the most effective manufacturing processes, which will provide significant benefit to the US economy and job creation in several major industries, and increase innovation in both academia and federally funded research and development (R&D) centers. We emphasize that it is essential that private industry, academia and government work closely together to identify joint investments in appropriate, commercially viable photonics technologies. This program should be implemented in evolving stages, and it should actively engage US industry at each stage as an integral participant in co-funding this initiative and ensuring its success.

Innovation is dramatically enhanced when R&D teams can rapidly explore the feasibility of new concepts by assembling prototypes and evaluating cost-effective manufacturing processes. This occurred with spectacular fashion during the 1980s in the semiconductor industry. Technologists in academic institutions, small and large companies and government laboratories were enabled by the government-initiated Metal Oxide Semiconductor Implementation Service (MOSIS) program to inexpensively prototype electronic integrated circuits. Photonics is poised to unleash the coming era of inexpensive and energy-efficient data center and computational technologies through photonic integrated circuits (PICs) for industrial and consumer devices requiring high data bandwidths, such as next-generation, super-resolution 4K displays.

Although a “foundry” for photonic integrated circuits has been a recommendation of every major optics and photonics study from the US National Academies of Science dating back to the 1970s, we still have not succeeded in lowering the prototyping barriers for PICs at any scale comparable to existing IC/semiconductor foundries. Recent developments in PIC technologies have evolved to a stage where multiple devices and capabilities can be designed from a common platform. Several countries (e.g., Belgium, China and Singapore) have recognized this evolution and are starting to provide some limited prototyping using specific platform technologies.

It is imperative that the US government help form a National Photonics Prototyping and Advanced Manufacturing Facility. By taking a leadership role in the formation of such a facility, the US government would not only stimulate economic growth and American jobs, but it would also launch a new frontier of opportunities for innovation. Even basic light sources, such as LEDs and lasers, have already shown enormous applicability in military systems, consumer electronics, urban infrastructure, medical diagnostics and advanced manufacturing – this list grows dramatically when other types of devices are included. Moreover, providing a platform for prototyping novel devices that combine optics and photonics with electronic integrated circuits, and exploring new methods for manufacturing these devices, will propel the next generation of communication, sensor, information and display technologies. With rising concerns about cyber-physical security, a national facility would ensure that a viable “first and assured access” supply chain of devices and technology fabrication is available within the United States.

A prototyping and advanced manufacturing facility will help develop the ability, skills and knowledge necessary for the United States to ensure its competitiveness and leadership in optics and photonics technologies critical to our national security and prosperity.

1.2 Photonics research at the intersection of biology and physics

The NPI is convening a Photonics Industry Neuroscience Group (PING) to focus on developing new optics and photonics technologies in support of the White House Brain Research through Advancing Imaging Neurotechnologies (BRAIN) Initiative. The NPI PING is comprised of top US industry leaders who will work closely as a group with the BRAIN leadership and neuroscience research communities to advance optics and photonics research and technology development.

The NPI industry group will commit to invest tens of millions of dollars in existing and future research and development spending over the next three years to advance optics and photonics technology in neurosciences challenges such as:

- Develop the imaging optics, laser sources and automated scanning technology and high-resolution cameras to provide a ten-to-one hundred fold increase in the capability of imaging groups of thousands of active neurons;

- Develop miniature, affordable and portable/implantable microscopes compatible with high-throughput facilities for therapeutic screening based on neural activity signatures;

- Using large-scale, high-throughput protein engineering technology, develop a new generation of fluorescent indicators of neural activity with tenfold improvements in efficiency and temporal response; and

- Develop automated software for detailed mapping of the human brain, architecture, neuronal wiring geometry and dynamic activity from three dimensional data sets generated by MRI, CT and microscopic imaging.

1.3 Development of sensing technologies for fuel extraction and utilization

Optical sensor technology is essential for efficiently developing and utilizing US energy resources. The United States uses more than 100 billion gallons of gasoline and nearly 300 trillion cubic feet of natural gas every year; a 1 percent increase in efficiency would save more than $50 billion dollars in fuel costs and reduce carbon dioxide emissions by more than 30 million metric tons. This objective can be accomplished by creating domestic sources for:

- Novel optical materials for sensors of critical oil and gas parameters;
- Exotic light sources and detectors for tracking combustion performance and emissions; and
- New methods for imaging geophysical properties through complex media.

Investing in a multi-site initiative to develop these critical photonic technologies will make America the leader in monitoring energy extraction and utilization at scales ranging from the oilfield to the engine.

1.4 Development of sensing technologies for agriculture

The demand for ever more efficient agricultural production has fostered a high-tech area referred to as Ag Tech. Particularly in Unmanned Aircraft Systems (UAS), markets around the globe in both developed and developing nations are quickly adopting this technology, which is providing them a host of data-gathering capabilities enabled by optics and photonics. This highly innovative space in the United States has, however, been stifled due to current laws prohibiting commercial use of UAS technology and the Federal Aviation Administration's (FAA) inability to finish modern guidelines – discussed further in section **2.2**.

At the core of agricultural technologies, integrated photonic devices are common price-limiting components. Since the scientific field supporting this area is still growing, tools sold to farmers are unable to be targeted-sensing systems and are therefore costly. Along with the recommendations outlined in section **1.5**, a thrust in agricultural research focused on spectral sensing would produce a body of knowledge and the corresponding tools needed to meet the demands of climate disruption.

1.5 Device and systems-level research in photonic integration

The global marketplace is ripe for a renaissance in photonic sensor technology. Delivery of small, low-cost sensor systems of this type will open wide existing industries as well as those that are just merely a dream. Photonic sensors are already being integrated into devices in our homes, cars and phones. These inroads, however, are just the tip of the iceberg. Photonic technology will emerge in the 21st century in ways comparable to the electronic revolution of the 20th century, and at its center are materials engineered for emission, transmission and detection of light.

Electronics began in this same way, addressing technological problems here and there, and promising a future of integrated devices. Nearly 70 years later, this market is dominating the global economy and is a key driver in improving quality of life. The NPI recommends a public-private partnership, where government-matched industry R&D funding is used to develop a clearinghouse of photonic materials, complete with standardized specifications, practices toward scalable fabrication, and the balance of systems required to make these materials perform at the peak of their potential.

Investing in establishing and standardizing photonic sensor integration and light-wave management processes will open wide the global application space of these technologies. US leadership in photonic sensor integration know-how and technology will spur economic growth, create US jobs and provide a cost saving to government agencies such as the Department of Defense (DoD) and National Oceanic and Atmospheric Administration (NOAA) by reducing the cost of environmental sensing tools.

Low-cost photonic sensors that enable real-time and distributed monitoring (individual sensors linked to a common data collection site) will benefit all facets of society by providing:

- Pipeline fault monitoring, down-well sensors for harsh environments and fuel-ship transportation sensors for the efficient exploration, extraction and consumption of fossil fuels;
- Soil content sensors, aerial crop health imaging and experimental growth condition illumination for agriculture;
- Stress monitoring for turbine blades in wind farms to promote energy production efficiency;
- Live safety and health indicators for drinking and coastal waters; and
- Monitoring for pollution to lower environmental impact.

1.6 Fundamental materials timeline to market

Without knowing it, most Americans carry a dense visible spectrum sensor array around with them every day in the form of a camera phone. Great opportunity now exists to bring low-cost sources and detectors to the market, from deep UV to the thermal infrared. The primary obstacle is the cost associated with bringing new material systems to market. The NPI recommends that the US government commit to an extended timeline and path to capture the know-how and fabrication processes necessary to fill out the working range of optical material systems for detection, emission and manipulation of light. This is key for materials research, which has many long-term equipment maintenance costs. The benefit of such an investment is domestic access to an array of materials –

engineered materials that take raw elements out of the earth and grow them like semiconductors, glass and electrical contact materials – that liberate the design process for innovators to develop a diverse new set of capabilities in a cost effective way.

1.7 Laser materials processing

Advanced manufacturing is vital for the economic well-being of the country; it is a sector in which substantial job growth is possible. Though the majority of display and photonics component manufacturing has moved overseas, the United States can be a leader in new and innovative areas of manufacturing involving a new generation of high-power and low-cost ultra-short pulsed lasers, as well as additive manufacturing, a subset of 3D printing. Additive manufacturing allows machines to make a range of customized products directly from electronically transmitted designs, saving costly material in the process. It allows fabrication of parts with novel material compositions and can simplify manufacturing of complex shapes. These advanced printers, which President Barack Obama called the future of manufacturing, can create objects ranging from prosthetic limbs and functional human tissue to jet engine parts and shoes. While the United States may struggle to compete successfully in high-volume, labor-intensive, low-cost manufacturing, our nation can be a strong competitor in custom, precision and high-added-value manufacturing.

The NPI recommends that the United States invest in a coordinated national effort to improve our understanding of laser-material interaction for applications in heavy industry and manufacturing for material processing of metals, ceramics, plastics, composites and glass. Such an investment will benefit the capture of manufacturing process know-how and access to domestic capabilities that will drive the production of the consumer and industrial products of tomorrow.

1.8 High-Energy Lasers and Systems for Defense and Advanced Manufacturing

Photonics is a major part of many high-performance systems used by the military and in advanced manufacturing. The use of photonics technologies in advanced manufacturing has improved key factors of production such as product size, weight, performance and cost. As such, photonics are a driving force behind the revitalization of manufacturing in the United States and have become an essential tool for the factory of the future. Today, high-power lasers are increasingly used in industry for cutting, welding, drilling, surface modification and additive manufacturing, and they play an increasing role in the manufacturing of military hardware.

High-power laser weapons strike at the speed of light. They are recognized as imminently viable for cost-effective defense against a variety of proliferating weapons. Modest-power lasers are widely used by the military in surveillance and guidance. Currently, they are used for protection against heat seeking missiles, but they may also prove effective in disabling satellites in the near future.

US leadership in high-field physics will require leadership in high-power lasers, as Europe moves to complete its version of the National Ignition Facility (NIF) and separately establish the equivalent of the CERN particle accelerator for laser technology.

Response to Question 2

2.1 Education to meet optics and photonics industry demands

Curriculum pipelines lag far behind the demands of the optics and photonics industry. This challenge is recognized by many progressive technology fields, and the cause is largely related to a lack of communication avenues between industry and academia.

Similar to other science and technology areas, work force training programs, including wide-ranging educational activities, are needed to ensure a skilled US optics and photonics work force. Education and training are needed for advanced, multidisciplinary research, laboratory protocols, design and packaging skills, and certification programs for skilled technicians. Optics and photonics jobs require a variety of educational levels that range from community colleges to graduate students and post-doctoral researchers.

2.2 Emerging photonics technologies and existing regulatory landscape

Truly disruptive innovations commonly come into conflict with existing regulation. An area of much excitement around the world, and one discussed in response to other questions in this letter, is biophotonics – a field promising leaps forward in medical device technology. Presently, however, the expense necessary to clear US Food and Drug Administration (FDA) filings for medical devices in both currency and time is a major hindrance to innovation, specifically with regard to time-to-market.

Biophotonics has begun to open the agricultural markets to advanced sensing technology. Unmanned Aircraft Systems (UAS) carrying spectral imagers are being adopted by farmers around the world in the hopes of alleviating water shortages and boosting crop yields. Yet, in the United States, the FAA has been slow to complete guidelines for these types of aerial systems, stalling an innovative market place that is ready for adoption.

2.3 New financing mechanisms

As optics and photonics hardware development struggles to secure investment from the finance community, crowdfunding has emerged as a promising alternative method for raising capital. The US Securities and Exchange Commission (SEC) has yet to finalize guidelines for equity crowdfunding based on Congress' 2012 "Jumpstart our Business Startups (JOBS) Act. While there is indeed room for this type of investment for optics and photonics hardware development, many innovative projects are stalled due to the slow turnaround speed of the SEC for defining crowdfunding regulations.

Global success is strongly tied to how well the private sector can predict the future and assess risks. Recently in the United States, research funding has become undependable, and existing regulatory processes have been greatly stifling to innovation. The modernization of the US regulatory framework across agencies is vital for small and large business to remain competitive in the world marketplace.

Response to Question 3

3.0 Technology infrastructure investments

There are a group of related technology areas ripe for national support. Infrastructure recommendations include investment into prototyping facilities for telecommunications technology, sensing systems for energy and environmental challenges, and high-energy laser systems development. Research thrust areas that represent the future of economic and health well-being around the world include biophotonics, fundamental materials fabrication, and laser-material interactions. The NPI has gathered task forces and working groups charged with dissecting these areas and offering input. Please reference sections **1** and **2** for more information.

Response to Question 4

4.0 *The NPI has no unique contribution to this question.*

Response to Question 5

5.0 *The NPI has no unique contribution to this question.*

INNOVATION TRENDS

Response to Question 6

6.1 Open-Innovation model

Electronics enjoys the benefits of having grown up in the Bell Labs era which saw grand public and private investment into standardization and process development around components to make the integration of components easy and approachable by those novice to the field. Since then, the United States has moved away from this type of direct industry-partnered investment in order to avoid biasing free market competition. In today's funding vacuum, a few models, including open innovation, have emerged to compensate.

Aided by moving advanced science into the hands of industrial partners, open innovation is a model by which a company looks outside its four walls and seeks to partner with experts around the world in the innovative areas necessary to their continued business success. This is particularly relevant in photonics, as the cutting edge is generally far from industrial practice. Fields of science like optics and photonics are not currently part of the core competency of companies – particularly small, innovative companies – and so they struggle to internalize the expertise necessary to overcome the integration of photonic components.

An open innovation initiative could be envisioned to create a "technology commons" in the United States, where researchers could better market their results to the nationwide body of commercial players interested in adopting new product advances or manufacturing processes.

6.2 More Effective Technology Transfer

Over 30 years ago, the Bayh-Dole Act gave US universities – as well as small businesses and nonprofit organizations – the ability to control intellectual property (IP) that results from federal government-funded research. The intent was that with a stake to claim, universities would be more effective in moving technology from the lab to the market than government, and in so doing, impact our society faster. The Bayh-Dole Act has accomplished what it set out to, but as academic institutes, many universities put very little effort or resources into the proactive licensing of their IP. Generally, technology transfer offices run at or near zero-net profit and more importantly have huge portfolios of technology sitting around gathering dust.

There is opportunity for the administration to foster university technology transfer through similar means, as discussed above, in regard to open innovation. A "national IP commons," made searchable for technology type, would bring visibility to this massive pool of cutting-edge technology that is otherwise daunting to the industrial technologist.

Response to Question 7

7.0 FTAC-OP

This spring, the National Science and Technology Council produced a report of the Fast-Track Action Committee on Optics and Photonics (FTAC-OP). Outlined in the report was a prioritized list of seven recommendations, which are organized into categories of research opportunities and research-related capabilities. The research opportunities address: biophotonics to advance understanding of systems biology and disease progression; faint to single photonics; imaging through complex media; and ultra-low-power optoelectronics.

The research-related capabilities, which will encourage innovation in optics and photonics research, are: accessible fabrication facilities, exotic photonics and domestic sources for critical photonic materials.

The NPI has seen these same priorities emerge in ongoing work with industrial and academic partners. As this report states, "Progress in the field of optics and photonics has the potential to generate new knowledge, promote economic growth, create new industries and new high-skilled jobs, and provide technologies for new applications."

On July 22, 2014, the National Science Foundation (NSF) identified optics and photonics research and education as a key area of interest. Charged with keeping the United States at the leading edge of discovery across a broad scope of scientific areas, the NSF is calling for innovative research proposals on optics and photonics that are relevant to one or more of the following: Divisions in the Directorates for Engineering (ENG), Mathematical and Physical Sciences (MPS), and/or Computer and Information Science and Engineering (CISE). Areas that would benefit from such broad research support include the Materials Genome Project, photonic integration and laser material processing. Other federal research agencies should follow NSF's lead to call for optics and photonics proposals in a single or multidisciplinary approach.

Response to Question 8

8.0 The NPI has no unique contribution to this question.

SCIENCE, TECHNOLOGY, AND R&D PRIORITIES

Response to Question 9

9.0 Discussed above in response to questions #1 and #2

The field of optics and photonics is one that defines a platform technology. The capabilities that have emerged from this field are firmly embedded in every piece of modern technology around the world. The future of innovation will undoubtedly depend on further advancements from optics and photonics. Infrastructure recommendations include investment into prototyping facilities for telecommunications technology, sensing systems for energy and environmental challenges, and high-energy laser systems development. Research thrust areas that represent the future of economic and health well-being around the world include biophotonics, fundamental materials fabrication and laser-material interactions. The NPI has gathered task forces and working groups charged with dissecting these areas and offering input. Please reference sections **1** and **2** for more information.

Response to Question 10

10.1 IT Telecommunications

In order to address the challenges of the global communications infrastructure, it is essential to both US economic and security interests to develop a domestic capability to develop and prototype advanced photonic technologies. Please reference sections **1.1** for more information about recommended actions to bring together academia, industry and government.

10.2 Biophotonics

At the intersection of biology and physics, a new field is emerging that promises advancements in neurological diagnosis and treatment. Central to this new field is biophotonics, the ability to measure and manipulate biological systems using light. The United States has a key strength in biomedical research infrastructure, so there is a great opportunity for impactful investment by the US government. This area is discussed in section **1.2** with regard to ongoing work in line with the BRAIN Initiative.

10.3 Sensors for energy and environment

Sensor technology drives myriad capabilities as discussed in sections **1.3**, **1.4**, **1.5** and **1.6** above. It is key that the United States invest in "cradle-to-grave" initiatives for sensor technology that establish materials sources, fabrication techniques, systems integration and user processes. The impact of progress in this area will have direct impacts on fuel costs and crop yield, and indirect but clear impact on environmental quality and domestic quality of life.

10.4 Laser material processing for advanced manufacturing

Manufacturing has been revolutionized by the development of laser technology. Traditional subtractive processing as well as the emerging area of additive processing (3D printing) have been forever changed by the precision and speed of lasers. Additionally, the field of welding and surface patterning is quickly growing in capability due to laser technology. The development of laser systems and processes as applied to manufacturing is discussed further in sections **1.7** and **1.8**.

Response to Question 11

11.0 *The NPI has no unique contribution to this question.*

SKILLED WORK FORCE DEVELOPMENT

This year, the NPI launched a Taskforce on Education and Workforce Development (NPI-TEWD) to address questions like those posed in this section. Initial results from this task force indicate that three primary activities are needed from the work force pipeline perspective in the optics and photonics field, as follows:

1. Skills roadmapping: identification and communication of the industry's forward-looking employment needs;
2. Careers marketing: raising the profile and adoption of careers in optics and photonics; and
3. Industry-partnered training: developing on-the-job training through internships, co-ops and apprenticeships.

In order to execute these projects, a sustainable coalition of employers will be gathered. The NPI-

Response to Question 12

12.0 *The NPI is pursuing more concrete responses to this question.*

Response to Question 13

13.0 *The NPI is pursuing more concrete responses to this question.*

Response to Question 14

14.0 *The NPI is pursuing more concrete responses to this question.*

MANUFACTURING AND ENTREPRENEURSHIP

Response to Question 15

15.0 *The NPI is pursuing more concrete responses to this question.*

Response to Question 16

16.0 Industrial-scale user tools

The key to accelerating advanced-technology innovation into commercial practice is access to industrial-scale fabrication and manufacturing tools. Great barriers exist for technology companies of all sizes in transitioning from prototype to production, including financial capital investment and process development. In order to assist innovators in surmounting these barriers, some precedent exists for the establishment of user facilities filled with industrial-scale fabrication tools capable of semiconductor growth, thin film deposition, metal growth and an array of more advanced processes. Commonly, these facilities are the result of academic-industrial consortia, which establish facilities to highlight industrial tools in hopes of attracting customers once capital investment is prepared, while granting cutting-edge capability to researchers and technologists alike.

This need for process development and prototype development is also relevant to responses to question 1.

Response to Question 17

17.1 Open Innovation

As discussed further in section **6.1**, Open Innovation has successfully drawn more and more innovative academic research into commercial road maps since its formal conception in 2003. Many large companies have adopted Open Innovation programs, and smaller companies are now learning to adapt the concept to their businesses. It is recommended that the administration drive the creation of a US technology commons to promote access to innovative solutions.

17.2 Crowdfunding

Hardware is expensive to develop and even more expensive to commercialize. In the funding vacuum created by venture capital investors who have set return-on-investment expectations on a trajectory that foreshadows a potential new dot-com bubble, crowdfunding offers a model for bridging the valley of death through direct engagement with customers. It is now necessary to accelerate regulation of this funding model in order to eliminate further stifling of this distributed private investment process. Please refer to section **2.3** for further discussion.

Response to Question 18

18.0 Prototyping Facilities

Proving the potential of new and disruptive technology is currently a challenge to those most capable of creating them. As discussed in section **1.1** and **16.1**, the NPI recommends the development of facilities intended to address exactly this problem by leveraging industrial technology needs and prototyping facility needs of innovators.

REGIONAL INNOVATION ECOSYSTEMS

Response to Question 19

19.0 Industrial clusters

There exist 12 optics and photonics industry clusters around the United States in 11 states:

- Arkansas Photonics Industry Alliance
- Arizona Optics Industry Association
- Carolinas MicroOptics Triangle
- Carolinas Photonics Consortium
- Colorado Photonics Industry Association
- Connecticut Optics and Photonics Association (CTOPA)
- Florida Photonics Cluster
- Michigan Photonics Cluster
- Montana Photonics Industry Alliance
- New Mexico Optics Industry Association (NMOIA)
- New York Photonics Industry Association
- Rochester Regional Photonics Cluster, Inc.

These groups perform an array of services for their membership including networking opportunities, organization for advocacy efforts, organization or regional proposal work, and interfacing with regional educational assets. Largely, however, these associations go underutilized from the national perspective. Potential exists to leverage existing organizational structures, like the optics and photonics clusters across the United States, to nucleate activities within the scope of the administration's technological priorities.

Response to Question 20

20.0 *The NPI has no unique contribution to this question.*

Response to Question 21

21.0 *The NPI has no unique contribution to this question.*

Novel Government Tools for Promoting Innovation

Response to Question 22

22.0 *The NPI has no unique contribution to this question.*

Response to Question 23

23.0 *The NPI has no unique contribution to this question.*

National Priorities

Response to Question 24

24.0 Photonics: An American platform for 21st century innovation

Discussed throughout this response, optics and photonics technologies present themselves as enabling capabilities. All fields of science and all high-tech industries depend vitally on advances in this field. Furthermore, there is great opportunity for the United States to capture a global leadership role in the implementation of these technologies by investing in infrastructure projects that:

1. Establish the United States' ability to fabricate specialty materials;
2. Integrate materials into sensor devices;
3. Prototype systems with industrial input; and
4. Manufacture systems of increasing precision and accuracy tolerances.

Establishment of The National Photonics Initiative was recommended by a National Academy of Science committee of academic, industrial and agency leaders in order to communicate the commercially disparate but immensely impactful field of optics and photonics to decision-makers in the US government. The voice of the telecommunications, biomedical, energy, defense and advanced-manufacturing communities around the United States is therefore captured in the responses to this request for information.

Response to Question 25

25.0 *The NPI has no unique contribution to this question.*

On behalf of the National Photonics Initiative and the community of scientists, engineers, and innovators represented thereby, I thank you for this opportunity.

Sincerely,

Matthew Weed
NPI Steering Committee

Submission to the Office of Science & Technology Policy
In Response to the RFI entitled "Strategy for American Innovation"
As described in the *Federal Register* on July 29, 2014
September 2014
National Venture Capital Association (NVCA)

Background

The RFI described above asked for responses on a number of topics, and NVCA's submission herein is meant to address the following questions in the RFI:

"Manufacturing and Entrepreneurship

"(15) What new or existing investment models should be explored to support entrepreneurship in new geographies, as well as in **technologies and sectors that are capital-intensive, relatively high-risk, and require sustained investment over long periods of time?**

"Angel and venture investment has tended to concentrate in a few regions and sectors, particularly sectors that are capital efficient and can provide "exits" for investors within 5-7 years. As a result, innovative technologies that do not meet these criteria may be better suited to different investment models.

"(16) For new technologies and products, how might "proof of manufacturability" be gauged sooner, and what entities would most appropriately provide the necessary resources and facilities? What sectors represent the most promising opportunities for the application of such models?

"Assessing the feasibility of **producing at scale remains a critical hurdle for manufacturing startups attempting to commercialize new or unproven technologies, but it is a challenge that firms do not face until relatively late in their evolution, after a great deal of early investment has already been committed. More effectively addressing this challenge at an early stage could yield more efficient allocation of investment capital**, and greater commercialization of important innovative technologies and products.

"(17) **What tools, business model innovations, financial innovations, or other developments hold promise for reducing the cost of starting and scaling a business in capital intensive sectors like the life sciences, advanced materials, and clean energy? What can the Federal Government do to accelerate these trends?"**

The NVCA understands that changes to the tax code require an act of Congress. But to the extent that the Administration seeks to shape tax reform – especially energy tax reform – in a manner that promotes innovation in the United States, we respectfully offer these thoughts and a proposal for your consideration.

Today's web of energy tax policies is in need of significant reform. Current policy is an amalgam of decades of regional priorities and inconsistent policies. No current policy supports the kind of innovation and adoption of new technology that ensures our long-term competitiveness in global energy markets.

NVCA is supportive of new policies that streamline and simplify the complex, technology-specific credits that exist across the energy sector. We believe that the tax code should create a level playing field for all technologies and establish the long-term certainty necessary to drive investment in the sector.

Continued innovation is critical. The United States needs to adopt a long-term energy tax policy that encourages corporations to invest in new technology, aligns with the needs of small emerging companies who are often the source of these innovations, and provides greater incentives to adopt new technologies. Regulations, standards, and incentives must balance support for existing technologies with the necessary incentives needed for continued innovation to meet our national priorities. They must also require that technologies can eventually compete on their own in the private market.

The approach discussed below would help create a more level playing-field for new energy technologies. Rather than support deployment of commercially-available products, the proposed energy innovation and manufacturing credit would target first-commercial projects to stimulate investment in innovative technologies. The proposed credit structure provides consistent, durable incentives for new technologies across the entire energy industry and ends the current practice of the government picking long-term technology winners. The proposed energy innovation and manufacturing tax credit structure would refocus federal support on early technology deployment where it is needed most and encourage private investment in innovation, which is one of the most critical components to unlocking new economic growth.

According to a report released by the Department of Commerce, "technological innovation is linked to three-quarters of the nation's post-WWII growth rate. Two innovation-linked factors – capital investment and increased efficiency – represent 2.5 percentage points of the 3.4% average annual growth rate achieved since the 1940's."[1] But historically, private investment in innovative technologies has been weaker within the energy sector than in almost every other industry. In 2010 the five largest oil companies spent just $3.6 billion on R&D which represents less than 2 percent of profits and less than 0.4 percent of total expenditures.[2] In the utility sector, the major utilities employ on average less than 5 people in R&D roles per 1000 employees. This

[1] U.S. Department of Commerce, *Patent Reform: Unleashing Innovation, Promoting Economic Growth & Producing High-Paying Jobs.* 2010

[2] Congressional Research Service. *Research and Development by Large Energy Production Companies.* August, 2011.

is the lowest level of any industry.[3] These numbers are a result of many industry dynamics, but also reflect how little incentive exists for energy companies to invest in new technology, even with R&D tax credits.

Policy Recommendations

For tax policy to effectively drive domestic innovation, it will need to address the scaling challenges and accommodate the financial constraints of smaller emerging companies in the energy sector. These companies play a major role in driving energy innovation, along with some larger companies, that are in fact committed to continuous innovation. And if they receive the private investment they will need to reach commercial scale, these companies will create thousands of new jobs -- just as entrepreneurial companies have done in the information technology and life sciences sectors over the past four decades.

Moreover, policy should be structured in a manner that encourages emerging, high-growth companies to develop a wide range of energy technologies (from renewables to fossil to nuclear), allows the private market to determine winners and losers among these technologies, and creates robust opportunities for new and improved technologies to access the market and compete on a level playing field.

A new approach is in fact possible. Creating a new, non-refundable credit would support technologies as they develop and begin to enter the market -- before they have fully reached economic scale. The structure would be focused on driving technologies down their respective cost curves and then automatically roll off tax credit support as these technologies reach maturity and can compete on their own in the market. America has the most robust private capital markets in the world, but long-term, reliable incentives that create a level playing field are required to unlock this capital. Such a framework would provide certainty to investors across all stages of investment – seed, early, growth, and debt financing for commercialization -- and help to attract the capital required to fill development gaps throughout the commercialization process.

[3] National Science Foundation, Research and Development in Industry: 2006-07 (Arlington, VA: National Science Foundation, 2011), 130-131. Table 31 and 261. http://www.nsf.gov/statistics/nsf11301/pdf/nsf11301.pdf

<u>The Energy Innovation & Manufacturing Credit</u>

NVCA, in coordination with industry partners and investors across the capital spectrum, has developed the following proposal for an "Energy Innovation & Manufacturing Credit":

Objective

Streamline the energy tax code toward a singular long-term policy that provides consistent, durable incentives for new technology across the entire energy industry; move away from the current practice of the government's picking long-term technology winners; refocus federal support on early technology deployment where it is needed most; and encourage private investment in innovation.

Credit Structure

Eligibility: The credit seeks to achieve technology neutrality and applies to any innovative technology used for the production of fuels, energy generation property, or any technology that can be paired with energy generation property to improve energy efficiency. Companies eligible to receive the credit must be operating qualifying facilities in the United States that manufacture or produce an eligible technology.

How is a technology deemed "innovative"? Qualifying technologies must be determined to meet a threshold as "new and significantly improved" relative to commercially available alternatives. This means that a technology must be only recently developed, discovered, or learned and there must be proven improvements to production processes – the technology must involve or constitute new or improved function, performance, reliability, or quality, in comparison to commercial technologies. Such requirements include as eligible the adoption of existing or previously proven commercial technologies at a different scale and/or for a wholly separate function in the market relative to their initially intended commercial value. If the claimed innovation has been in use by three or more facilities for the five-year period preceding the claim of the credit, the technology will be deemed "in commercial use" and thus not a qualifying innovation.

Permanence & Commercial Scale Roll-Off: The credit structure will be permanent in the tax code (until repealed by statute, so not requiring periodic and uncertain "extensions" by Congress), but will not be available to individual companies forever. As a company grows and reaches commercial scale, the credit will reduce to zero once the company reaches a "roll-off trigger" -- a cap on "qualifying capital expenditures," calculated as the aggregate capital expenditures by an individual company associated with the implementation of new or improved technology elements of the system. Once the company has received tax credits equaling 50% of its capital expenditures associated with the innovation, the credit is no longer available to the company.

Claiming the Credit: Claiming the credit does not require any pre-approval by any government agency. If the company's board of directors is satisfied by the opinions of its legal counsel and auditing firm that the company qualifies for the credit under the statute, the company simply claims the credit on its annual tax return. That return is subject to audit, of course, and companies will follow the guidance that the IRS shall provide for the credit after the credit in enacted in the Internal Revenue Code.

Transferability: The credit will be transferable upstream and downstream in a company's supply chain of business relationships to allow pre-revenue and emerging growth technology companies to obtain its full value. This transferability feature will also encourage larger companies in the energy manufacturing industry to become strategic partners with smaller companies that develop the innovations that earn the credit.

CASE STUDY 1: Innovative Wind Turbine

The tax credit is available to manufacturers of innovative electricity-generating equipment who invest in manufacturing facilities that produce innovative technologies or that use innovative production methods. The credit is only available up to a 50% of the capital invested in the specific manufacturing equipment needed to enable the innovation.

Any technology must meet the following four criteria in order to qualify:

Qualification Criteria	
The end product is used to generate electricity	√
The end product or production process is "innovative"	√
Capital is invested in the manufacture of the end product	√
The capital is invested in US manufacturing facilities	√
The end product is manufactured and sold	√

A company is deciding whether to invest in commercializing a new 5 MW turbine design. The new turbine has shown promise in its initial pilot deployment, but has never been commercially produced. As the company works out the financing terms for a commercial manufacturing facility, they want to make sure the technology is eligible for the tax credit and they make the following four determinations.

- ✓ **The turbine will be used to generate electricity.**
  The new turbine design has the largest capacity of any onshore turbine in the world. Project developers plan to deploy the turbine in massive new wind farms and sell electricity onto the commercial grid. The credit is received when the company sells the manufactured turbines to the project developer.

- ✓ **The turbine is an innovative technology.**
  The credit is only available if the company is able to certify that the turbine is a true innovation. The turbine provides a functional or performance enhancement over existing technology in its improved energy conversion rate and significantly reduced maintenance

requirements.

A third-party audit must confirm that the new turbine is produced in no more than three existing facilities, and that none of those facilities have been in existence for more than five years.

- ✓ **Capital is invested in manufacturing the turbine.**
  The credit only supports capital investment in elements of manufacturing facilities that are necessary to enable the production of the innovative turbine. Qualifying costs are limited to equipment, engineering, construction, or other specified costs.

- ✓ **The turbine is manufactured in the United States.**
  The credit is only available for manufacturing activity located in the United States.

- ✓ **The turbine is manufactured and sold.**
  The credit only becomes available to the company after the electricity-generating equipment has been both manufactured and sold.

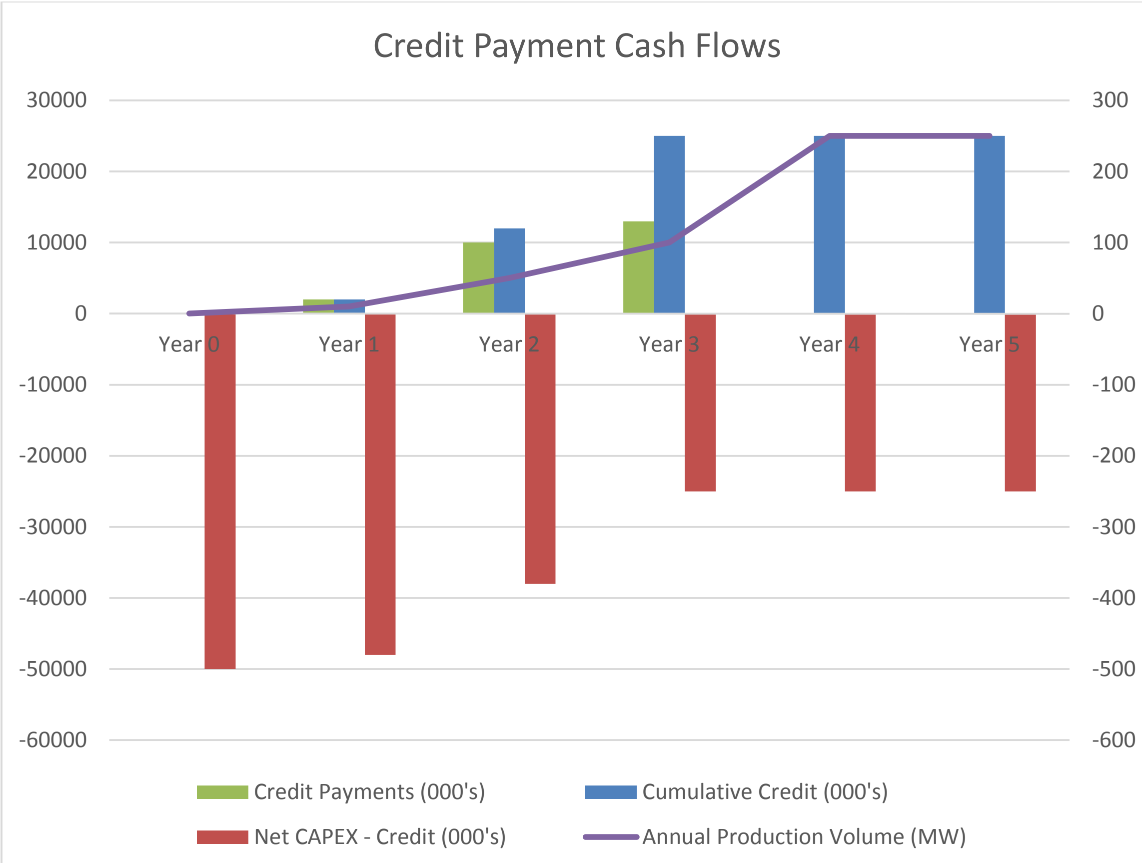
After the determination has been made that the turbine is eligible to receive the credit, the company will subsequently seek to understand how much the credit will be worth. It is essential for the company to be able to forecast this value while negotiating its terms of financing for the facility. To cross the commercialization “valley of death,” the company must build in revenue projections associated with the tax credit to make the project more enticing for investors and bring down the facility’s cost of financing.

The credit provides $200 per kilowatt (KW) of nameplate generating capacity of the turbines, up to the equivalent of 50% of qualifying capital investment. The company would earn the $200/KW credit per turbine produced and sold in a taxable year.

The cap on the credit is 50% of the total qualifying capital investment made by the company in the manufacturing facility. Qualifying capital investment is limited to the capital investment required to enable the innovation, and does not include capital investment that would have been made in a similar facility without the qualifying innovation.

For example, if the company invested $500 million in its new turbine manufacturing facility and $50 million of that investment was determined to be necessary to enable the innovative turbine, then the credit limit would be 50% of that $50 million (for a total credit value of $25 million).

The following chart depicts the annual impact of the credit relative to capital expenditures over the manufacturing facility’s first five years of operation. The turbine facility would begin receive the credit as production volume increases (beginning in Year 1), up to the 50% capital expenditures cap, which in this case is reached in Year 3. At that point, no further outlays are expended.



<u>CASE STUDY 2</u>: 3rd Generation Biobutanol

The tax credit is available to producers of innovative transportation, heating, or electricity generation fuel who invest in production facilities that produce innovative technologies or that use innovative production methods. The credit is only available up to a 50% of the capital invested in the specific production equipment needed to enable the innovation.

Any technology must meet the following four criteria in order to qualify:

Qualification Criteria	
1) The end product fuel meets ASTM standards for use as a fuel for transportation, heating, or electricity generation	√
2) The end product fuel or production process is "innovative"	√
3) Capital is invested in the manufacture of the end product fuel	√
4) The capital is invested in US production facilities	√
5) The end product fuel is produced and sold	√

A company is deciding whether to invest in commercializing a new process to produce biobutanol. The molecular structure of the fuel molecule and sustainable feedstock pathway have shown promise to be cost effective, but have never been commercially produced. As the company works out the financing terms for a commercial biorefinery, they want to make sure the technology is eligible for the tax credit and they make the following fiver determinations.

- ✓ **The biobutanol meets ASTM standards for use as a fuel for transportation, heating, or electricity generation.**
  The new biobutanol molecule has proven to match all of the characteristics of traditional butanol at lab and pilot scale development. In particular, airline carriers are interested in the company's cellulosic sugar-to-jet fuel pathway. The biobutanol is submitted to ASTM for testing and demonstration to meet the updated jet fuel standards. ASTM either certifies the fuel, or the fuel is demonstrated to meet ASTM standards by an independent third party, for use as a fuel for aviation transportation.

- ✓ **The biobutanol is an innovative technology.**
  The credit is only available if the company is able to certify that the biobutanol molecule is a true innovation. The biobutanol fuel provides a performance enhancement over existing technology in its improved energy input/output ratio while maintaining functional performance characteristics.

  A third-party audit must confirm that the new biobutanol is produced in no more than three existing facilities, and that none of those facilities have been in existence for more than five years.

- ✓ **Capital is invested in producing the biobutanol.**
  The credit only supports capital investment in elements of production facilities that are necessary to enable the production of the biobutanol. Qualifying costs are limited to equipment, engineering, construction, or other specified costs.

- ✓ **The biobutanol is produced in the United States.**
  The credit is only available for manufacturing activity located in the United States.

- ✓ **The biobutanol is produced and sold.**
  The credit only becomes available to the company after the fuel has been both produced and sold.

After the determination has been made that the biobutanol is eligible to receive the credit, the company will subsequently seek to understand how much the credit will be worth. It is essential for the company to be able to forecast this value while negotiating its terms of financing for the facility. To cross the commercialization "valley of death," the company must build in revenue projections associated with the tax credit to make the project more enticing for investors and bring down the facility's cost of financing.

The credit provides $0.50 per gasoline gallon equivalent (GGE) of the biobutanol, up to the equivalent of 50% of qualifying capital investment. The company would earn the $0.50/GGE credit per gallon produced and sold in a taxable year.

The cap on the credit is 50% of the total qualifying capital investment made by the company in the biorefinery. Qualifying capital investment is limited to the capital investment required to enable the innovation, and does not include capital investment that would have been made in a similar facility without the qualifying innovation.

For example, if the company invested $300 million in its new biobutanol refining facility and $50 million of that investment was determined to be necessary to enable the innovative molecule, then the credit limit would be 50% of that $50 million (for a total credit value of $25 million).

The following chart depicts the annual impact of the credit relative to capital expenditures over the biobutanol refinery's first five years of operation. The biorefinery would begin receive the credit as production volume increases (beginning in Year 1), up to the 50% capital expenditures cap, which in this case is reached in Year 3. At that point, no further outlays are expended.

Venture Capital Plays a Key Role in Innovation

According to a 2011 IHS Global Insight report, companies that were founded as small start-ups with venture capital accounted for 12 million jobs and $3.2 trillion in revenues in the United States. These figures equate to 11 percent of private U.S. employment and 21 percent of our country's GDP.

Venture-backed companies are responsible for the creation of entire industry sectors here in the United States including semiconductors, biotechnology, Internet content and software. Today, we are creating the companies that will serve as cornerstones for cloud-based computing, internet security, healthcare, social media and new energy. Many companies founded with venture capital are household names today, including Apple, Genentech, Starbucks, Facebook, Home Depot and FedEx.

Over the past 10 years, venture capitalists have invested over $25.0 billion in 762 energy and cleantech companies. With this burgeoning growth of venture capital investment in energy companies over the last ten years, the next generation of successful companies innovating in energy is poised to follow in their footsteps.

The chart below highlights the considerable increase in venture capital investment in energy and cleantech over the past ten years. The data is from the MoneyTree Report by PricewaterhouseCoopers LLP and the NVCA, based on data from Thomson Reuters.

Investments by Year	$M Invested
2003	228.97
2004	431.08
2005	630.94
2006	1,800.84
2007	3,123.66
2008	4,279.31
2009	2,519.23
2010	4,091.53
2011	4,615.18
2012	3,325.42
TOTAL	25,046.16

Conclusion

NVCA encourages the Administration to focus on innovation as it considers a long-term approach to tax reform. The Energy Innovation & Manufacturing Credit we propose would ensure a productive, focused role for the federal government in helping energy technology innovation reach commercial scale – but not beyond that point. Furthermore, the Energy Innovation & Manufacturing Credit would help increase participation of private-sector investors who will ultimately drive economic growth and ensure U.S. leadership in the global energy economy.

NEW MEDIA RIGHTS

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Dan Correa
Office of Science and Technology Policy
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Washington, DC 20504.

Dear Mr. Correa,

I am writing in response to the July 29, 2014 request for comment from The Office of Science and Technology Policy and the National Economic Council regarding updating the *Strategy for American Innovation*. Your call for responses indicated that the *Strategy for American Innovation* "helps to guide the Administration's efforts to promote lasting economic growth and competitiveness through policies that support transformative American innovation in products, processes, and services and spur new fundamental discoveries that in the long run lead to growing economic prosperity and rising living standards."

I submit these comments as Executive Director of New Media Rights. New Media Rights is an independently funded, non-profit program of California Western School of Law (a 501(c)(3) non-profit) whose core service is providing one-to-one legal services to creators, innovators, and Internet users whose projects require specialized Intellectual Property, Internet, and media law expertise. New Media Rights is known for our work providing preventative and transactional services on hundreds of cutting edge matters every year. New Media Rights has created a system and process to efficiently handle a large number legal service inquiries, producing value for clients by quickly identifying their legal issues and finding a path to services. In addition to direct, one-to-one legal services, New Media Rights innovates by taking what we learn from individuals and turning it into hundreds of freely available videos and written legal education guides for creators and innovators. This helps individual creators and innovators empower themselves. New Media Rights also takes what we're learning from clients and uses it bring underrepresented perspectives in regulatory proceedings at the Copyright Office, USPTO, FCC, and California Public Utilities Commission, including DMCA Anti-circumvention proceedings, Copyright Reform, and the Copyright small claims court proceedings.

New Media Rights is responding to this innovation inquiry, most specifically to your question 21 regarding Intellectual Property and Antitrust. (21)

(21) What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation (including, e.g., through the growing use of open innovation, combinatorial innovation, user innovation, internet-enabled innovation, and big data-driven innovation)?

While there are obviously many tensions and interactions between innovation and existing intellectual property and competition policy, we wanted to share recent comments we've made at the Federal Communications Commission and the USPTO / Department of Commerce. These comments address two important aspects of competition and intellectual property policy, protecting and preserving an open Internet, and reforming copyright law for the Twenty-First Century. We are attaching three comments in their entirety which address these issues, which I will summarize briefly below.

Comments and Reply Comments of New Media Rights in the FCC's Protecting and Preserving the Open Internet proceeding.

In July and September, New Media Rights joined millions consumers, creators, and businesses in filing public comments about the future of Internet. We argued that the Federal Communications Commission and the Administration now have an opportunity to choose a communications future of innovation, creative exchange, and consumer choice, rather than one where powerful broadband Internet companies can alter the Internet to support entrenched business models.

Specifically we are urging the FCC to reclassify broadband internet access providers as common carriers subject to Title II of the Telecommunications Act, and to reconsider its recently proposed Net Neutrality rules. Preserving an Open Internet is one of the most important social, economic, and legal issues of the twenty first century. It is critical that the FCC have the authority to protect it, and then that the FCC actually uses its authority to enact and enforce rules that uphold the tenets of an Open Internet for years to come.

In our filing, we stressed several important points:

• Broadband internet access speeds and quality in the United States are lagging behind the rest of the world and broadband internet access providers have no motivation to innovate and improve access because they do not compete. The FCC must have the authority to address issues raised by these powerful, entrenched broadband internet access providers.

• American innovators, creators, and consumers need world class internet speeds and quality at affordable prices or their ability to do business and compete in the global online marketplace will be severely limited.

• Broadband internet access providers have already taken actions that violate accepted tenets of an Open Internet (Transparency, No Blocking, No Discrimination), such as Comcast's throttling of Bittorrent data, and AT&T's sponsored data plans for mobile broadband.

• The FCC must reclassify broadband internet access providers as common carriers if it is to have any hope of having the authority to pass the kind of rules necessary to protect Net Neutrality.

• Reclassification of broadband internet access providers as common carriers, and consequently reclassification of broadband internet access as a "telecommunications service" as opposed to an "information service" (which it is currently classified as), is necessary because internet access is a distinctly different service from other “information services”. Broadband internet access has been wrongly grouped together with services that like Facebook, Twitter, Pinterest, and others and have thus been able to maintain enormous market power while being subject to very little oversight.

• The FCC must reconsider its proposed rules, because do not adequately protect key tenets of Net Neutrality. The “No Commercially Unreasonable Practices” rule in particular must be revisited in order to bring it more in line with its much more effective 2010 version – “No Unreasonable Discrimination” – in order to ensure that broadband internet access providers cannot abuse their power by discriminating between those who are willing or able to pay for faster access to end users and those who are not.

Again, New Media Rights urges the FCC to take advantage of this important opportunity to ensure that America’s internet ecosystem will remain free to create, innovate, and thrive long into the future, rather than captured by business practices of entrenched broadband internet access providers.

New Media Rights’ USPTO / Department of Commerce Green Paper Comments on Copyright Reform

On July 31, 2013 The United States Department of Commerce, United States Patent and Trademark Office and National Telecommunications and Information Administration released a Green Paper on Copyright Policy, Creativity, and Innovation in the Digital Economy. On September 30, 2013 they released a request for comments on that paper. All three offices were particularly interested in how copyright law could be reformed to better promote the growing digital economy. The request for comments was incredibly broad and ranged from questions about the first sale doctrine as it relates to digital goods to the role of fair use in remix culture.

In our November 13, 2013 comment New Media Rights sought to address three of the most critical issues that affect the remixers, entrepreneurs, creators and internet users we work with every day. First, our comments addressed five key copyright law problems that need to be solved to help remix creators spend their time creating rather than fighting legal disputes including the current failure of 17 USC §512(f) to protect creators from content bullying. Second, we discourage the widespread implementation of intermediary licensing modeled off YouTube’s Content ID system because it is not, in fact, an intermediary licensing system. We also explain the implementation of such a system could be incredibly detrimental to users’ rights largely due to the lack of an effective appeals process and various design challenges in the system. Finally, we address the Department of Commerce’s question regarding how best to go about fashioning a multi stakeholder process that would create a working set of best practices for the DMCA. We hope that our comments in these three areas will spark discussion and encourage badly needed copyright reform for the digital age. Our full comments are below.

Above all we hope our comment will spark discussion and encourage badly needed copyright reform for the digital age. This reform need not, and should not, take the form of any radical evisceration of copyright. At the same time, reform should not be used as an opportunity to continue unreasonable expansion of copyright law without concern for the collateral damage it causes to artistic progress, freedom of speech, and the intellectual enrichment of the public. Rather, much like one would tend to a garden, it is time we examine our current copyright law, remove the old weeds of law that no longer serve us, and plant the seeds of new law that will help to foster a new generation of artists and creators.

Conclusion

We hope the attached comments are informative regarding the impact protecting the open internet, as well as reforming copyright law has upon independent creators, early-stage innovators, and consumers. As you update the *Strategy for American Innovation*, please realize that these groups, often under-represented in policy debates, are the fuel for the kind transformative innovation you seek to promote. If you have any other questions about our work, or would like any more insights from our work with over 1000 creators and innovators, please do not hesitate to contact me at your convenience. Thank you for your time and consideration of these comments.

Sincerely,

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[redacted]

First of all, I'd like to ask what makes you think that government is, was or should be responsible for innovation, scientific or otherwise in America? Here are some excerpts from the president's plan at **http://www.whitehouse.gov/innovation/strategy** that demonstrates this administrations total detachment from reality.

"*To win the future, we must out-innovate, out-educate, and out-build the rest of the world. We also must take responsibility for our deficit, by investing in what makes America stronger, cutting what doesn't, and reforming how our government operates so it focuses on promoting our economic growth and preparing for the challenges of a new century.*"

And, who created this deficit? This administration has piled up more debt, bailing out the banks, GM and green companies than all of the last three administrations combined. Responsibility means coerced taxes and you may count on that message getting out. Yes, winning the future by allowing the EPA to regulate cow flatulence, farm dust, and dictate CO2 levels in the atmosphere. I don't think a cogent argument is possible with you people.

"*This document updates the Innovation Strategy issued in September 2009, detailing how the Administration, the American people, and American businesses can work together to strengthen our long-run economic growth.* "

Fascism is not the road to long term prosperity. Just ask the Germans.

"Strategy for American Innovation: Appendix A: Invest in the Building Blocks of American Innovation"..Educate Americans with 21st century skills and create a world-class workforce

Yeah right! Common Core is not the means to innovate education but merely serves to promote 21st century ignorance and slavery. The problem is that government is more often than not an unwanted and unnecessary partner.

"Create a first-class system of early education"

Well then Project *Head Start* should have been a rousing success. But, it wasn't because the same morons are busy pushing yet another failing education agenda. America needs better instruction than how to put a condom on a banana or a cucumber.

Fulfill a new transportation vision with high-speed rail

President Obama has set the ambitious goal of connecting 80% of Americans to the high-speed rail system within 25 years. To accomplish this he proposes sustained investments that build on the Recovery Act and would help create an efficient, high-speed passenger rail network of 100- to 600-mile intercity corridors that will better connect communities across America. --

WHY? Nobody wants a trillion dollar rail system ($80 million a mile construction costs) but that won't deter you. 'Sustained Investments' are nothing but taxes and you can't tax your way into prosperity. So you'll have to drive the cost of gasoline up to $15.00/gallon where we'll all have to ride your rail cartel where friends of the administration can get even richer.

The president's plan is just a greater recipe for American disaster than the one he's implemented for the last six years. Apparently, you're unable to recognize a failed administration when you're in one.

Editor - **http://newpatriotsblog.com**

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RESPONSE TO REQUEST FOR INFORMATION
Strategy for American Innovation
79 FR 44064

Response Filed By:
The NoCopyright Party of the United States

Document Number:
2014-17761

This is the NoCopyright Party's response to the RFI for "Strategy for American Innovation," 79 Fed. Reg. 44064 (July 29, 2014).

The NoCopyright Party represents the interests of over 319 million stakeholders, all of whom have an interest in a generous public domain for creative works and technology ranging from literature to medicines. Our response describes our proposal for an enhanced role for the government in bringing important medical treatments to the public without patent restrictions. Should you have any questions or need additional information, contact us at [redacted]

A National Laboratory for Drug Development

This proposal is most responsive to questions 5, 7, 8, 10, 21, 22, and 24, and it has implications for question 11. After explaining the proposal, we tie it to these questions.

The thrust of the RFI suggests that the government must work hand-in-hand with the private sector in order to accomplish the stated goals. We acknowledge this approach, but nevertheless urge one critical exception to the mindset that private industry can solve all our problems. In fact, some of the most pressing problems of today are best addressed head-on by intensive government engagement.

The development and delivery of pharmaceuticals to the public is one such area. In this regard, the NIH simply does not fulfill its potential – again and again, path-breaking findings made by NIH scientists at the public's expense are converted into the intellectual property of corporations, with the result that the public pays for them twice. The Bayh-Dole Act institutionalizes this sort of double-dipping, and its alleged "successes" have blinded legislators and policymakers to what could be far more successful approach to innovation and delivery of useful technology to the public.

Accordingly, we urge the Administration to propose and support a pilot project that would test the government's ability to conduct <u>all</u> phases of drug development, as an alternative to relying on private industry and the patent reward to finish the job. In this initiative, the government would develop the drugs, and then pay for (or conduct) the required animal and clinical testing, and would undergo the same FDA review process (IND and NDA) as commercial pharmaceutical companies. If the clinical testing is successful, the results should speak for themselves, and generic companies will be able to apply for FDA approval based on the government's submissions to the FDA. There would be no exclusivity period and no Hatch-Waxman litigation, and the medicines developed through this program would be instantly within the public domain all around the world. This could help the U.S. to become not just the most powerful, but also the most generous and compassionate, nation the world has ever known. We explain the proposal through a dialogue.

Q: How does this comport with the prevailing "free market" philosophy?

A: The better question to ask is "How does the current patent system, as applied to the pharmaceutical industry, comport with free market philosophy?"

Q: Ok, answer that one.

A: Hardly at all. With the patent system, the government has given up on the free market – at least for a period of time. A patent is a government-sponsored monopoly, which, like any other monopoly, creates great inefficiency, deadweight loss, suboptimal distribution, and high prices for consumers. We accept the temporary monopoly because the monopoly reward will promote beneficial innovation. In fact, the pharmaceutical industry is often seen as the poster child for the patent system – without the patent incentive, these private companies would not invest the millions of dollars needed to bring drugs to market. That's true enough, but it doesn't mean patents are the <u>only</u> way to promote innovation in this area. As we're about to demonstrate, patents are an incredibly inefficient way of promoting innovation the critical field of human health and welfare.

More fundamentally, beyond the distortions introduced by patents, the very idea of a market-driven model for fighting disease is misconceived. Given that (1) the average American consumer (i.e. "the market") has little clue as to the medicines the country needs to develop; and (2) drug companies will always make more money off of drugs that alleviate symptoms or recurring conditions (like erectile dysfunction and social anxiety disorder) than those that actually cure diseases (like Ebola), a market-driven model will not produce the kinds of pharmaceuticals the world needs most. And yet, despite this, the U.S. government has essentially delegated the function of deciding what drugs to develop to the "market."

Q: So how are patents for pharmaceuticals inefficient?

A: Here is a partial list. There are several common and overlapping themes, including imperfect and distorted information, perverse incentives, and undue influence in the political process. This is not to criticize the pharmaceutical industry – except when they engage in criminal activity, these corporate entities are simply doing what is best for their shareholders, under the letter of the law. Our point is merely that the result has been an unnecessarily expensive and inefficient system for inventing and delivering needed medicines to those who need them the most.

1. **Lack of meaningful price controls.** In a free market, market pressures cause prices to fall to the marginal cost of production. With patent protection and FDA exclusivity, pharmaceutical prices will for many years be a large multiple of the cost of production. The result is high insurance premiums, large Medicaid, Medicare, and Affordable Care Act expenditures, and suboptimal distribution of these drugs. A current example is the controversy over Sovaldi – a patented Hepatitis C drug that currently costs $84,000 per treatment.[1]

2. **Imperfect Information.** Economics 101 tells us that the free market works best when consumers have perfect information. It's almost the opposite in the pharma world. Because of patent protection, drug companies have incentives to flood the market with "information" that will boost sales of patented drugs, rather than drugs that are off patent.

   So the information is distorted to begin with. And beyond that, because their prescriptions will be covered by insurance or a government program, consumers typically have little incentive to pay much attention to the ultimate price charged.[2]

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[1] We believe that recent outcry over Gilead's reasons for charging such a high price for Sovaldi misses the point. The high price is a result of the patent, combined with demand for the drug. Under our system's current rules, that's the way the game is played. What we propose is another way to develop that same treatment, which would make it instantly available at a fraction of the price.

[2] It is well documented that certain pharmacies take advantage of this information apathy by charging exorbitant prices for drugs even after they have gone off patent See generally "Same generic drug, many prices," Consumer Reports magazine: May 2013 (finding wide price variations at different drug stores on generic versions of Lipitor, Plavix, and other common drugs) (available at http://www.consumerreports.org/cro/magazine/2013/05/same-generic-drug-many-prices/index.htm). For support for other points in this section, *see generally* Ben Goldacre, Bad Pharma, How Drug Companies Mislead Doctors and Harm Patients (Faber & Faber 2012); Marcia Angell, The Truth About Drug Companies, How They Deceive Us and What to Do About It (2004); Katherine Greider, The Big Fix: How the Pharmaceutical Industry Rips off American Consumers (2003). Or do a google search.

3. **Skewed incentives.** Yes, the patent lure provides an incentive, but it's not just an incentive to innovate. It's also an incentive to perpetuate the lucrative patent monopoly, and to do everything possible to ensure consumers pay the higher patented prices. Some specific examples, all of which are antithetical to the free-market and bad for consumers, are:

    a. The incentive to extend patent terms without actually doing any more innovation.

    b. The incentive to steer patients toward patented medicines instead of perfectly good generic alternatives.

    c. The incentive to pursue inventions that will be lucrative in the western market, as opposed to those that actually cure disease and thus have the potential to save lives.

    d. The incentive to pursue new and potentially patentable compounds, while older and more promising ones will never be tested, because even if the tests show amazing results, there will be no patent profit.

4. **Persuasive Money**

    a. Campaign contributions to federal legislators in exchange for patent term extensions.

    b. Campaign contributions to politicians not to enact price controls (which are present in every other industrialized Western country).

    c. Campaign contributions to state legislators to enact laws against use of generic drugs.

    d. Providing doctors with lucrative consulting contracts, in exchange for the doctors' goodwill.

    e. Encouraging doctors to prescribe particular medications (e.g. through use of kickbacks plus good-looking pharma reps).

    f. Direct marketing to consumers – advertising that tells consumers to ask their doctors for drugs that they don't truly need.

5. **Misleading Science**

    a. Development and promotion of new drugs that do not actually perform better than the older off-patent drugs that they replace, except in the studies reported by the patent-holder (see RFI Q11).

6. **Legal Pretexts**

    a. Evergreening of patents through follow-on patents and Orange Book gimmickry

    b. "Pay-for-delay" reverse settlements with generics

7. **Illegal Tactics**. Unfortunately, the amount of money to be made by extending the patent monopoly – often millions of dollars for every extra day without competition – can cause drug companies cross legal boundaries.[3]

8. **Duplication and lack of cross-pollination.** With different multinational pharmaceutical companies pursuing patent protection, there is no guiding hand to ensure that duplicative work is avoided, or that work is shared in a synergistic manner.

9. **Deadly Consequences.** The "need" to keep prices high through the patent system has led to catastrophic consequences abroad in the past. [4] This, incidentally, is one reason that governments should work together to get all potentially life-saving medications into the public domain, by whatever means necessary. The solution might be as simple as compensating patent holders up front to break or relinquish their monopolies. In the United States, it would be perfectly legal for the government to do just that, under the "just compensation" clause of the Constitution's Fifth Amendment.

Q: But you can't seriously mean that the government should take over all pharmaceutical research. Everyone knows that the government is incredibly inefficient.

A: It is hard to imagine any system less efficient at delivering what the public needs than pharma. NIH is already a prestigious institution that attracts top talent; we envision an extension of NIH that would literally be the most prestigious place in the world for top minds to work and collaborate towards solving the world's problems, like a combination of Bell Labs and the Peace Corps. People with that mindset and mission are naturally efficient.

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[3] *See, e.g.*, Katie Thomas, J.&J. to Pay $2.2 Billion in Risperdal Settlement, New York Times, November 2, 2013; Katie Thomas and Michael S. Schmidt, Glaxo Agrees to Pay $3 Billion in Fraud Settlement, New York Times, July 2, 2012; Gardiner Harris, Pfizer Pays $2.3 Billion to Settle Marketing Case, New York Times, Sept. 2, 2009.

[4] *See* Fire In the Blood (2013 documentary) (documenting death of millions of Africans from AIDS stemming from big pharma's blockage of generic drugs).

Q: Why do you refer to the "world's problems"? Why should our research be free for other countries? Isn't intellectual property our most important export?

A: No. Drug companies are mostly foreign-owned, and even U.S.-owned companies have most of their employees in other countries.[5] At this point in world history, good will might well be our most important export. Think of how much good will we would build up if this project were to generate a cure or vaccine for the Ebola virus, such that it could instantly be produced by generic companies, and sold at marginal cost.

Q: Has any country tried anything like this before? (RFI Q5)

A: Well, the U.S. has – that's basically what the Apollo Program, Bell Labs, and the Manhattan Project were all about. In each of those cases, the government (or Bell, the government-sponsored monopolist) did more than just the research – it created the final products.

Q: But that's not pharmaceutical research.

A: Cuba is a good example of a country that has made all stages of pharmaceutical development a national priority and has reaped the rewards.[6]

Debra Evenson explains why the Cuban model has worked:

> Two factors differentiating the Cuban biotech industry are the high level of integration and cooperation among scientific institutions, and their "closed loop" approach, which emphasizes translational research and coordinates the entire process among institutions – from research to marketing – of any given biotech product. . . . For example, Cuba's Haemophilus influenzae type b vaccine (Hib), the world's first synthetic antigen vaccine, was the result of the collaboration by five institutions . . . .
>
> Cuban research also prioritizes developing affordable vaccines for diseases affecting poor populations, such as typhoid fever and cholera: a fundamentally needs-driven, rather than market-driven approach. This can be contrasted with transnational pharmaceutical companies, which have come under increasing criticism for

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[5] Jonathan Band & Jonathan Gerafi, "Foreign Ownership Of Firms in IP-Intensive Industries," at 23-24 (Mar. 2013) (available at www.infojustice.org/wp-content/uploads/2013/03/foreignownrep.pdf).

[6] *See, e.g.*, Debra Evenson, Cuba's Biotechnology Revolution, MEDICC Review, Fall 2007, Vol 9, No 1, at 8-10 (available at file:///C:/Users/twk/Downloads/mr_57.pdf); Elio Delgado Legon, Cuba's Overlooked Development in Science, Havana Times, July 3, 2012 available at http://www.havanatimes.org/?p=73510).

> placing market interests before global health solutions, resulting in investment of 90% of R&D dollars worldwide in developing treatments for diseases affecting the 10% of the world's population that can afford the results. Cuba also produces generic drugs, including HIV/AIDS antiretrovirals, selling them to developing countries at a fraction of the price sold by transnationals."

There are three great points here – first, the fact that the work and knowledge is shared almost certainly leads to inventions and insights that would not have been made by labs working alone, in competition with each other. Second, the Cuban success underscores the importance of a needs-driven approach, rather than a market-driven approach, when a nation's – or the world's – health is at stake. And a needs-driven approach means that there must be some central planning. Third, the last sentence says it all – while transnational corporations make it very hard for sick people in developing nations to get needed medicines (because of the need to keep prices high), Cuba has stepped in and produced generic drugs and made them available at a fraction of the price. We could do that too.

Q: But isn't Cuba a communist country?

A: Central planning is a terrible idea in most sectors of the economy, but a centrally-planned pharmaceutical development policy will almost certainly be better than one that relies on the "invisible hand" of the patent incentive. Cuba is demonstrating that. Acknowledging that central planning is a more sensible deviation from free market principles than patent monopolies in this area doesn't make us communists.

Q: Do you have a name for this project?

A: It's probably simplest to call it the "National Laboratory for Pharmaceutical Development" (NLPD). But the idea can be achieved by modifying the NIH's mission slightly, so maybe a new name isn't necessary. An umbrella term for the concept could be the "Asclepian Revival." Asclepius was the Greek god of medicine and healing, but Zeus killed him with a thunderbolt. You figure out the metaphor.

Q: If the NLPD had existed in 1989, what kind of work would it have done?

A: It would probably have been researching and finding a cure or a vaccine for the Ebola virus. That produced a real scare here in the DC area at the time.[7] And today again, it would be working on the Ebola virus.

Q: Can you be more specific about how you would implement this?

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[7] *See* Richard Preston, The Hot Zone: A Terrifying True Story (1994)

A: There are already good people at institutions that have the equipment and resources to start implementing the project today – the NIH, the FDA, the CDC. These people could form the nucleus of the program. And business could proceed much as usual, except that (1) there would be more central planning, and (2) once a promising research result is obtained, the government would proceed with the next stages, just as if it were a private pharmaceutical company. The "implementation" aspect – getting the drugs through animal and clinical testing could be done by procurement personnel in these agencies, or it could be outsourced to procurement personnel in other government agencies. Beyond that, ideally we would hire more geniuses and give them more and better equipment, and create a network of such labs across the country. Perhaps some university laboratories could become part of the overall mission – even now it would make sense to condition grants to universities on their promise to relinquish any claims to patent rights developed with government funds.

Q: How much would this cost?

A: A poorly-informed congressman might say "we don't have any money, so we'll leave drug development to private industry and the free market." But that's the most expensive solution of all, and it's disingenuous. As we've shown, that approach virtually guarantees that any new medicines that are created will for many years only be available at monopoly prices. The "cost" of any one such drug developed by drug companies can run into the billions of dollars per year, and that cost is paid by patients and taxpayers – exactly the same people who would be paying for NLPD.

This is a political problem that must be overcome. Congress does not have to account for money that is spent on patent premiums, but that is an enormous cost to society – to the health care system, and ultimately to the government – just the same. If we are right that this is a more efficient way of creating needed health care treatments, then this would actually save money, not cost money. In other words, any drug that NLPD develops that can substitute for a patented drug will save society the of the costs of paying the patent premium price.

If we're right, then society will recoup much more than a dollar for every dollar invested in this. If so, there is no "real" cost at all, and it would make sense to pour almost unlimited resources into this project.

Q: What kinds of medicines would you suggest for the pilot program?

A: Cancer drugs. Cancer drugs are of little use when they fall into the public domain after patent expiration, because by that time they are considered substandard. The result is that cancer drugs are always under patent, and always very expensive.[8] So this is an area where there may never be effective generic competition, unless we provide it.

Q: Aside from researching new drugs, what else could the NLPD do?

A: As already mentioned, one of the problems with tying everything to patents is that if a compound is already in the public domain, drug companies will have little incentive to invest the millions of dollars in animal and human testing that is needed to get approval for the drugs. So this introduces a great distortion – even if the public domain compound is objectively more promising than a newly-synthesized compound, drug companies will have no incentive to make the investments to bring those promising drugs to the market. The NLPD could step in and do the necessary testing, and bring the drugs to the market, at generic prices.

Another way that the NLPD's activities could pay for themselves, and even yield a net gain to patients and taxpayers, would be for it to do selective double-checks on the work of drug companies who are marketing follow-on drugs that they say are superior to drugs that have become generic. The NLPD could evaluate and assess the data provided and provide reports that could then be used by physicians (and patients, insurance companies, and government payors) in deciding whether or not a particular patented treatment is really better than a generic one. In some cases, the NLPD could perform "retests" to see if the results obtained by the drug companies are, in fact, reproducible. If pharmaceutical company advertising has effectively led consumers to pay millions of dollars in patent premiums for a treatment that is no better than a generic treatment, that is a completely unnecessary healthcare expenditure. If the NLPD were able scientifically prove that there the patented drug is no better than a generic, that could save the health care system many millions if not billions of dollars.

Q: So you're saying that it's not appropriate to look at this as the question of whether we can "afford" to pour more of our health care dollars into this. You are saying that after everything is netted out, we will have profited, right?

A: Right – we think the pilot program will confirm the logic, and we'll find that for every dollar invested in this program, the system will save at least two dollars. If that's the case, nothing should hold us back.

Q: Do you have anything else to say?

A: Let's just wrap up by reiterating that a program like this should be seen as a moral and social imperative, and that it's not just the right thing to do as a matter of

[8] *See* Mustaqeem Siddiqui and S. Vincent Rajkumar, "The High Cost of Cancer Drugs and What We Can Do About it," Mayo Clin. Proc. Oct. 2012.

economics, but it's also the right thing for a country like the United States to do at this time in world history. It would really increase the moral force of our democratic message.

Q: Do you have any other ideas in this area?

A: Yes. Starting from the same premise – that the patent lure is a useful incentive, but that the patent itself causes great inefficiencies and suboptimal distribution – the government should seriously think about buying up patents (and any exclusivity that comes with them). Any given patent must have a true dollar value (discounted for present value): a measure of the value that the ability to charge a monopoly price for a period of time confers on the patent owner. No matter how high that dollar value is, it comes as a direct result of consumers – individuals, insurance companies, government programs – paying money for that drug. In other words, if the "value" of a patent is $10 billion, that's because the public has paid $10 billion dollars in monopoly premiums when buying the drug.

Q: With you so far.

A: So that means that the public should be willing to simply pay $10 billion to remove the patent. That's $10 billion that it would have spent on patent premiums anyhow, and by spending the money up front all of the inefficiencies associated with the patent monopoly are removed up front. Generic companies would simply come in and produce the drug at generic prices. All of the extra work that drug companies and the government have to do to fight off knockoffs, is no longer needed. There is also no need to "ration" the drug to maintain monopoly pricing. Assuming the drug is relatively cheap to produce (and as we know from Target and Wal-Mart, many off-patent drugs can be produced and sold to the public at $4 a bottle), we could even eliminate the insurance company middle-man for these drugs.

Q: So instead of paying the $10 billion over the period of patent term (and other exclusivity), the public would pay that same $10 billion up front, and thereby get all the benefits of the medicine, plus eliminate all the inefficiencies associated with the monopoly?

A: Exactly.

Q: Have you written this up anywhere else?

A: We have written up something very similar in the copyright context. See Ann McGeehan and the NoCopyright Party, "Worth More Dead Than Alive: Join the NoCopyright Party and Start Killing Copyrights for Their Own Good" (available at http://ssrn.com/abstract=2498530). As with patent, we agree that copyright provides a useful incentive to producers of useful things. Copyright enables authors to make good money in the first few months or years after a book is published. But after that initial period, in most cases, the copyright does more harm than good – the author's royalty stream dwindles to almost nothing, and the public, if it still wants the work, has to pay a copyright-premium price. In that area too, it would make sense for the public to simply "buy" the copyrights and place the work in the public domain. If the author receives an amount equivalent to or greater than the value of the expected royalty stream, the author should be happy, and the work now becomes available to everybody. For books, that would mean that anyone doing a Google® search might encounter the book, and would benefit from it. Assuming, for any given book, that it is worth one penny to each member of the public to have that work in the public domain, that means that putting any given book in the public domain confers $3 million on the public. If an author is willing to part with a book for $100, that $100 creates $3 million in value.

Q: Wow. That sounds like something that needs to be implemented.

A: Right, we're working on setting up a website that will enable people to use crowdfunding to get works into the public domain. The same concept would work in principle for patents as well, but since the dollar amounts are so much greater, it's unlikely that crowdfunding by itself will be able to do the trick.

Q: Is there anything the government can do to help on the copyright side?

A: Well, another way of implementing the same concept for copyrights, which is consistent with the questions in this RFI, would be for the government to offer "just compensation" to any copyright owner willing to turn in a copyright that is doing more harm than good. Copyrighted works – especially those relating to science and innovation – are themselves powerful engines of further innovation. And yet many such works are under-read, and under-available, because they are languishing under copyright. If the government were to simply offer $100 for anyone who has written a book (or inherited a copyright in a book) that somehow relates to innovation, and then put the book in the public domain, that could potentially create great value and could directly promote innovation.

Q: Any concluding thoughts?

A: No, that's it.

Relationship to questions:

(5) What innovation practices and policies have other countries adopted that deserve further consideration in the United States?

See discussion of Cuba above. OSTP should seriously study the Cuban biotech industry before dismissing this proposal out of hand.

(7) What emerging areas of scientific and technological innovation merit greater Federal investment, and how can that investment be structured for maximum impact?

Drug research and development is not an "emerging area" of innovation, but nevertheless, as we've shown above, investment in a centrally-planned agenda for such research and development would have a much greater impact than leaving it to the "market," especially a market distorted by patent forces.

(8) What are important needs or opportunities for institutional innovation and what steps can the Federal Government take to support these innovations?

If a government-run lab is an "institutional innovation," then we've answered this question.

(10) Where are there gaps in the Federal Government's science, technology, and innovation portfolios with respect to important national challenges, and what are the appropriate investment and R&D models through which these gaps might be addressed?

The "gap" is in bringing the results of government-funded research to market – rather than let private companies do it, the government needs to be more involved.

(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

In cases where the public pays a very high price based on claims made by single studies, the government – through the NLPD or NIH – should look very closely at the studies and ensure that they really support the claims. In some cases, flaws can be seen by looking at the methodology and the data, but in some cases, the government may find it necessary to replicate the tests. Again, if the public (and government-funded programs like Medicaid and Medicare) is spending millions of dollars on a patented drug that is no better than a non-patented drug, the cost savings of identifying those distortions and refuting those claims would make retesting well worth it.

(21) What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation?

As explained above, the patent incentive has a distorting effect on our system for producing needed medicines. A new model of direct investment that does not rely on the patent reward for recouping the costs of investment will remove those distortions, and help the public realize a much better return on its drug development investment.

(22) What are specific areas where a greater capacity for experimentation in law, policy, and regulation at the Federal level is likely to have large benefits?

As above, the health care area could greatly benefit from the "experimentation" in policy that a national laboratory for drug development would provide.

(24) Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?

The idea of creating a National Laboratory for Pharmaceutical Development (or simply making this part of NIH's mission) should be a national priority. As explained above, it will improve the delivery and reduce the cost of medical treatment. Because the results will be IP-free, they will be available to the world at large, for free, with significant implications for national security. This aspect of the project cannot be overemphasized and must not be ignored.

Northeastern

September 23, 2014

Via E-mail to: innovationstrategy@ostp.gov

Mr. Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue NW
Washington, DC 20504

Dear Mr. Correa:

On behalf of Northeastern University's President, Joseph E. Aoun, I am submitting comments to the Office of Science and Technology Policy Request, for Information regarding the Strategy for American Innovation in the July 29, 2014 *Federal Register*.

Timothy E. Leshan
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For more than a century Northeastern University has been a leader in cooperative education and experiential learning. Through this, students alternate their classroom studies with long-term professional internships at nearly 3,000 companies, nonprofits, and government agencies around the world. Our unique global model, in which students work and learn in over 114 countries, enables them to bring what they learn in professional environments back into the classroom. Northeastern's use-inspired research—that is, research that can be applied directly to solve real-world problems and improve lives—is grounded in an industry-aligned approach that meets the needs of employers in our U.S. locations of Boston, Charlotte and Seattle.

Question (3): What specific actions can the Federal Government take to build and sustain U.S. strengths including its entrepreneurial culture, flexible labor markets, world-class research universities, strong regional innovation ecosystems, and large share of global venture capital investment?

The federal government should consider the creation of programs modeled after the ARPA-E program in non-energy disciplines. ARPA-E's hallmarks are high-risk, high-reward investments that typically foster deep industry-academia collaborations oriented towards early research with strong commercial potential. Northeastern has had very good experience with the ARPA-E program, which has helped university researchers demonstrate significant scientific progress on one project and helped spawn a spin-out company to commercialize resulting technology on another.

Question (20): How should the federal government promote the development of metropolitan "innovation districts," where large research institutions, companies, start-ups and business accelerators congregate to facilitate the knowledge flows that sustain innovation?

Northeastern has worked to build a university-wide ecosystem of innovation and entrepreneurship among its faculty, staff, and students. Students at our D'Amore-McKim School of Business have developed a student-run venture accelerator called IDEA, which is supported by the university. IDEA empowers students from across Northeastern to develop their own companies and products with the assistance of student coaches and successful entrepreneurs. Currently, more than 200 business ventures are in development through IDEA, and several startups have been launched. Just as importantly, IDEA is preparing our students to seize the challenges and opportunities in today's global economy, enabling them to be entrepreneurs for a lifetime.

Northeastern has been a leader in developing entrepreneurial co-ops, six-month and full-time work internships, in early stage ventures. A certain number of these co-ops are subsidized by the university to help start-ups foot the bill for their hiring. Many of these co-ops are located in Boston's Seaport Innovation District. Additional investment in such academic-industry partnerships is one way the federal government can promote the development of such districts.

Moreover, Northeastern's Center for Research Innovation offers real-time business advice to faculty entrepreneurs. This advice includes, assistance negotiating exclusive licenses that become cornerstones of a company, finding helpful contacts within the Northeastern community, and suggesting board of directors' candidates and investors. In addition, technology-focused faculty also sponsor their graduate students in a course offered through the Lab to Ventures program. The students' startups then enter the IDEA venture accelerator. Faculty members can become Chief Scientific Officers and/or shareholders in the new ventures.

In addition, Northeastern has developed a unique corporate partnership, which could serve as a model going forward.

Northeastern has formed a partnership with The Rogers Corporation, establishing the Rogers Innovation Center at George J. Kostas Research Institute for Homeland Security on our satellite campus in Burlington, Massachusetts. This partnership demonstrates the emergence of a new opportunity for university corporate collaborations aimed at accelerating the commercialization of basic research.

As a global technology leader in advanced materials and components for consumer and power electronics, transportation, telecommunications, and defense systems, Rogers' expertise closely aligns with Northeastern's focus on use-inspired research in health, security, and sustainability.

The partnership allows Northeastern and Rogers to leverage their complementary research and development initiatives in advanced materials. Rogers is a world leader in developing and manufacturing unique, high-performance materials used in high-frequency printed circuits, power electronics, impact protection, and sealing applications. Northeastern brings to the partnership a broad range of materials research expertise in areas as diverse as super strong carbon fibers and metamaterials designed for invisibility cloaking.

Through this partnership, the University basically becomes the research and development arm of the company, enabling the company to focus on innovation and manufacturing. Focused on the earliest stages of technical and commercial development, the center will foster a collaborative environment for developing new high-tech materials solutions in close alignment with market needs. At the same time, Rogers and Northeastern were able to develop a novel agreement for shared intellectual property that will enable both parties to benefit from discoveries. This new approach could become a model for other moderate sized companies looking for innovative research that spurs the development of new products. At the same time Northeastern is working to attract other corporate partners through this model and is planning to develop a maker space on the Burlington campus for smaller companies looking to take advantage of proximity to university researchers.

We encourage the federal government to facilitate similar partnerships through financial incentive, grants and other mechanisms that enable companies and universities to partner around themes of similar and complementary interest. Development of standards for shared intellectual property for universities and corporations would also speed the development of such partnerships.

Question (23) Beyond current Federal efforts to promote open data and open application programming interfaces (APIs), what other opportunities exist to open up access to Federal assets (such as data, tools, equipment, facilities, and intellectual property from Federally funded research) in order to spark private sector innovation?

Companies are increasingly turning to Open Innovation to make their innovation requirements public to other companies, researchers and others. There is no comprehensive central repository or clearinghouse for open innovation requests, making it difficult for universities to stay current on a wide range of corporate needs.

Developing or funding the development of such a clearinghouse would be very useful to research universities. Meanwhile, a similar database embodying intellectual property from federally funded research would offer universities additional exposure for their intellectual property. Over time, based on feedback and searching behavior on both databases, both technology requests and IP could be tagged with increasingly valuable meta-data enabling better searches and faster matching.

Thank you for the opportunity to provide comments on this important initiative.

Sincerely,

Timothy E. Leshan
Vice President for Government Relations

BEFORE THE OFFICE OF SCIENCE AND TECHNOLOGY POLICY AND THE NATIONAL ECONOMIC COUNCIL

COMMENTS OF THE OWNERS' RIGHTS INITIATIVE ON THE STRATEGY FOR AMERICAN INNOVATION

The Owners' Rights Initiative (ORI) is an organization of over 20 companies and trade associations that have joined together to protect ownership rights in the United States.[1] We believe in the fundamental premise that **if you bought it, you own it**, and should have the right to sell, lend, or give away your personal property. ORI formed when the *Kirtsaeng v. Wiley* case was pending before the Supreme Court. We now are dedicated to preserving that holding, and making sure that it is not undermined in Congress, the executive branch, or in the courts. We also work to protect the principles of the first sale doctrine as technology continues to evolve, such as when software is incorporated into other products. Additionally, we try to prevent the misuse of IP law as a trade barrier that obstructs legitimate competition in other countries.

A balanced intellectual property system is critical to promoting innovation. A balanced system provides authors and inventors with the economic incentive to invest their time and effort in intellectual creation, while at the same time allowing them to build on existing intellectual creations. A balanced intellectual property system permits

[1] A list of ORI members can be found at http://ownersrightsinitiative.org/about/.

incremental inventive activity that promotes competition between incumbents and new firms.

The first sale doctrine plays a critical role in the maintaining balance in the copyright law. Because it limits the scope of the distribution right under the copyright law, it gives space for innovative distribution models, both online and in the physical world. By allowing secondary markets, the first sale doctrine enables companies to sell used durable goods with copyrighted elements such as logos or software, which in turn frees capital to buy new, more innovative products. The secondary markets created by the first sale doctrine also permit new firms to enter the market by purchasing used products as discounted prices. Further, the first sale doctrine allows resellers to customize products to meets specialized manufacturing needs.

These comments respond to the first three overarching questions by focusing on how the Administration should promote innovation by preserving and strengthening the first sale doctrine. The comments first describe the importance of the first sale doctrine to the U.S. economy. Next, they explain why the international exhaustion rule adopted by the Supreme Court is sound policy. They then identify a problem that requires Congressional action: ensuring that consumers and resellers can transfer products that contain software. Finally, the comments discuss how IP can be used as a trade barrier. **The updated *Strategy for American Innovation* should uphold the first sale doctrine by leaving the *Kirtsaeng* decision undisturbed and by supporting the You Own Devices Act, H.R. 5586, introduced by Congressman Blake Farenthold. Additionally, the *Strategy for American Innovation* should recognize how trademark**

law can act as a trade barrier in the Transatlantic Trade and Investment Partnership negotiations.

I. The Importance of the First Sale Doctrine

Justice Breyer, writing for the U.S. Supreme Court in *Kirtsaeng v. John Wiley & Sons, Inc*., 133 S. Ct. 1351, 1363 (2013), stated that the first sale doctrine "is a common-law doctrine with an impeccable historic pedigree." He quoted a 17th century articulation of "the common law's refusal to permit restraints on the alienation of chattels," *id*., and observed that "a law that permits a copyright holder to control the resale or other disposition of a chattel once sold is similarly 'against Trade and Traffi[c], and bargaining and contracting.'" *Id*. Justice Breyer underscored "the importance of leaving buyers of goods free to compete with each other when reselling or otherwise disposing of these goods." *Id*. Competition, "including the freedom to resell, can work to the advantage of the consumer." *Id*.

The first sale doctrine operates at every level of our economy. It allows wholesalers to sell products covered by copyright, including products distributed in copyrighted packaging, to retailers without first securing distribution licenses from the manufacturers. The first sale doctrine likewise permits retailers to sell products to consumers without obtaining distribution licenses. Finally, the first sale doctrine permits consumers to rent or lend the products to other consumers, or to sell or give the products away when they no longer need them. The first sale doctrine reduces transaction costs and enables competition between sellers of new products as well as between new and used products. In *Kirtsaeng*, the Court recognized the importance of the first sale doctrine to libraries, used-book sellers, car dealers, technology companies, retailers, and consumers. The limitation on the distribution right provided by the first sale doctrine is critical to the functioning of our economy because the distribution right applies not only to products whose primary value is their protected expression, such as books, films, and sound recordings, but also to the protected expression in the packaging of all products.

II. International Exhaustion

A. *Kirtsaeng v. Wiley*

At issue in the *Kirtsaeng* case was how the first sale doctrine applied to goods purchased abroad. Section 106(3) of the Copyright Act grants the copyright owner the exclusive right "to distribute copies or phonorecords of the copyrighted work to the public by … lending."[2] However, the first sale doctrine, codified at section 109(a) of the Copyright Act, terminates the copyright owner's distribution right in a particular copy "lawfully made under this title" after the first sale of that copy.[3] In recent years, there had been extensive litigation over the meaning of the phrase "lawfully made under this title" in section 109(a). Rights holders generally argued that "lawfully made under this title" meant "lawfully made in the United States." This interpretation would allow the rights holder to prohibit some "parallel imports" or "gray market goods"—that is, the rights holder could prevent a third party from importing legal but less expensive foreign-made copies. Conceivably, this interpretation would also allow the rights holder to prohibit the resale of foreign-made goods sold initially in the United States with the rights holder's authorization.

[2] 17 U.S.C. § 106(3).
[3] 17 U.S.C. § 109(a).

On March 19, 2013, by a 6-3 majority, the Supreme Court rejected this interpretation.[4] In an opinion written by Justice Breyer, the Supreme Court found that "lawfully made under this title" meant manufactured in a manner that met the requirements of American copyright law, *e.g.*, manufactured with the permission of the rights holder. The Court reached this conclusion after a careful examination of the context of the words in Section 109(a), the common law history of the first sale doctrine, the legislative history of Section 109(a), and the Court's earlier decisions. In effect, the Court adopted an "international exhaustion" rule; the distribution right in a copy was exhausted after the first sale of that copy anywhere in the world.

B. The Correct Policy Going Forward

Now that the Supreme Court has issued its decision, there is no point in arguing over whether the Court properly interpreted the relevant statutory provisions, although we think it did. What matters going forward is whether the Court reached the right policy outcome, or should Congress intervene. We believe that the Court did reach the right policy outcome, and there is no reason for Congress to disturb it.

There are three basic policy choices: 1) the first sale doctrine should apply to all legal copies, regardless of where manufactured or sold (the Court's international exhaustion rule); 2) the first sale doctrine should apply only to legal copies sold in the United States with the rights holder's authorization (domestic exhaustion); or 3) the first sale doctrine should apply only to legal copies manufactured in the United States (the Second Circuit's rule in *Kirtsaeng*).

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[4] *Kirtsaeng v. John Wiley & Sons*, 133 S. Ct. 1351 (2013).

Option 3 makes absolutely no policy sense. Even the Second Circuit agreed that there was no logical reason to give foreign-made copies more protection that U.S.-made copies, as it would encourage the export of jobs. Also, this approach would grant rights holders too much control over the alienation of property, given the large amount of goods that are foreign-made and sold in the U.S. with the rights holder's authorization.

Thus, the real choice is between applying the first sale doctrine to all copies, regardless of where manufactured or sold (international exhaustion), or applying the first sale doctrine only to copies sold in the United States (domestic exhaustion).

The policy argument in favor of domestic exhaustion is that it permits rights holders to price discriminate by preventing arbitrage—to charge U.S. consumers higher prices than foreign, less wealthy, consumers. This in theory enables higher profit margins from U.S. sales while benefiting consumers in less developed countries.[5]

How does this benefit the U.S. economy? Rights holders claim that the additional production for foreign markets means more jobs in the United States. Additionally, the profits from the foreign sales would be reinvested here in the development of new products.

But this argument makes two enormous assumptions. First, it assumes that the copies are manufactured in the United States. But for many copyrighted products, this is not the case. Even if the underlying work was created in the United States, the manufacturing of copies occurs in other countries with lower labor costs. Thus, the jobs resulting from increased production aren't in the United States. A motion picture might

[5] However, in some less developed countries, media prices are actually higher in absolute terms than in the United States because the distributors sell only to wealthy, price-insensitive consumers.

be filmed in the United States, but the DVDs could be printed in Mexico.[6] So, the increased production of DVDs to keep up with foreign demand leads to more production jobs in Mexico, not the United States.

Second, this argument assumes that the rights holders are U.S. companies that will reinvest the profits in the United States. But again, in many instances, this isn't true.[7] Four of the six largest English language trade publishers, which sell 70% of the popular books in the U.S., are foreign owned. Four of the five largest science, technical, medical, and professional publishers are foreign owned. Two of the three major record labels are foreign owned. Omega, the plaintiff in the previous first sale case in the Supreme Court, is a Swiss company.[8] Pearson, which brought several cases against book importers, is a British company.

Indeed, Justice Ginsburg said in her dissent that "the Court embraces an international-exhaustion rule that could benefit U.S. consumers but would likely disadvantage *foreign* holders of U.S. copyrights." 133 S. Ct. at 1385 (emphasis supplied). It is hard to see how U.S. consumers paying higher prices to benefit foreign workers and corporations would benefit the U.S. economy. At the same time, the economic benefits of

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[6] It should be noted that many motion pictures made by U.S. studios are actually filmed in whole or in part overseas. *See* J. Band and J. Gerafi, *Foreign Ownership of Firms in IP Intensive Industries* 15 (2013), available at http://infojustice.org/archives/28840. The leading special effects companies relied upon by U.S. studios are located in the UK, Canada, and New Zealand. *See* Richard Verrier, "California visual effects artists fight foreign film tax credits," *Los Angeles Times*, December 21, 2012, http://articles.latimes.com/2012/dec/21/business/la-fi-ct-visual-effects-protest-20121221.

[7] J. Band and J. Gerafi, *Foreign Ownership of Firms in IP Intensive Industries* (2013), available at http://infojustice.org/archives/28840.

[8] *Costco v. Omega*, 131 S. Ct. 565 (2010).

an international exhaustion rule—robust secondary markets resulting in lower prices—are obvious.

At a minimum, much more rigorous study would need to be performed to determine whether a domestic exhaustion rule would be a net positive or negative to the United States in light of our increasingly globalized economy. In the absence of compelling evidence of the benefit of shifting to a domestic exhaustion rule, the default position should be free trade unimpeded by government regulation. As Justice Breyer observed, "the 'first sale' doctrine is a common-law doctrine with an impeccable historic pedigree."133 S. Ct. at 1363. It is rooted in "the common law's refusal to permit restraints on the alienation of chattels." *Id*.

Further, there is no inherent right under copyright law to price discriminate and segment markets. As Justice Breyer noted, "the Constitution's language nowhere suggests that its limited exclusive right should include a right to divide markets or a concomitant right to charge different purchasers different prices for the same book, say to increase or to maximize gain.… We have found no precedent suggesting a legal preference for interpretations of copyright statutes that would provide for market divisions." *Id*. at 1371.

Moreover, there is a long history of copyright law, through the first sale doctrine, limiting a rights holder's ability to price discriminate and segment markets within the United States. If a rights holder should have the ability to force a U.S. consumer to pay a higher price for a book than a Mexican consumer, then why shouldn't a rights holder have the ability to force a consumer in New York or California to pay higher price for the book than a consumer in Mississippi or West Virginia? If arbitrage is bad in international markets, why is it acceptable in domestic markets?

In any event, even after *Kirtsaeng*, rights holders can still price discriminate and segment foreign markets—it just isn't quite as easy to do so. They can use contracts to prohibit foreign wholesalers from importing to the United States. They can restrict the number of copies distributed in any country to meet local demand. They can engage in modest product differentiation sufficient to discourage importation. In short, they can act exactly as every other business that cannot rely on copyright to enforce price discrimination.

A domestic exhaustion rule discourages the development of innovative distribution models that rely on buying products at the lowest possible prices. The defendant in *Costco v. Omega* was a discount retailer that competed against the established distribution channel for luxury watches. The defendant in *Kirtsaeng v. Wiley* was a graduate student who sold textbooks purchased abroad over eBay.

Finally, a domestic exhaustion rule would create a minefield for charitable organizations such as Salvation Army or Hadassah that raise money by selling donated goods. These organizations would have no way of knowing if an item donated to them had first been sold in the United States with the manufacturer's authorization. Thus, they could potentially incur liability for selling a genuine product that had been imported by someone further up the supply chain without the manufacturer's permission.

III. Applying the First Sale Doctrine to Software Essential to the Operation of Hardware

Given the importance of the first sale doctrine, we support the Patent and Trademark Office's ongoing examination of how the doctrine could be applied to digital goods. While we understand the need to assess carefully the nuances involving digital goods, we believe that the concept of ownership and consumer expectations mean that stakeholders ultimately should work towards a solution that enshrines the first sale principle when discussing the rules of the road for the resale of digital goods.

While the PTO's consideration of digital first sale is underway, the updated *Strategy for American Innovation* should not overlook an aspect of digital first sale of concern to our members that affects a specific category of tangible goods: products that are distributed with software essential to their operation. More and more everyday products, ranging from high-end servers to toasters, are distributed with software essential to their operation. Even though the consumers buy the physical products, the manufacturers can claim that they are just licensing the software essential to the products' operation. These licenses can contain a variety of restrictive terms that limit ownership rights by interfering with resale of the products, thereby harming the consumers that want to sell equipment they no longer want and the secondary market consumers that want to buy that equipment. Often, these secondary market consumers are new, innovative firms attempting to enter the market. The You Own Devices Act (YODA), H.R. 5586, solves this problem by creating an unwaiveable right to transfer software essential to the operation of hardware.

A. The Scope of the Problem

Manufacturers currently employ software licenses to place the following impediments on the alienability of physical products:

- **Prohibition on transfer.** Some license agreements provide that the software license is non-transferable. For example, the license for the software that comes installed on a NetApp product states that the software is not transferable. As a practical matter, NetApp gets paid twice for the right to use the same software: once by the original purchaser of the product, and a second time by the purchaser of the used product. Purchasers of Cisco equipment often find that it is cheaper to buy new equipment than pay the excessively high price for a license for the software essential to the operation of the used equipment.

- **Refusal to provide updates.** Some license agreements specify that routine updates such as security-patches or bug fixes will be provided only to the original licensee. For example, Oracle refuses to supply routine updates to the purchasers of used hardware products containing essential Oracle software, unless they make an additional payment.

At present, primarily manufacturers of sophisticated equipment, such as computer and telecommunications equipment or machines used in manufacturing, misuse software license agreements to interfere with resale. Yet as more products are dependent on software for their operation—for example, cars and consumer appliances—this problem will become more widespread. The software could be pre-installed in the product by the manufacturer, or the first purchaser could install the software from a disc that comes "in the box" or from the Internet. Sometimes the software essential to the operation of a machine actually runs on a separate device, such as a laptop computer, that is attached to the machine. Manufacturers use license agreements to interfere with the sale of used products by consumers as well as the sale of unused products by resellers.

B. The Legal Basis of the Problem

The legal fiction on which these restrictive practices is based is that the essential software is licensed, not sold, to the purchaser of the hardware. The manufacturers argue that because the purchaser is merely a licensee of the copy of the software, it does not have rights that normally accrue to the owner of a copy, such as the first sale doctrine (which allows a person to sell a copy that he owns without infringing the Copyright Act's distribution right) or the right to make temporary internal copies necessary for the operation of a computer. *See* 17 U.S.C. §§ 109(a) and 117(a). The U.S. circuit courts are split on the validity of the manufacturers' argument. The Ninth Circuit has accepted this argument, *Vernor v. Autodesk*, 621 F.3d 1102 (9th Cir. 2010), while the Second Circuit has rejected it, *Krause v. Titleserv*, 402 F.3d 119 (2d Cir. 2005). Underlying this split concerning whether a person who acquires a copy of a computer program is an owner or a licensee of the copy is an even more profound split concerning preemption of contract terms inconsistent with the Copyright Act. Compare *Bowers v. Baystate Techs., Inc.*, 320 F.3d 1317 (Fed. Cir.), *cert. denied*, 539 U.S. 928 (2003)(holding that the Copyright Act does not preempt contractual terms prohibiting actions permitted under fair use), with *Vault Corp. v. Quaid Software Ltd.*, 847 F.2d 255 (5th Cir. 1988)(holding that under the Supremacy Clause of the U.S. Constitution, contract terms prohibiting copyright exceptions are unenforceable).

C. The Solution

YODA, introduced on September 19, 2014 by Congressman Blake Farenthold (R-TX), solves this problem by adding a new subsection to section 109 of the Copyright Act, which contains the first sale doctrine. New subsection (f)(1) provides that if a computer program enables any part of a machine or other product to operate, the owner of the machine is entitled to transfer the computer program when he sells or otherwise transfers the machine. This right to transfer the program cannot be waived by license or other agreement.

New subsection (f)(2) provides that the purchaser of the machine is entitled to receive any bug patches or security fixes that the person who sold him the machine was entitled to receive from the manufacturer.

New subsection (f)(3) makes clear that nothing in this subsection allows the seller of the machine to retain an unauthorized copy of the computer program after he transfers the machine to the purchaser.

YODA is not retroactive; it applies only to transfers of software that occur after its enactment.

Congress previously dealt with a similar issue in the context of software rental. In 1990, when Congress was considering amending the Copyright Act to prohibit the rental of software because it facilitated infringement by consumers, companies that rented cars and other equipment that contained software expressed concern that the amendment could prevent these rentals. Accordingly, Congress added an exception to the software rental prohibition that applies to a computer program embedded in a machine or product. *See* 17 U.S.C. § 109(b)(1)(B)(i).

Preserving the resale rights of consumers of physical products that contain software is important for reasons that go beyond the protecting the economic interests of these consumers and the secondary market consumers who would purchase these products. If the manufacturer refuses to provide to the secondary market consumer the security patches it provides to the original consumer, the security of the secondary consumer's computer system could be compromised. Such security patches typically are provided to the original consumer free of charge. In essence, the original purchase price entitles the consumer to receive security patches and other patches that fix bugs in the program.

Preserving a secondary market in these physical products is also important for the environment. If older products can be refurbished and resold, those products stay out of landfills. Moreover, the recycling of the older products reduces the need to mine raw materials and produce new components.

The problem of restrictions placed on software essential to the operation of hardware implicates complex issues of legal theory at the intersection of Constitutional preemption, the Copyright Act, and contract law. Nonetheless, this is a very concrete practical problem of manufacturers attempting to leverage the copyright in a component into perpetual control over a much larger device. YODA solves this problem with a simple amendment to the Copyright Act. The updated *Strategy for Innovation* should support enactment of YODA.

IV. IP as a Trade Barrier

The International Trade Commission (ITC) recently issued a report, *Trade Barriers That U.S. Small and Medium-sized Enterprises Perceive As Affecting Exports to the European Union*, which identifies the European Union's use of trademark law as a trade barrier.[9] The purpose of the ITC's report is to catalogue trade barriers as a tool for the U.S. Trade Representative in conducting the Transatlantic Trade and Investment Partnership (TTIP) negotiations with the EU. The ITC report's list of EU trade barriers

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[9] ORI testified at a hearing that was part of the inquiry that resulted in the report.

specifically includes “excessive rights of original trademark owner,” and the EU’s restrictive trademark regime is mentioned at several points. In particular, the report focuses on the use of trademark law to prevent the importation of genuine goods outside of authorized distribution channels. This harms U.S. businesses and individuals trying to sell used and new products in the EU. ORI commends the ITC for recognizing that trademark law can act as a trade barrier. The updated *Strategy for American Innovation* should likewise recognize the importance of this issue in the context of trade negotiations in general and TTIP in particular.

V. Conclusion

The updated *Strategy for American Innovation* should:

- **uphold the first sale doctrine by leaving the *Kirtsaeng* decision undisturbed;**
- **support enactment of the You Own Devices Act, H.R. 5586; and**
- **recognize how trademark law can act as a trade barrier in the Transatlantic Trade and Investment Partnership negotiations.**

September 23, 2014

By Andrew M. Shore

Executive Director

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Partnership
for American Innovation

September 23, 2014

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Sent via email: innovationstrategy@ostp.gov

RE: The Partnership for American Innovation's Comments on the new *Strategy for American Innovation*

The companies that form the Partnership for American Innovation (PAI) – Apple, DuPont, Ford, GE, IBM, Microsoft and Pfizer – commend the Obama Administration and the Office of Science and Technology Policy (OSTP) for their outreach to the business community regarding an update to the *Strategy for American Innovation.* We appreciate the opportunity to provide our input on the questions posed, as strategies to maintain and grow our innovation economy are of critical importance to PAI members. Together, PAI companies invest more than $40 billion every year in research and development and depend on intellectual property (IP) protections to safeguard those investments. Its members support over 1.2 million jobs and have created iconic products on which consumers depend.

The Importance of a Strong IP System

The United States' intellectual property system protects investments in R&D, allowing companies to make big, bold bets on the future. IP protection creates value for these innovations during product and service development, across industries including software, pharmaceuticals, manufacturing, bio-tech and IT services. These IP-intensive industries contribute $5 trillion in economic activity to the American economy every year and are responsible for 40 million jobs, nearly half of private sector employment in the U.S. They also make up nearly three quarters of all U.S. exports.

The protections afforded by America's IP system motivate venture capitalists to invest in new startup companies, which are a huge driver of job creation in our nation. IP enables the return on investment a company needs to invest billions every year in research, allows them to bring new products to market, and accelerates the pace of innovation. Without IP protection, businesses shift their R&D resources and commercialization strategies toward the types of innovations that cannot be easily duplicated by competitors. Heavy reliance on this practice clearly limits collaboration and can decrease the overall pace of innovation.

Previous versions of the *Strategy for American Innovation* have reflected an understanding that American innovation builds off and requires substantial investment in research and development, and that IP provides one of the most effective means for encouraging those investments.

Question 21 – IP and New Models of Innovation

We are pleased to see a question related to intellectual property included in this year's request for ideas. Question 21 inquires what challenges and opportunities for intellectual property are posed by new forms of innovation. The PAI believes that the patent system is complementary to, and in many ways enables, innovation models that are based on collaboration.

In the 19th century, inventors obtained patents on sewing machines, telegraphs and electricity, and naysayers worried that these patents would drive up costs and close off innovation. A similar cycle of breakthrough innovation protected by patents and a wave of concern occurred again in the 20th century with airplanes. In each instance, rather than foreclosing advancements, these technologies thrived, filled the consumer market and continued to improve and evolve. The public disclosure provided by the patent system provides valuable information to other inventors, and enables knowledge transfer through licensing, cross-licensing and joint agreements. Today's computerized looms, smartphones and smart appliances are heirs to the innovations of the past centuries, and brought to market thanks in part to the patent system.

This 'all of the above' approach to innovation continues today. Members of the PAI have some of the largest and most valued patent portfolios in the United States. Members are also committed to open and collaborative innovation. IBM is a leader in the development of open source software solutions and industry standards, bolstered through numerous patent pledges, to encourage and enable the development of open platforms critical to the information technology industry. Microsoft has a business unit dedicated to open source development and encourages collaboration through opening their code to the developer community. Apple was the first major computer company to make open source development part of its software strategy, and continues these efforts today. DuPont has opened Innovation Centers in every region of the world dedicated to stimulating innovation and collaboration between business partners, customers and DuPont scientists and engineers. GE has a dedicated Open Innovation Unit focused on crowdsourcing innovation, internally and externally, to drive advancements. Pfizer has partnered with software companies to develop open source products for scientists and lab technologists. Ford is the first and only automaker to provide open source connectivity to vehicles; namely, Ford's dedicated "Smart Device Link" for connecting smart devices to vehicles, and the "OpenXC Platform," which includes both open source software and open source hardware, to enable innovators to receive data from vehicles.

These experiences, coupled with the research on cycles of innovation throughout history, demonstrate that effective IP rights actually promote open innovation by incentivizing disclosure and enabling knowledge transfer. However, the reverse is sadly not the case – without the protections afforded by the patent system, companies work to develop technologies that cannot easily be replicated under a heavy veil of secrecy. This significantly limits the ability of open and collaboration models to exist and thrive.

The Path Forward – Challenges and Opportunities

As Question 21 notes, we are not facing a dearth of innovation in this country. In fact we are home to some of the most talented and prolific innovators in the world. The *Strategy for American Innovation* needs to empower these innovators so that their ideas can be translated into jobs and long-term economic growth.

For many innovators, the success of their efforts lives or dies on the ability to secure quality IP rights quickly. The U.S. Patent and Trademark Office (USPTO) has already made great strides in reducing backlog, increasing quality and educating its customers. Yet the agency does so under significant constraint, without control over its own budget despite the fact it is fully funded by user fees. Even though these fees are now held in reserve thanks to the Leahy-Smith America Invests Act, the USPTO must still approach Congress each time to free up these much needed funds. The *Strategy for American Innovation* should empower the USPTO to be a world-class institution focused on encouraging innovation and promptly issuing the assets that pave the way for investment in technology advancement.

Without these high quality assets, innovators will be hard-pressed to develop the technology that leads to increased jobs and exports. And these assets are at risk. There is a vocal minority waging an ongoing, increasing and significant assault on patent rights. Unending legal challenges to patent eligibility, driven by an organized campaign to redraw legal interpretations of abstractness and indefiniteness, are creating uncertainty about the future of patent protections that will ultimately make it harder to invest. An overly expansive view of abstractness and obviousness could imperil nearly all commercially relevant innovations, and harm the U.S. economy. While breakthrough innovations are certainly valuable, it is often incremental innovation that enables products and services to enter or be adapted for particular markets. These advances most directly support the creation of American jobs.

Heated rhetoric often based on the bad behavior of a few patent assertion entities has fueled an environment where a company is demonized for good faith enforcement of its hard-earned, legitimate property rights. The corresponding policy discussions lead our country away from a balanced IP system that enables collaboration and innovation. If this lopsided model of innovation is adopted, we risk creating a system where foreign competitors gain a competitive advantage by patenting their ideas while copying American IP without consequence.

This is a particularly pernicious problem in the discussion of technology and software patents. Software underlies and enables the endlessly varied functionality and utility that computers provide, and is an indispensable aspect of innovation in every field of technology and sector of the economy. Software-based innovations power amazing technologies ranging from the modern smartphone to advanced robotic manufacturing, fly-by-wire systems, artificial retinas, driverless cars, GPS, medical and diagnostic tools, and numerous products developed across industries by PAI companies. The vast majority of companies obtaining software patents are not traditional software companies, but are manufacturing companies that integrate software with the products they manufacture. Discriminating against a form of innovation that is increasingly critical to technological advancement in all industries would have far-reaching implications, all of which are detrimental to the future of American innovation and our ability to compete in the global market.

Also critical to U.S. competitiveness is the protection of knowledge through trade secrets. Without the need for formalities or the outlay of significant financial resources trade secrets are a critical tool for many innovators and can offer broader protection than other forms of IP. They also provide a pathway to increase collaboration and as a result accelerate technology development by enabling firms to share critical details more widely than in the absence of meaningful protection. However, with the ease and speed in which information can flow combined with the labyrinth of laws which must be navigated to recover from trade secret theft, it can be difficult for innovators to rely on this type of protection. Instead many companies choose to protect themselves by keeping their critical information close to the vest, turning down opportunities to collaborate or engage important market opportunities. Improving trade secret protection, both at home and abroad, is essential to furthering the American economy.

Within the U.S. a strong federal civil trade secret law, as being currently contemplated by Congress, could greatly improve the landscape for our innovators by allowing them to decide their own fates when their confidential information is stolen, potentially preventing devastating losses. Such legislative action, combined with diplomatic efforts could also provide other countries the impetus to upgrade their own trade secret regimes. With globally distributed supply chains and the need for international collaboration to further technology development, safeguarding the security of U.S. know-how needs to be a core part of the Strategy.

Our IP system is a major contributor that has allowed the U.S. to lead in innovations for more than 150 years. The United States must continue to protect and champion our innovators who rely on intellectual property in our innovation economy. Enabling inventors to succeed regardless of technical field and improving the climate of innovation policy is crucial if the United States hopes to retain its global economic leadership. We encourage the next *Strategy for American Innovation* to include measures that will maintain the balance of our world-class patent system, while improving its effectiveness and efficiency.

PATENT PROPERTIES

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September 23, 2014

Cristin A. Dorgelo,
Chief of Staff, Office of Science and Technology Policy
John M. Galloway,
Chief of Staff, National Economic Council
The White House
Via Email: *innovationstrategy@ostp.gov*
Subject: *Strategy for American Innovation*

Dear Ms. Dorgelo and Mr. Galloway,

Thank you providing this opportunity to exchange information that can assist in the development of an update to the *Strategy of American Innovation*. This letter and attached materials is a response to questions 1, 2, 6, 8, 17, 18, and 21 in the Notice of Request for Information (Document Number 2014-17761) published in the Federal Register on July 29, 2014.

Background

My name is Jon Ellenthal and I am the Vice Chairman and CEO of Patent Properties, a publicly traded company. We are focused on improving America's innovation capacity by creating the United States Patent Utility™, a voluntary and affordable marketplace for patent owners and users alike. Jay Walker, our Founder, Executive Chairman and Lead Inventor, is the creator of over a dozen startups and companies including Priceline.com, is the curator of TEDMED, serves on the STEP Board at the National Academies and is the 11th most patented living inventor. Our Board of Directors and Board of Advisors include many prominent individuals with public service and professional experience in innovation policy. Please see http://www.patentproperties.com/ to view their biographies.

The vast majority of patent owners and American businesses are unable to benefit from the trillions of dollars of R&D that are embodied by more than 2 million active U.S. patents. These patents are frozen out of the economy – unable to improve products, create new jobs and improve global competitiveness – by a dysfunctional system of how patented technology currently gets licensed.

In today's marketplace, lawsuits are the first (and, often, the only) way to make licensing deals. Unfortunately, the high cost of litigation is unaffordable to the mass market and effectively keeps most patents and most companies frozen on the commercial sidelines.

Patent Properties is developing and will soon launch a voluntary new system that patent owners and users will like a lot better than what they have now (which is nothing). This new system will be offered by a brand new type of organization –The United States Patent Utility™ – a neutral platform that will provide a full package of patent-related licensing, information and financial services at disruptively low prices to patent owners and users alike.

Why is it so important to unfreeze the economic value of America's patented inventions?

Patents and innovation have played a central role in the growth and competitiveness of the American economy from the very beginning. Article 1 of the Constitution - reflecting the wisdom and foresight of our nation's Founders - provides for the creation of the patent system. Patents were intended as instruments to spread knowledge.

America's Founders knew then what remains true today: Invention fuels progress, but invention will be limited unless patents can function as "teachings" and a fair balance is achieved between the owners and users of patents.

A fair and balanced system that allows patent owners and users to freely exchange commercial value is essential to spreading the benefits of innovation throughout the economy. For this reason, smooth and efficient licensing is – or should be – the backbone of America's invention ecosystem.

Unfortunately, today's system is anything but efficient. In fact, the courts are filled with record numbers of costly patent infringement suits and at the same time, more than 95% of all active U.S. patents are not licensed to a single third party. These patents do not earn the first dollar of licensing revenue. This clearly hurts inventors who fail to realize an economic return on their investment in research and development, but American businesses suffer as well.

The best of American invention is not used to improve products, raise standards across industries, spur the creation of new jobs, fund the next generation of companies — and they do not contribute to U.S. global economic competitiveness as much as they could. In a global economy where everyone has access to the same raw materials and prices, intangibles are the difference between winning and losing.

The U.S. patent licensing process has essentially collapsed**.**

Part of the problem is that patents can be difficult to understand and value. Patents are intangible assets with "fuzzy" borders, unlike other forms of property, like music copyrights and real estate. Patents are written in dense, arcane legal language that only a technical expert can read. What's more, it's not even clear what the exact property is, until a federal judge defines the "claim" language in a court proceeding.

This gives owners a built-in incentive to wait until a federal judge can establish infringement with legal certainty, and users an incentive to wait to see if they are even using the protected property before discussing a license. A patent has basically become a legal argument waiting to happen.

But, litigation works for an extremely limited number of patent disputes – i.e., high-stakes disagreements between two deep-pocketed parties - but the high transaction costs and bonafide complexity make litigation completely inaccessible to the mass market of patent owners and users. The precision and certainty of a fully litigated resolution is simply not scalable for the mass market.

The “certainty standard” may be fitting for courtrooms and legal conclusions, but it’s a poor substitute for a commercial standard. Demanding certainty is a terrible way to run a business, if only because certainty is so expensive to obtain and, therefore, available to so few.

Essentially, we need an "innovative way to license innovation."

The United States Patent Utility™ will introduce an entirely new kind of patent license that will shift the discussion from finding fault, which is just too expensive, to a lower but more scalable standard of “no-fault,” based on “statistical probability.” Markets have always been able to price in information that is not known. In this case, No-Fault patent licenses will price for not knowing with certainty whether infringement is taking place or not.

In addition to No-Fault licenses, the United States Patent Utility™ will provide a broad range of patent-related services such as relevant market and litigation intelligence, patent and product comparison testing, and many others. For the first time, the huge un-served market of patent owners and users will be able to benefit from the invention marketplace by participating in a simple and affordable way.

<u>Responses to Questions</u>

Question #1 -- What specific policies or initiatives should the Administration consider prioritizing in the next version of the Strategy for American Innovation?

It may be useful to review the performance of the licensing of government created patents.

Question #2 -- What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?

Licensing is a robust contributor to America’s trade surplus. Policy should encourage efficient licensing and value creation. Presently policy is focused on intellectual property enforcement, sanctions for infringement, and mechanisms for invalidating patents.

Question #6 -- How has the nature of the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?

Innovation increasingly occurs online. So should licensing. Licensing should as well be systematized, be as real time, interactive, transparent and information rich as so many other constant online experiences are for so many people and kinds of transactions.

Question #8 -- What are important needs or opportunities for institutional innovation and what steps can the Federal Government take to support these innovations?

Businesses used to do clearance searches before releasing new products and services to see if there was any potential patent infringement. This is cumbersome, duplicative and fraught with liability risk or fear of such risk. Today there is so much information available about patents and what they touch. It is time to harness this resource via an easy to use system that enables businesses, researchers, innovators and the public to know what patents are relevant, who is innovating, and where the market is going.

Question #17 -- What tools, business model innovations, financial innovations, or other developments hold promise for reducing the cost of starting and scaling a business in capital intensive sectors like the life sciences, advanced materials, and clean energy? What can the Federal Government do to accelerate these trends?

Capital-intensive sectors need certainty and one key indicator of certainty is intellectual property. Democratization of patent licensing via a voluntary online system for owners and users that provides a greater amount of information to participants about relevancy and trends is a tool with much potential and one that may also be able to help to lower the threshold to enter into a capital intensive business.

The Federal Government has an important educational role as the private sector moves from an exclusively adversarial model for patent licensing to a market-based model. For one, the RFI Strategy for American Innovation effort can add the voice of national policymakers to the economic value to be found in greater patent licensing, and to the need to develop and implement business models that enable licensing to scale rather than remain caught in our high-cost legal system. For another, in recognizing that America needs more patents, more innovation, more licensing, and more commercialization, this effort will contribute to the key foundational elements of our nation’s future competitiveness.

Question #18 -- What investments, strategies, or technological advancements, across both the public and private sectors, are needed to rebuild the U.S. “industrial commons” and ensure the latest technologies can be produced here?

Sharing information about behavior and ranking behavior is an asset unto itself and can unleash innovation if applied to patent licensing. We’ve seen promising results in the related areas of bottom-up activities such as crowdsourcing and prizes. Old large firms such as Procter & Gamble and new small firms such as Quirky, for example, are leveraging and building the online world to foster sourcing of new innovation from communities of people outside of their firms and to involve them in evolving an idea into a product and building market demand and yet more feedback and new ideas. This may be a rebuilding of the US industrial commons but not necessarily tied to any one physical place. Democratization of patent licensing can help open up, broaden and support this activity as it becomes mainstream.

Question #21 -- What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation (including, e.g., through the growing use of open innovation, combinatorial innovation, user innovation, internet-enabled innovation, and big data-driven innovation)?

Challenges in intellectual property, such as the cost, time and uncertainty of patent litigation, present an unfriendly environment for innovators. It is time to change how licensing takes place and to foster more innovation by increasing the number of people participating in the use of patents by licensing. The barrier to entry can be reduced by: placing licensing online and in a system that is accessible; having decisions on statistical relevancy of a patent made by algorithms (rather than depositions and cross-examination); and operating at scale via automation and on a voluntary, non-exclusive platform. And with the barrier to entry reduced and more participants involved, then patent licensing becomes a much more attractive activity for others to pursue innovation and further improve the system by direct competition or by creating new services connected to the system.

Again, thank you for this opportunity to comment and to be involved in shaping the next version of the your *Strategy for American Innovation*. To supplement the information presented I'm including in the Appendix a copy of an essay by our chairman, Jay Walker, published on September 22, 2014 in *Corporate Counsel* magazine.

Most Sincerely,

Jon Ellenthal
Vice Chairman & CEO

Appendix

Priceline Founder Has a Plan for the US Patent System

Jay Walker, *Corporate Counsel*

September 22, 2014

The time has come for the U.S. to take back its patent system and put it to work again creating new jobs, new products and competitive advantage for companies of all sizes—not just the very largest ones.

The largest Fortune 500 companies, after all, have dedicated patent teams to help them navigate the rocky shoals of our increasingly litigious patent licensing system. They have the financial and legal clout needed to wage high-stakes patent wars with competitors. And they have the expert knowledge and resources required to exploit the often-invaluable technical information contained in patents and put it to use to enhance their product and service offerings.

But what about the rest of American businesses? What about the vast majority of mid-size and smaller companies for which patents unfortunately represent not a treasure trove of new technical knowledge but a growing source of litigation risk and executive distraction? These firms largely are excluded from the patent system's benefits, and are stuck with its perils instead.

So, after two years of product development and testing, I have developed a market-based alternative to today's failed licensing system—one that I believe finally will make the benefits of patents available to a much broader universe of mid-size and smaller companies. But before I describe it, let's quickly review the scope of the problem.

More than 28 percent of corporate counsel say that patent litigation has become a major concern for their companies, according to a Norton Rose Fulbright litigation trends survey. That's a 50 percent increase in the percentage of counsel who cited major patent worries just one year earlier. And 34 percent of these anxious counsel work at companies with less than $1 billion in revenues, indicating that patent litigation worries are hardly exclusive to the largest organizations.

Interestingly, the biggest uptick in patent concerns comes from the manufacturing sector, where 49 percent of counsel reported that patents have become a major worry—double the previous year's 25 percent. Within the tech and communications industries, however, a whopping 65 percent of corporate counsel say patent cases are their greatest litigation concern.

It's not hard to see why. Ten years ago, patent litigation was a form of competitive combat waged only by the largest patent-rich companies. But with 80 percent of corporate value now residing in intellectual assets such as patents and other IP, the patent wars nowadays have reached deep down into the ranks of mid-size and smaller companies. Indeed, firms with less than $100 million in revenues now account for an astonishing 61 percent of defendants in patent infringement cases, according to a 2013 patent litigation study from RPX Corp. It's enough to make corporate counsel reach for their Rolaids.

If it's any comfort to counsel, today's patent licensing system isn't working any better for the vast majority of patent owners, either. More than 95 percent of patentees never see their technical advances put to use in new products or services—and never earn a dime for all their inventive efforts. They, too, are locked out of our exclusionary patent licensing system, which in most cases requires the financial and legal resources to credibly threaten a multimillion-dollar patent suit in order to secure a successful licensing deal.

Let's face it: A patent licensing system that does all its deals in federal court is not in good shape. The result is that the vast majority of patented discoveries in the U.S. lie dormant, unused in new products, and unable to foster job creation and overall economic growth.

It's time for a new approach—one that unfreezes the patent system so we can put the $5 trillion in untapped R&D embodied in the nation's 2 million active but unused patents to work in creating new products and services and in growing the economy. Just as important, American companies need an economically sensible way to mitigate their infringement risk without the exorbitant costs of the "litigation or bust" licensing system they have to endure today.

In the next couple of months, my company will launch a new, voluntary, no-fault patent licensing system called the United States Patent Utility. For a monthly fee of roughly $1,000—less than the cost of meeting with an outside patent attorney to discuss an infringement suit—subscribers will get up to 50 licenses in a package of patents that most directly relate to their products and services. They also will get legal fee warranty coverage to all 2.3 million active patents in the U.S. (The legal fee warranty covers $100,000 of the first $250,000 in legal defense fees for any subscriber. It can be used five times, for a maximum warranty benefit of $500,000.)

The price of a no-fault package of patents is so low because companies will be buying probability, not legal certainty as decided by a federal court after the expenditure of thousands of billable attorney hours. Statistical analysis of a firm's product lines, matched against millions of patent claims, will establish which patents are most relevant to a company and, therefore, have a probability of needing a license.

Put simply, probability costs less than certainty. But, as the insurance industry knows, probability is a commercially sensible basis upon which to do business.

Along with the no-fault license and warranty coverage, companies will also receive a suite of information services. Each subscribing firm will get quarterly reports on the patent landscape surrounding their products, updates on the patent filings of competitors, and alerts about new patents and patent litigation most relevant to their product lines. Subscribers also will receive a free semiannual litigation check-up by a top litigator, and discounted flat-rate pricing on patent prosecution services for companies that want to strengthen their own portfolios.

But here's the real kicker: Not only will subscribers greatly reduce their infringement risk (and resulting legal costs), they also will gain access for the first time to the rich reservoir of technical know-how contained in those packages of patents. In effect, companies will now be able to inexpensively "crowd-source" the R&D they need to make major product improvements.

This is no small matter—not when you consider that up to 80 percent of the world's current technological knowledge is found only in patent documents, according to some estimates. Yet U.S. companies often are discouraged from reading and learning from patents for fear of the legal risk of willful infringement and treble damages. This despite the fact that no company has ever been convicted of willful infringement simply for reading others' patents. As a top litigator noted, that's because willfulness requires not merely knowledge of a patent, but also that the accused acted (e.g., used a patented technology in its products) even though it knew or should have known that there was an objectively high likelihood that its actions constituted infringement.

In fact, the whole purpose of the patent system is to disclose and share new discoveries so that others may learn from and build upon these to create even more advances. In 1886, for example, the inventor Elias E. Reis reported that when he read a patent issued to Elihu Thomson for a new method of electric welding, "there immediately opened up to my mind a field of new applications to which I saw I could apply my system of producing heat in large quantities." Thomas Edison also was known to frequent the patent office and study other inventors' patents to spark ideas of his own. And even in my own case, many of my 719 issued and pending patents certainly owe a debt to the ingenuity of inventors who came before me.

That's how the invention process is supposed to work, and it's a popular misconception that patents block research and development by others. Recent research, for example, shows that Thomas Edison's seminal 1880 incandescent lamp patent (No. 223,898) actually "stimulated downstream development work" that resulted in "new technologies of commercial significance [including] the Tesla coil, hermetically sealed connectors, chemical vapor deposition process, tungsten lamp filaments and phosphorescent lighting that led to today's fluorescent lamps."

The need for change is great. As no less an authority than Judge Paul Michel, retired chief judge of the U.S. Court of Appeals for the Federal Circuit (the main court for patent appeals), recently noted, "Sooner or later we must develop a commercialization alternative to litigation. The courts simply can't handle it all. They are too expensive, too slow and cumbersome, too uncertain, too inefficient, and too adversarial to be able to serve the vast majority of patent owners and businesses.”

Sixteen years ago, I founded Priceline, the “name your own price” hotel and airline reservation system that revolutionized the travel industry. Many scoffed at us at first, but thanks to the innovations we made in the pricing of perishable airline and hotel inventory, Priceline and its affiliated brands today book $40 billion in travel reservations annually, and we are a recognized world leader in travel accommodations.

My new goal is to transform patents from ticking time bombs into rich R&D assets for companies. The only way to do that, however, is to upend our exclusionary licensing system with a new one that serves the majority of patent owners and users.

Who knows—the U.S. Patent Utility may even help the patent system again become the most effective instrument of knowledge-sharing and technology transfer ever devised by man.

Jay Walker is executive chairman of Patent Properties Inc., which will launch its new no-fault patent licensing system this year. He is the founder of Priceline.com and the world’s 11th most-prolific living inventor and patentee.

As part of the request from The Office of Science and Technology Policy and the National Economic Council for public comments to provide input into an upcoming update of the *Strategy for American Innovation,* the open access academic publisher 'PeerJ' offers a response in answer to the following question: *"Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?"*

Reproducibility is critical in science. Without it science is unable to flourish, and scientists are unable to build on the work of others. Aristotle's dictum that there is 'no scientific knowledge of the individual' seemingly holds true today, as much of the research published in the 21st Century is the result of building on, or testing the findings of others.

The term *reproducible research* refers to the idea that the ultimate product of academic research is the paper, along with the full computational environment used to produce the results in the paper such as the code and data (1). The full academic output can then be used to reproduce the results and create new work based on the research. Alongside reproducibility lies repeatability – the idea that anyone in the same lab can repeat the same experiment using the same methods and specimens. For science to flourish it is imperative that reproducibility and repeatability become the corner stones.

Science can only advance on the foundation of the trusted discoveries of others. But like any good building project there is a financial cost to laying these foundations. Scientific research is often funded by governments, and other associated funding bodies, all looking to ensure their money is spent optimally. For instance, some recent research published on reproducibility in the field of cancer studies at the MD Anderson Cancer Center (2) points to the statistic that only 41.5% - 45.4% of scientific outputs were actually reproducible by those surveyed. Other research in this area suggests alarmingly lower figures still of 11% (3).

The US government gives around $30 billion every year in science funding through the NIH(4) which is mainly distributed in research grants to academic scientists. If you were to take the lowest reproducibility rate of 11% that potentially could mean up to 89% of this money (over $26 billion) is wasted. As a tax paying member of the general public you would want to ensure that the government is able to plough your hard earned capital into funds that yield results over and above those figures. It is therefore commendable that the Federal Government is looking to address this issue and leverage it's role as a significant funder of scientific research.

Beyond the practicalities of finance, there is also an interesting philosophical dilemma. Since the middle of the 20th century, life science research concepts and technologies have rapidly grown from the discovery that DNA is the blueprint for life to sequencing and synthesizing new life altogether. Amazing technologies like microarrays, mass spectrometry, high-throughput assays and imaging have been developed, making biology a data-rich science. With all these new tools you could reasonably expect that science would be made more rigorous and precise, but with the reproducibility crisis it appears that something entirely opposite could be happening.

So how do we ensure that scientists are provided with the right conditions for their work to be reproducible?

The current state of affairs results from a combination of the complex nature of modern scientific research, a lack of accountability for researchers, and the incentives created by a publish-or-perish culture in academia.

For a scientific researcher to disseminate their work they are hugely reliant on scientific publishers. The publishing of scientific research has always had a large part to play in the visibility of research, and ultimately the reproducibility of science. At PeerJ we believe that the more scientific outputs are made available to all, the better it is for science. We would therefore encourage the Federal Government to put more resource into enforcing open access mandates, to ensure scientific research is opened up to all.

PeerJ publishes articles using a Creative Commons CC-BY licence, which means that authors retain their own copyright, while at the same time others can freely copy and reuse the articles without needing to ask for further permission. If a publisher asks an author to sign over copyright then it becomes difficult, expensive, or impossible for others to access the research. Just as we don't believe in paywalls blocking access to research, nor do we believe in authors being unable to retain full ownership of their work. By being fully CC-BY, authors and readers don't need to worry about sharing or reusing articles, so everyone benefits and ultimately science flourishes. The challenge facing those authors who do wish to publish through open access licensing is the proliferation of choice. Choice of licence can be a good thing, but only if there is interoperability in these licences. For instance there is not one common standard among OA licences, and the recently released STM OA licences don't necessarily operate alongside Creative Commons licences (5). We recommend the move towards everyone using one specific interopable OA licence.

Scientific journals have a significant role to play in encouraging reproducibility in the first place. They can require more descriptive materials and methods sections and provide unlimited space for them, so that other scientists will know exactly how an experiment was conducted and how they can replicate it. At PeerJ we encourage authors to submit relevant data during the review process, and we would encourage the Federal Government to ensure that more scientific publishers are asking their authors to do so when they submit their work to journals. The current incentive structure for authors does not reward the publication of replication studies. At PeerJ we not only encourage this for our authors, but most importantly our publishing platform enables authors to do just that. We recommend that the Federal Government, and all funders, set aside financial commitment for the replication and publication of the work they fund. We also suggest that the Federal Government looks to set up a specific program incentivising authors to make their data, trackable identifiers, and materials available with publication.

We believe in an open and transparent peer review process. Journals need specialized reviewers to ensure that manuscripts for technically or statistically advanced experiments are vetted thoroughly prior to publication. PeerJ harnesses the talent of thousands of reviewers able to bring their scientific expertise to bear on assessing the science behind the article. But unique to other scientific publishers we encourage our peer reviewers to provide their name as part of their review; and we also give our authors the option to publish the full peer review history of their article alongside the published version. We are hopeful that as more and more journals allow this, and as more and more authors and reviewers experience it, it will become a standard feature of all journals. Ultimately, the reason for doing this is to improve the process of review and publication and to provide fresh new insights for readers. We would ask that the Federal Government consider encouraging and rewarding those publishers practicing some form of open peer-review.

Authors should also be in a position to publish more *negative results* – those in which an experiment had no effect or clear outcome – because the lack of a finding can sometimes be as important as a finding itself. As technology enables cloud-based storage of all data and file types we encourage authors to openly share their negative results through open data platforms in order that others may learn from the outcomes of their experiments. We would ask that the Federal Government supports those researchers in making their negative data openly available to the world, perhaps by making the reporting of negative (as well as positive) results a requirement of funding.

Scientists are in the privileged position of being able to shape the world for the benefit of mankind, nature and our planet's future. As outlined, reproducibility and repeatability are the cornerstones for building on scientific discovery and making breakthroughs that help make the world a better place. Without it scientists can't learn from the work of others, or indeed ensure their own work leaves a legacy to others. It is up to the publishers of scientific research to ensure we do everything we can to provide the best ecosystem for this. It is up to our governments to foster the right environment for that to happen, and reward those who contribute to engendering this.

Notes:

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About PeerJ

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PeerJ has an Editorial Board of almost 900 respected academics, including 5 Nobel Laureates. PeerJ was the recipient of the 2013 ALPSP Award for Publishing Innovation.

PhRMA
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September 23, 2014

VIA ELECTRONIC SUBMISSION

Dan Correa
Senior Advisor for Innovation Policy
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20504

RE: Request for Information on a Strategy for American Innovation

Dear Mr. Correa:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to respond to the Office of Science and Technology Policy's (OSTP's) Request for Information to inform the development of a Strategy for American Innovation. PhRMA represents the country's innovative biopharmaceutical companies, which lead the world in the pursuit of new, life-saving and life-enhancing medicines. The U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business research and development ("R&D"), accounting for about one in five dollars spent on domestic R&D by U.S. businesses.[i] PhRMA member investment in discovering and developing new medicines reached an estimated $51 billion in 2013.[ii] As the Congressional Budget Office has stated, "[t]he pharmaceutical industry is one of the most research-intensive industries in the United States. Pharmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm."[iii]

The industry's strong record of investment has produced large improvements in health across a broad range of diseases – in the last ten years alone, the FDA has approved more than 400 new medicines, including the first medicine to treat the underlying cause of cystic fibrosis, the first vaccine to prevent cervical cancer, and the first therapeutic vaccine to treat prostate cancer.[iv] With continued investments, our understanding of biomedical knowledge will continue to grow, creating new opportunities for profound advances against our most complex and costly diseases. As just one example, the discovery of a medicine that could delay the age of onset of Alzheimer's disease by five years would mean 1.6 million fewer Americans would have Alzheimer's, and this in turn could save $100 billion in annual medical costs by 2030.[v]

Overarching: Questions 1-2

Continued scientific and technological innovations are critical to fostering sustained economic growth and global competitiveness. As the National Academies of Science has stated, "without high-quality, knowledge-intensive jobs and the innovative enterprises that lead to discovery and new technology, our economy will suffer and our people will face a lower standard of living."[vi] These "innovative enterprises" include industries that are R&D- and capital-intensive, require a highly-skilled workforce, and look to innovation for increased productivity and continued growth.

As an industry rooted in science and propelled by advanced manufacturing, the innovative biopharmaceutical industry is uniquely positioned to help maintain U.S. leadership in new technologies and scientific breakthroughs that will continue to create high-quality, high-wage R&D and manufacturing jobs and enhance America's global competitiveness in the future. Among U.S. manufacturing industries, the biopharmaceutical sector is a leader in innovation-related activity, as measured by R&D investment, intellectual property (IP) generation, venture capital investment, and share of total U.S. R&D employment.[vii] The biopharmaceutical industry also makes important contributions to U.S. gross domestic product, contributions likely to grow if the underpinnings for large-scale R&D and manufacturing investments remain intact.

A recent study by Battelle Technology Partnership Practice recognized the innovative biopharmaceutical industry as "a dynamic and innovative business sector generating high-quality jobs as well as powering economic output and exports for the U.S. economy," which contributes substantially to national, state, and local economies.[viii] It directly and indirectly supported approximately 3.4 million U.S. jobs in 2011, including more than 810,000 direct jobs.[ix] The industry's overall economic impact is substantial – in 2011, the industry accounted for nearly $800 billion in economic output.[x] Across all occupations involved in the biopharmaceutical sector, the average wage is higher than across all other private sector industries, due to the sector's role as a high-value added industry. In 2011, the average total compensation per direct biopharmaceutical employee was $110,490, compared to $54,455 in the overall economy.[xi]

These characteristics reinforce the importance of fostering an environment that will improve the industry's ability to harness research innovations to meet national health challenges and continue to create high-wage, high-skill jobs. As with other knowledge-intensive industries, America's biopharmaceutical companies face increasing challenges ranging from the cost and increased complexity associated with R&D, the prospect of attracting and sustaining the capital needed to fund continued investment in research, and intensifying competition from other countries. A long-term commitment to science, technology, and innovation is vital to enabling U.S. biopharmaceutical companies to improve health outcomes and establish the foundation for economic growth and high-value jobs. A range of policies are needed to foster a favorable environment for biopharmaceutical innovation. Chief among them are strong IP protections, a free-market system that supports patient access to new medicines, and a regulatory environment that enables rather than inhibits innovation.

Like innovators across the spectrum of American industries, biopharmaceutical companies make the substantial R&D investments that yield new medicines in reliance on a legal regime that provides protection for any resulting IP. Developing a new medicine costs an average of $1.2 billion or more of investment in R&D and takes between 10 and 15 years.[xii] Biopharmaceutical companies rely on IP (including patents and data protection also known as data exclusivity) to protect these costly inventions and provide an opportunity to recover their research investments. But IP rights and incentives are particularly important to biopharmaceutical innovation given the research-intensive nature of this sector and the substantial investment needed to discover and develop products that meet FDA approval requirements.

In order to continue to foster economic growth and the much-needed medical breakthroughs that will save lives and lower overall health care costs, the U.S. must continue to pursue IP policies that promote innovation, including the following:

- Policies to ensure well-functioning patent systems in the United States and abroad, including support for comprehensive patent rights and adequate remedies for enforcement of patents;
- Fair protection in the United States and abroad for data generated by biopharmaceutical companies to demonstrate that medicines are safe and effective, which includes policies to prevent unfair commercial use of company data by third parties; and
- Targeted proposals to incentivize R&D where market incentives are inadequate to address specific medical needs.

The need to control rising health care costs has been especially apparent during the recent economic downturn. Yet too often, approaches are pursued to control rising costs that, whether intended or not, thwart medical innovation and actually lead to higher future health care spending. Many experts agree that medicines are a good investment in terms of lives saved, independence and productivity enhanced, hospital stays reduced, and surgeries and other costly, time-consuming procedures avoided. But in order to reap the societal and economic benefits of innovative new medicines, patients must have access to them. Accordingly, PhRMA encourages the adoption of market-based solutions that improve patient access to new medicines and support rather than undermine incentives for continued investment in innovation.

A strong, science-based regulatory system is critical to ensuring the safety and efficacy of new medicines. The rapid pace of development and scientific advancement necessitate efforts to advance regulatory science and to ensure that the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and related federal research agencies are sufficiently funded and remain up to date on the leading science and technological advances. It is critical that regulatory barriers which impede or prevent biomedical innovation are addressed. For this reason, PhRMA supports collaboration among all stakeholders, including industry, FDA, patients, health care providers, and the government to ensure that there are appropriate and targeted regulatory approaches that will continue to accelerate the development and availability of innovative medicines.

Overarching: Question 5

Innovative biopharmaceutical R&D and manufacturing activities represent a competitive advantage for the U.S according to research by Harvard Business School professor Arthur Daemmrich, which found that the U.S has long prevailed as the "pharmacy to the world," despite the industry's origins in Europe.[xiii] According to Daemmrich, this sustained competitive advantage is attributable to a number of factors, including strong IP policies, funding for biomedical research through the NIH, the absence of government controls on drug prices, and the availability of venture capital funding to foster the rapid growth of the biotechnology industry.[xiv] In line with these findings, a recent study by Battelle found that the U.S. currently leads the world in clinical trial activity, biopharmaceutical IP generation, medical journal publications, and biopharmaceutical venture capital investment.[xv]

But while the U.S. has led the world in biopharmaceutical R&D for the past three decades, an increasing number of countries are focusing on the biopharmaceutical sector and related industries in their economic development, innovation, and science and technology strategic plans. According to another study by Battelle, trends show that the U.S. is not improving on several key innovation indicators whereas other countries are seeing significant advances, suggesting that "the U.S. environment for innovation is showing signs of relative weakening compared with other nations in such areas as net output, exports, publications, and patents."[xvi]

The Battelle report found that out of the 18 countries examined, all but two had innovation strategies in place to help grow a knowledge-based economy, with the majority of these plans targeting bioscience-related sectors for growth and development. More than half of the countries examined also had a separate strategy focused specifically on the development of the biopharmaceutical sector. These strategies largely aim to build the type of R&D infrastructure found in the U.S. and have generally focused on the following areas:

- Building R&D excellence and seeking to accelerate commercialization of research findings by constructing an R&D infrastructure;
- Ensuring access to financial capital for companies, particularly startups and emerging companies; and
- Attracting, retaining, and developing talent.[xvii]

PhRMA believes that such pro-innovation policies and programs being implemented around the world warrant further examination in the U.S. to ensure a level playing field for U.S- based knowledge-intensive industries like the biopharmaceutical sector.

Innovation Trends: Question 6

As the nature of the innovation process for biopharmaceuticals has become increasingly complex, greater collaboration is needed among the public and private sectors to ensure the efficient production of innovative therapeutics. Hence, PhRMA supports the need to foster the development of effective public-private partnerships among the NIH, the FDA, academia, patient groups, and the biopharmaceutical industry to address a range of scientific and technological challenges and make significant progress in areas such as target validation, qualification of drug development tools, and modernization of clinical trials, including the establishment of sustainable networks to improve efficiency and connectivity in the ecosystem.

According to a report by the Tufts Center for the Study of Drug Development, "as the scope of some of the scientific challenges is so large, collaboration is viewed as increasingly important to making significant progress."[xviii] The report found that partnerships and other forms of collaboration are growing in number and importance as the translational gap between discovery and clinical development has become increasingly difficult to bridge. Sustaining productivity in medical research is critical for the health of the economy as well as U.S. competitiveness in the global marketplace, which underscores the importance of fostering partnerships to harness the full potential of new scientific discoveries.

PhRMA supports policies that foster and expand such collaborative efforts, including assessing whether and how existing regulatory policies need to be adapted to ensure consistent and predictive regulatory adoption of the output of collaborations.

Preserving the sustainability of clinical research, while maintaining its high standards, is essential to the future of biomedical innovation and public health. The fragmented U.S. clinical trial ecosystem is facing many challenges, including increasing costs, reduced funding, a shortage of clinical trial participants and qualified investigators, and a fragmented and antiquated infrastructure. Biopharmaceutical companies have put forth great efforts to address a number of operational challenges in clinical trials, both individually through internal improvements and more recently through participation in broader industry initiatives. While such efforts are making strides, there is a need for a coordinated transformation of the clinical trial ecosystem to accelerate translation of scientific knowledge into new health solutions.

A further opportunity to accelerate the translation of scientific knowledge into new health solutions is presented through the broader use of valuable data generated through the real world use of medicines (as opposed to being generated through clinical trials). This "real world evidence" is generally not used by regulators for the evaluation of the benefit of a drug. Even new indications for a product that has already demonstrated safety and efficacy for another use (i.e., supplemental indications) are most often approved based on additional randomized controlled trials. Clearly defining the contexts within which it may be appropriate for real world evidence to complement, or potentially replace, randomized controlled clinical trials would foster the broader use of this underutilized data. Broader appropriate use of real word evidence would significantly benefit patients and other stakeholders in the healthcare ecosystem. These benefits can only be achieved through open and robust scientific dialogue between biopharmaceutical companies, patients, and FDA.

Skilled Workforce Development: Questions 12-14

Central to the nation's ability to develop needed scientific and technological innovations is a highly skilled workforce. We need to nurture the development of workers in the fields of science, technology, engineering, and mathematics (STEM) for high-growth, high-value industries that are the most powerful engines of job growth. Worldwide trends indicate the U.S. is falling behind other countries in developing the educated and well-trained workforce necessary to compete globally and to meet the projected needs of the knowledge-intensive companies in the U.S. This is particularly the case for the biopharmaceutical industry, whose continued growth is critically tied to its base of high-skilled STEM workers, ranging from production technicians with high school degrees to engineers, mathematicians, and scientists with advanced degrees, who are involved in every stage of the R&D and manufacturing process that results in new treatments and cures. [xix]

As part of its Strategy for American Innovation, the U.S. should work to improve the nation's global STEM rankings through such efforts as improving coordination and accountability among federal STEM education programs and expanding federal support for graduate and early-career research in STEM fields. PhRMA also urges an increased emphasis on the biosciences in federal and state workforce training and retraining programs to ensure more Americans would be qualified to fill high-wage, high-quality jobs in the biopharmaceutical industry. The U.S. should also explore with the private-sector ways to improve the nation's ability to grow a robust STEM-skilled workforce, including attracting and retaining highly-skilled foreign workers.

At a time when other countries are devoting increasing funds and developing strategies to build a 21st Century STEM workforce, the U.S. cannot afford to continue to lag behind its global competitors. Improving STEM education in the U.S. is an extensive and long-term, but necessary undertaking that requires a multi-stakeholder approach.

Regional Innovation Ecosystems: Questions 19-20

As geographic concentrations of interconnected companies, suppliers, service providers, and related institutions in a particular field, robust clusters foster innovation and positively influence regional economic performance. Cluster development is particularly beneficial within the biopharmaceutical R&D ecosystem because of the particular specialized characteristics, capital requirements, unique talent needs, and long-term business commitment required for sustained growth that calls for especially close ties between industry, clinical care, and academic research communities. PhRMA supports policies to help strengthen state and regional innovation clusters, including expanding the scope of current federally supported innovation collaborations funded by the Small Business Administration and Economic Development Administration to include the life sciences industries, particularly the innovative biopharmaceutical industry.

Intellectual Property/Antitrust: Question 21

As detailed above, strong IP protections are particularly important to innovative biopharmaceutical companies as they invest in costly, uncertain, and lengthy R&D to discover tomorrow's new treatments and cures. As rapidly changing models of innovation may create uncertainties for industry IP, PhRMA encourages the assessment of current IP incentives and supports robust enforcement of IP rights in the U.S. and abroad. It is imperative that competition policies recognize the importance of, and allow for, new pro-competitive models of innovation. IP incentives and the ability to enforce IP rights are critical to allow the sector to continue attracting the resources needed for a large-scale biomedical research enterprise that can deliver the medical advances society needs and desires.

Sincerely,

Anne McDonald Pritchett, Ph.D.
Vice President, Policy and Research

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September 23, 2014

Memorandum

To: **Cristin A. Dorgelo, Chief of Staff, Office of Science and Technology Policy**

John M. Galloway, Chief of Staff, National Economic Council

From: **Jan Leach, Chair, Public Policy Board, American Phytopathological Society**

Kellye Eversole, Eversole Associates, consultant for the American Phytopathological Society

RE: **Request for Comments on the *Strategy for American Innovation***

Subject: **Strategy for American Innovation RFI**

The Phytobiomes Initiative: Establishing a New Paradigm for Crop Improvement and the Discovery of Antibiotics

The American Phytopathological Society (APS) appreciates the opportunity to respond to the request for comments regarding the Strategy for American Innovation that was issued by the Office of Science and Technology Policy and the National Economic Council. The APS is the premier scientific society dedicated to high-quality innovative plant pathology research. The 5,000 public and private sector based APS members represent a broad range of specialties, from pushing frontiers in the accuracy and speed of field diagnosis and food safety to increasing our fundamental understanding of the interactions between plant associated microbes, plants, soil, insects, and the environment that determine the health, safety, quality, and productivity of our agricultural crops and forests.

As Secretary Vilsack stated in his testimony to the House Agriculture Committee in April, agriculture accounts for about $746 billion in economic activity and supports one out of every twelve US jobs (Vilsack, April 3, 2014). Since 1960, the net trade surplus from agricultural exports has helped to counter the persistent deficit in nonagricultural US merchandise trade (USDA ERS). Federal investments in agricultural science, technology, extension, and education have been the key contributing factor to the success of the US food and agricultural enterprise for more than 150 years. Every dollar invested in agricultural research generates at least $20 in economic activity (Vilsack, April 3, 2014).

While we applaud the emphasis that the Administration has placed on utilizing science and technology investments to spur innovation and long-term economic growth for many industries, we strongly urge the administration to focus significant, new strategic investments in agricultural science and technology. With world population expected to exceed 9.5 billion by 2050, changing diets, more erratic and extreme weather events coupled with increasingly hotter and drier surface areas due to climate change, and the increased need to reduce its environmental footprint, we believe that the time is right for a new "moonshot" initiative in agricultural science that will underpin disruptive innovation for the 21st century food and agricultural enterprise.

Specifically, we request that the Administration provide annually $100 million in new funding for a Phytobiomes Initiative (www.phytobiomes.org). This new national priority will build a foundation of knowledge on the interactions among plants, animals, microbes, and the environment that will accelerate the development of new, more environmentally friendly and sustainable crop production methods, inform and guide efforts to double the production of food, feed, and fiber, and create plant and soil associated microbial resources that will hasten the discovery of new antibiotics.

A phytobiome is all of the living organisms in, on, and around plants, and encompasses the many organisms that influence or are influenced by the plant or the plant environment, including the soil. The phytobiome consists of other plants, animals (insects and nematodes), and a wide diversity of microbes (viruses, bacteria, fungi, slime-molds and algae). Due to the diverse and dynamic processes carried out by biome members, the phytobiome has an important role in the sustained health and productivity of plants, plant ecosystems, and consumers of plants and plant products. In much the same way that microbes affect the health of humans, microbes in, on, and near plants, in the soil, as well as in and on animals contacting or near plants, influence plant health, productivity, quality, and safety. In some instances, the presence of certain plant associated microbes or microbial communities prevent the uptake of toxic human pathogens or enable a crop to survive abiotic stressors.

Recent advances in high-throughput sequencing, computational biology and many '-omics' technologies are enabling exploration of the composition, function and activities of phytobiomes. Application of these technologies to fundamental and applied questions will advance not only our understanding of phytobiomes, but also our ability to use this knowledge to enhance crop productivity for sustained global food security and bioenergy production.

Our current paradigm for how microbes interact with plants, soils, and the environment has grown from a broad community of researchers. For example, plant pathologists and plant physiologists have elucidated how pathogens induce and manipulate plant defense pathways, whereas entomologists and chemical ecologists have highlighted how microbes can manipulate plant responses to insects and even modulate insect behavior. Bacteriologists and mycologists have detailed sophisticated developmental processes by which symbiotic nitrogen-fixing bacteria and mycorrhizae collaborate with plants to create structures that dramatically enhance plant nutrition, including access to water and usable nitrogen and phosphorus. The increasing availability and affordability of '-omics' technologies, particularly involving nucleic acids, is positioning this broad community of researchers to investigate an expanding array of questions. For example, are the net effects of the phytobiome on the host different from the effects of individual microbes, the plant microbiome, or the soil microbiome? Are there genetic loci in the host that shape the phytobiome? Can we identify universal principles underlying community development or compositional changes in response to the environment? How do phytobiomes affect plant performance? What useful organisms, genes and products can be mined from phytobiomes? How can phytobiomes be manipulated to increase agricultural production in an environmentally sound manner? These are only a few of the many fertile areas for research under the umbrella of phytobiome research.

The recent research thrust on the human microbiome has dramatically shifted the view of human-associated microbes from primarily commensalistic residents with an occasional pathogen to participants in unexpected processes, such as early programming of the immune system (6), brain development (7) and possibly premature births (8). This body of research is greatly advancing the development of tools and analytical approaches for microbiome characterization. Phytobiomes (including their component plant microbiomes and soil microbiomes), however, present distinct challenges from human microbiome studies, many of which are focused on the gut. One challenge is the dynamic nature of the ecosystem itself. Whereas the gastrointestinal tract is relatively static in structure, plant microhabitats continuously change due to plant growth, as illustrated by the wave-like oscillations of microbial growth associated with the transient presence of young roots; this transiency reflects a need for constant root growth to obtain insoluble soil nutrients. Also, whereas dysbiosis may be recognizable in a gut microbiome as a disruption to homeostasis, this concept may not be appropriate for phytobiomes due to their open and dynamic nature. Similarly, human microbiomes generally exist in relatively buffered and host-dominated environments whereas phytobiomes exist in complex ecosystems in which they interact not only with other plants, but also animals (nematodes and insects) and diverse and typically fluctuating environmental conditions. Thus, understanding phytobiomes requires systems-level, convergent approaches that encompass a broader range of system components than most human microbiome studies. Importantly, the extensive management systems that have evolved with the development of modern agriculture provide opportunities for rapid application of knowledge of phytobiomes for agricultural improvements.

The innovative potential for the Phytobiomes Initiative is significant. In agriculture, we need practices that optimize the phytobiomes for production. Are there cover crops that are particularly good at enhancing beneficial organisms? What are the optimum tillage practices for balancing pathogen control and promoting beneficials for distinct crops? What are the impacts of fungicides on beneficial endophytes and mycorrhizae and are there strategies for minimizing damage to these beneficials? Can microbial communities be managed to suppress pests and diseases? Which microbes optimally enhance plant N and P in low-input systems? How can microbial contributions to N and P uptake be maximized in moderate- and high-input systems? What novel microbes and microbial functions are enhancing plant health and productivity? How do these vary with crop, soil, and climate? What are the principles driving microbial community development? Can these be used to improve the integration of introduced microbes into a community? Can we exploit plant germplasm to optimize the beneficial functions of phytobiomes? What plant genes exert selective pressure on the colonizing microbes? How are these genes regulated? Are they subject to feedback responses by the microbes? Are there fingerprints of beneficial microbial communities that can be employed in breeding programs? Answers to these and similar questions will provide the basic framework for downstream applications.

The key challenge for the Phytobiomes Initiative will be to build a foundation of knowledge that can be exploited and manipulated to design a new paradigm for crop development. This will require expertise in fundamental and applied science related to metagenomics, plant pathology, soil health, plant physiology, agronomy, plant breeding, extension pathologists, and education. Engineers will be needed to help design new mechanisms for measuring and sampling microbial communities in fields, while physicists, mathematicians, and statisticians will be needed to design high throughput tools for understanding the data.

Funding of the Phytobiomes Initiative and implementation of the systems level approach to crop development will allow the US to take the lead in this new field in a manner similar to the US leadership in plant genomics that began in the late 1990s. Recent estimates indicate that the market for agricultural biologics is expected to reach

$9 billion by 2020 and a strategic, US investment in the Phytobiomes Initiative could lead to doubling this one market by 2025 and cementing US leadership.

As the focus of the Phytobiomes Initiative is on agriculturally related plants, we believe that the USDA should lead this initiative. Other agencies, however, will be critically important to the overall success and the ability to optimize the innovative capacity of the initiative. Specifically, we request the following:

- Establishment of an interagency task force/working group chaired by the Chief Scientist of the USDA;
- Support for the international conference "Phytobiomes 2015: Designing a New Paradigm for Crop Improvement" during which efforts will be made to identify knowledge gaps and establish high priority research needs;
- $35 million, annually for the next 5 years, in new, competitively awarded funding for crop and forest-related phytobiomes research administered through the USDA Agriculture and Food Research Initiative that includes, but is not limited to:
    - Plant and soil microbiome studies empowered through metagenomics;
    - Plant, soil, animal, and environment interaction studies;
    - Metagenomics of plant and soil microbiomes and screening of existing microbial collections for discovery of new antibiotics;
    - Crop-microbe-animal-environment modelling studies;
    - Projects focused on utilizing the science of convergence to bring together the life sciences, physical sciences, engineering, and extension disciplines to establish innovative mechanisms for understanding, predicting through modeling, and manipulating phytobiomes;
    - Establishment of a public-private consortium focused on identifying high priority, pre-competitive research needs;
    - A research coordination network that brings together experts from the life sciences and physical sciences;
- $10 million, annually in new funding, for the USDA Agricultural Research Service (ARS) to implement a national culture collections program to preserve and make accessible an extensive supply of well characterized microbial resources for exploitation, including for new antibiotics and crop related biologics;
- $10 million, annually in new funding, for the USDA ARS Long-Term agricultural research sites;
- $25 million, annually in new funding, for the National Science Foundation, to support basic science in metagenomics, modelling, data mining and analytics, information technologies, artificial intelligence, and physics focused on understanding, predicting, and manipulating crop phytobiomes;

- $10 million, annually in new funding, for the Department of Energy to support metagenomics studies of Phytobiomes and host-pathogen-environment interaction studies; and
- $10 million, annually in new funding, for the National Aeronautics and Space Administration for designing and exploiting phytobiomes for fulfilling the need for food in space travel.

Implementation in 2015 of the Phytobiomes Initiative will ensure that we have a comprehensive understanding of key crop and forest phytobiomes by 2025 and a foundation for the discovery of new antibiotics.

For questions or further information:

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IN THE OFFICE OF SCIENCE AND TECHNOLOGY POLICY AND THE NATIONAL ECONOMIC COUNCIL

In re: Request for Information on the Strategy for American Innovation	79 Fed. Reg. 44064

COMMENTS OF PUBLIC KNOWLEDGE

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COMMENTS OF PUBLIC KNOWLEDGE

Public Knowledge respectfully submits the following comments in response to the Notice of Request for Information on the *Strategy for American Innovation* dated July 29, 2014. These comments specifically respond to the Intellectual Property/Antitrust issue number 21, which relates to "**new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation**."

Public Knowledge is a nonprofit organization dedicated to preserving the openness of the Internet and the public's access to knowledge. As part of that mission, Public Knowledge often looks closely at the precise question posed by the Request for Information, namely how the "increasing diversity of models of innovation" can pose "new challenges and opportunities for intellectual property."

As discussed in detail in the comments below, Public Knowledge believes that a careful rebalancing of intellectual property rights, particularly with respect to copyright and patent law, is warranted and necessitated by the rapid development of new technologies and their attendant business and innovation models. Incumbent rightsholders have historically sought to enlarge the scope of their intellectual property rights in order to monopolize their entrenched business models, to the detriment of new technological development. Thus, we urge the Office of Science and Technology Policy and National Economic Council to strongly support innovative growth over monopolistic power, and call for balanced intellectual property policy as a major part of the strategy for American innovation.

I. How Overbroad Intellectual Property Impedes Innovation

For too long, policymakers have made the default assumption that increasing the scope, term, and remedies for various types of intellectual property can only increase innovation. This has increasingly and definitively shown to be a vast oversimplification in many instances, and simply false in others.

Rather, the traditional operation of IP is best seen as a method for promoting innovation by balancing incentives for authors and inventors against the costs of those incentives to the public. The standard incentive mechanism in copyrights and patents—the grant of exclusive rights—creates a natural tension with competitive concerns. In ordinary cases, this tension is resolved through the natural limits of the grant of exclusive rights—for patents, the exclusivity must be on a novel, non-obvious invention of patentable subject matter; for copyrights, the exclusivity is solely granted for original works of creative expression. Both specifically exclude abstract ideas and other inapposite subject matter, exist for only limited times, and feature a number of limitations and exceptions to their application.

However, the limitations and boundaries places upon these exclusive rights have not been immutable over time. Not only have their boundaries and remedies expanded in recent decades, the exclusive rights have been increasingly linked to activities that would not or should not in themselves infringe upon the exclusive rights granted by the law. This artificial extension of the scope of IP law creates a powerful tool that can be abused to restrain competition and innovation, counter to the constitutional purpose of the law. Below is a non-exhaustive description of some of those abuses and potential problems.

II. Accounting for All Inventors in Patent Policy

The diversity of innovation models poses substantial challenges for patent law and policy, down to the very underpinnings and rationales for the patent system. The following section explores how patent law interacts with the multiple incentives for innovation, ranging from open source development to the small startup economy, and considers how patent policy might better account for the wide variety of innovators in today's technology economy.[1]

The traditional rationale behind the issuance of patents is utilitarian: by granting limited monopolies on inventions, the government can incentivize individuals and firms to spend resources on

[1] This section is drawn from Charles Duan, A Five Part Plan for Patent Reform (2014), *available at* https://www.publicknowledge.org/documents/a-five-part-plan-for-patent-reform.

inventing. The limited monopoly, namely the right to exclude others from practicing the invention for a period of time, both gives a financial reward to those who invent and grants an opportunity for them to commercialize their inventions without interference from competitors.[2]

The empirical evidence for this rationale is mixed. The area in which the patent incentive most clearly succeeds is in the pharmaceutical industry,[3] but some have suggested that this is primarily the case because of artificially imposed regulatory requirements that necessitate the exclusive lead time offered by patents.[4] In other fields of technology, surveys and other evidence have suggested that the patent incentive is insubstantial or vastly ignored.[5]

In any event, it is unnecessary to consider in too much depth the empirical evidence for the patent incentive, because it is certainly not the only incentive for innovation. The fast-paced startup community, open source software, the prestige of publication, and prizes and rewards for new discoveries, among other things, are all alternative incentives for innovation beyond patents, as explained below.[6]

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[2] *See, e.g.,* Jeanne C. Fromer, *Patent Disclosure*, 94 Iowa L. Rev. 539, 547 & n.31 (2009) (citing sources).

[3] *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 Mich. Telecomm. & Tech. L. Rev. 345, 350 (2007), *available at* http://www.mttlr.org/volthirteen/eisenberg.pdf ("Biopharmaceutical research is often held out as a shining example of the success of the patent system in motivating private investment in R&D.").

[4] *See id.* at 346 (noting that patent advocates cite drug regulation "as a large part of the cost of drug development that can only be recovered if firms are allowed to charge patent-protected premium prices for new products."). *But see id.* at 359 (arguing that FDA regulation of new drugs in fact acts as a "pseudo-patent" complementing patent exclusivity).

[5] *See, e.g.,* Wendy Seltzer, *Software Patents and/or Software Development*, 78 Brooklyn L. Rev. 929, 929 (2013), *available at* http://www.brooklaw.edu/~/media/PDF/LawJournals/BLR_PDF/blr_v78iii.ashx ("Patents do not provide a useful incentive to innovate in the software industry, I contend, because the patent promise ill-suits the engineering and development practices and business strategies of software production."); Mark A. Lemley, *The Myth of the Sole Inventor*, 110 Mich. L. Rev. 709, 736–38 (2012); Brief of *Amici Curiae* Checkpoint Software, Inc., et al., in Support of Respondents at 3, Alice Corp. Pty. Ltd. v. CLS Bank Int'l, No. 13-298 (U.S. Feb. 27, 2014), *available at* http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v3/13-298_resp_amcu_cs-etal.pdf ("Software patents are not necessary to spur innovation among the Amici. Our engineers do not innovate because they hope to get patents.").

[6] *See* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 484 (1974) ("Certainly the patent policy of encouraging invention is not disturbed by the existence of another form of incentive to invention.").

A. Computer Software Startups

The widespread use of the Internet and computer technologies has led to a proliferation in small software startups. The market of mobile device applications, for example, is globally valued at over $53 billion[7] and accounts for approximately 466,000 jobs created since 2007.[8] Many of the major Internet companies today have their roots in such a small business.[9]

Small software technology startups often do not rely on patents for protecting their innovations. With patent applications costing about $25,000 to file and prosecute,[10] they are well beyond the financial reach of these small startups that may not even have $25,000 to run their business in the first year.[11] Yet the number of such startups is proof that there is sufficient incentive to innovate in that arena even without patents.

Instead, different incentives predominate. The first mover advantage is particularly valuable in the fast-paced world of computer software.[12] Network effects hold strongly with software, as adopters of a company's technology are less likely to move to competitive offerings due to built-up social networks, cost of converting data, and familiarity with user interfaces.[13] Additionally, software companies are prone to failure for numerous reasons, so many software engineers are com-

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[7] Andreas Pappas, VisionMobile Ltd., App Economy Forecasts 2013–2016 (2013).

[8] Michael Mandel, Where the Jobs Are: The App Economy 13 (2012).

[9] *See* Peter S. Menell, *Indirect Copyright Liability and Technological Innovation*, 32 Colum. J.L. & Arts 375, 389 (2009) ("Many of the notable innovations—from Napster's peer-to-peer system to the Google search engine, YouTube, and Facebook—were hatched and initially developed in the Web 2.0 equivalent of the Silicon Valley garage: a dorm room."); Seltzer, *supra* note 5, at 973 (noting that the software industry features "lower capital costs . . . ; lower pure research costs and a focus on implementation; and lower uncertainty of development").

[10] Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. Small & Emerging Bus. L. 137, 138 n.3 (2000) (citing that cost as "not unreasonable based on my experience"); *see also* Gene Quinn, *The Cost of Obtaining a Patent in the US*, IPWatchdog (Jan. 28, 2011), http://www.ipwatchdog.com/2011/01/28/the-cost-of-obtaining-patent/ (citing costs of $5,000 to $15,000 for filing the application alone).

[11] The startup accelerator Y Combinator, for example, invests $20,000 for a three-person startup. *See* Steven Levy, *Y Combinator Is Boot Camp for Startups*, Wired (May 17, 2011), http://www.wired.com/magazine/2011/05/ff_ycombinator/.

[12] Seltzer, *supra* note 5, at 982–83.

[13] *Id.* at 983–84.

fortable with frequent "pivots" to entirely new ideas.[14] The mere experience of starting a software company, say many such engineers, is incentive enough to innovate even in the face of daunting odds, as it is easy and nearly cost-free to abandon one idea and move on to the next.

B. Open Innovation Communities

Open innovation communities are collectives of individuals and entities who openly share their innovations, making those innovations available to others for use, adaptation, and improvement.[15] Although the open source software community is perhaps the best known of these, open innovation communities may be found in many other areas of technology besides software development, including electronic hardware manufacturing, 3D printing, biology, and environmental engineering.[16]

To strong proponents of the patent incentive theory, open source software and related models of innovation present a quandary: how can innovation occur in a world where products are given away for free and competitors are allowed—even encouraged—to copy? Yet widespread use and constant improvement of open source software suggests that those incentives must still be present. Some of the most widely used software programs today, including the GNU/Linux operating system, the Apache HTTP server, and the Firefox web browser, were developed by the open source community.

Indeed, scholars have documented those alternative incentives that have contributed to the growth of the open source software and other communities. Reputation benefits play a significant role: as one seminal work put it in describing two popular software projects, "by properly rewarding the egos of many other hackers, a strong developer/coordinator can use the Internet to capture the benefits of having lots of co-developers."[17] Companies like IBM and Red Hat invest in open

[14]*See* Eric Ries, The Lean Startup: How Today's Entrepreneurs Use Continuous Innovation to Create Radically Successful Businesses 149 (2011) (describing a pivot as "a structured course correction designed to test a new fundamental hypothesis about the product, strategy, and engine of growth").

[15]The term "open innovation community" is from Jason Schultz & Jennifer M. Urban, *Protecting Open Innovation: The Defensive Patent License as a New Approach to Patent Threats, Transaction Costs, and Tactical Disarmament*, 26 Harv. J.L. & Tech. 1, 2 n.1 (2012), *available at* http://jolt.law.harvard.edu/articles/pdf/v26/26HarvJLTech1.pdf.

[16]*See id.* at 2 & n.1.

[17]Eric S. Raymond, The Cathedral and the Bazaar: Musings on Linux and Open Source by an Accidental

source development to accrue returns such as consulting services.[18] And basic ideals of sharing and disseminating knowledge motivate others.[19] Thus, a variety of incentives, entirely apart from the patent incentive, can spur innovation within open innovation communities.

C. Alternative Rewards for Invention

Patents are one type of reward for innovation, but there are many others. Prizes for innovation have been suggested as a solution to the economic inefficiency of patent monopolies. "The alternative of awarding prizes would be more efficient and more equitable," writes one prominent economist.[20] And numerous prizes are granted to incentivize societal progress: Alfred Nobel, for example, bequeathed his fortune to establish prizes awarded to "those who, during the preceding year, shall have conferred the greatest benefit to mankind."[21]

There are many examples of rewards for innovation, beyond the straightforward prize. Academics are rewarded for their ideas and discoveries by having their papers accepted in journals. Foundations run competitions for the first person to solve an unsolved problem, to encourage inventors to develop creative solutions. Governments provide tax incentives for research and development. And researchers with new ideas can apply for grants, both government and privately-funded, to pursue those ideas.[22]

Revolutionary 43 (rev. ed. 2001) (describing Linux and fetchmail); *see also* Schultz & Urban, *supra* note 15, at 17.

[18] *See* Yochai Benkler, The Wealth of Networks: How Social Production Transforms Markets and Freedom 46 (2006), *available at* http://www.benkler.org/Benkler_Wealth_Of_Networks.pdf; Jon Brodkin, *How Red Hat Killed Its Core Product—And Became a Billion-Dollar Business*, Ars Technica, Feb. 28, 2012, http://arstechnica.com/business/2012/02/how-red-hat-killed-its-core-productand-became-a-billion-dollar-business/.

[19] *See, e.g.,* Richard M. Stallman, Free Software, Free Society 129 (2d ed. 2010), *available at* http://www.gnu.org/doc/fsfs-ii-2.pdf ("My work on free software is motivated by an idealistic goal: spreading freedom and cooperation. I want to encourage free software to spread, replacing proprietary software that forbids cooperation, and thus make our society better.").

[20] Joseph Stiglitz, *Give Prizes Not Patents*, New Scientist, Sept. 16, 2006, at 21, *available at* http://www2.gsb.columbia.edu/faculty/jstiglitz/download/2006_New_Scientist.pdf; *see also* Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 The Quarterly Journal of Economics 1137 (1998) (proposing an auction process by which the government buys out most patents, offering the buyout price as a prize).

[21] Alfred Bernhard Nobel, *Alfred Nobel's Will* (Nov. 27, 1895), http://www.nobelprize.org/alfred_nobel/will/will-full.html.

[22] For a comprehensive overview of rewards for innovation, see generally Daniel J. Hemel & Lisa Larrimore Ouel-

An example of the last of these types of rewards incentivizing innovation may be found in the development of the Internet. Many Internet technologies were built under federal grants,[23] which incidentally restricted acquisition of patents on the technology.[24] Further Internet development was supervised by standards organizations like the W3C, which expressly disallows patenting of technology adopted into standards.[25] The reward of a federal grant or incorporation into an Internet standard was sufficient to bring about incredible technological development without the use of patents.

Certainly none of these alternate incentives can entirely supplant the patent system, as each person is motivated by different incentives. What is important, though, is that no single type of incentive is the sole or predominant engine of new innovation and technology.

D. Conflicts Between the Incentives

While, in an ideal world, all of these incentives would complement each other to maximize invention, in reality these incentives conflict and sometimes work at opposing purposes. The focus here is particularly on how the patent incentive can conflict with other incentives to innovate, and how reforms to the patent system can reduce these conflicts.

For example, the first mover advantage is an incentive for startup entrepreneurs, and that incentive is undercut when second movers or even non-movers acquire and assert patents. Thus, there is substantial anecdotal evidence of innovative software startups dropping products or closing shop altogether in the face of patent threats.[26]

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lette, *Beyond the Patents—Prizes Debate*, 92 Tex. L. Rev. 304 (2013), *available at* http://www.texaslrev.com/wp-content/uploads/HemelOuellette.pdf.

[23]Much of early Internet technology research was funded by the Advanced Research Projects Agency (ARPA, now DARPA). *See* Robert H. Zakon, Request for Comments 2235: Hobbes' Internet Timeline 1–6 (1997), http://tools.ietf.org/html/rfc2235.

[24]35 U.S.C. §§ 200–212 (2013).

[25]More specifically, if a participant in a W3C standard acquires a patent essential to the standard, the participant must generally grant a royalty-free license to the public for that patent. Daniel J. Weitzner, *W3C Patent Policy*, W3.org §§ 3.1, 5 (Feb. 5, 2004), http://www.w3.org/Consortium/Patent-Policy-20040205/.

[26]*See, e.g.,* Colleen V. Chien, New Am. Found., Patent Assertion and Startup Innovation 16–17 & fig.3 (2013), http://www.newamerica.net/publications/policy/patent_assertion_and_startup_innovation; *When Patents Attack!*, This American Life 6:20–37 (July 22, 2011), http://www.thisamericanlife.org/radio-archives/episode/441/when-patents-attack ("[Interviewer]: Did it put your business in danger? [Startup founder] Jeff Kelling: It did, and they knew

The interference between patents and open source software is also well known. One study from 2004 has shown that the Linux kernel, a popular and widely-used open source program, potentially infringes 283 patents.[27] Indeed, when a bundle of 882 patents were proposed to be sold in 2011, the Department of Justice intervened out of concern that the patents would "jeopardize the ability of open-source software, such as Linux, to continue to innovate and compete."[28] Similarly, the authors of the GNU General Public License are of the view that patents "obstruct free software development," which led to the inclusion of a mandatory patent license in the most recent version of the GPL.[29]

There is also a conflict between the patent incentive and incentives of alternate rewards. Patents can interfere with the ability of scholars to conduct research, thereby diminishing the ability of academia to pursue innovative ideas. However, this example is instructive, because patent law already provides an accommodation for this conflict: an exception for experimental use. That doctrine, which exempts from patent infringement non-commercial experimental uses of patented inventions,[30] accommodates those who invent to obtain public or academic recognition. Additionally instructive, however, is the degree to which this experimental use doctrine has been narrowed over time,[31] reflecting an unfortunate shift in the relative valuation between the patent incentive and rewards-based research incentives.

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that. The settlement they wanted to get was just enough to put us in danger, but not to close us, and I'll stop there.").

[27]Press Release, Karen Duffin, Bite Commc'ns for OSRM, *Results of First-Ever Linux Patent Review Announced, Patent Insurance Offered by Open Source Risk Management* 1 (Aug. 2, 2004), http://www.osriskmanagement.com/press_releases/press_release_080204.pdf.

[28]Press Release, Dep't of Justice, *CPTN Holdings LLC and Novell Inc. Change Deal in Order to Address Department of Justice's Open Source Concerns* (Apr. 20, 2011), *available at* http://www.justice.gov/opa/pr/2011/April/11-at-491.html.

[29]Richard Stallman, *Why Upgrade to GPLv3* (July 29, 2013), https://www.gnu.org/licenses/rms-why-gplv3.html; *The GNU General Public License v.3.0* § 11 (June 29, 2007), http://www.gnu.org/licenses/gpl.html.

[30]*See* Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) ("[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments."); *In re* Rosuvastatin Calcium Patent Litig., 703 F.3d 511, 527 (Fed. Cir. 2012) ("However, patenting does not deprive the public of the right to experiment with and improve upon the patented subject matter."); *see also* CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1322–25 (Fed. Cir. 2013) (en banc) (Newman, J., concurring and dissenting) (discussing experimental use doctrine), *cert. granted*, 134 S. Ct. 734 (2013).

[31]*See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. Chi. L. Rev. 1017, 1019–20 (1989) ("For the most part, the courts have held that the experimental use defense does not apply to the facts of the particular cases before them.").

E. Finding the Right Balance

One task for patent reform, then, is to consider adjustments to the patent system that better accommodate these alternate incentives for innovation. The goal of such adjustments is to better encourage these inventors incentivized by factors other than patents, and to ensure that patents do not stand in the way of those inventors.

Consider the following ideas for recalibrating the patent system in view of these alternate incentives and alternate inventors.

For one thing, the standards for granting patents should be reconsidered. Many aspects of the current patent system reflect an assumption that patents are the primary driver of innovation, and modern developments challenge that assumption. This question of patent quality is discussed in Section F.

Along similar lines, patent law includes an old doctrine called "experimental use," which protects those who engage in experimentation from the risk of patent infringement.[32] However, over the years courts have sharply narrowed the availability of the experimental use exception, exactly at a time when more and more experimentation is occurring, on the part of consumers, home inventors, and other small parties. Expansion of this doctrine could provide protection to that grassroots innovation that could otherwise be threatened by patents.

Additionally, some have considered the possibility of using specially-configured patent licenses to promote open innovation rather than interfere with it. The idea is that a properly crafted license agreement attached to a patent could encourage others to share knowledge rather than hold it closed behind patents, in the same way that copyright licenses like the GPL and Creative Commons licenses encourage others to share creative works.

One such proposal, the Defensive Patent License (DPL), institutes a system by which an entity may agree not to assert its patents against other DPL members, and in exchange the entity receives an automatic, free license to all other patents under the DPL.[33] Thus, the DPL "blends the general strat-

[32] *See* discussion *supra* note 30 and accompanying text.

[33] Schultz & Urban, *supra* note 15, at 38–39.

egy of defensive patenting with the [open innovation community] values of openness and freedom" to "provide an interoperable, technologically neutral, reliable, and legally binding commitment to defense."[34] Proposals like these take the patent system, which is built around the singular patent incentive, and turn it around to incentivize other values shared by different kinds of inventors.[35]

F. Improving Patent Quality

A common complaint about the patent system is the number of "low-quality" patents that are issued.[36] There are frequent reports of patents on old or obvious ideas, particularly in the field of software.[37] Many people believe that these poor quality patents are the root of the problems that the patent system faces today. They thus call for better examination of patents through increased funding to the Patent Office, better training of examiners, and longer time for examination.[38]

Improving patent quality is a key component of accounting for all inventors and innovators. The process of invention is incremental,[39] so inventors depend on a pool of knowledge not encumbered by patents, on which their inventions may be based. Part of this pool comes from unpatentable abstract ideas, laws of nature, and physical phenomena, which the Supreme Court has described as

[34] *Id.* at 38.

[35] For another example of such an alternate patent license, see Adam Messinger, *Introducing the Innovator's Patent Agreement*, The Official Twitter Blog (Apr. 17, 2012), https://blog.twitter.com/2012/introducing-innovators-patent-agreement.

[36] *See, e.g.,* Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy ch. 4(II)(A)(3), at 8 (2003), *available at* http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf ("Several participants voiced concern about too great an issuance of obvious patents.").

[37] *See, e.g.,* Press Release, Elec. Frontier Found., *EFF Files Challenge with Patent Office Against Troll's Podcasting Patent* (Oct. 16, 2013), https://www.eff.org/press/releases/eff-files-challenge-patent-office-against-trolls-podcasting-patent.

[38] *See generally* Sara-Jayne Adams, *Quality Is the Key to a Bright Patent Future*, Intell. Asset Mgmt., Apr./May 2008, at 55, *available at* http://www.iam-magazine.com/Issues/Article.ashx?g=7ec06ce7-8c64-4402-9222-f79e3aaaf171 (collecting numerous views on patent quality).

[39] "The world goes ahead because each of us builds on the work of our predecessors. 'A dwarf standing on the shoulders of a giant can see farther than the giant himself.' " Sony Corp. of Am. v. Universal City Studios, Inc., 464 U.S. 417, 477 n.28 (1984) (quoting Zechariah Chafee, Jr., *Reflections on the Law of Copyright: I*, 45 Colum. L. Rev. 503, 511 (1945)); *see also* Lemley, *supra* note 5, at 714; Letter from Isaac Newton, to Robert Hooke (Feb. 5, 1675), *available at* http://digitallibrary.hsp.org/index.php/Detail/Object/Show/object_id/9565 ("If I have seen further it is by standing on the sholders [*sic*] of Giants.").

"part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none."[40] Another part of this pool comes from old technologies in the prior art,[41] as well as the knowledge that would be obvious to a "person having ordinary skill in the art."[42] If a patent erroneously issues on a technology within that public pool, or if courts misread the boundaries of the pool too narrowly, then future innovators and future innovation are hindered.[43]

The need to account for all inventors extends to many areas of the patent quality problem. Patent examination is one such area. The Patent Office traditionally searched for prior art primarily in the library of past patents,[44] but today, where so much innovation occurs outside of the patent system, the Patent Office is starting to seek out external sources of information to discover prior art.[45]

The basic standard for patent quality is another area where accounting for all inventors must play a role. The Supreme Court recognized this in the case *KSR International Co. v. Teleflex Inc.*[46] For many years, the courts had used a test for what would be obvious to a person of ordinary skill in the art, namely that some "teaching, suggestion, or motivation" to combine two different ideas must exist before the combination could be deemed obvious.[47] The Supreme Court rejected that test,

[40]Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)) (omission in original).

[41]*See* 35 U.S.C. § 102 (2013).

[42]35 U.S.C. § 103.

[43]*See* Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152–53 (1950) (an obvious patent "withdraws what already is known into the field of its monopoly and diminishes the resources available to skillful men").

[44]*See* U.S. Patent & Trademark Office, Manual of Patent Examining Procedure § 902.03(e) (8th ed., 9th rev. 2012); Beth Simone Noveck, *"Peer to Patent": Collective Intelligence, Open Review, and Patent Reform*, 20 Harv. J.L. & Tech. 123, 135 (2006).

[45]There have been several formal efforts toward externalizing, or "crowdsourcing," the prior art review effort. *See* Press Release, Peter Pappas, U.S. Patent & Trademark Office, *USPTO Launches Second Peer To Patent Pilot in Collaboration with New York Law School* (Oct. 19, 2010), http://www.uspto.gov/news/pr/2010/10_50.jsp; 35 U.S.C. § 122(e)(1) (preissuance submissions by third parties in pending patent applications); Press Release, Office of the Press Sec'y, The White House, *Fact Sheet—Executive Actions: Answering the President's Call to Strengthen Our Patent System and Foster Innovation* (Feb. 20, 2014), http://www.whitehouse.gov/the-press-office/2014/02/20/fact-sheet-executive-actions-answering-president-s-call-strengthen-our-p ("[T]he USPTO is announcing a new initiative focused on expanding ways for companies, experts, and the general public to help patent examiners, holders, and applicants find relevant 'prior art' . . . .").

[46]KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[47]*Id.* at 1734.

based on its reasoning that the "diversity of inventive pursuits and of modern technology counsels against limiting the analysis" to that test—that is, because the test failed to account for all types of inventors and technology.[48] Nevertheless, the requirement for some sort of motivation to combine even persists after *KSR*.[49]

That conflict between the "motivation to combine" test and actual inventors is placed sharply in focus when considering open-source software developers, for example. Non-proprietary software developers and other innovation communities value interoperability and combinability of software. Thus, the legal assumption that new combinations are uncommon and often worthy of patents conflicts with the experiences of those software developers, for whom new combinations are routine and expected. Uncorrected, this mismatch means that patents would likely stifle rather than encourage the tinkering and exploration that drives many innovators today.

A critical step in improving patent quality, then, is accounting for the ways in which all types of inventors work and innovate. The Patent Office and the courts need to know how a "person having ordinary skill in the art" approaches problem solving and invention. Without sufficient contact with actual innovators of all types, these decisionmaking bodies will not be able to craft patent policy that promotes innovation for all.

So it is important for these decisionmakers to reach out to inventing communities, even those that do not file for patents, and it is important for those communities to reach out to the Patent Office and other decisionmakers.[50] Indeed, the White House and Patent Office have initiated several programs to obtain input on patent policy,[51] and these initiatives should be continued and broadened to reach the whole innovating community.

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[48] *Id.* at 1742.

[49] *See, e.g.,* Kinetic Concepts, Inc. v. Smith & Nephew, Inc., 688 F.3d 1342, 1368–69 (Fed. Cir. 2012) (reversing a finding of obviousness for a patent due in part to a lack of expert testimony on motivation to combine).

[50] *See* Charles Duan, Pub. Knowledge, *Comments of Public Knowledge, the Electronic Frontier Foundation, and Engine Advocacy on Prior Art Resources for Use in the Examination of Software-Related Patent Applications* 4–6 (Mar. 17, 2014), *available at* https://www.eff.org/files/2014/03/17/comments_to_pto_from_public_knowledge_eff_engine.pdf.

[51] *See, e.g.,* Request for Comments and Notice of Roundtable Event on the Use of Crowdsourcing and Third-Party Preissuance Submissions to Identify Relevant Prior Art, 79 Fed. Reg. 15,319 (U.S. Patent & Trademark Office 2014).

III. Anti-Competitive Restraints in Copyright Law

Numerous restraints on productive innovation also exist within copyright law and policy. Three in particular are considered below: the anticircumvention provisions of the DMCA, restrictions on ownership and sale of digital goods, and bottlenecks in the content licensing and distribution industries. However, a balanced view of copyright, as presented through the recommendations set forth in this section, can promote innovation rather than entrenching the status quo.

A. Anticircumvention Under the Digital Millennium Copyright Act

One particular mechanism is the anticircumvention provisions of the Digital Millennium Copyright Act.[52] The provisions prevent the circumvention of technical protection measures used to access copyrighted works, as well as the trafficking in devices or services used to circumvent either such access protections or protections on the rights of a copyright holder. Some courts have held that violating the anticircumvention provisions does not require a violation of the underlying copyright.[53]

This leads to a significant problem in which consumers and competitors alike can be found liable for activities that do not infringe copyright, or are not even remotely related to the exclusive rights. Merely circumventing a protection measure to access the work supposedly triggers liability.

Some of the most egregious attempts to abuse this provision to stifle competition involve preventing interoperability. In one case, a printer manufacturer attempted to use the anticircumvention provisions to sue the manufacturer of generic toner cartridges, claiming that bypassing its lockout codes circumvented a technological protection measure to gain access to the copyrighted software that ran its printers.[54] In another case, a garage door manufacturer claimed that the maker of universal remotes was circumventing protections that controlled access to the software on its door openers.[55] These particular instances have risen to prominence due to being litigated in appellate

[52] 17 U.S.C. § 1201 (2013).

[53] *E.g.,* MDY Indus., LLC v. Blizzard Entm't, Inc., 629 F.3d 928, 944–45 (9th Cir. 2010).

[54] Lexmark Int'l, Inc. v. Static Control Components, Inc., 387 F.3d 522 (6th Cir. 2004).

[55] Chamberlain Group, Inc. v. Skylink Techs., Inc., 381 F.3d 1178 (Fed. Cir. 2004).

court; many more documented instances exist,[56] and many others will likely never come to light, being settled before suit or simply because consumers and competitors are chilled form legitimate activity through the threat of a lawsuit.

The most recent example of anticircumvention's potential for anticompetitive effects to garner widespread media attention was the recent controversy over cell phone unlocking.[57] Even in the absence of any lawsuits against consumers, various manufacturers were willing enough to argue to the Copyright Office that circumventing code that locked consumers' phone to particular wireless networks would be a violation of the anticircumvention provisions. Under this theory, consumers would be liable for civil and criminal penalties for engaging in perfectly legitimate behavior, simply because copyrighted software and digital lacks were being used in the furtherance of the carriers' anticompetitive goals.

B. Restrictions on Ownership and First Sale

The modern ubiquity of copyrighted software leads to copyright being leveraged for anticompetitive purposes in other areas as well, particularly when coupled with restrictive agreements that purport to restrict ownership of the software. While most chattels can be transferred by their owners without any restrictions from previous owners or manufacturers, copyright holders have for centuries attempted to restrain downstream distribution of their products.[58] While Supreme Court precedent, and later, statutes, ensured that owners of copies could distribute them freely, copyright holders today have increasingly been using end user license agreements to reinstate this means for post-sale restraints.[59]

End user license agreements attached to software will frequently attempt to characterize the

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[56]Elec. Frontier Found., Unintended Consequences: Sixteen Years Under the DMCA (2014), *available at* https://www.eff.org/files/2014/09/16/unintendedconsequences2014.pdf.

[57]R. David Edelman, *A Call Answered: Unlocking America's Cell Phones*, White House Blog (July 25, 2014), http://www.whitehouse.gov/blog/2014/07/25/call-answered-unlocking-america-s-cell-phones.

[58]*See* Bobbs-Merrill Co. v. Straus, 210 U.S. 339 (1908).

[59]For more on the antitrust origins of the first sale doctrine, see Ariel Katz, *What Antitrust Law Can (and Cannot) Teach About the First Sale Doctrine* (Jan. 23, 2012), http://papers.ssrn.com/sol3/papers.cfm?abstract_id.

relationship between vendor and consumer as one of lessor and lessee, rather than buyer and seller, regardless of the realities of the transaction. By claiming in this fine print that consumers do not own the physical copies they have paid for, copyright holders can claim that any further distribution by the consumer is a copyright infringement, without having to show any privity of contract or affirmative agreement between the parties.[60]

This same scheme allows software manufacturers and the owners of copyrights in digital media to bootstrap what should be contract claims into claims of copyright infringement.[61] Since the use of digital media often necessarily results in it being reproduced in RAM or buffer copies, copyright holders can claim, under existing law, that those copies infringe copyright, unless the uses of the media followed the specific permissions they grant. In other words, opening an ebook and reading it subjects a user to copyright liability unless she abides by the terms of the license. Frequently, such licenses will place conditions upon media users that include prohibitions on reverse engineering, usage with compatible competitors' devices, maintenance by competitors,[62] and so on.

C. New and Old Bottlenecks in Content Licensing and Distribution

Concentration in the entertainment industry, combined with the exclusive rights granted by copyright, can further result in anticompetitive bottlenecks. In the chain of production from artist to consumer, a piece of music faces potential bottleneck control by any number of intermediaries, ranging from publishers and record labels to broadcasters and performing rights organizations to newer digital platforms.[63] At each of these inflection points, increasing horizontal concentration

[60]Vernor v. Autodesk, Inc., 621 F.3d 1102 (9th Cir. 2010). The rationale in *Vernor* was further used as a justification by the Library of Congress in denying the exemption for cell phone unlocking in its last anticircumvention proceeding. Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 77 Fed. Reg. 65260, 65265 (Oct. 26, 2012).

[61]*See, e.g.,* MDY Indus., LLC v. Blizzard Entm't, Inc., 629 F.3d 928 (9th Cir. 2010). Though the Ninth Circuit in *Blizzard Entertainment, Inc.* declined to read the restrictions at issue as a condition on the license, it is not difficult to see a differently-drafted "license" agreement leading to a different result, as in *Vernor*.

[62]Using copyright law to restrict competition in post-sale maintenance is by now something of a tradition. MAI Sys. Corp. v. Peak Computer, Inc., 991 F.2d 511 (9th Cir. 1993); NLFC, Inc. v. Devcom Mid-Am., Inc., 45 F.3d 231 (7th Cir. 1995); Storage Tech. Corp. v. Custom Hardware Eng'g & Consulting, Inc., 421 F.3d 1307 (Fed. Cir. 2005).

[63]*See Comments of Public Knowledge and the Consumer Federation of America on Music Licensing Study* 9–20 (Copyright Office, Library of Cong. May 23, 2014), *available at* https://www.publicknowledge.org/assets/uploads/documents/

and even more rapid vertical combinations can easily serve to stifle newer, independent artists and platforms.

The same problems exist in a slightly different form in the television and motion picture industries, as existing, concentrated distributors exploit a legal landscape that has been shaped in large part by and in the service of incumbents.[64] Even as new entrants seek to enter and possibly disrupt these industries, policymakers should be aware of the threats that they will merely reinforce concentrated market power, or create new opportunities for monopoly control themselves.

D. Rebalancing Copyright Law to Promote Knowledge and Innovation

Copyright law's purpose is to further knowledge and learning. Remunerating authors is merely the means to that end—albeit a powerful means justified in the Constitution. To ensure that the copyright incentives do not work against their ultimate goals, copyright law and policy should keep several principles in mind.

First, legal systems should not assume that industry structures are static, permanent, or most beneficial in their current form. Assuming that existing agreements will always be the basis for creation can result in a self-fulfilling prophecy—in some cases, explicitly discouraging innovation that would disrupt incumbent businesses.[65]

Second, the law should remain flexible to account for changes—not just to technology, but to the ways in which works are used. The inevitability of temporary digital reproductions in RAM and buffer copies that do not affect the market for the copyrighted works, for instance, should not give rise to a raft of pretextual copyright litigation or threatened litigation. Nor should increased creation of transformative works by an increasing number of expressive consumers be discouraged through overzealous application of exclusive rights. The doctrine of fair use remains one necessary,

PKCFAComments.pdf.

[64] *See* John Bergmayer, Tomorrowvision: The Shocking Truth About the Policy Tweaks that Could Help Promote Online Video 2–7 (2012), *available at* https://www.publicknowledge.org/files/Tomorrowvision.pdf.

[65] *See, e.g.*, 17 U.S.C. § 801(b)(1)(D) (2013) (requiring, in calculating royalty rates, Copyright Royalty Judges to "minimize any disruptive impact on the structure of the industries involved and on generally prevailing industry practices").

but insufficient, source of such flexibility for the public, and not just for copyright holders.

Third, policymakers must recognize the extent to which the omnipresence of copyrighted works, the high penalties associated with their infringement, and the ease and flexibility of licensing practices surrounding them make it easy for copyright to become a pretext for any number of goals at odds with public policy, or at least far removed from the purpose of copyright.[66] The characteristics meant to make copyright enforceable and flexible for copyright holders has also led to the specter of it being abused either for improper purposes, or in lieu of necessary statutes in some unrelated, but inapposite field.

IV. Conclusion

Public Knowledge thanks the Office of Science and Technology Policy and National Economic Council for providing the opportunity to submit these comments. If there are any remaining questions relating to the matters presented herein, the undersigned would be happy to provide further information as necessary.

Respectfully submitted,

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[66] *See, e.g.,* Matt Schruers, *IP's "Immigration" Policy*, Disruptive Competition (DisCo) Project (Sept. 9, 2014), http://www.project-disco.org/intellectual-property/090914-ips-immigration-policy/; Matt Schruers, *IP's "Immigration" Policy, Part 2*, Disruptive Competition (DisCo) Project (Sept. 18, 2014), http://www.project-disco.org/intellectual-property/091814-ips-immigration-policy-part-2/.

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Accelerating the next technology revolution.

1. The Strategy should explicitly consider revolutionary, as opposed to evolutionary, technology objectives. The SEMATECH consortium approach is to identify and invest in game-changing, disruptive technologies that span several disciplines. Innovative ideas can spawn entire new industries, built on robust R&D and a strong manufacturing base. The adoption of disruptive technologies allows companies to leapfrog existing industry solutions, open up new markets, and create new revenue opportunities. Moreover, the rapid adoption of disruptive technologies levels the playing field, changes the competitive landscape, and strengthens the innovation ecosystem, removing cost barriers and providing the U.S. with a competitive advantage in a global marketplace.

2. The SEMATECH experience has reaffirmed that we as a nation can benefit from an ambitious national strategy to drive broad collaboration at sufficient scale to create technology roadmaps and standards; build R&D and manufacturing infrastructure; reduce cost and improve efficiency across the supply chain; conduct both collaborative and proprietary technology programs; and provide access to pilot facilities to demonstrate innovations at manufacturing scale. In our view, public-private initiatives – that focus on investments that are too large for any single company or organization, and too long-term for companies that need to demonstrate quarterly results – are critical for the United States. In addition to leveraging our country's strong universities and venture capital system, we as a nation must nurture disruptive technology development and robust manufacturing, if we are to build the infrastructure for sustainable growth and leadership in the global economy.
Being **industry-led** and member driven ensures that consortia activities are responsive to industry needs. SEMATECH is a **global** organization, protecting national interests and IP while collaborating globally in areas such as environmental health and safety (EHS), quality/reliability, and the need for common roadmaps, critical materials and equipment sets. Bridging research and commercialization means providing members with the means to prove new technologies and processes **at scale**. The scale is what unambiguously differentiates industry-led consortia such as SEMATECH from that of universities and federal labs. Members cooperatively fund and conduct projects to fill key gaps in the R&D/manufacturing infrastructure, thus **enabling manufacturing and supporting the supply chain**. Given that the American taxpayer still funds the bulk of the underlying research, these activities return a significant ROI: in terms of generating revenue and high-value jobs, attracting companies to form a virtuous cycle of innovation-driven economic development, and thus enabling taxpayer-funded research to be commercialized in the United States.

6. Tooling costs at the leading edge of capital-intensive industries are increasingly beyond the reach of small- and medium-sized manufacturers. A new model is not needed to address this challenge, but new platforms using the proven industry led consortium model model pioneered by SEMATECH will be essential to support the growth of these companies. By way of example, SEMATECH has helped top tier equipment suppliers adapt their equipment to new applications including low resistance contacts and conformal doping for advanced device manufacturing. Similarly, SEMATECH has helped startup companies develop industry standard tools for high-k metal gate passivation on several generations of leading-edge semiconductor devices..

7. The ability to produce highly specialized custom products can drive manufacturing back to the United States. Recognizing this potential, the Administration has made significant investments in additive manufacturing capabilities. A similar opportunity exists in customizable electronics. Developing the necessary tools will require hundreds of millions of dollars, but this investment will enable entirely new opportunities for commercial as well as military products. For the military, low cost secure source customizable electronics means access to leading edge technology even at low production volumes.

9. As a general direction of scaling nanotechnology to manufacturing scale, the emerging area of nanomanufacturing can enable several nano-industries. Among the most fundamental enablers and needs for nanomanufacturing are tools and metrology equipment for detecting, identifying, and characterizing nanomaterials to accommodate a range of nanoscale materials standards. For example, nanodefect characterization is essential for gauging the impact of nanodefects on product performance and reliability and is required for developing mitigation solutions. This need is widespread and critical. Few vendors have the ability to measure or characterize their products or materials at the nanoscale, as the costs of the instrumentation and expertise put these crucial steps out of reach for most small- and medium-sized manufacturers. Understanding and managing yield of materials driven by the physics of sub-20nm particles in terms of their dynamics, formation, detection, and removal requires characterization capabilities that are simply beyond the capacity of most manufacturers.
Other technical challenges include:

- Deposition equipment, processes, and manufacturing protocols for industrial scale-up of these nanomaterials (ESH, factory integration of nanomaterials, etc.).
- Establishing a suite of testing equipment to validate reliability at the nano-level.
- New packing designs and materials development, especially for harsh environments
- Preparing existing technology manufacturing sites such as Si fabs to manage cross-contamination and environmental health and safety risks, much like SEMATECH developed fab protocols to manage Cu, and now III-V in a Si fab. For example, SEMATECH prepared top equipment suppliers such as TEL, AMAT, DNS, and KLA-Tencor for the impending introduction of III-V on Si in300 mm Si fabs and developed processes and risk management techniques to enable them to become process of record. In addition, SEMATECH has been the key interface with the Semiconductor Industry Association and the Environmental Protection Agency to address greenhouse gases produced in etch processes.

10, 16. Increasingly, manufacturing yield control metrology and inspection capabilities are not keeping pace with other manufacturing practices. The ability to control processes at the atomic scale has developed more rapidly than the standards and metrology required to demonstrate manufacturability. SEMATECH has a longstanding partnership with NIST to advance our understanding in this area, but much more is needed to keep pace with high value industries and maintain global competitive advantage. The Strategy should recognize the critical role metrology plays in enabling new products and new industries.

17. Broadly speaking, success is driven by manufacturing know-how that translates advances in research into the goods and services that yield economic growth. The United States continues to have some of the world's premier research centers but has continued to struggle with bridging the "valley of death". There are several factors contributing to this "valley of death". For example, there is often a gap between researchers working in universities (where a great deal of U.S. research on nanotechnology is performed) and the industries that could benefit from this research. This research may not be informed by or connected to the back-end of the innovation process, which involves the knowledge, skills, and assets of the private sector. As technology moves from universities to industry, this time and readiness gap for application raises costs and extends the time it takes to commercialize new technologies. Cost competitiveness and time-to-market are increasingly more critical factors in business decision-making and ROI. These time and cost factors are critical and may require more systematic approaches to university research-industry collaboration. In addition, many of the technologies that emerge from research lack cost and performance validation at the product and manufacturing process prototype stage, as well as for scale-up manufacturing. This performance data is vital for attracting investment and industry commitment to commercialization. In the case of nanoscale sensors, development and commercialization of involves long development cycles, high risk and cost, and the need to move from low yields to high volumes in a time frame compatible with ROI expectations.

18. We believe industrial consortia are the most effective means of achieving the objective of enabling manufacturing scale industrial commons. SEMATECH is often cited as the model for successful public-private partnerships, based on our pioneering of the industrial R&D consortium model and our success in helping the U.S. semiconductor industry regain market share in the face of stiff competition from foreign competitors. SEMATECH is one of the few entities around the world that has continuously accelerated the RD&D timeline and delivered substantial value to its participants on an annual basis. Our experience over that time tells us that the following are required to be successful:

- In any emerging/disruptive technology sector, a U.S. **prototyping capability** is needed to supplement R&D and bridge to manufacturing – that is, a manufacturing development facility (or facilities) that provides researchers and companies with the capability to test and prove out innovative technologies and manufacturing processes, either collaboratively or as part of a proprietary program or fee-for-service arrangement. This service goes well beyond what universities and national labs provide, with capabilities at sufficient scale to provide the data necessary to determine whether to adopt an innovation. A manufacturing development facility provides companies shared access to analytical, metrology, and advanced pilot line equipment required for integrating new materials, developing new equipment, and prototyping new products – services and manufacturing infrastructure not available in a lab environment.
- **Collaboration with, and alignment of, a U.S. supply chain** is needed to provide insight and guidance on the strategic investments required to achieve consortia goals; suppliers' direct engagement in collaborative R&D fosters innovation and accelerates progress toward commercialization. This is what Pisano and Shih have identified as the development of the industrial commons. ("Restoring American Competitiveness", HBR, July-August 2009)
- **An efficient allocator of R&D funding** is required – a consortium model provides a pre-competitive mechanism to bring the industry together, prioritize and narrow technology options, reduce the risks of technology R&D, and maximize return on investment, to assure that funds are driven to productive applied research resulting in the acceleration of advanced manufacturing. It is difficult to evaluate long-term R&D programs, or adapt to rapid changes in technology. In these circumstances, the informed judgment of a combined cross-functional team of experts in a consortium is a better method of allocating R&D funding than a simple analytical model based on arbitrary assumptions when data or even reasonable estimates do not exist.
- **A bridge between innovative research and funding/commercialization** (e.g., across the Valley of Death) is needed, through a consortium model that spreads benefits/risk across all stakeholders, working with universities and national centers to pull critical research into the industry mainstream,

working with industry to reduce costs/risks and accelerate precompetitive technology and process development, and working with government to realize the potential for economic benefit and job creation.

- **Building and sustaining links to international partners** is required. Industries are global; U.S. firms rely on global suppliers and have operations abroad, while many international firms make significant contributions to the development of U.S. innovation and manufacturing. While protecting our national interests and building our national technology and manufacturing capabilities, there are areas where international collaboration makes sense. To develop solutions that will be globally competitive, a consortium must have engagement with the global supply chain, especially in areas such as establishing common roadmaps, and providing access to critical materials and equipment sets. In particular, the issues of Environment, Health and Safety (EHS), standards, and quality/reliability are ones in which we all have a vested interest in establishing and maintaining a baseline standard. Ultimately, we have the know-how and methodologies to collaborate globally, while protecting national interests and protecting IP.
- The organization's success or failure rests on the integrity of the **intellectual property management**. A consortium must have an effective structure and methodology allowing collaborative, pre-competitive work while maintaining the integrity of the contribution of consortium members' IP and enabling the continuation into the competitive phase.
- A consortium is a collaborative effort that **leverages resources**; by combining both public and private resources, the consortium can expand the scope of its programs, investigate multiple technology options, and produce higher quality solutions, thereby multiplying many times over the undertaking that any single entity could afford.
- At the same time, the consortium must have a glide path to **financial sustainability**. We believe the membership model that draws member companies from all along the supply chain is critical to ensure that the consortium remains responsive to industry needs.
- A successful consortium must have the **trust and confidence** of the federal government, private corporations, and researchers/idea generators to provide the framework for, and realize the benefits of, our next generation of innovation-driven manufacturing. Trust and confidence comes from experience; the SEMATECH model has evolved with proven success in fostering technology innovation, reducing the costs of R&D, enabling advanced manufacturing, and creating high wage jobs and is respected worldwide.

SIA SEMICONDUCTOR INDUSTRY ASSOCIATION

Comments of the
Semiconductor Industry Association (SIA)
On
The Strategy for American Innovation
September 23, 2014
Submitted by email to: innovationstrategy@ostp.gov

The Semiconductor Industry Association (SIA) appreciates the opportunity to submit comments in response to the Request for Information from the Office of Science and Technology Policy (OSTP) and the National Economic Council regarding the White House Strategy for American Innovation.

SIA is the voice of the U.S. semiconductor industry, one of America's top export industries and a key driver of America's economic strength, national security and global competitiveness. Semiconductors – microchips that control all modern electronics – enable the systems and products that we use to work, communicate, travel, entertain, harness energy, treat illness, and make new scientific discoveries. The semiconductor industry directly employs nearly a quarter of a million people in the United States. In 2013, U.S. semiconductor company sales totaled $155 billion, and semiconductors make the global trillion dollar electronics industry possible.

No industry has a greater reliance on and commitment to the future of American innovation than the U.S. semiconductor industry. Semiconductors were invented in America, and the U.S. still leads the world in cutting-edge manufacturing and design. One of the principal benchmarks by which the semiconductor industry measures its technological advancements is Moore's Law, which states that the number of transistors on a semiconductor doubles every 18 to 24 months. Thirty years ago, an advanced semiconductor had about 100,000 transistors. Today, microprocessors that operate in the 5 GHz range are about one thousand times faster and have more than a billion transistors. As a result of Moore's Law, the price of end products like PCs and smart phones decreases while performance increases.

In the semiconductor industry and across the broader tech sector, Moore's Law and other innovations are made possible through the hard work and ingenuity of tech workers and smart public policy from the federal government. At SIA, a common theme of the initiatives we support – policies to drive innovation, research programs of our affiliated organizations, etc. – is that all of them are intended to maintain and accelerate technological advancements. The federal government plays a vital role in furthering these initiatives.

To help remove barriers to innovation and ensure America's continued technology leadership, policymakers should take action on the following five initiatives:

1. **Support federal funding for university research.** If there's one thing history has taught us, it's that nothing can stop the forward march of innovation. But one thing that can slow it down is a failure to invest in research, the lifeblood of innovation. Funding for basic scientific research has enabled some of the most revolutionary inventions of the last 60 years, including the Internet, the Global Positioning System (GPS), the laser, and the large-scale integrated circuit. These technologies haven't just improved our everyday lives; they have helped build a healthier, cleaner, stronger America.

Unfortunately, U.S. investments in R&D as a share of GDP have decreased in recent decades. For example, the percentage of U.S. gross domestic expenditures on R&D funded by the government declined from 47.1% in 1981 to 33.4% in 2011. Furthermore, over the last 10 years, R&D expenditures as a share of economic output have remained nearly constant in the U.S., but have increased by nearly 50% in South Korea and nearly 90% in China. Policymakers should reverse this trend by supporting funding for basic scientific research programs at federal agencies such as the National Science Foundation (NSF), the National Institute of Standards and Technology (NIST), the Defense Advanced Research Projects Agency (DARPA), and the Department of Energy (DOE) Office of Science.

2. **Strengthen America's technology workforce.** For too long, America's outdated and ineffective immigration system has been a barrier to innovation, forcing highly educated immigrants – many of whom have advanced degrees in the STEM fields from America's top universities – to leave the U.S. because they are unable to obtain visas. This system undermines America's economic strength and global competitiveness by preventing U.S. companies from recruiting and retaining the world's best innovators. Indeed, many of these highly skilled workers move abroad and work for competitors of American companies.

Policymakers should reform the high-skilled immigration system to create American jobs and boost U.S. competiveness. With U.S. businesses' increasingly urgent need for access to the world's top talent, and burgeoning competition from competitors abroad, the time for action on immigration is now. In the absence of congressional action on comprehensive immigration reform, the President should take executive action to address some of the problems with our green card system.

3. **Facilitate open markets.** As the semiconductor industry continues to expand to new areas across the globe, it has never been more important to promote free and open international trade. SIA continues to work to achieve broad duty-free coverage of advanced semiconductor technologies in the updated Information Technology Agreement (ITA). In the pending

negotiations on the Trans-Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP), the U.S. should advance strong protections for trade secrets and strong encryption language that commits signatories to not restrict the import, use, and sale of products containing encryption for the commercial market.

4. **Reform the corporate tax system.** America's tax structure lags behind many other countries' systems, blocking possible pathways to innovation in the U.S. A more competitive tax structure would grow investments, create jobs, and spur economic growth. To level the playing field, policymakers should 1) reduce the corporate tax rate to align more closely with globally competitive rates; 2) adopt a territorial tax system similar to those used by most global competitors; and 3) enact permanent, robust incentives for research and innovation competitive with other countries. As a first step, the Congress must extend (and strengthen) the R&D tax credit that lapsed last year.

5. **Safeguard intellectual property.** Intellectual property is the lifeblood of the U.S. semiconductor industry. Semiconductor companies invest on average 22 percent of revenues for research and development, the highest percentage of any industrial sector. This investment results in trade secrets and patents (semiconductor companies comprise 6 of the top 15 patent recipients), and this valuable IP is a key factor in our industry's continued success. Domestically, the U.S. should work to strengthen the protection of trade secrets and implement balanced reforms to minimize abusive patent litigation practices. Globally, the U.S. should insist on strong protections for IP in trade deals.

In today's world, innovation can occur anywhere, from New York to New Delhi, and competition for technology leadership is fierce. Other nations are implementing aggressive policy incentives to bring the semiconductor industry to their shores. To maintain our global technology leadership, America must rise to this challenge by enacting policies that invest in growth opportunities and remove barriers to innovation.

SIOP | SOCIETY for INDUSTRIAL and ORGANIZATIONAL PSYCHOLOGY

SCIENCE FOR A SMARTER WORKPLACE

September 23, 2014

Society for Industrial and Organizational Psychology Response to *Strategy for American Innovation*

The Society for Industrial and Organizational Psychology (SIOP) supports the Administration's effort to solicit stakeholder input to update the *Strategy for American Innovation* and thanks the Office of Science and Technology Policy (OSTP) and National Economic Council (NEC) for the opportunity to comment. SIOP represents a community of more than 8,000 members worldwide with a common interest in enhancing human well-being and performance in organizational and work settings through the science, practice, and teaching of industrial and organizational (I-O) psychology.

In response to OSTP and NEC's overarching question as to which policies or initiatives should be considered in the next version of the *Strategy for American Innovation*, SIOP recommends the Administration include an I-O psychology expert in economic and innovation policy-making and evaluation teams, cross-government and inter-agency. SIOP also strongly encourages the Administration to adopt I-O psychology evidence-based models and practices in federal decision- and policy-making processes, as they relate to fostering innovation, economic growth, and workforce development.

Including I-O psychology considerations in the forthcoming update of the *Strategy for American Innovation* would leverage a unique science readily applied to the development of high performing teams, workforce training and retention, mentoring, employee engagement and satisfaction, cognitive and personality testing, and other talent management initiatives. For example, the *Journal of Applied* Psychology published I-O research on the impact of leadership on innovation. The article demonstrates certain types of leaders are more successful at fostering innovation in their research and development teams because their approach to leadership cultivates a positive climate for innovation.[1]

The current *Strategy for American Innovation* emphasizes the importance of cross-sector collaboration to foster long-term economic growth and increased productivity, leveraging the diverse experiences and strengths of scientists, researchers, entrepreneurs, government officials, and others. To effectively capitalize on these skills and strengths, the I-O psychology perspective must be included in the federal policies and programs that support these efforts. I-O psychologists have developed data-driven methods to measure and evaluate individual and program performance, select appropriate team members, develop executive leadership, and overcome economic and workforce challenges. For the Administration to wholly address American innovation and foster national economic growth, it is necessary to include the psychological science perspective—the human element—in the economic equation.

Thank you for the opportunity to respond to the *Strategy for American Innovation*. The Society appreciates OSTP and NEC's consideration of these comments, and we hope to serve as a resource to the Administration in the development and implementation of the updated strategy.

[1] Chen, G., Frah, Jiing-Lih., Campbell-Bush, E.M., and Wu, Zhiming. (2013). Teams as Innovative Systems: Multilevel Motivational Antecedents of Innovation in R&D Teams. *Journal of Applied Psychology, 98.6, 1018-1027.*

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STC's Responses to the White House Strategy on American Innovation RFI

Prepared by: Society of Technical Communication Board Members Charles Fisher, Kit Brown-Hoekstra, Deanne Levander, and Jane Wilson

The Society for Technical Communication (STC, www.stc.org) is pleased to provide the following responses to the White House Strategy on American Innovation RFI. These responses were prepared by the STC Board of Directors and the Executive Director.

STC is the world's largest and oldest professional association dedicated to the advancement of the field of technical communication. The Society's members span the field of the technical communication profession and reach across every industry and continent.

After reviewing the RFI, STC has determined that questions 11 through 14 are areas in which technical communication skills can help advance American innovation.

Science, Technology, and R&D Priorities, question 11: Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

Technical communication professionals focus their careers on the ability to curate and clearly communicate technical information to those who must make use of the information, and in this case, reproduce the study. STC believes that the Federal Government has significant leverage to influence issues related to the inability to reproduce scientific findings. Some specific, actionable requirements to address these issues are as follows:

- Increase funding to STEM education programs to include courses in technical communication.
- Evaluate samples of lab reports and other documents during the RFP process when funding research efforts to ensure demonstrated competency in technical communication.
- Establish evaluation criteria to measure the reproducibility of scientific research, and make future funding conditional on the ability of research organizations to publish findings that are reproducible.
- Require research organizations to include an experienced or certified technical communicator as part of the research team.

Skilled Workforce Development, question 12: What novel mechanisms or models might facilitate matching skilled STEM workers with employers and helping individuals identify what additional skills they may need to transition successfully to new roles?

STC believes involvement in relevant STEM professional associations can help STEM workers and employers network and identify required skills. These associations can develop career paths to identify and help STEM workers acquire these skills. Professional associations can also provide mentoring opportunities to STEM workers. These associations can also partner with colleges and universities to drive needed changes to curriculum, or offer learning opportunities such as workshops, conferences, and training courses.

Many STEM-related associations, such as IEEE and AMA require their members to take CE credits to maintain their professional credentials. These associations could leverage CE initiatives by partnering with STC to provide courses in technical communication, and could require a certain number of credits in technical communication. For example, programs such as the STC's Technical Communication 101 for Engineers certificate program can help engineers acquire relevant technical communication skills to better prepare them for roles that require effective articulation and communication of technical information.

Skilled Workforce Development, question 13: What emerging areas of skills are needed in order to keep pace with emerging innovations or technologies? What are successful models for training workers with these skills to keep up with emerging innovations?

To keep up with new and emerging innovations and technologies, STC believes that STEM workers need to develop skills in effectively analyzing, curating, organizing, and presenting information. These communication skills are critical for STEM workers because of the complex nature of the subject matter in these fields. In order for others to understand a new scientific or technical breakthrough, it must be communicated in a way that others can understand it.

STEM workers must also develop critical thinking skills to not only understand new technologies, but also to evaluate their impact on existing technologies and business practices.

Professional associations and higher education institutions can partner with each other to help STEM workers keep up with emerging innovations and understand their impact. For example, STC partners with the Institute of Electrical and Electronics Engineers (IEEE) to develop standards for communicating technical information in the engineering profession.

Skilled Workforce Development, question 14: What mechanisms or programs can effectively increase the supply of workers with technical training, from industry-recognized credentials and postsecondary certificates to two- and four-year degrees?

Professional associations, such as STC, can work with higher education institutions to incorporate technical communication skills as part of a core competency in STEM areas of study. Unlike general writing and communication courses, which emphasize expository writing skills, technical communication courses emphasize the skills required to clearly communicate technical information to a specific audience so that it can be easily understood and used. Technical communication programs specifically prepare students for careers involving scientific, technical, and computer-related communication skills.

Professional licensing and certification organizations can incorporate technical communication competency as part of their credentialing program, or partner with other organizations to provide certification of these skills.

SUCCESS ACADEMY CHARTER SCHOOLS

INPUT FOR UPDATING THE OBAMA ADMINISTRATION'S *STRATEGY FOR AMERICAN INNOVATION*

September 2014

A top priority for the Administration must continue to be reforming public education so that all children have access to a world-class education, especially in the fields of Science, Technology, Engineering, and Mathematics (STEM).

As a nation, our ability to thrive in the globalized economy depends on whether we are able to develop a highly educated workforce that can innovate. However, the United States currently lags far behind many countries in preparing the next generation for the future. On the most recent international PISA exams, more than 30 countries outperformed the United States in math, and the United States ranked 20th in science.[1] Only 9% of American students were top scorers in math, compared to 55% in Shanghai and 31% in Korea.[2]

Yet, unlike so many challenges faced by the United States, educating children at extraordinarily high levels is not a problem without a solution. We know what works. There are far too few great schools, but models of rigorous learning and engagement are emerging as proof points, even in communities that have been traditionally disadvantaged.

The 32 public charter schools operated by Success Academy Charter Schools in New York City serve as one such example of what is possible. Among other signature features, our curriculum includes science five days per week beginning in kindergarten, during which students (whom we call scholars) perform over 100 experiments – laying the foundation for a strong understanding of and passion for science. In middle school, scholars take two years of computer science, and many scholars choose robotics as an elective. About 30% of middle school scholars are on the math team and compete internationally in the Math Olympiad. By high school, scholars can pursue a STEM-track program, with courses in applied science, engineering, and advanced math, culminating in a related internship and senior thesis. Together, these and other experiences comprise a joyfully rigorous education – one that equips public school children with the skills they need to help usher in a new era of American leadership in STEM fields.

The results speak for themselves: on the 2014 state exams, among all New York public schools, Success Academy schools scored in the top 1% in Mathematics and top 3% in English Language Arts. The state science exam is administered in fourth and eighth grades, and all of our fourth and eighth graders passed the science test in 2014, with 99% receiving the highest possible score.

These outcomes are particularly significant because of the students who earn them. About three out of four Success Academy scholars qualify for Free or Reduced Price Lunch, and 94% are minorities. These low-income, minority children are not only closing the achievement gap in New York, they are reversing it. On the 2014 state exams, for example, nearly all of our African American and Hispanic scholars (94% and 96% respectively) passed the Mathematics exam, compared to 56% of white students at New York City district schools. These scholars demonstrate that every child has the potential to excel in STEM if provided a world-class education.

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[1] OECD, PISA 2012 Results, *Snapshot of performance in mathematics, reading, and science, available at* http://www.oecd.org/pisa/keyfindings/PISA-2012-results-snapshot-Volume-I-ENG.pdf (last visited July 22, 2014).
[2] *Id.*

Now more than ever, the Administration should incentivize the creation and rapid growth of world-class public schools, particularly among traditionally disadvantaged populations. In New York State alone, about three quarters of a million students did not pass the 2014 state Mathematics and English Language Arts exams.[3] This failure is especially acute in the 351 elementary and middle schools in New York where the average passage rate on the 2014 state Mathematics and English Language Arts exams was 10% or less.[4] The majority of local public elementary and middle schools in Rochester (75%), Syracuse (67%), and Buffalo (53%) are failing at least 90% of the children they educate.[5]

Given the troubling current state of K-12 public education, the Administration should focus on ways to incentivize rapid growth of high-performing schools – particularly those focused on STEM – in its next iteration of its *Strategy for American Innovation*. As part of this priority, the Administration should seek ways to support quality public charter schools that have strong track records of academic achievement. Freed from bureaucratic obstacles, charter schools are themselves incubators for innovation, discovering new and more effective ways to help students master the skills and content needed to thrive in the 21st century. In turn, their highly educated graduates are and will continue to be among the best positioned to help the United States innovate its way into the future.

Specific recommendations for the update to the *Strategy for American Innovation* include urging Congress to scale the practices of high-performing schools and better meet the deep need for quality education by:

- Providing greater funds to the US Department of Education's Charter Schools Program competition for the replication and expansion of high-performing charter management organizations.
- Reauthorizing the Higher Education Act and Elementary and Secondary Education Act in ways that incentivize high performance in K-12 public education, acting upon input from schools that are already helping students achieve at extraordinary levels.
- Investing in high-performing teacher preparation and support programs, especially in STEM fields, that focus on rigorous clinical experience and whose public funding is tied largely to academic outcomes of the students whom their graduates teach. Congress and the Administration should also help address teacher shortages by incentivizing states to reform teacher certification rules by tying continued certification to student outcomes and by offering broad certification exemptions for teachers receiving training at high-performing schools.

In sum, we cannot prosper without innovation, and we cannot innovate without education. It is possible to provide children – no matter their circumstance or background – with the skills and training necessary to fill our jobs and fuel our economy, to become our greatest resource, and to realize their own dreams. But we must act with urgency. Global competition is becoming stronger and moving with greater velocity than ever before. Education needs to move as rapidly and dramatically as the rest of our economy. To ensure that education keeps up with the globalized economy, we urge the Obama Administration to include in the updated *Strategy for American Innovation* ways to incentivize great public schools to grow and help all children fulfill their potential.

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[3] New York State Education Department, *Release of Data*, Aug. 14, 2014, *available at* http://www.p12.nysed.gov/irs/pressRelease/20140814/home.html (last visited Sept. 17, 2014). Data excludes schools where less than 50 students took the state exams.
[4] *Id.*
[5] *Id.*

techvision21

TechVision21 Submission to Request for Information on Strategy for American Innovation

September 23, 2014

- Kelly Carnes, President and CEO, TechVision21; former Assistant Secretary of Commerce for Technology Policy
- Carol Ann Meares, Vice President, Techvision21; former Senior Policy Analyst, Office of Technology Policy and former Technical Information Specialist, Office of Productivity, Technology, and Innovation, U.S. Department of Commerce
- Anita Balachandra, Vice President, TechVision21; former Senior Policy Analyst, Office of Technology Policy, U.S. Department of Commerce

(1) The Federal government should add a new dimension to its focus on innovation: policies that facilitate innovation-driven reorganization of the economy. The process of growth and productivity through innovation and technology involves three broad stages: 1) inventing/ conceiving new technologies, products, and services arising from the creation and synthesis of new knowledge and R&D; 2) commercialization, supported by investment, design, prototyping testing, fabrication, etc.; and 3) technology and innovation-driven reorganization of the economy driven by user applications, competitors entering the market, ancillaries building new products/services around the innovation fostering new business formation and industry establishment, capital and labor reallocation, new skill acquisition, development of new industrial commons, new regulation and policy formation, etc. Reorganization can take place at many levels of the economy. For example, digital technology has driven reorganization of the economy at every level—from the way work is organized to industry structure in the United States. Even smaller innovations can drive reorganization of the economy at some level.

The Federal government has paid greatest attention to the first stage of innovation (i.e., science policy, R&D investment, etc.), and some attention to the commercialization stage (i.e., tech transfer, technology demonstrations, NNMI, etc.), though much more attention is needed. The least amount of attention is paid to reorganization, even though this stage generates the greatest value in terms of jobs, growth, productivity, and wealth creation.

High levels of innovation-driven reorganization of the economy are expected as biotech and nanotechnology come to full flower, and the digital revolution continues to be transformative, for example, with Big Data and the Internet of Things. Personalized medicine is another example with the potential to drive significant reorganization. As technological change accelerates and technical capabilities increase among competitors around the world, it is vital that innovation-driven reorganization occur more quickly and efficiently in the United States.

Areas of concern include: new business formation, capital allocation, regulation, standards, worker displacement, labor mobility, rapid skill acquisition, new equipment acquisition, new business models, etc. Legal, regulatory, and policy infrastructure often favors/focuses on mature industries and traditional/incumbent products and producers, and Federal policy should provide more on-ramps and opportunity for new entrants.

The 1993 Clinton Administration *National Information Infrastructure Initiative and Agenda for Action* is a good example of government anticipating and envisioning a technology-driven reorganization of the economy. It described the potential of a new information infrastructure, defined its scope, suggested how it may change the economy, and committed to a range of government regulatory, tax, research investment, and other policies to speed development, deployment, and integration of information infrastructure across the United States.

(2) The current historic low level of new business start-ups—the lowest point on record for new firm births—and young firms' declining prominence in the economy is a significant red flag. Small firms have higher rates of patenting than large firms, more technologically important patents, they often specialize in high-tech and high growth industries, and new firms have been responsible for all net new jobs in the past decade. This falling rating of new business formation signals a less dynamic economy and less robust creative-destruction, a burden on technology- and innovation-driven economic growth, entrepreneurship, and job creation. Government should seek to understand if and how it is contributing to this trend—be it taxes, regulation, or policy uncertainty—and seek to mitigate negative impact on business start-ups.

Also important is addressing the challenges such firms face in moving from the start-up phase to production and then through developing successive generations of their products. In many industries, R&D costs are beyond the reach of smaller firms, which can significantly limit the growth of these firms. Industrial consortia can play an important role, making this critical infrastructure–expensive tools and metrology expertise—available to firms who wouldn't be able to afford it individually. Helping more companies navigate this stage of growth is a significant opportunity for the Nation, as it generates jobs and return on the investment in the underlying research—which is often publicly funded.

(4) For decades, the Federal government had an organization in the Department of Commerce charged with examining and promoting policies and other initiatives to enhance U.S. innovation and competitiveness, for example, the Office of Productivity, Technology, and Innovation; and later the Office of Technology Policy within the Technology Administration. These organizations analyzed factors affecting innovation and competitiveness, and developed and promoted policies and new models such as the National Cooperative Research Act, the Federal Technology Transfer Act, industrial consortia, etc. This crosscutting analytical capability has been completely lost. Mission agencies—such as those focused on science or trade—do not have this integrated view. This capacity should be reestablished in government. In addition, arising from the growing pool of micro-data, an increasing number of economic studies examine the effects of factors and policies on innovation and competitiveness. However, authors of these studies typically do not translate their findings into the policy and program arena, where they could provide insight for innovation- and competitiveness-related policy development and evaluation. An organization, with the capacity described above, could play a role in applying this new body of knowledge to policy-making and program initiatives.

(6) Innovation has become more inter- and multidisciplinary, and many of the challenges that government seeks to address through investment in R&D are also multidisciplinary in nature. Yet, the Federal civilian R&D portfolio remains dominated by smallish, narrow, principal investigator-driven projects that lack the scale and scope required to drive multidisciplinary innovation or address large challenges. For example, of NSF's $5.8 billion in R&D investment, just $267 million—4.6%—is invested in its centers program (FY 2014), which NSF characterizes as its principal means to foster interdisciplinary research. The Federal government should invest in more multidisciplinary and/or challenge-driven projects. These would bring together diverse knowledge and skills, allow for systems integration, enable cost-performance trade-offs, enable design and manufacturing considerations, etc. Such projects could also link to other key actors to facilitate the innovation process such as industry, financiers, and related policy makers.

As the costs for some critical areas of new technology development have escalated, and their complexity increased, industrial consortia remain a key model for addressing challenges beyond the scope and capabilities of a single firm, for bringing diverse technical capabilities into projects where systems are needed, and for building technical capability across an entire industry.

(7) Nanotechnology is moving from "science" to application and manufacturing. However, industry needs tools and metrology to identify and characterize defects in nanotechnology-based materials and products, and to ensure quality control in manufacturing. Lack of these tools and metrology could present significant barriers to U.S. nano-manufacturing. It is unlikely that a full range of these tools, metrology, etc. would be developed by the private sector. The Federal government could play a key role in supporting their development, or stimulating formation of consortia or public-private partnerships to develop them. In addition, small firms may lack the financial resources to test and validate new nano-based materials and products (generating the cost and performance data needed for commercial financing), and initiate scale manufacturing. The government should consider how the NNMI could support this stage of nano-commercialization, and generally, should begin to shift some of its investments into the programs addressing the "valley of death".

(8) The structure of the U.S. R&D enterprise has inherent barriers to rapid technological development and commercialization. The separation of researchers in universities, and users in industry necessitates a culture of technology push, greater costs to innovate as industry must make investments to bring academic research to commercial readiness, and lengthens the time it takes to commercialize innovations due to this technology transfer time gap. This is a major contributor to the "Valley of Death." Models of Federal research funding that help close this gap could improve the rate and speed of U.S. innovation, for example, requiring more Federally-supported R&D projects to involve industry partners, adding points in scoring grant proposals that include industry, or better integration of the back end of the innovation process (financing, industry expertise, and manufacturing considerations) earlier in the process. Industry's perception of the value of academic R&D, or challenges of accessing it for commercial use, may be reflected in the fact that, of industry's $285 billion R&D investment, it spends just 1.1% for R&D at universities and colleges.

(9) There is growing interest in encouraging more people to participate in the innovation process through collaborative tools and crowding sourcing. DARPA's Adaptive Vehicle Make is a prime example. There appears to be latent innovative and entrepreneurial potential in the U.S. population, for example, as demonstrated by the growing Maker Movement. It also appears that firms are interested in open innovation and crowd sourcing, for example, in initiatives such as P&G's Connect+Develop, Innocentive, Ninesigma, Tongal, etc. Given the need to move the United States to an "innovation-based" economy, the Federal government could foster development of platforms and tools for open innovation, crowd-sourced innovation, collaborative creativity, and to connect problem solvers with solution seekers.

(10) Government has sought to bring discipline and oversight to the management of its R&D portfolio, for example, by bringing cutting-edge knowledge from experts into the policy making environment through advisory bodies, workshops with business and academic experts, peer reviews, proposal review panels, etc. However, R&D plans may be captive to those who attend meetings or participate in planning processes, and ideas not represented overlooked; hewing too closely to roadmaps and multi-year R&D plans may exclude new or different ideas; there may be a lack of timely means to incorporate new entrants or technical directions; annual program peer reviews do not address ideas outside the pool of current grant recipients or lab researchers; and many Federal competitive grant solicitations are written narrowly to conform to the goals and technical pathways articulated by the agency or R&D program plans, excluding other promising solutions from consideration.

Academic researchers tend to have a bias toward conventional thinking and incremental advancement, and bias against: breakthrough or radical, game-changing discoveries, technologies, and solutions; high-risk, high-reward projects; and commercially oriented projects. However subtle, a bias toward conventional wisdom, or against high-risk, high-reward is exacerbated by constrained budgets and the risk aversion inherent to Federal program management. In this environment, safe, incremental projects are attractive. Academic researchers may not be aware of propriety developments or—given the narrow nature of many science and technology disciplines—developments in other fields that may have significant and relevant impact.

In addition, academic and Federal lab researchers are selected for peer-review panels based on extensive credentials and their years of academic research, and are biased toward those with similar qualifications. As a result, they may shun young investigators, or project technical personnel who cut their teeth in industrial work, rather than in academic or Federal labs.

Finally, small innovators have an inherent disadvantage in competing for applied R&D funds. Agencies may seek test and validation data from prototypes and pilot manufacturing that may be too costly for small innovators to accomplish and generate. Moreover, the level of required cost share may be prohibitive for many.

The following are some ideas on how to help ensure new ideas have open pathways for consideration in the Federal R&D investment portfolio, and how to improve the merit review process associated with funding opportunities:

- **Calls for New Work:** When appropriate, R&D funding agencies should signal interest in ideas that have not been in their current scope of work.

- **Set-aside for New Entrants:** Another mechanism to increase diversity among applicants is a set-aside for new entrants; that is, companies or organizations that have not previously received funding under the Federal agency program issuing the funding opportunity announcement.

- **More On Ramps:** As a portfolio of R&D projects matures through a technology pathway and projects are winnowed out (off-ramped) or moved forward based on merit considerations, consider establishing periodic on-ramps to solicit new projects that offer new and promising approaches with substantial technical merit and performance promise.

- **Retain and Expand the DARPA Model:** DARPA casts a broad net when soliciting ideas through its annual Broad Agency Announcements (BAA). BAAs list a diverse range of technical areas for which ideas are sought, and DARPA does not define specific technical approaches. Similarly, ARPA-E's non-restrictive funding opportunities have generated thousands of concept papers, demonstrating that a great deal of innovative energy is focused on developing energy-related technologies. Unrestricted solicitations can provide for broader idea sweeps that would encourage outliers with innovative ideas to come forward with concept papers falling outside restricted calls. Asking initially for an abbreviated concept paper, followed by a more exclusive call for bigger concept papers, and then an even more exclusive call for full proposals could open up the system more.

- **Simplify Proposal Requirements for Smaller Dollar Awards:** In many government grant programs, **t**he amount of work required and the complexity involved in preparing a project proposal is almost the same for a $1-$10 million project, as it is for a $100-$200 million project, when clearly the government risk is not the same. The time and cost burden of responding to the numerous and complex requirements for smaller projects can prevent small innovators from attempting to participate or producing competitive proposals. This burden could be reduced without raising the government risks significantly.

- **Open Architecture Initiatives:** Invest in pilot open architecture initiatives. These initiatives could involve small amounts of initial funding for many promising ideas. This approach could bring new independent players into the R&D system—from garage tinkerers, to corporate and academic researchers—and foster new multidisciplinary collaborations for systems development.

- **Provide an Applicant Feedback Period:** Review panels often find omissions, weaknesses, and technical claims unsubstantiated with data, research, or citations of previous corroborating work and, as a result, score proposals lower than the technical merit warrants. Such deficiencies are, to some degree, products of the: complex nature of developing proposals for government funding opportunities under significant time constraints; inexperienced proposers; and, with respect to small innovators, the financial inability to marshal impressive data and research in support of their proposals. It would be beneficial to offer a cycle of feedback prior to making final award decisions; that is, allow a short period during which proposers can offer additional documentation, and written clarification or rebuttal responding to deficiencies review panels identify. This would help ensure otherwise worthy projects are fairly judged.

- **Raise the Importance of Impact in Merit Review Criteria:** In many government grant programs, project impact is one of numerous sub-criteria under technical merit, which may also include sub-criteria such as a proposer's understanding of work in the field, technical feasibility, and soundness of the proposer's management plan. However, impact is ultimately what the government seeks. Rather than burying impact with other sub-criteria, raise impact from a sub-criterion in technical merit, to a more heavily weighted, independent merit criterion for separate scoring. This could help level the playing field for outliers and grant novices with high-potential projects that might otherwise be buried by other proposals with higher technical novelty, better management plans, or more proposal-writing experience.

Vehicle safety is a promising area for increased government attention. New technology—from new materials to intelligent driver-vehicle interfaces to high performance computing, modeling and simulation—is presenting new ways to enhance vehicle safety. The government could establish a significant partnership initiative with vehicle makers, modeled after the Partnership for a New Generation of Vehicles—to drive developments that would underpin a leapfrog in vehicle safety and crash survivability.

(12) A major contributor to the STEM skills matching problem is the increased level of specialization employers seek in STEM professionals. This requirement for highly specialized skills began in the IT industry, but has spread to other STEM disciplines. For example, employers do not recruit for merely an electrical engineer, but rather one with very specialized skills and experience. There maybe thousands of electrical engineers looking for a new job, yet none would have the requisite skills and experience. This phenomenon can be seen by simply reviewing the descriptions of job openings in corporate recruitment databases. This is a major reason why employers cannot find technical professionals that meet their needs, even though a large pool of technically skilled workers exists, and why STEM workers may find it difficult to secure a job.

Short of a constrained supply of STEM workers in a particular discipline that causes employers to reduce their specialized skill requirements for new hires, or to increase their willingness to hire a partially qualified candidate and provide training, it seems only closer relationships and stronger feedback loops between employers and universities training STEM workers can improve matching. Possible approaches include industry advisory councils to university STEM departments, more or part time instructors from industry, regular university surveys of employer needs, and greater industry involvement in university R&D.

(13) The accelerating rate of technological change is shortening foresight about future technology trends, making it more difficult to forecast future workforce and skill. This creates challenges both in educating and training new STEM workers, and ensuring that incumbent worker skills are kept up to date. In addition, universities are slow to respond to new technical skill needs by establishing new STEM education programs or changing STEM curricula. Closer feedback loops between employers and the education community, and pressure on universities to be more responsive to employer needs, are needed. Possible approaches include industry advisory councils to university STEM departments, more or part time instructors from industry, regular university surveys of employer needs, and greater industry involvement in university R&D. Another approach is to explore ways or new platforms for rapid skills acquisition.

(16) Many investors require a degree of technology readiness before they will invest to bring an emergent technology closer to market. Moving from proof-of-concept to commercial readiness can be an extremely capital-intensive process. Many small innovators do not have the financial resources needed to achieve the higher readiness and lower risk investors require. As a result, many leading-edge technologies languish in the "Valley of Death." Moreover, small innovators need capital to establish their initial manufacturing processes and production capacity. But, funding for pilot manufacturing and scale-up is often out of reach. This is especially challenging for new-to-the-world technologies, when commercial lenders may see increased risks in the absence of historical operating and performance data from commercial applications of the technology.

Government programs to address these problems have been inadequate. They either focus on a narrow set of technologies (i.e., energy or military technologies), available funding is too low, cost sharing requirements are too large, or the program structure—such as loans and loan guarantees—may not be suitable for some small innovators that do not have assets or regular cash flows to service debt.

A C-MANTECH (Civilian Manufacturing Technology) program would provide the crucial link between technology invention and development, and new U.S. manufacturing capacity. C-MANTECH would help small innovators advance their new-to-the-world technologies to readiness for commercialization, transition them to pilot manufacturing, and jumpstart production scale up. C-MANTECH would provide merit-based grants to small innovators with prototypes that could be game changing high-tech products of the future. Grants would support:

- Development and testing of production prototypes to demonstrate and validate product or system costs, performance, and reliability.

- Development and validation of manufacturing processes and pilot production lines to prove and improve manufacturability.

- Scaling manufacturing processes, and establishment of initial manufacturing capacity.

In addition, in support of commercializing new-to-the-world technologies, the Federal government can increase its role as first purchaser.

The Federal government could also consider the use of refundable tax credits to spur investment in scaling manufacturing for new-to-the-world technologies. For pre-revenue firms, such tax credits would help them attract commercial investors to fund upfront costs. Refundable tax credits would not favor a particular industry or technology, but rather be broadly available. There is little risk to the taxpayer as the credit could only be claimed once production capacity was built, operating, and producing corporate revenues.

NIST is positioned to implement a C-MANTECH program. NIST has: world class expertise in a wide range of leading edge technologies; significant experience in evaluating leading edge technologies for their technical feasibility, manufacturability, and economic promise; and MEP centers could help small innovators shape grant proposals, help recipients implement activities supported by the grants, and offer some modeling, equipment, and manufacturing environments that will help grant recipients evaluate design options, develop and validate production prototypes, develop production processes, and establish pilot manufacturing lines.

In addition, traditionally, SBIR project funding ends when a prototype has been developed, at the point when funded is needed for prototype testing and validation, demonstration, and manufacturing scale-up. Data from testing and validation, and demonstration are often needed to attract private financing, the aim of SBIR Phase 3. Given the increases in agency SBIR set asides, reaching 3.2% in FY 2017, significant new program funding will be available. A portion of this funding could be used to support testing and validation, demonstration, and initiating manufacturing scale-up, either through an expanded scope of activities supported in Phase 2, or a new SBIR Phase.

(18) Manufacturing industries are not monolithic, and it is important to understand the diverse drivers of manufacturers' decisions on where they will invest and build production facilities. For example, capital-intensive manufacturing is not particularly sensitive to the relative cost of labor, but often highly sensitive to the cost of energy. With the shale gas boom reducing the cost of energy for industry and the cost of natural gas chemical precursors, chemical companies have made numerous announcements about their intent to invest in new plants and manufacturing capacity in the United States. For the pharmaceutical industry, Federal R&D investment, U.S. regulation, and drug approval processes are critical factors.

Among the most important ways to rebuild U.S. manufacturing is to create a more manufacturing-friendly business environment. The relatively higher U.S. corporate tax rate—compared to the OECD average—is a U.S. disadvantage. The shale gas boom offers a rare opportunity to reduce manufacturing costs in the United States, make U.S. industry more globally competitive, and should be strongly encouraged. A wide array of regulatory reforms, streamlining, and simplification should also be pursued to reduce the cost burden on U.S. manufacturers, especially smaller producers. In addition, government should consider outcome performance-based approaches to regulation, rather than dictating technical approaches.

(19) In addition to regional innovation ecosystems, sectoral initiatives that seek to foster national innovation ecosystems across geographically dispersed industries and their supply chains are important. National consortia that involve industry, suppliers, R&D enterprises, skills developers, and others have proven valuable in building such ecosystems and new technical and innovation capacity across industry.

(20) With the growth of cities and metropolitan areas in the United States and around the world, there is a growing need and market opportunity for a wide range of innovations in infrastructure, sustainable systems, and their components. U.S. cities and metro areas could serve as platforms for research, development, and demonstration of infrastructure innovations—from new materials and sensors, to intelligent highways, to new water systems technologies and modes of transportation. This would encourage growth of "innovation districts" and new global markets for U.S. goods and services, and contribute to the needed modernization and repair of U.S. infrastructure. The Federal government's large investment in infrastructure could play a significant role.

(24) Several trends are converging on U.S. automakers, creating a perfect storm for vehicle innovation—more global competitors who are rapidly advancing their capabilities, greater consumer interest in more fuel-efficient vehicles (although consumers do not want to sacrifice performance, safety, and vehicle amenities for better fuel economy), higher CAFÉ standards and increasing emissions regulation, and prospects for large vehicle markets in emerging economies. A broad spectrum of automotive innovations is on the horizon, for example: the shift from emphasis on mechanical technology to electronic/digital technology; new power train and other technologies such as turbo-charging, intelligent driver-vehicle interfaces, and new materials; and innovations in vehicle architecture such as modularity and open standards that could expand the pool of ideas for automotive innovations.
However, traditionally, U.S. automakers have shunned outside innovation and maintained closed product architectures. This closed system of innovation—coupled with tight vertical integration and top-down OEM-driven product development—inhibits entrepreneurship and entry of new U.S. industry players.

The United States should seek to transform the U.S. auto industry into a hotbed of innovation, with OEMs positioned as nodes in a vibrant and dynamic entrepreneurial innovation ecosystem. More game-changing automotive innovation could be stimulated by:

- Casting a wide net to identify and move new ideas and innovations from outside to inside traditional OEMs;
- Supporting entrepreneurship and innovation along the whole automotive supply chain; and
- Exploiting the growing role of automotive electronics and digital design/development tools to encourage traditional OEMs to adopt more open innovation systems.

A range of initiatives could include:

Dialogue on the "Future of the U.S. Auto Industry." Designed to gather visions and advice to drive a transformation of the U.S. auto industry, this dialogue should include: OEMs and Tier 1 suppliers, entrepreneurial companies with innovative products that are outside the traditional automotive supply chain, advanced materials suppliers, fuels industry, electronics industry, automotive-related service providers, venture capitalists, government and academic experts, regulators, etc. A series of meetings would analyze various industry challenges and issues, identify visions for the future, and make recommendations to achieve those visions. Findings and recommendations generated at the meetings would roll-up into a National Summit to form the best of them into a national agenda.

Develop an **"Open Automotive Systems Innovation Strategy"** (OASIS), and suite of supporting programs to encourage a dramatic increase in entrepreneurship, innovation, and collaboration along the entire automotive supply chain:

- ***ARPA-V (Vehicle):*** Solicit white papers on game-changing vehicle technologies and systems, and provide grants for research, development, and in-vehicle demonstration of the most promising ideas.

- ***Open Automotive Innovation Design and Simulation Centers:*** Provide high performance computing, modeling and simulation, prototyping, and testing services to serve small companies and entrepreneurs with innovative vehicle-related ideas and technologies.

- ***Automotive Innovation Demonstration and Validation:*** Provide support, test-beds, pilot manufacturing lines and equipment, and other services for innovators, entrepreneurs, and small businesses with innovative vehicle technologies to demonstrate and rapidly validate their technologies.

- ***Innovator Matchmaking:*** Provide matchmaking between innovators with promising validated technologies and OEMs.

- ***Open Vehicle Architecture Pilot:*** A pilot program would involve developing pilot vehicle architectures that would accommodate "plug and play" innovations installed by third parties.

Accelerate Commercialization of Automotive Innovations and Build Supporting Manufacturing Capacity and Infrastructure

- **Advanced Vehicle and Component Demonstrations:** A major barrier faced by new industry entrants with innovative vehicle technologies is the need for in-vehicle demonstrations. Costs of building and testing demonstrator vehicles equipped with major new components and systems can top $1 million per vehicle. This program would be limited to new entrants seeking to demonstrate advanced vehicle technologies in small fleets (5-10 vehicles).

- **Advanced Vehicle Manufacturing Grants:** This grant program would be modeled after the recent advanced battery manufacturing initiative, and support the development of **new** manufacturing capacity for highly innovative vehicles, components, and systems that directly and dramatically improve vehicle fuel economy.

- **Automotive "Region of the Future" Showcases**: Bring automotive innovations, and new vehicle-related OEMs and component companies into existing and/or idle factories to stimulate new automotive industry clusters. Support development of these showcases by packaging current government assistance such as: EERE grants, Trade Adjustment Assistance, EDA grants for redeveloping Brownfield sites, Labor Department worker training funds, funds allocated for integrating renewable resources and smart grids to support production facilities, support for automotive engineering programs from the National Science Foundation, etc.

- **Advanced Vehicles and Components Innovation Hub**: Establish multidisciplinary Advanced Vehicles and Components Innovation Hub to rapidly create, validate, and integrate a wide range of automotive innovations. The hub would coordinate teams of experts from multiple fields to blend technology development, engineering, design, economic, regulatory, and policy-related issues needed to accelerate automotive innovation. The hub would:

    - Focus on breakthrough technologies, new concepts, new materials, and new designs, rather than incremental improvements to existing technologies
    - Serve as a focal point in developing skills and expertise needed to support new automotive innovations
    - Serve as an incubator for small automotive innovators and entrepreneurs, and a magnet for risk capital
    - Maintain a strong focus on rapid commercialization, working in parallel with OEMs to validate and optimize innovations for integration into production vehicles
    - Develop highly efficient and flexible production processes for rapid commercialization of innovations, and greater vehicle diversity
    - Work with a wide range of regulators to speed regulatory approval of new automotive-related innovations.

- **Public-Private Research on Accelerating Innovation in Automotive Manufacturing and in**

Auto Companies: Work with key OEMs, Tier 1 suppliers, and new industry entrants to examine management, manufacturing, and engineering strategies/technologies that would enable more rapid integration of new technologies into vehicles, to more rapidly introduce innovations in manufacturing, and to lower the break-even point on production of vehicle platforms to enable OEMs and their suppliers to produce a greater diversity of vehicles cost-competitively.

September 23, 2014

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RE: Response to Request for Information – Input for Upcoming Update of *Strategy for American Innovation*

Dear Ms. Dorgelo, Mr. Galloway and Mr. Correa:

The University City Science Center, a nonprofit organization located in Philadelphia, Pennsylvania, hereby submits this letter in response to the Notice of Request for Information (RFI) issued on July 29, 2014 by the Office of Science and Technology Policy and the National Economic Council.

Background on the Science Center

The University City Science Center is a private, independent, nonprofit research park and technology-based economic development organization serving the Greater Philadelphia region. Our 31 nonprofit shareholders include many of the leading colleges, universities, hospitals and research institutions in Pennsylvania, New Jersey and Delaware. A list of our shareholders is attached to this letter.

Situated in West Philadelphia, adjacent to the University of Pennsylvania and Drexel University, the Science Center is the nation's oldest and largest urban research park. Our campus includes nearly 2.5 million square feet of laboratory, office and medical facilities. The Science Center is a dynamic hub for innovation, entrepreneurship and technology commercialization. For more than 50 years, we have helped scientists, entrepreneurs, startups, and growing and established companies throughout the region as they move their technologies into the marketplace, where they can benefit the region and the world. We accomplish this by offering a steady stream of networking, professional development, and entrepreneurial support programs designed to leverage the rich resources available on our campus and in the region. Since we were founded in 1963, graduate organizations and current residents of the Science Center's Port business incubator have created more than 15,000 direct jobs that remain in the region today.

For additional background about the Science Center, please see our 2014 Annual Review at http://ucsc2014review.org.

Questions Addressed in This Response

This letter will address all of the following questions set forth in the RFI:

(1) What specific policies or initiatives should the Administration consider prioritizing in the next version of the Strategy for American Innovation?

(3) What specific actions can the Federal Government take to build and sustain U.S. strengths including its entrepreneurial culture, flexible labor markets, world-class research universities, strong regional innovation ecosystems, and large share of global venture capital investment?

(15) What new or existing investment models should be explored to support entrepreneurship in new geographies, as well as in technologies and sectors that are capital-intensive, relatively high-risk, and require sustained investment over long periods of time?

(16) For new technologies and products, how might "proof of manufacturability" be gauged sooner, and what entities would most appropriately provide the necessary resources and facilities? What sectors represent the most promising opportunities for the application of such models?

(17) What tools, business model innovations, financial innovations, or other developments hold promise for reducing the cost of starting and scaling a business in capital intensive sectors like the life sciences, advanced materials, and clean energy? What can the Federal Government do to accelerate these trends?

(19) What partnerships or novel models for collaboration between the Federal Government and regions should the Administration consider in order to promote innovation and the development of regional innovation ecosystems?

(20) How should the Federal government promote the development of metropolitan "innovation districts," where large research institutions, companies, start-ups, and business accelerators congregate to facilitate the knowledge flows that sustain innovation?

Response

A. (Questions 1, 3, 15, 16 and 17)

The Federal government should prioritize and encourage the development of multi-institutional regional mechanisms to facilitate and promote R&D and technology commercialization, with the assistance of intermediary technology-based economic development organizations.

The Federal government should encourage academic institutions, corporations, and other research organizations to work together on joint initiatives in R&D and technology commercialization that will allow funding to be more effectively deployed, thereby increasing the likelihood of successful outcomes. These outcomes will include the creation and growth of high-tech companies, high-paying jobs, and high-demand medicines, medical devices and other technologies that, in turn, will fuel economic development in the United States and beyond. Such collaborations can be successfully organized and managed by neutral, intermediary organizations with connectivity to the marketplace. Regional strengths can be emphasized, and appropriate incentives to collaborate and communicate can be provided, in order to foster an environment that facilitates the productive exchange of ideas and technologies.

For its part, the Science Center has developed and currently operates two commercialization programs – QED and Phase 1 Ventures – that leverage the participation of multiple interests in the science and technology sector, including academia, industry, venture capital and other groups. These programs have been recognized by government agencies at all levels, as well as by foundations and other private sector interests, as models for technology commercialization from R&D.

QED Proof-of-Concept Program

Our QED Proof-of-Concept Program – which we established in 2009 as a privately-funded pilot initiative, and subsequently expanded into a public-private partnership with government support – is the nation's first multi-institutional proof-of-concept center (POCC). QED funds early-stage academic research projects in the life sciences and health IT, and helps position them for transfer to the commercial sector. The program – named "QED", after the Latin phrase "*quod erat demonstrandum*" or "proven as demonstrated" – provides funding and business advice for academic researchers throughout the Greater Philadelphia region who are developing early-stage life science technologies with high commercial potential. QED helps promising researchers translate their publicly-funded basic research into privately-funded technology commercialization and product development opportunities. As angel investors, venture capitalists, and established companies increasingly shift their investments to later-stage initiatives, QED fills a critical gap in the innovation pipeline.

Ultimately, the success of the program will be judged according to the metrics of academic technology transfer, including new venture formation, license execution, and outside investment. To date, QED has attracted more than 400 proposals and overseen the development of 67 proof-of-concept plans by scientists at 16 research institutions across the region. A total of 20 projects have been funded; six of them have resulted in licensing events that have generated approximately $12 million in follow-on investment from the private sector.

QED leverages the Science Center's relationships with universities, government agencies, and public and private companies, driving technology transfer and new business formation, advancing entrepreneurship, and encouraging innovation, competitiveness, and knowledge-base retention and expansion. The program's key operating principles are (a) to focus existing regional resources on substantially reducing early-stage business risk, and (b) to evaluate and position early-stage technologies for follow-on investment by established companies and private investors, thereby reducing the proliferation of sub-scale, undercapitalized ventures already in the market.

QED began with 10 participating research institutions; the number has since expanded to 21. Cooperation and competition among the institutions serve to increase the regional technology pool and leverage regional resources more effectively, ultimately maximizing the program's impact. Also, the broad range of institutional participants aligns well with the Science Center's role as a facilitator of the region's dominant "innovation ecosystem" in the life sciences. Although other organizations elsewhere in the country – notably MIT and the University of California at San Diego – offer similar business advisory and funding resources, their reach is limited to projects at the host institution. QED's multi-institutional scope features a diversity of institutional sizes and characteristics within a versatile program model that minimizes administrative overhead. We believe that this model can be readily adapted to other regions in the US.

QED builds upon the Science Center's extensive relationships with research centers, tech transfer offices, entrepreneurs, investors, public and private companies, and economic development organizations in order to address the multiple aspects of commercialization for all projects that enter the program. In particular, third-party scientific and commercial guidance is a critical component of QED. This guidance takes the form of business advice from experienced investors, entrepreneurs and industry representatives; technical and clinical review of technology by outside scientific reviewers; and market-based screening and selection teams that evaluate the projects with a focus on both the potential for follow-on investment and the anticipated market demand for the end-stage product. It is this collaborative and comprehensive approach that sets QED apart. Our intention is to organize and deploy the wealth of scientific, technological, and entrepreneurial talent and resources within our region – which transcend institutional, city, county, and state boundaries – towards a common goal of more efficient and effective technology commercialization.

From a funding/financing standpoint, QED represents a true "public-private partnership." Nearly $2.0 million has been provided by the participating academic institutions themselves, to cover costs incurred by award recipients in connection with funded projects; each research proposal that is selected for funding receives up to $100,000 from the Science Center and a matching $100,000 from the host institution. Additional funding has come in the form of a two-year, $1.0 million grant from the US Economic Development Administration (EDA), plus support from state and local government agencies as well as corporations and foundations.

For all of the foregoing reasons, we believe that QED represents a new paradigm for technology development, in which neutral "commercialization intermediaries" like the Science Center can serve as facilitators. These intermediaries can, uniquely, promote greater collaboration and dialogue among the various stakeholders in the technology transfer process, which are essential to the emergence of successful POCCs that accelerate commercialization into the marketplace. They can also help to align often-mismatched incentives and cultural differences between academia and industry, creating an environment that supports the successful flow of R&D from basic research, through proof-of-concept projects, to product development and technology commercialization. Importantly, the opportunity exists to scale up, expand and/or translate the QED program to other parts of the nation; to other sectors of the technology economy, such as advanced manufacturing, energy and cleantech; to large companies with specific needs no longer supported by their own R&D capabilities; and to Federal laboratories with under-commercialized research output. Organizations – such as the Science Center – that have a proven track record in technology commercialization can be utilized as reference points, in order to develop a national model for efforts to accelerate commercialization.

Phase 1 Ventures

Following the successful launch of QED, in 2014 the Science Center initiated a new multi-institutional commercialization program, Phase 1 Ventures (P1V), a technology accelerator for new business formation and growth. P1V will identify and guide the development of promising new companies around technologies that have moved beyond the initial technical proof-of-concept stage. P1V is a managed and standardized process to launch new companies in a cost-efficient manner, leveraging Federal SBIR/STTR funding. P1V will test the scientific and market feasibility and strength of technologies for new company formation and launch, thereby enhancing the ability of these projects to attract grants and private sector investment. Through P1V, the Science Center will capitalize on and expand its deep relationships with universities and healthcare institutions throughout the tri-state Greater Philadelphia area and beyond, in order to facilitate more (and better) start-up company formation that will ultimately lead to economic growth and job creation. The Science Center will provide resources and support for P1V. Partnering academic institutions will also provide funding and other support.

P1V provides a turnkey approach to the market-driven creation and development of new investible companies around high-priority academic technologies. P1V differs from internal academic "start-up" programs because it is driven by market need and is an independent mechanism that draws from regional business resources; and it differs from traditional seed funding programs because it leverages non-dilutive funding and managed economies of scale to achieve value creation for new companies.

While SBIR/STTR programs were developed for (and have been extraordinarily successful in providing) R&D funding to established start-up companies with independent management teams and existing resources, using SBIR/STTR to launch new companies around inventor-managed projects is more difficult. This is especially true with respect to academic technologies, even though the inventors involved are typically well-positioned to compete for government grants. The primary barrier to launch for a new company built around an academic technology is the need to establish the company and commit resources to it before SBIR/STTR (or other) funding can be secured. Moreover, even when grant funding is secured, inventor-launched companies face several challenges, including the following: (a) "Phase I" SBIR funding (typically $150,000 or less) is not sufficient to cover both the R&D and the incidental expenses of starting a new company; (b) without additional financing, it is difficult to obtain competent independent management with business development and market expertise; (c) consequently, scientist-run companies often end up as part-time endeavors, suffer from conflict-of-interest issues, and risk becoming trapped as "cost centers" in the inventor's academic institution; and (d) to attract funding and expertise, there is often a need for a commercially managed entity, but many high-potential scientific projects are simply too early-stage to justify the creation of a dedicated corporate entity.

What is needed is an independent mechanism that uses commercial insight to identify and guide promising technology opportunities, applies project management independently of (but collaboratively with) academic inventors, and leverages economies of scale to attain efficient resource allocation. The goal of P1V is to create a process – drawing upon the Science Center's expertise, networks, and proven capabilities – that will effectively launch new, investment-ready, high-growth companies in the target region built around academic-based technologies, thereby enhancing technology commercialization and technology transfer at the region's universities, hospitals and other research institutions.

P1V will use SBIR/STTR funding, along with a small-business, SBIR-eligible commercialization partner, to independently "road-test" the market-worthiness of new company concepts across diverse technology sectors. P1V's fundamental premise is to use the intersection of market opportunity and Federal funding competitiveness to target and then transition academic technologies for potential development in new companies. P1V will supplement the capabilities of the researcher-inventors with market intelligence, business guidance, infrastructure, and product development resources, in order to prepare a compelling SBIR or STTR funding proposal. Projects in P1V that are successful in receiving "Phase I" SBIR/STTR funding will be provided with access to more facilities, resources, expertise, and project management; as these projects progress through "Phase II" SBIR/STTR funding, they will graduate as independent new companies with dedicated management that will be able to attract private sector funding.

For projects that obtain SBIR/STTR funding, the P1V program combines the attributes of a start-up company (licensing intellectual property for product development), an investor (making direct investments to supplement public-sector grant funds), an incubator (managing resources for new company development and growth), and a contract research organization (performing strategic research and development in collaboration with the inventor and other partners). Companies that graduate from P1V will be well-positioned for growth because they will have built both sound technologies and robust corporate and management platforms.

P1V is well-suited for projects that need approximately $1 million each (most of which is provided by SBIR/STTR funding, supplemented by direct funding by P1V) to progress toward becoming independent and privately-funded entities. P1V will start with a focus on the life sciences and related manufacturing and digital technologies, but will expand to other sectors including advanced manufacturing, materials, cleantech, energy and digital media. Specific focus areas within these sectors will be determined by funding opportunities.

P1V's principal stakeholders include academic institutions and inventors seeking to license their technologies, entrepreneurs seeking new business opportunities, and industry and investors looking for effective and cost-efficient ways to identify and manage potential new assets. For academic institutions and inventors, P1V offers a new, practical means to test the feasibility of, and develop further, their early-stage technologies and their ability to attract public funding and private investment, while managing institutional conflicts of interest. By involving outside commercial expertise during project selection and planning, P1V provides a means for developing high-quality solutions to market needs and identifying potential future investment or acquisition opportunities. P1V will provide access to strategic funding; independent management, corporate structure and resources that avoid institutional conflicts of interest; proven expertise in early product development and project management; and connections to networks of entrepreneurs, investors, and industry partners. As a public-private partnership, P1V will be economically viable because it will leverage SBIR/STTR funding and aggregate resources that can be shared among several projects, creating economies of scale. As a collaborative platform, P1V will provide greater opportunities for inventors, institutions, entrepreneurs and investors to form and grow spinout companies around early-stage technologies with high commercial potential.

Currently, ten academic organizations located throughout the target region have indicated their interest in participating in, providing funding for and/or supporting P1V. On the industry/investor side, the Science Center will partner initially with a local technology development company that will provide for-profit corporate infrastructure for the program (a requirement for SBIR/STTR funding and commercialization), and other accelerator partners in the region will be brought into the program as it expands. P1V will provide a direct benefit to the region by engaging with all of these stakeholders while leveraging existing relationships with more than 50 investors and companies, more than 100 entrepreneurs, and more than 150 professional service providers throughout the Science Center's networks. In addition, the EDA recently announced a new two-year, $1.0 million grant to facilitate the program's launch and development.

B. (Questions 19 and 20)

Federal innovation strategies should focus on regional economic growth by identifying and scaling existing local assets and infrastructure that encourage innovation and entrepreneurship, while sharing best practices among regions.

The Science Center strongly supports EDA's recently announced $15 million 2014 Regional Innovation Strategies Program competition to spur innovation capacity-building activities in regions across the nation. Under this program, EDA is soliciting applications for three separate funding opportunities, including: the "i6 Challenge", focusing on new POCCs and growing or expanding existing centers or programs, and considering funding for later-stage commercialization centers which provide opportunities for fine tuning and refinement of innovations; science and research park development grants; and cluster grants to support the development of seed capital funds.

However, because each geographic region has unique strengths and cultures, a one-size fits all national innovation policy would be an inefficient use of time and resources. There are many regions across the country utilizing local resources to make statewide and even national economic impacts. Federal policy should encourage these ecosystems of innovation to further prosper, share experiences, and provide resources to emerging regions, and to facilitate asset identification and infrastructure development. Federal funding could also be used to extend successful state and local programs beyond jurisdictional boundaries in clusters and ecosystems with multi-jurisdictional footprints. Moreover, Federal programs should be more open to "reinvesting' in ideas that work, rather than typically seeking to fund only new concepts – the bias toward new ideas can ultimately limit the impact of models that, while not completely "new," are not yet fully developed.

The recent Brookings Institution report, "The Rise of Innovation Districts: A New Geography of Innovation in America" (www.brookings.edu/about/programs/metro/innovation-districts), identifies the three components that make up an innovation ecosystem, "economic assets, physical assets and networking assets." At the Science Center, we provide all of these resources for the region, serving as an intermediary between academia, industry and capital investment. We believe that local economies across the nation, with guidance and support from existing successful innovation regions, can scale their efforts to leverage greater impact.

C. (Questions 1, 3 and 15)

The Federal government should allocate the previously scheduled increase in STTR funding to technology commercialization programs at venture development organizations.

SBIR and STTR are intended to stimulate a partnership of ideas and technologies between innovative small business concerns and non-profit research institutions, through Federally-funded research and development, which leads to technology commercialization.

Each Federal agency with an extramural R&D budget exceeding $100 million participates in STTR. These agencies include the Department of Defense (DOD), Department of Energy (DOE), National Aeronautics and Space Administration (NASA), National Institutes of Health (NIH), and National Science Foundation (NSF).

Each fiscal year, participating agencies set aside a percentage of their extramural R&D budgets for STTR. For FY 2014 and 2015, the applicable set-aside is 0.40%; this percentage will increase to 0.45% in FY 2016 and 2017. This increase in funding allocation presents an opportunity to support innovative approaches to accelerate the impact of STTR funding on commercialization of university technologies, through small business launch and growth.

The Science Center supports a change in legislation that would allow the use of these funds for programs (such as QED and P1V), run by venture development organizations (VDOs), which facilitate and accelerate the commercialization, via small businesses, of technologies developed at universities, hospitals and other research institutions. VDOs are public or private nonprofit organizations that contribute to regional or sector-based economic prosperity by providing a portfolio of services intended to accomplish at least three of the following: (a) accelerating the commercialization of taxpayer-funded research; (b) assisting in the creation of high-growth private enterprises that are commercializing technology; (c) strengthening the competitive position of existing small enterprises through the development and/or commercial adoption or deployment of technology; (d) providing expert assistance to: private companies; faculty, staff and students of institutions of higher education; or entrepreneurs commercializing new products and services; or (e) making financial grants, loans or direct equity investments in small businesses commercializing technology.

The Science Center is only one of many VDOs across the country working successfully in partnership with universities to commercialize research via small business. Allocating monies from the scheduled increase in STTR funding to VDO programs, such as QED and P1V, that launch and grow small businesses to develop and market technologies emerging from universities and other research institutions will increase the effectiveness and impact of the STTR program and ultimately benefit the economy through increased company growth and job creation.

D. (Questions 3, 19 and 20)

The Federal government should allow venture development organizations to compete, as lead applicants, for NSF grants and commercialization grants from other agencies that are similarly restricted to academic or degree-granting institutions.

NSF is a central pillar of federal research activities. Providing grants for basic, applied and translational research, the NSF touches students, researchers, universities and entrepreneurs across the nation.

In recent years, a greater focus has been placed on translational research and commercialization activities across all federal research disciplines. The NSF operates a number of programs aimed to accelerate research and encourage innovating thinking. These initiatives include the Accelerating Innovation Research and Building Inner Capacity programs, housed under the Partnerships for Innovation umbrella, as well as the Innovation Corps and Industry/University Cooperative Research Program. Currently, only degree-grant institutions of higher education are eligible to compete as lead applicants for grants administered through these and other NSF commercialization programs.

The Science Center strongly supports the mission and objectives of these innovative programs and urges Congress to allow for non-profit VDOs, such as the Science Center, that facilitate commercialization of technologies developed by institutions of higher education to also compete as lead applicants for these programs. Allowing entities like the Science Center to apply as the lead for NSF grants would allow for greater collaboration of research institutions and enable researchers with NSF grants to access increased private programming that assist with proof-of-concept, prototyping and business mentorship.

For example, the Partnerships for Innovation (PFI) program at NSF was created by the America COMPETES Act of 2010 to accelerate commercialization of Federal research. Both of the subprograms, Accelerating Innovation Research and Building Innovation Capacity, provide funds for operations taking place successfully every day at the Science Center. VDOs specialize in assessing market-value and facilitating collaboration between business and academia, mission goals of the PFI. They would leverage Federal research dollars and maximize results. The Science Center is only one of many VDOs across the country working successfully in partnership with universities to commercialize research via small business.

* * * * *

Please feel free to contact me if you have any questions or comments on this letter, or if you would like any additional information. In addition, I would be happy to meet with you at your convenience to discuss our programs and proposals in more detail, and I invite you to visit us here at the Science Center in Philadelphia to tour our facilities and learn more about who we are and what we do to support technology commercialization and economic development in the Greater Philadelphia region.

Thank you for your consideration.

Sincerely,

Stephen S. Tang, Ph.D.
President & CEO

UNIVERSITY CITY SCIENCE CENTER

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UNIVERSITY OF CALIFORNIA, DAVIS

September 23, 2014

Attn: Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Ave. NW, Washington, DC 20504

Re: Strategy for American Innovation

We are delighted to send this letter in response to the **Notice of Request for Information (RFI)** issued by the Office of Science and Technology Policy and the National Economic Council, via **Federal Register, Vol. 79 Issue 145**.

The Office of Science and Technology Policy (OSTP) and the National Economic Council (NEC) requested public comments to provide input into an upcoming update of the Strategy for American Innovation. We believe that universities can serve as major hubs in the national innovation ecosystem through multiple mechanisms, including the building blocks of American innovation mentioned in the RFI (education, fundamental research, digital and physical infrastructure) on one hand, as well as through knowledge transfer (includes formal and tacit information flows) to other players in the innovation ecosystem such as industry, philanthropic foundations, research institutes and other organizations, on the other hand. The federal government must also play an essential role in facilitating innovation and promoting economic prosperity for generations to come, particularly through progressive policies.

It is generally known that most of the results of federally-funded research are either answering fundamental scientific questions or at most reach the proof-of-concept stage, and need significant development before private investors agree to invest in commercializing resulting new products and technologies. **Targeted government funding and coordination with other players in the innovation ecosystem is paramount for de-risking valuable technologies and advancing them to where they can benefit patients and the taxpayers at large.** This letter provides a few specific suggestions for how the federal government could support commercialization of universities-developed technologies, while addressing the following categories among the 9 listed in the RFI:

C1. Overarching Questions

C2. Innovation Trends

C4. Skilled Workforce Development

C6. Regional Innovation Ecosystems

We assembled below a list of specific suggestions that we believe will contribute to economic growth and competitiveness:

1. Create a new agency for innovation, for example a **National Foundation for Innovation** that has the mission to advance innovation in the US, including advancing the development of university-based discoveries to take them closer to commercialization. [Addresses C1.]
2. Earmark funding for **technology maturation programs within universities**, with investments going to program infrastructure and prototyping labs, IP development (reduction to practice, filing/legal fees), market and technology assessments. Technology maturation and acceleration programs are important and could be different than (while also complementary to) SBIR/STTR grants, as some technologies do not lend themselves as base for a new startup, but they still need to be developed up to the point where companies are interested to license them. Such funding should also cover the costs of training scientists in entrepreneurship and technology commercialization. [Addresses C1, C2, and C4.]
3. We strongly recommend a **mandate that university tech transfer programs receive a percentage of each federal research award specifically for knowledge transfer and commercialization support activities**, to protect against universities balancing their budgets by cutting critical, but under-valued commercialization programs. Like above, some of this funding could be used for activities that educate scientists about entrepreneurship and technology commercialization. [Addresses C2, C4 and C6.]
4. In parallel, we recommend **expanding the concept of technology transfer to the more encompassing concept of knowledge transfer, and** providing universities with resources specifically focused on building extensive networks both within and outside the university. Knowledge transfer entails both contractual and non-contractual exchanges amongst people from academia, industry, and other organizations. Many such non-contractual interactions, that do not generate immediate funding for the university, are extremely valuable as they allow universities to nurture relationships as the foundation for successful alliances. The Science and Technology Center (STC) and Engineering Research Center (ERC) programs at NSF already mandate knowledge transfer / industry liaison expertise, and we argue that it would be useful to expand such expertise. [Addresses C2.]
5. **Provide dedicated and substantial funding for public-private partnerships (PPP) focused on bridging the valley-of-death**, including and especially for PPPs dedicated to medical technology innovation, biotech and pharma. These industries face a particularly wide and deep valley-of-death due to the large amounts of investments necessary and the associated risks. Training and education in entrepreneurship and technology commercialization for interested scientists at all levels must be an important component of such PPP partnerships. [Addresses C1, C2, C4 and C6.]
6. Innovation ecosystem stakeholders (including the federal government) and PPP participants must **give carefully consideration and agree on what the metrics of success are and how they should be measured**, given that such PPP programs span two or more cultures with different inherent value systems. [Addresses C1, C2, C4 and C6.]
7. Fund **Entrepreneurs in Residence (EIRs)**, which are experienced entrepreneurs and business executives who will work with faculty and researchers to assess the potential for technology commercialization and to spin off valuable technologies into startup companies, if necessary.

In support of these suggestions, we describe below our experience with an exciting program, titled the **Ecosystem for Biophotonics Innovation (EBI) at University of California, Davis**. EBI could possibly serve as a model to be applied and improved upon in most academic environments, and that could grow into a national program administered at research universities throughout US. The design of the EBI program touches on categories C1, C2, C4, and C6 listed in the RFI and above.

The EBI program leverages the investment of the National Science Foundation (NSF) in a Science and Technology Center, i.e. Center for Biophotonics Science and Technology (CBST), to facilitate translation of its technologies into marketable products, startup companies, and jobs.

CBST was funded by NSF and partner institutions for 11 years, to advance research, development, and application of new optical/photonic tools and technology in medicine and the life sciences. Its scientists developed numerous technologies, some of them in collaboration with industry. The mission of EBI is to foster an ecosystem for biophotonics and biomedical innovation, that leverages the research and technology created by an NSF Science and Technology Center, by strengthening alliances among this academic center, third party investors, and a variety of academic, commercial and philanthropic partners, committed to translating research-based technologies to the marketplace, while also providing entrepreneurship and product development training to postdoctoral Entrepreneurial Fellows (eFellows). NSF funds EBI via its Partnerships for Innovation: Accelerating Innovation Research program, with matching funds provided by industry, philanthropic foundations, an economic development organization and in general by "third party investors". EBI partners include GE Healthcare, BD Biosciences, Keaton Raphael Memorial Foundation, Tahoe Institute for Rural Health Research, Sacramento Area Regional Technology Alliance, with additional organizations in process of joining the program.

Over a four-years period, projects in the EBI portfolio are being accelerated towards commercialization either through startups or collaborations with large, medium or small companies. NSF invested approximately $2.1M, and our partners invested approximately $2.9M (over 75% in cash, balance as in-kind contributions). Seven eFellows attended entrepreneurship programs and networking events, and worked with collaborators from industry to advance technologies closer to the marketplace. An outstanding Board of Directors, which includes leadership representatives from university and all partners, provides oversight of and strategic advice about the direction of the program, its impacts and sustainability.

Some of the **lessons learned** during the EBI program's tenure are:

i. Innovation ecosystems need to be built on strong foundations of **successful research alliances**. It takes time and dedicated resources to build and sustain such alliances, and an infrastructure that includes **extensive networks and knowledge transfer expertise**.

ii. Engaging postdoctoral researchers as **entrepreneurial fellows** (eFellows) is highly valued by our private sector partners. The EBI program provides access and active engagement in training, education, and mentorship activities, where eFellows acquire skills that go beyond a regular postdoctoral experience. In effect, EBI allows for accelerated professional development, which benefits all stakeholders.

iii. Beyond funding for technology development and the training of junior scientists/eFellows, significant value comes from the **interactions among the ecosystem players, and ecosystem participants diversity**: scientists from academia and industry, small, medium and large companies, business executives, economic development professionals, venture capitalists, and entrepreneurs. Scientists receive valuable market validation information, companies get access to talent and technologies, and have opportunities to assess startups as acquisition targets, junior scientists receive training that makes them more marketable – thus, all EBI participants benefit.

iv. Therefore, **open communication amongst the ecosystem participants** must be encouraged and facilitated as it contributes to the vitality of the ecosystem, through maximizing the flow of information.

v. **Significant backing from NSF** or other federal agencies (time, funding) is necessary in order to get and maintain financial commitments from third party investors and other members of the ecosystem. The reason for this is simple: the original conditions for designing a program such as EBI continue to exist even later in the program, meaning that resources are necessary specifically for new technology assessments (for commercialization potential) and technology maturation. It generally takes a long time to generate an income stream from licensing fees and royalties.

vi. Members of the ecosystem slowly but surely realize the value of their thematic network through frequent meetings and through experiencing **both tangible and intangible benefits of working in the ecosystem**. Tangible benefits include opportunities to mentor and hire talented scientists who received training in product development and technology commercialization, to develop technologies of interest, access to new technologies, easy access to academic researchers, and leverage of research funds. Intangible benefits include increased awareness on campus about specific third party investors and partners, connections with ecosystem players active in the same or complementary industry, and tacit knowledge transfer (tacit knowledge is knowledge that cannot easily be transferred from one person to another via written or verbal means) for example by hiring EBI eFellows.

vii. The **ecosystem is truly a multi-lateral partnership among all its participants** and it is validated and held together by NSF participation and sponsorship. This format facilitates flows of information, expertise and people/talent, optimized as necessary for accelerating technologies towards the marketplace. EBI's value proposition is that it facilitates acceleration of technologies towards commercialization, while working closely with industry to ensure that these technologies will fulfill real unmet needs in the marketplace. We strongly believe that **matching university-based technology acceleration with market demand / market pull** is a recipe for success.

viii. While a variety of metrics (quantitative and qualitative) are recorded for the EBI program in order to assess progress and success, we are well aware that **EBI bridges two or more different cultures that value very different end results**. It may be difficult for some of the innovation ecosystem participants to accept that failure is part of the innovation process, as it may run counter to their organization's culture. Not all projects funded within an innovation ecosystem (or technology maturation) program will result in successful commercialization. But in order to determine commercial viability, it is **necessary to dedicate resources to technology maturation until the stages where sufficient information becomes available** to assess the commercialization potential of a technology.

ix. A corollary to the point above is that **we need more innovation, not less**: more efforts like EBI and other technology maturation activities are necessary to support innovation ecosystems, more aggressive partnerships among the ecosystem's participants, and better innovation policies.

We cannot emphasize enough how much the EBI program benefits from an actively engaged Board of Directors, under the leadership of its Chair, Professor of Management and Dean of the Graduate School of Management at UC Davis, Dr. Steven C. Currall. The Board plays an essential role not only in providing oversight and strategic advice for the direction of the program, but also in building trust among the stakeholders, developing additional partnerships and exploring new opportunities. Its Chair is a behavioral scientist who applies organizational psychology to study innovation, emerging technologies, negotiation, and corporate governance. Dr. Currall has published extensively on innovation, societal impacts of science and engineering, and organizational trust. His latest book "Organized Innovation: A Blueprint for Renewing America's Prosperity" (Oxford University Press) provides a framework for optimizing conditions that best generate high-impact technologies, based on three pillars: Channeled Curiosity, Boundary-Breaking Collaboration, and Orchestrated Commercialization. The model is based on the authors' decade-long study of the highly successful Engineering Research Centers, interdisciplinary research centers funded by NSF, and is congruent with the EBI processes.

Why should the federal government continue to fund innovation ecosystems and other similar programs (technology maturation/ technology commercialization)?

There are multiple reasons that justify recurrent support for innovation ecosystems that include universities and a diverse array of organizations as participants:

a) Ensure that federally-funded research will result in marketed products and technologies that benefit society and advance national prosperity.

b) Develop tomorrow's workforce through programs where junior scientists receive research training as well as accelerated professional development to better prepare them for careers in industry, entrepreneurship, or academia.

c) Allow scientists to engage in industry-relevant research. Feedback and frequent communication among the innovation ecosystem's participants lead to efficient information flows and quick iterations, where participants discuss unmet needs and other market-relevant challenges, pertinent solutions, as well as accelerate the time to developing and marketing solutions.

d) Overall, the return on investment for federal agencies can be significant, especially if federal funds for technology maturation are leveraged with funds from industry and other partner organizations.

We strongly applaud the Administration's efforts to support American innovation and economic growth. Having experienced a successful innovation ecosystem at UC Davis, we believe that this is a viable model that could be further enhanced with continuous feedback from its stakeholders. We've learned that **a vibrant innovation ecosystem is based on partnerships among organizations and individuals where barriers are broken down and solid bridges allow efficient flows of information and talent, that benefit all participants, where collaboration happens across disciplines and sectors, and whose culture supports risk taking, tolerates failure, and celebrates success.** Federal agencies can and should catalyze the formation of innovation ecosystems that advance the health and prosperity of our nation.

We welcome questions and additional discussions in support of policies that support the innovation economy.

Sincerely,

Steven C. Currall, PhD
Dean and Professor of Management
Graduate School of Management, UC Davis
Chair of the Board of Directors, Ecosystem for Biophotonics Innovation, UC Davis
Chief Strategic Advisory, UC Global Health Institute
[redacted]

Gabriela Lee, MBA, MS
Chief Knowledge Transfer Officer, Center for Biophotonics, UC Davis
[redacted]

Dennis Matthews, PhD
Professor Emeritus, Department of Neurological Surgery, UC Davis Health System
Director Emeritus, NSF Center for Biophotonics Science and Technology
Principal Investigator, Ecosystem for Biophotonics Innovation, UC Davis
Site Director, UC Davis, NSF I/UCRC Center for Biophotonics Sensors and Systems
Chief Scientist, Tahoe Institute for Rural Health Research
President, LifeLight Resources, LLC
Director Emeritus of CBBB, Lawrence Livermore National Laboratory
Program and Division Leader Emeritus, Lawrence Livermore National Laboratory
[redacted]

VENTUREWELL™
idea to impact

September 21, 2014

Dr. John P. Holdren, Director
The White House Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Dear Dr. Holdren:

Thank you for the opportunity to comment on the update of the *Strategy for American Innovation.* As President and CEO of the National Collegiate Inventors and Innovators Alliance (NCIIA), I provided comments for the 2011 *Strategy*; NCIIA has since rebranded as VentureWell as our work fostering innovation and entrepreneurship on U.S. university and college campuses is becoming rapidly more globalized and diverse covering most fields of science and industry. While VentureWell's comments on the update to the *Strategy* will primarily address the focus area, *Invest in the Building Blocks of American Innovation,* our lens is the transformation of undergraduate and graduate education and research. Our recommendations build on our experience working with emerging STEM innovators with relevance and lessons that can inform the *Strategy's* two other pillars, *Promote Market-Based Innovation* and *Catalyze Breakthroughs for National Priorities.*

The essence of our message is this: a successful *Strategy for American Innovation* must include **fostering student-led invention and innovation in science and technology by investing in and transforming higher education institutions**. This strategy is synergistic with the Office of Science and Technology Policy's (OSTP) 5-Year Federal Science, Technology, Engineering, and Mathematics (STEM) Education Strategic Plan. In order to strengthen teaching institutions and connect them to the commercial economy, we must build their capability to support experiential learning and doing in STEM entrepreneurship. We must also provide catalytic support in the form of very early proof-of-concept funding and structured training programs that support innovation in science and technology.

VentureWell's experience and demonstrated impact shows that investments in student-led innovation are important for advancing innovations and engaging universities alike. Chief among those investments are opportunities for students to participate in experiential entrepreneurship training designed to cultivate the potential and interest of scientific innovators and move the best ideas rapidly forward from the classroom or research lab to commercialization. STEM focused innovation and entrepreneurship programs using an experiential, engaging approach empower student innovators and increase the ability of universities to take an appropriate role as a cornerstone of an innovation-based economy.

We recommend further investment and emphasis in the following critical areas:

1. **Engage faculty** and their institutions in creating scalable experiential learning environments that focus on innovation and entrepreneurial thinking and doing.
2. **Focus on Students** and provide environments and resources that nurture innovative thinking connected to paths to realize those ideas.
3. **Support the emergence of innovations** from the research environment by providing training and support for the early translation of discoveries to applications led by student researchers.

At VentureWell we believe that invention, innovation and entrepreneurship are essential to American economic success and vitality—and to job creation for today's students. The programs we've created are helping to foster the next generation of collegiate innovators and help them bring their ideas to impact—but we are catalyzing only a fraction of the creative potential of this generation in America. While VentureWell is driving change through its membership of 200 institutions, there are thousands of other colleges and universities that could be using proven methods to teach tens of thousands more students to invent and innovate, and commercialize promising research-based ideas.

Recommendation 1: *Engage faculty and their institutions in creating scalable experiential learning environments that focus on innovation and entrepreneurial thinking and doing.*

Building a national and international community of engaged faculty supported by partners in the private and public sectors can revolutionize education for university innovators. Building scalable programs that transform institutions and individuals, the institutional focus engages faculty at the grassroots level and supports the development of courses and co-curricular and network building programs that develop inventive ideas and enable promising innovators to gain the entrepreneurial skills they need to bring inventions to market. VentureWell's experience in supporting the development of courses and programs established across 155 campuses nationwide is a scalable model for the transformation of higher education, including STEM, engineering and business.

- **Faculty Programs:** Catalytic faculty grants support the creation of new courses and programs in which students develop ideas and gain the skills to bring them to market. Faculty are challenged to pioneer new ways to engage their students in the entrepreneurial process. Our grants help students to *learn by doing*–and create courses and programs that have a strong likelihood of continuing beyond the grant period and becoming part of a campus culture of innovation. To date, 92% of these programs are ongoing.
- **Epicenter:** Epicenter, a partnership between VentureWell and Stanford University supported by the NSF, is dedicated to transforming undergraduate education for engineers by placing innovation and entrepreneurship at the heart of the curriculum. Programs directly engage researchers, faculty and students alike to lead and drive institutional change. They include:
    - **Pathways to Innovation:** an institutional change program led by faculty to transform the experience of their undergraduate engineering students. Campus teams work on a multi-year transformation plan to incorporate innovation and entrepreneurship into a range of courses as well as strengthening co-curricular and extra-curricular offerings.
    - **University Innovation Fellows (UIF):** Engages and empowers students to foster a culture of innovation on their campuses through highly

creative outreach activities and events. UIF teaches students to conduct analyses of their campus ecosystems; provides them with resources and mentorship; and connects them with one another digitally and at live events to promote creative collaboration. UIF and OSTP are collaborators in initiatives that address support for student and diversity in entrepreneurship opportunities in higher education.

Recommendation 2: *Focus on Students and provide environments and resources that nurture innovative thinking connected to paths to realize those ideas.*

Student inventors are at the heart of our approach. By enriching classrooms, curriculum and campuses with opportunities to cultivate their skills and creativity, ideas are brought to inception. Typically the programs we support are the first to validate, support and guide an idea that has great potential. We provide support to help realize an ingenious idea, launch a business or create value for industrial partners. To directly catalyze innovation we've made $7.5 million in very early stage grants to more than 500 student-led teams. They have gone on to collectively raise more than **$620 million** to launch and build new businesses. More than half of these start-up ventures are in business today, reaching millions of global consumers in over 50 countries. These companies are recognized as innovative leaders and include Ecovative Design, Helix Technologies and Sanergy. They are transforming the sectors in which they do business with environmentally sustainable products that address big challenges in globally scalable ways.

The program structures and resources created to nurture and launch these innovators are scalable and work in many different geographies and sectors. Each of the programs described below has already achieved national scale, and the time is opportune to make this approach truly mainstream through investment in regional and local capacity.

- **E-Team Programs:** Cultivate opportunities for collegiate entrepreneurs by providing early-stage support and funding of up to $75,000. The E-Team program gives college students the chance to move ideas out of the lab and classroom and into the marketplace. The three-stage process provides grant funding, experiential workshops, veteran coaching and a potential investment opportunity to help teams manifest their projects' full commercial potential.

Recommendation 3: *Support the emergence of innovations from the research environment by providing training and support for the early translation of discoveries to applications led by student researchers.* Our nation's multi-billion dollar investment in research can be substantially more productive of economic value while providing a powerful opportunity for engaging the best and brightest STEM researchers in learning the process and tools of innovation. Over 80% of current STEM doctoral students will pursue a career outside of academia. Providing low threshold, aspirational opportunities to learn how to evaluate the potential of research discoveries to create useful and economically scalable solutions to the needs of industry and society. The two approaches described below are scalable approaches to changing the trajectory and productivity of the American research enterprise.

- <u>I-Corps National Innovation Network:</u> A National Science Foundation initiative to increase the economic impact of federally funded research. The I-Corps program was created by the NSF building on the E-Team model of a student led innovation team with catalytic funding in 2011 to help move research it has funded to market. Through a dynamic collaboration with VentureWell, the NSF offers select participants from US academic laboratories the opportunity to participate in a special, accelerated version of the Lean LaunchPad course developed by Steve Blank. This revolutionary course engages students and faculty from across the nation in moving products out of the lab and into the market by talking to potential customers, partners and competitors and encountering the real-world challenges of creating and implementing successful innovations. VentureWell runs this course as part its role in coordinating a National Innovation Network to share knowledge and build a community supporting advancement of our nation's multibillion-dollar investment in basic research. The model is currently in the process of being scaled to other research agencies such as the National Institutes of Health and Department of Energy.

- **<u>Support the Xcelerator training program</u>: A partnership between USAID and private philanthropies such as The Lemelson Foundation and the Gates Foundation** provides training and coaching specifically for Grand Challenges Explorations grantees. The training prepares research-based global innovators to address the complexities of implementing new technologies in the developing world, helping speed up the process by which their ideas are turned into products that can have a real impact and save lives.

These examples illustrate how our process and program models make the difference. Leading institutions, from foundations to government agencies to major businesses, have joined us in our mission to transform higher education to enable its pivotal role in the innovation economy. The Lemelson Foundation, National Science Foundation (NSF), Bill and Melinda Gates Foundation, Intel and USAID are among those who recognize the effectiveness of these models to train and launch a new generation of scientists and engineers that will change the world.

Young scientists and engineers are both creating and clamoring for a culture of collaboration and knowledge sharing; as a result there has never been a better time for them to become inventors, innovators and entrepreneurs. With the right educational programs and opportunities, students will enter the ecosystem and gain the focus, experience and skills they'll need to confidently propel innovation and improvements in the world. We support the focus of resources on this critical area of opportunity for the American economy and stand ready to work in partnership with those who share this vision to continue to scale and disseminate this powerful approach.

Sincerely,

Phil Weilerstein
President and CEO
VentureWell
www.venturewell.org

Nicholas Adams

Berkeley Institute for Data Science

Data Science Fellow

For many studies, social scientists categorize text -- extracting variable/attribute data from words, phrases, sentences, and context in ways that machines cannot. This work is fundamentally irreproducible if there is no clear record of which categorical labels were applied to which text.

The Federal Government should support the development of Text Thresher software that makes this process of classifying text feasible at scale and totally transparent. Then, in the future, skeptics will be able to see exactly how meaning is converted into numbers and we can all quickly know which aspects of a study merit further review.

Learn about textthresher.org

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Nick Adams

Data Science Fellow, Berkeley Institute for Data Science

Instructor and Services Coordinator, D-Lab

Principal Investigator, The Deciding Force Project

Ines M. Anchondo

Texas Tech University

Assistant Professor, Department of Pediatrics

In response to this question:

Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

My answer is:

Stipulate that Federal grants must include sharing data with other researchers. To make this easy create a repository for data. A big issue with reproducibility and irreproducibility is researchers don’t share their data even though technically we all should.

Thank you,

Inés M. Anchondo DrPH, RDN, LD, CSP, MPH
Assistant Professor | Pediatric Nutritionist

Christopher Anderson
Schenectady County Community College

This is a critical issue - without assurances that sciences are committed to reproducibility, we are wasting a large amount of tax dollars on scientific fraud, misleading the public about personally-relevant science, and reducing trust in the scientific enterprise.

The following reforms make sense:

1. Make sharing of data and research materials the default for all publicly funded research.

2. Require federal agencies to dedicate a small portion of their research dollars toward replication of important results.

3. Promote transparency across the entire research lifecycle, including preregistration.

4. Support the development of infrastructure to increase discoverability of research, regardless of whether it was published.

5. Promote and support training of methodology and reproducibility practices.

Edward Archer

Nutrition Obesity Research Center

Post-Doctoral Fellow

Hello,

The greatest impediment to innovation in obesity and nutrition is the diversion of funds to pseudoscientific research (i.e., research paradigms clearly demonstrated to be invalid). The field of nutrition epidemiology relies on anecdotal evidence that my work (and others) have clearly demonstrated to be not only invalid but completely lacking in value.

Targeting research funding to novel paradigms of nutrition and obesity (and not mere tangents from the existing paradigm) will engender progress much more than any other initiative.

Ruben Arslan

Georg August University Goettingen

Require pre-registration of all funded studies. Publish the pre-registrations automatically after the timeframe needed to conduct the study and report its outcomes has expired.

Financially punish those who do not at least self-publish the results of the pre-registered analyses (bar them from future grants, withhold installments etc.).

Jordan Axt

I am writing this comment to address a few changes that I would like to see made to our current scientific practices. First, I think it is important to make the sharing of data and research stimuli the norm, and give special permission for researchers to not provide such information. Second, I ask that federal agencies dedicate a percentage of research funds towards supporting replications of important results. Finally, I write to support the development of tools that can increase the discoverability and replicability of research, regardless of publication outlet.

Sheeva Azma
Georgetown University
Department of Neuroscience

Neuroscience research has shown that poverty experienced in childhood has a deleterious effect on brain development, affecting individuals' life trajectories. I summarize research on the neurocognitive effects of poverty and discuss potential solutions in a recent paper published in the journal Synesis (affiliated with the Potomac Institute of Policy Studies), which is attached. Thank you for considering my comments.

Sheeva Azma
Georgetown University
Department of Neuroscience

I am writing in regards to the recommendations made in the 2009 document â□œA Strategy for American Innovation." These recommendations are focused on the goals of ensuring sufficient financial support for research agencies and working on critical scientific problems. I applaud the OSTP for identifying these important issues. I would just like to add that several recent news articles in the New York Times and elsewhere have described the sexism that still pervades research institutions. That bigotry exists in academia is no secret, and the government should ensure that obtaining an advanced degree is as much as possible based on merit rather than on traits such as race or gender. I would like to see STEM fields in general become more diverse and inclusive and since most STEM research is federally-funded, that can only be accomplished by providing oversight at the highest levels of government. A workforce rooted in equality is a highly productive and innovative one.

Reba Bandyopadhyay

American Association for the Advancement of Science (AAAS)

Congressional Science & Technology Policy Fellow

Dear Sir or Madam,

In your recent document soliciting comments for consideration in the process of updating the Strategy for American Innovation, one item concerns questions of scientific reproducibility:

"(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?"

A significant contributor to problem is that researchers cannot get grants to reproduce results - only projects that are pitched as entirely 'new' (although of course clearly following on from already-published results) can get funded, especially in the current constrained budget environment. There is no mechanism for getting funds to test/reproduce results, either one's own or the results of others' work, even in the case of results which are potentially groundbreaking or which may appear suspicious. This is one of several examples of how the current distribution of grant funding may not be serving us well, either as a scientific community or as a country. (Note that I am a firm advocate for our current peer review system; the issue is what factors we put a "premium" on as we consider grant proposals).

We need to explicitly create ways for researchers who want to test/reproduce results (their own or others') to get funds from their granting agencies. One option would be to create a specific grant program line for this in each agency, so that the criteria for judging proposals would primarily be a team's ability to execute the program, plus the importance of the result to be tested; or perhaps have a pool of funds dedicated for this purpose which could be awarded when "triggered" by the publication of a significant result - the PI of the program or a competing team could request these funds as soon as the result is published. Alternatively, perhaps the creation of some way to allow PIs to ask for a 'sub-award' on their 'new research' grant that would have a dedicated budget explicitly devoted to reproducing or testing previous results on which the new grant is based.

I'm afraid that the only remedies I can think of for this problem require (1) significantly more funding to be available in the grant pool and (2) longer-term grant awards which allow employment stability of 5+ years for the postdoctoral and research scientists who execute most of these experiments, who would then have the knowledge and experience to carefully reproduce the work - and then publish the results of those tests. The constant turnover of knowledgeable researchers (either to new jobs or onto new projects) that is required by the pressure of having no stable career paths significantly hampers reproducibility efforts as does the incentive structure in the grant system that favours novelty (or the appearance thereof) over nearly all else.

James B. Bassingthwaighte

University of Washington

Professor, Bioengineering & Radiology

This is a huge issue. When a scientific experiment is repeated by someone else, how can that be? Is it incompetence (the original? or the repeptition?) Or the environment? Or the chemical ingredients? It's not usually dishonesty. Because biology is complex, there are few simple hypotheses that can be expressed so exactly that one can make a mathematical model of the idea and devise explicit experiments about how to test it, nevertheless this is the goal. Such a goal provokes the mind to maintain its ""active doubt"" or degree of skepticism that is fundamentl to advancing science. One of the difficulties we have in the USA is the blind acceptance of ""whatever"", be it fad, advertisement, ""policy or religion"", withoout a search for reproducibiity, truth, or common sense.

Chris Beecher
IROA Technologies
Chief Science Officer

I have worked on both the academic and industrial side of this question.

When I recently returned to a very prestigious academic position at the University of Michigan as a full professor I was appalled by the realization that most academics do not care about the poor quality of their data. The students need the publications to graduate, the professors need the publications for their grants. The Universities need the publications to support their income. In none of these cases is the quality of the publication every the deciding factor. In every case I observed the number of publications always trumped the quality of the publication. The reality is that even the best journals are simply choosing the best stories even though they sort-of understand that the underlying data is questionable.

I am sorry to say I actually made enemies within my peers by asking them about the variance, CV, or other measures of data quality. The story was always the same - Senior top professors (of which I was their equal) would tell me "It cost too much" to do an additional test." because they knew they did not need the quality or assurance for publication, and anyway, the student deserved to graduate" . . . "By the way" they would say "Didn't I know that NIH only counted publications?". Another aspect is the fact that the data, which is rarely made available, is almost always worked up by the same person who generates it. I feel very strongly about this issue; to the extent that I almost feel all grants should be required to have different people responsible for analyzing data than the people who generate it.

It is very clear that the industrial side, which is dependent on reproducibility for their bottom line can do it correctly. They will make the hard decisions and spend the extra time and money when needed because they are rewarded for being correct. In industry it is almost always true that the data is analyzed by different people than the people who generate it.

Please feel free to contact me if I can help.

Response to RFI: Strategy for American Innovation

John Bottoms, President
FirstStar Systems, Concord, MA USA
Tel: [redacted]

(currently 2800 words)

Summary

The emphasis of this report is on several key aspects:

- The development of new education standards and curricula for college and universities outlining the goals for development of grammar-based expert systems. (Q. 12)
- The development of a semantic network web for expert system applications. (Q. 7)
- The development of applications for the expert web that facilitates education, contracting and procurement and for use by an Innovation Community. The Innovation Web works as a component of an Innovation Community that provides knowledge sharing among participants. (Q.3, 4, 18, 24)
- The theme is stressed that new growth will not come from existing corporations, but from 2nd tier companies that find new opportunities for participation in the knowledge marketplace. Increased participation is needed by representatives of the Academy of Science with 2nd tier companies and developers at Regional Innovation Centers. (Q. 2)

This report assumes or suggests that the following is performed during the policy design.

A. An assessment of opportunities in Greenfields, in currently outsourced technology and in strategically critical technology which would benefit national GDP. This would extend knowledge of the existing SIC codes with more specific identifiers that can be used to trace to each GDP revenue sector. The goal of this effort should be 100% coverage for all production and service sectors and identification of those areas for improvement that maximize GDP and reduce risk.

B. Identification of State Innovation Partner opportunities. This option should made available to states to permit flexibility in obtaining or working with available resources that may not be available within the Federal guidelines.

C. Identification of University Innovation Partner. This will involve soliciting universities to determine what resources can be provided and the types of cooperative agreements that may be available.

D. Identification of Association Innovation Partners. These are existing and new industry association that can focus attention and resources of participants on the opportunities provided by the *Strategy*.

E. Innovation Corporate Partner. Corporate partners, particularly those represented in the Academy, are expected to take the lead in providing technical direction and participation at all levels of Innovation. These partners are expected to respond to requests for assistance in educating developers and universities and in the assessment of new developments. This requires the development by the Academy of a set of cooperation and confidentiality guidelines to inform this process.

F. Innovation Developer. Individuals should be permitted access in order to track promising

developments and provide a channel for education and the gathering of feedback comments.

G. Identification of companies capable of contractual work for the federal government and those able to subcontract work from existing government contractors.

H. Identification of infrastructure consultants that can provide assessment and technical services for strengthening the infrastructure across the entire system. These consultants should not be specialists in participating industry sectors but those who provide services across multiple industry segments and provide information and improvements to the OSTP and NEC.

I. The development of a streamlined contracting process using a secure network. The network should be available only to authorized users at one of several levels of authorization. An approach that should be considered is to add this capability to the Defense controlled NIPRNet. Access authorization should include, beyond the Regional and Metropolitan Centers, the following levels at a minimum and require qualification against specified standards

Overarching Questions

(1) What specific policies or initiatives should the Administration consider prioritizing in the next version of the Strategy for American Innovation?

Response: The development of a semantic computing network is of the highest priority.

(2) What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?

Response I – Extensible Knowledge Systems
Problem: Current approaches to knowledge systems are implemented as extensions of current operating system designs. These are typically windows driven with the computer adding little knowledge to the process. Knowledge data is generally provided by the user. Further, because the systems are provided by a vendor, changes must be provided by the vendor with some significant lag in the process.

Model: New systems should permit extensibility of the data and expert processing for functions. Existing expert systems within the government can be modified to permit extensibility for industry sectors. Associations working within the Innovation System can then provide an information view of how their products can be integrated with others identified within the system.

Details: An extensible system that segregates concepts and component definitions should ensure 100% coverage and cooperation among the various parties that develop products. Tools developed as part of the Innovation Network computing system facilitates the addition of new elements and local regional and local participants can contribute through crowdsourcing contributions. The developed system and applications can be made available to the U.S.'s trading partners to recoup a portion of the development costs.

Response II – Curriculum for Knowledge Systems
Problem: The skills needed to support the knowledge economy including information specialists and linguists skilled in information theory. These skills will not be available until curricula are in place to train the specialists in the several areas of knowledge development.

Model: The Academy of Science should take the lead in developing standards for knowledge systems in discussions with schools, colleges and universities. The standards should provide for knowledge for all skills required for the next generations of knowledge workers. The standards should cover frameworks for expert systems, extensibility and the development of R&D and marketing applications. Skill training should be provided for: information scientists and computer grammar linguists.

Details: Template standards can be provided within three (3) months and made available for review to participants. The goal should be to complete the initial curricula within twelve (12) months.

(3) What specific actions can the Federal Government take to build and sustain U.S. strengths including its entrepreneurial culture, flexible labor markets, world-class research universities, strong regional innovation ecosystems, and large share of global venture capital investment?

Response: the development of a crowdsourcing platform for R&D would provide benefit at low cost.

(4a) How can the Federal Government augment its overall capacity for analysis of both the forces that determine the competitiveness of specific sectors and the impact of Federal policies—including, but not limited to, science, technology, and innovation policies—on sector-specific productivity and competitiveness?

Response: Existing economic knowledge from the CIA and government agencies should be made available to Regional Innovation Centers and second tier companies. This should be done if the knowledge is made available in a human and machine-readable ontology.

(4b) What are the most important outstanding questions about innovation policy and process and how might government promote systematic research and program evaluation in those areas?

Response: (none)

(5a) What innovation practices and policies have other countries adopted that deserve further consideration in the United States?

Response: The Bits to Atoms Lab at MIT has worked to place labs at four locations around the world. Neil Gershenfeld, the director of the lab, has spoken about the strategic importance of these labs by pointing out that in addition to furthering education; they serve as a focal point for knowledge about the local environment. Any cultural, economic or political change will affect the operation of the lab and will provide an opportunity for response. He refers to this process as “cultural interdiction”, particularly when satellite labs are provided at the local level along national boundaries. Mechanisms for gathering information can be tailored to work within the network joining elements of the Innovation Network.

(5b) What innovation practices and policies have been adopted at the state or local level that should be piloted by the Federal Government?

Response: One significant channel for education and sharing of knowledge is from local meetings that are coordinated through the Web. A similar mechanism should be created to inform those interested of new meetings and solicit request for meetings on topics of interest.

Innovation Trends

(6) How has the nature of the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?

Response: (none)

(7) What emerging areas of scientific and technological innovation merit greater Federal investment, and how can that investment be structured for maximum impact?

Response: (none)

(8) What are important needs or opportunities for institutional innovation and what steps can the Federal Government take to support these innovations?
Response: (none)

Science, Technology, and R&D Priorities

(9) What additional opportunities exist to develop high-impact platform technologies that reduce the time and cost associated with the "design, build, test" cycle for important classes of materials, products, and systems?

Response: (none)

(10) Where are there gaps in the Federal Government's science, technology, and innovation portfolios with respect to important national challenges, and…

Response: build on the current standards and frameworks provided by the Academy of Science can demonstrate how the frameworks can be used to translate from existing expression of technology to higher-level expression of concepts. As mentioned in Q9, there is a need for expert system curricula and tools for applications that permit the use of expert systems.

(10b) what are the appropriate investment and R&D models through which these gaps might be addressed?

Response: (none)

(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

Problem: Current efforts at Reproducible Results are individual and locally defined.

Model: National standards for RR should not only meet current academic requirements but should be tailored to work with expert systems for implementing the systems. Ideally, the expert system would be used from the beginning of an experiment.

Details: A university consortium should be formed under the umbrella of the Academy and report to the OSTP and NEC.

Skilled Workforce Development

(12) What novel mechanisms or models might facilitate matching skilled STEM workers with employers and helping individuals identify what additional skills they may need to transition successfully to new roles?

Response: (none)

(13a) What emerging areas of skills are needed in order to keep pace with emerging innovations or technologies?

Problem: The following skills are not being taught at most U.S. universities: ontology development, computer linguistics, meta-grammar development, and psychometrics for expert systems. Once knowledge systems begin to develop there will be a shortage of logicians and mathematicians skilled in applied logic for expert systems.

Model: The development of educational standards and curricula for these areas needs to begin immediately.

Details: OSTP and NEC should inform the Academy of Science of the immediate need for standards for semantic expert systems and related disciplines outlined above. A report from the Academy should be made available to students and the public concerning project employment opportunities in these areas.

(13b) What are successful models for training workers with these skills to keep up with emerging innovations?

Response: (none)

(14) What mechanisms or programs can effectively increase the supply of workers with technical training, from industry-recognized credentials and post-secondary certificates to two- and four-year degrees?

Problem: Currently most courses in expert systems are taught by graduate students or professors with limited field experience. They may have antidotal information from journal articles that relate the develop of systems, however, this does not replace the knowledge gained by implementing systems. Further there is little sharing of knowledge between The Academy and second tier companies and developers.

Model: Historically knowledge sharing has been done through a Socratic method of teaching. The advantage there is the pairing of the youngest students with more experienced professionals serves to leapfrog decades of knowledge development compared to other teaching methods. The result would be a speeding of the development of technology. The goal is to put experienced researchers in contact with developers. The researchers from corporations and universities could meet with developers who are originating projects or who are looking to contribute on existing projects. Regional Innovation Centers working with OSTP, NEC and The Academy could schedule regular meetings at each Regional Center to update developers on new directions within R&D and industries.

Details: This effort should be assigned to regional innovation centers coordinating with The Academy, corporations and universities. The OSTP and NEC should promote these objectives among Academy members, corporations and universities. The regional centers should report monthly to OSTP and NEC on the number and types of meetings that have occurred.

Manufacturing and Entrepreneurship

(15) What new or existing investment models should be explored to support entrepreneurship in new geographies, as well as in technologies and sectors that are capital-intensive, relatively high-risk, and require sustained investment over long periods of time?

Response: (none)

(16) For new technologies and products, how might “proof of manufacturability” be gauged sooner, and what entities would most appropriately provide the necessary resources and facilities?
Response: (none)

(16b)What sectors represent the most promising opportunities for the application of such models?

Response: (none)

(17a) What tools, business model innovations, financial innovations, or other developments hold promise for reducing the cost of starting and scaling a business in capital intensive sectors like the life sciences, advanced materials, and clean energy?

Response: (none)

(17b) What can the Federal Government do to accelerate these trends?

Response: (none)

(18) What investments, strategies, or technological advancements, across both the public and private sectors, are needed to rebuild the U.S. “industrial commons” and ensure the latest technologies can be produced here?

Problem: An Innovation Network is needed that streamlines sharing of information, identification of employment and contracting opportunities. In conjunction with these opportunities, the related information systems must flexible enough to evolve in sophistication as knowledge increases. A move to the use of abstract concepts is needed to avoid becoming bogged down with verbose syntactic references to increasingly large database sets. The use of abstract concepts introduces additional problems related to specificity and context in terms of extensibility. However, there are techniques that allow this to be done.
The web system components should be put into use before moving to next set of concept mechanisms.

Model: An initial infrastructure in the form of a concept-based component framework should be put in place before applications are created that use the framework. The framework consists of a number of Semantic Engine (SE) components that process concepts. These Semantic Engine systems have been used effectively by DARPA for field hand-held units for translating natural languages. In practice in a web site, each SE processes Natural Language (NL) sentences and processes them using procedures in the system’s lexicon.

The lexicon is one of a set of elements within the framework that works with other SE’s. The concepts accessible by the framework are maintained in an ontology. The framework is extensible, an open architecture that allows individual developers to tailor applications for the needs of a particular industry sector. Regional Innovation Centers may focus on certain sectors that are allied with corresponding university research interests such as materials, metallurgy or MEMs.

References:
“Controlled English to Logic Translation”, Chp 11, “The Theory and Applications of Ontology”, 2010, Springer Publishing, New York, NY 10036

"A Prototype Query-Answering Engine Using Semantic Reasoning", Kapil Dukle, Univ. of South Carolina. http://jmvidal.cse.sc.edu/papers/kapil-msthesis.pdf

Details:

Regional Innovation Ecosystems

(19) What partnerships or novel models for collaboration between the Federal Government and regions should the Administration consider in order to promote innovation and the development of regional innovation ecosystems?

Response: (none)

(20) How should the Federal government promote the development of metropolitan "innovation districts," where large research institutions, companies, start-ups, and business accelerators congregate to facilitate the knowledge flows that sustain innovation?

Response: The OSTP and NEC should provide annual reviews and guidelines for the Innovation Network. Tools provided during the network design should permit streamlined reporting of progress, goals met and identification of opportunities.

Intellectual Property/Antitrust

(21) What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation (including, e.g., through the growing use of open innovation, combinatorial innovation, user innovation, internet-enabled innovation, and big data-driven innovation)?

Response: (none)

Novel Government Tools for Promoting Innovation
(22a) What are specific areas where a greater capacity for experimentation in law, policy, and regulation at the Federal level is likely to have large benefits?

Response: (none)

(22a) Are there useful models of experimental platforms in the public or private sectors that the Federal Government can adopt?

Response: (none)

(22a) How might the Federal Government encourage state and local experimentation?

Response: (none)

(23) Beyond current Federal efforts to promote open data and open application programming interfaces (APIs), what other opportunities exist to open up access to Federal assets (such as data, tools, equipment, facilities, and intellectual property from Federally-funded research) in order to spark private sector innovation?

Response: (none)

National Priorities

(24) Which new areas should be identified as "national priorities," either because they address important challenges confronting U.S. security or living standards, or they present an opportunity for public investments to catalyze advances, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?

Problem: The development of an Innovation Enterprise that is open for public investment will speed the development of the system. Bonds could be issued in the system to segregate it from commercial markets and provide financial stability for the system.

Model: <tbd>

Details: <tbd>

(25) What Federal policies or initiatives could unleash additional corporate and philanthropic investment for critical national priorities, such as energy innovation?

Response: (none)

Jim Bessen

Boston University School of Law

Lecturer

Historically, one important way that government has fostered innovation is through well-designed procurement programs. Government agency contracting, including R&D contracts, spurred development of computers, semiconductors, the Internet, digital wireless communications and, in an earlier era, precision machining. The uniquely American success of these programs helped make the U.S. into the world's innovation leader.

But not all procurement programs have such effects. Indeed, many military procurement programs that have aimed to develop dual-use technologies have benefited more from independent civilian innovation than they have spurred civilian innovation. In some cases, private industry developed technologies independently after military programs failed to develop non-military uses.

Economic analysis shows that innovative outcomes depend on whether the technology has major applications in private industry but also on how the contracting program is designed. Past successes have been major new technologies where the government program fostered the development of new technical skills and knowledge among a broad community of people working with the technology. This broad community of skilled technical workers was able to use their knowledge to make innovation happen in the private sector on a large scale.

However, a procurement program will not necessarily encourage the development of such a broad-based workforce unless it is properly designed. In particular, the successful programs have: 1) involved diverse parties, including university researchers, spinoffs and startups; 2) promoted knowledge sharing between people working with the technologies, for instance, by requiring subcontractors to open their workshops to others or by requiring technology licensing among subcontractors; 3) promoted the use of open standards.

Generally, one important thing government can do to promote innovation is to direct contracting and procurement programs to follow these design principles. Government already encourages some of these policies to some extent. OMB’s Circular A119 fosters government support for voluntary industry standards; health care agencies encourage the formation of common standards for electronic health records. But there are important opportunities to go further. For example, some procurement programs could require not only adherence to industry standards, but standards in particular that provide meaningful guarantees that essential technologies will be licensed to other private parties for free or with minimal royalties that are fair, reasonable and non-discriminatory. Such a policy would encourage the broadest use of the new standard.

In the past, U.S. procurement has been better at following these principles than many other countries and this superiority has contributed to an American advantage in innovation. For example, procurement programs in other countries have often failed to spur broader innovation because they favored certain players too heavily or the programs discouraged military researchers from communicating with their civilian counterparts. By building on America's historical strength, government’s contribution to innovation can be strengthened.

G.Steven Bova

Xiopub

Founder and Executive Director

Dear Dan:
I am replying to "Strategy for American Innovation" RFI, specifically the question of how the Federal Government can leverage its role as a significant funder of scientific research to increase reproducibility:

(II) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

I was on the faculty of Johns Hopkins School of Medicine for 20 years, from 1991-2011, and I am now a visiting professor in Finland part-time. I live in Baltimore. I have published nearly 100 articles, most of them in top journals, I have started three businesses, and have several U.S. Patents. My area of expertise is cancer genomics, pathology, urology, and medical informatics.

I began witnessing the poor level of reproducibility in published and unpublished research findings very early on in my career, and in 2006 I formed Xiopub, a 501(c)3 nonprofit specifically to address the problem. Xiopub would create a tool called Symeme that would be used by publication authors, reviewers, editors, and the general public to track adherence to reporting and other standards. By enabling authors to conveniently learn about, and implement existing and new reporting standards, and by allowing publication users and automated systems to track this adherence, reproducibility would be measurably increased.

I was able to put together great teams of people to work on creating Symeme and to flesh out and enable the Xiopub business model, but what I wasn't successful at was receiving funding from appropriate sources. I submitted the proposal three times to the National Library of Medicine for research grant funding (R01), and while one reviewer was highly positive, one middle of the road, and one highly negative reviewer thought the publishing system is just fine as it is, so why create Symeme. This was in the 2006-2009 time frame. I tried hard to make the case with NLM officials for the proposal being "outside the box" and of fundamental importance, but the program officers saw it as "too applied" and "not fundamental reseach" ("too practical" is what I heard, it would have a huge and useful research component), and it went nowhere.

More recently, my colleagues and I polished the idea further, created a four minute animation about Xiopub, and received rave reviews of the idea when we presented it to at a seminar at the Agency for Healthcare Research and Quality (AHRQ), which advises Medicare on new scientific findings relevant to Medicare recipients. We applied for funding for pilot funding from new new PCORI (Patient-Centered Outcomes Research Institute) funded by the Affordable Care Act, and the idea again fell on deaf ears. The problem is that what we propose brings together existing parts to the publication "system" but does not cleanly fall into the portfolio of any one entity using this system.
I was able to raise $15,000 dollars to fund a pilot from friends and family, but we would need about $3 million for a 5 year pilot project. The idea is lying dormant now as I focus on other things, but I would be glad to go back to this if I could find a way to get it off the ground. I believe this is the fundamental base needed to make good reproducibilty the rule rather than the exception.

Sara Bowman

I have particular interest in item number 11, regarding the irreproducibility of published scientific findings. As a scientist, the issue of irreproducibility startles and concerns me. The current climate is such that there is little incentive for researchers to share any negative results or anything other than the "prettiest" picture they can paint with their data. Likewise, there is little incentive for researchers to make their data and materials available to other researchers. The consequence is irreproducible research, and much wasted time, effort, and federal funding spent on research without sound scientific backing. This effect been seen across disciplines, from psychology to economics to cancer biology to chemistry. The Science and Technology Policy Office is in a position to shift the culture of scientific research, by incentivizing and/or requiring the sharing of data and materials generated from federally funded research (true public sharing of data in an open access way, not simply "data available on request"). The Science and Technology Policy Office can encourage federal agencies to dedicate a small part of their research budget to allow researchers to replicate key findings in various disciplines, as there is currently no funding or incentive for researchers to do this. The Office may also support infrastructure to promote sharing of data -- even unpublished data -- and enable its discovery, to reduce the "file drawer" problem, in which unpublishable data is never shared with anyone. The "file drawer" problem leads to unfathomable amounts of wasted time and money as researchers, independently, repeat experiments others have already discovered do not work. Infrastructure to store, share, and discover data would enable scientists to work together to improve reproducibility of scientific research. Adequate infrastructure for data sharing and discoverability, federal funding for replications, and data sharing mandates would go a long way toward mitigating the reproducibility crisis science is facing.

Steven Briggs

University of California, San Diego

Distinguished Professor, Section of Cell and Developmental Biology, Division of Biological Sciences

Innovation depends upon new knowledge about a problem to guide the development of solutions. As the US has tried to accelerate innovation to solve practical problems, funding for curiosity-driven research has been dramatically reduced. Funding for grants targeting scientific questions, without clear practical outcomes, has become nearly impossible to obtain. In my field of plant biology, grant funding rates are below 5% for programs that include basic research. Without new knowledge, innovation has slowed, precisely because of the shift in support toward innovation. Basic research is the least expensive and highest impact stage of the innovation pipeline. A small increase in funding for basic research has a large impact on innovation. Without new knowledge to exploit, most of the investment in innovation will be wasted on re-examination of old ideas.

The “Strategy for American Innovation” should restore funding rates for basic research to levels that can sustain a research community (30%). The cost required to do this is relatively small. The impact on innovation will be enormous. In fact, industry/investors will provide the funding required for innovation if the government will do its part by supporting basic research.

Andrew Brown

The University of Alabama at Birmingham

Scientist, Office of Energetics & Nutrition Obesity Research Center

Dear Mr. Correa,

I am writing in response to the Request for Information regarding the Strategy for American Innovation. As a scientist that studies meta-research, research integrity, and research reporting fidelity, I took a particular interest in item 11, which requests information on how to improve the reproducibility of published scientific findings. I would like to call your attention to three ongoing initiatives, followed by potential paths to improvement, particularly in health sciences. I add the caveat that some of my suggestions are not necessarily backed by evidence that they will improve matters, nor have I necessarily fully considered the feasibility of the suggestions.

1) The EQUATOR network (Enhancing the QUAlity and Transparency Of health Research, http://www.equator-network.org/)
Description: This site pulls together a number of reporting guidelines designed to improve the reporting of scientific studies, from pre-clinical animal work through clinical trials. A number of journals have made the use of such guidelines mandatory.

Suggestion: Some funding sources, most notably the NIH, require the reporting of grant funding and the submission of documents into PubMed Central upon study publication. Perhaps such requirements could be extended to requiring completion of guideline checklists, which should both improve the reporting of scientific studies as well as the meta-data collected by PubMed.

2) Trial registration
Description: All eligible trials are required to register at ClinicalTrials.gov, and a number of top medical journals require registration for studies to be published. Results are also required to be submitted within 12 months of trial completion.

Suggestion: ClinicalTrials.gov and other trial registries are typically flexible enough to allow the registration of small to large clinical trials, as well as animal studies and observational studies. Increasing the scope of mandated registration, especially for federally funded projects, could help in determining the full scope of conducted biomedical literature. A current concern with reproducibility is that only significant results or results concordant with a particular dogma tend to be published. Thus, knowing only the scope of animal or observational data that were published without knowing much about those that were not published severely hinders the ability to evaluate the totality of evidence. It is also important, though, that mandated reporting of research results be enforced. Presently, many trials have been completed but have failed to report results.

3) Reproducibility initiatives
Description: Some fields have self-selected to test the reproducibility of important work. Psychology is the most notable example, in which paradigm-shifting work is now being retested by groups of researchers.

Suggestion: Support large scale reproductions of important, widely accepted, but poorly studied, scientific principles. Intensive replications that involve repeating entire studies in the same or different contexts are important, but so are simpler replications in which data from studies are made available and independent groups are invited to analyze them in different ways. In both cases, the robustness of findings to different contexts, assumptions, or calculations can be tested. I advocate for what some call ‘replicating up,’ in which studies with particularly important implications are tested for replicability. My field of nutrition and obesity is particularly rife with presumptions about what does and does not improve health, many of which seem feasible but have little scientific basis. We have written about various unscientific beliefs that are perpetuated on all levels of society because the solid scientific evidence was never collected or replicated to actually demonstrate the causal influence of particular exposures. Replications in this domain could be particularly important. For instance, confirming whether there is an actual causal effect of trans-fat intake on cardiovascular disease is important; confirming whether there is an association between the number of dentists in an area and obesity rates may be less so.

There are many other programs and suggestions, including proposals I have submitted for funding that involve an independent review of scientific reporting quality. However, many such suggestions receive pushback or are considered the ‘bureaucratization of science’. In a fiscally-tight time for most scientists, we spend an inordinate amount of time submitting grants instead of actually conducting research, and it would be unfortunate if the pursuit of better-reported science resulted in an even greater decrease in productivity. It is therefore of paramount importance that implementing such putative improvements in the scientific enterprise be as streamlined and unobtrusive as possible.

Although a number of suggestions for improving reproducibility are borne out of scientific theory, there is a dire need for empirical evidence to establish whether such recommendations actually result in improvements in reporting and reproducibility. Supporting research programs and funding mechanisms that attempt to create such empirical evidence is one of the clearest ways that the Strategy for American Innovation could address reproducibility issues.

Sincerely,

Andrew W Brown, Ph.D.
Scientist
Office of Energetics &
Nutrition Obesity Research Center
The University of Alabama at Birmingham

Leonid Bystrykh

University of Groningen

Here is my view on the issue of irreproducibility in science. I have a personal knowledge of medical biology, in particular hematology.
Irreproducible papers, or in other words scientifically poor publications are a net product of

1. Irresponsible PI (professor)
2. Poorly educated student
3. Low morality in the lab and high stakes of winning research grant money.
4. Poor technical reviewing in current journals.

Education in medical sciences should be restructures in such way that statistics is included into medical courses. Now it is usually given by different people who barely understand each other. A logics of a scientific experiment is nearly absent in our education programs. It must be included.

A problem with mighty and famous PIs is more complicated. Usually urge for a fame comes together with poor professional skills. Indecent and offensive behavior of some PIs during submission of their manuscripts to the journals (especially high ranking journals) is known, yet never discussed in public. Editorial board must be legally protected from such offenses, otherwise they are forced to publish papers even though the papers might be technically questionable. Internal conflicts in the lab is another problem, where irresponsible PI can be spotted, yet I do not see how it can be resolved.

Post-publication discussion is nearly absent. Most of reviews are written in a non-critical way summarizing someone achievements. Methodological reviews with balanced view on the problem are rare, technical pitfalls are nowhere to discuss. There must be a change of the editorial policies to pay more attention to critical points in research instead of glamorizing few names and their successes. Probably each journal should promote a blog forum, probably allowing anonymous critics of publications.

Financial support should not be oriented only on the promises and recent publications, it must be focused more on the quality of research including math, stats and ethics. I am more in favor of Howard Hughes type of support. Unprofessional behavior must be considered as serious offense and probably have some legal consequences.

Although we have a free market of scientific journals a quality and protocol of scientific reviewing must meet some common standards. I personally know PI who review in "glossy journals", who claim that current methods in molecular biology cannot be understood so they must be trusted. Such unprofessional reviewing by impression is not acceptable. Some reviewers literally kill manuscripts of their competitors by providing completely false arguments (usually lack of novelty). I have only accidental knowledge of those reviews, but they must be a lot. Editorial boards must demand from their reviewers cumulatively understanding every part of the paper, technical (or more narrowly statistical checkup) must be obligatory, not optional. Considering the group of authors submitting the manuscript, we must stop with or culture of delegating all experience (and credits) to one communicating author (who is usually senior PI, and often the least aware of details of the experiment). Every publication must be accompanied by names and skills of each contributing author. We must know who did what.

Crowdfunded Innovation Prizes

In trying to explain why regions such as the Bay Area, New York, and Boston consistently outperform other US regions in terms of high-growth entrepreneurial activity, access to capital is often invoked as an explanation: the path-dependent nature of early-stage venture financing, combined with a disproportionate availability in these regions of high-quality mentorship through VC and angel networks, make it extremely difficult for a startup that does not have a presence in these regions to raise capital at the same scale and speed.

Crowdfunding is a new form of capital with the potential of changing, in theory, the geography of early-stage finance. In practice, empirical evidence so far (Agrawal, Catalini and Goldfarb, 2013) points to two countervailing forces: on the one hand, crowdfunding has been reinforcing existing agglomeration, with states such as California and New York attracting a disproportionate share of capital on online reward-based platforms such as Kickstarter as well as equity-based platforms such as AngelList; on the other hand, capital has also been flowing to new regions, to sectors in those regions that do not fit the existing economic specialization of the area (e.g., technology in Minnesota; fashion in Massachusetts etc.), and to individuals that could not get funded through traditional channels (e.g., Eric Migicovsky from Pebble).

When Kickstarter launched in 2009, all regions of the US immediately had the same degree of access to the online platform. At the same time, adoption outside of technology hubs was extremely heterogeneous, and cannot be explained by the level of economic activity or employment in a region: in the ranking of regions by crowdfunding activity per capita, college towns outperform other regions, pointing to something different taking place in these areas. Moreover, the regional response to crowdfunding is positively correlated with the presence of unemployed college graduates.[1] College students are a natural demographic for crowdfunding: they are often tech-savvy, they may have ideas that are too novel for traditional investors, they have limited access to alternative sources of capital such as housing collateral, bank loans, angel and venture capital. Moreover, they are embedded in an intellectually active and creative environment, where they can relatively easily find team members to experiment with on a new entrepreneurial idea[2].

Acemoglu et al. (2014) point out that the most dynamic and entrepreneurial economies grow because of their ability to give opportunities to people who are “young, restless, and creative”. Whereas online platforms have been successful at removing many of the economic frictions

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[1] A known stylized fact about entrepreneurial activity is that it rises during periods of high-unemployment, as individuals may accept higher risk when their outside option is substantially worsened (Koellinger and Thurik, 2012). In a similar vein, recessions have been shown to spur higher levels of user-innovation (Shah and Tripsas, 2007).

[2] When colleges are on break, we document a rise in crowdfunding activity in their immediate proximity which is consistent with the types of students involved: e.g., breaks at top engineering schools are correlated with an increase in technology projects, breaks at design schools with design and artistic crowdfunding projects (Agrawal, Catalini and Goldfarb, 2014b).

associated with geographic distance, offline social relationships between entrepreneurs and funders still influence how capital is allocated online (Agrawal, Catalini, and Goldfarb, 2014a), limiting the extent towards which access to capital can be ultimately democratized.

Crowdfunding has the potential to support entrepreneurs that are less likely to have access to traditional sources of capital not necessarily because of the lack of talent, but because of the lack of an existing entrepreneurial track-record and the resulting social ties with investors. In a similar fashion, crowdfunding could be used to fund projects that are difficult to fund through traditional channels (e.g., because they are too novel or risky), in cases where market failures lead to underinvestment, and for the direct provision of public goods.

One of the advantages of crowdfunding is that it allows to estimate the demand for a future product, service or public good at a low cost. This can be achieved even if early-adopters are geographically dispersed. Moreover, on crowdfunding platforms funders may support a project or startup also for philanthropic reasons, which expands the pool of potential funders (mixed incentives). Since 2012, Kickstarter has been allocating more funding to the arts than the National Endowment for the Arts (NEA). At the same time, investment decisions by the crowd have been shown to exhibit high overlap with those of experts in the field (Mollick and Nanda, 2014), illustrating how crowdfunding could be used to screen high-potential ideas at a lower cost.

How can crowdfunding be used to incentivize innovation and entrepreneurial experimentation? The basic idea would be to combine crowdfunding with a matching grant system, where projects that reach a certain threshold on the targeted platforms, and at the same time meet the criteria defined by policy makers (e.g., in the call for an innovation prize) automatically receive matching funds. The only country that has experimented with a similar approach so far is the United Kingdom, which allocated over $100M to multiple peer-to-peer lending platforms to incentivize crowdfunded loans in 2013 (using a 20% matching rate), and then allocated another $70M to Funding Circle in February 2014 (this time using a lower 10% matching rate).

A crowdfunded innovation prize would allow policy makers to sustain innovation in industry verticals and research areas of strategic importance that are relevant to the public (e.g., clean energy, education, health information technologies) at a lower cost. It would also expand the capital available to entrepreneurial segments of the population with less access to traditional sources of early-stage capital (e.g., minorities, younger entrepreneurs, inventors and creative individuals from regions with limited access to professional investors).

Reward-based platforms such as Kickstarter and Indiegogo could be used for matching grants on initiatives that are directly relevant to the public (e.g., civic crowdfunding, clean energy, education), whereas specialized platforms such as Experiment would be used to support science (e.g., healthcare, biotechnology). Finally, equity-based platforms such as AngelList or FundersClub, could be used to promote market-based innovation and entrepreneurship in a way that is consistent with key national priorities.[3] The basic structure of a crowdfunded innovation prize would follow two steps: in the first phase the criteria for participation in the innovation prize would be defined[4], whereas in the second phase the top projects would be selected through crowdfunding. Matching funds would be then allocated to all projects that meet the selection criteria.

This comment applies to the following categories:

- *Novel Government Tools for Promoting Innovation*
- *Regional Innovation Ecosystems*
- *Innovation Trends*
- *Science, Technology, and R&D Priorities*
- *National Priorities*

[3] The online syndication model could be particularly effective at combining the expertise of domain experts and professional investors with the market demand signal coming from an online crowd.
[4] This step could be potentially crowdsourced to domain experts.

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Russell Clay
College of Staten Island

A small portion of federal research money should fund independent replication of key scientific findings. This would reduce the overall funding for new scientific innovation, but would increase the overall quality of the research that federal funding supports by ensuring robustness in scientific findings.

Joanna Cohoon

Increasing access to and the transparency of scientific research is critical to driving innovation and producing quality results and products.

Access to more information is crucial. This can be done by lowering the barriers to actually look at research and findings through limited (or removed) paywalls, improved means of presenting findings to the public, and supporting new standards of reporting. If more information on a particular research topic, like a more complete summary of the procedure, or a full dataset, or pre-registered hypothesis, is available, more ideas and insights can be made. Furthermore, with greater transparency, less money and time can be wasted on tried and failed methods or dead end research trails.

Wayne Conlan

National Research Council Canada

Principal Research Officer, Human Health and Therapeutics Portfolio

I am a biomedical research scientist of 33 years standing who has grown increasingly worried about the perceived drop in ethical practices within my profession, especially regarding the abuse of statistics, and image manipulation software to "enhance' the quality of their work. A particular problem seems to be the use of composite Western blots in which only the "bands of interest" are shown on each gel. A simple solution here is to insist that the whole gels from which the bands were obtained be published as supplementary data. In part, the demand from Journals for the prettification of pictures is to blame. In the past, it was common to publish papers with all of their warts openly acknowledged by the authors. Now, such honesty ensures rejection of ones manuscripts. Style over substance is demanded, especially by the "top" journals which increasingly rush to publish incredible findings without due forethought. This isn't new, as anyone who remembers the infamous water memory paper published in Nature a few decades ago. No matter how many faddish papers these journals end up retracting, their reputations suffer no harm. Perhaps, it is time to think of some way of punishing these journals for their recidivism?

There have been a few instances in my career when I have tried to replicate work that I simply did not believe to be true. I was proven correct in each instance, and simply avoided using the original work as guidance for my own future work. Likewise, I once tried to engage the senior author regarding a claim in their paper that simply could not be true, for which I received no response. Again, I didn't pursue the matter any further. Interestingly, these authors either never published similar findings ever again, or published subsequent papers with data one would have expected them to obtain the first time around. These were not instances where the lack of reproducibility could be simply written off as subtle changes in experimental protocols. I'm sure that many federally-funded scientists have found themselves in the same boat. Several websites have devoted themselves to detecting scientific fraud over the past few years (Science Fraud, Retraction Watch, PubPeer), but they rarely focus on failure to replicate issues. Therefore, I would suggest that ORI at NIH or some other independent watchdog establish a portal for scientists to deposit hard data showing their failure to replicate published science. ORI could then share the data with the original researchers after removing any identifiers of the complainant. The onus would then be on the original researchers to release their raw data for further scrutiny, or to repeat the suspect experiments. Alternatively, when it would be relatively straightforward and inexpensive to try to replicate certain suspect experiments, NIH could use its intramural program or pay for a third party of relevant experts to try to replicate the experiments in question.

Lidia Cova

Centro di Ricerche e Tecnologie Biomediche Istituto Auxologico Italiano-IRCCS

Laboratorio di Neuroscienze/Laboratory of Neuroscience

Reproducibility has a key role in science, but in biology it's complicated by the reciprocal interactions between the living subjects (tissues/organisms or cells) with the surroundings (see Bissell, Nature 2013, 503:333-4). Nowadays it is preferred to focus only on outstanding results publishable on higher impact journals easily transferable to media enhancing a “scoop” unhealthy approach to science.

Anyway it's worthy to face this topic by expanding the technical/methodological and statistic parts in scientific publications/communications as well as encouraging the work of fair rigorous scientists with a well-documented lab experience, high citation reports by colleagues and critical approach to science.
In the revision of papers/ grants the scientific proposal and CV of the PIs/groups should be separated and critically evaluated by at least 3 different reviewers unaware of PI identity which could be revealed only in the conclusive round when a committee expert in the field would collect all the information in a meritocratic rank.

Hope that my considerations on the topic could be useful

Ashley DaSilva

University of Texas at Austin

Department of Physics

(1) It is absolutely critical for science funding to increase. If this point doesn't change, then nothing else will help: as long as researchers struggle in competition for dwindling funding resources, there is a very high incentive to quickly publish work that's "high impact." This will always lead to dishonest practices, whether intentional (fabricating data, questionable analysis) or unintentional (in rush to publish, don't fully check the quality of work.)

(2) Open up the scientific process. Every published work should be supplemented with data and methods (experimental, statistical, etc.) The journals could host these items, but other options are university libraries and private services (e.g. github for data analysis codes), which could be cited in the article. It would be great if the article and all materials were open access. Requiring gov't funded work to be open access just makes sense: the taxpayers that fund the work should have access.

(3) Out-dated rewards system for professors must be improved. The gov't should focus on funding the long-term high risk/high reward work which will not get done in industry. However, this is impossible if we don't increase science funding (see point 1). Researchers should also be rewarded for their public outreach work and for making their work accessible to the public. These are things which should be important to gov't funding agencies, which serve the public.

Thanks for your attention.

Thomas E. DeCoursey

Rush University Medical Center

Professor, Department of Molecular Biophysics and Physiology

My comments are focused mainly on biomedical research, and mainly that funded by the NIH. A major contributor to the problem of irreproducibility is the extreme pressure on scientists to generate high-profile publications in a climate of diminishing funding. Extreme scarcity of funding breeds exaggeration of the importance of findings and in some cases outright fraud. For example, your manuscript will be accepted by Nature if only you do three more experiments, and they MUST come out a certain way. If they do not, do you abandon your high-profile publications that will enable funding, and possibly the continuation of your career, or do you falsify the data to make the story "complete"? Anyone who thinks the answer is obvious does not understand human psychology in a climate of funding scarcity. The obvious solution is to increase NIH funding, which has decreased in real dollars for two decades.

Whether funding is increased or not, the NIH should spend its resources more wisely. Unfortunately, a major problem is that funding decisions are made by politicians and not by scientists. No offense intended to politicians who read this, but you REALLY do not know how science works, or how discovery and innovation works! This is evident from the huge amounts wasted by the NIH and DoD on "Disease-Directed" research and on "Big Science" research. The only "scientists" who support Big Science are the Empire-Builders who head these projects and who squander the money to boost their reputations. Ever since Richard Nixon tried to cure cancer by throwing money at it, we have known that progress comes not from Directed Research, but from unexpected places. The major discoveries are made by good scientists, not by those who are willing to prostitute themselves in order to obtain funding. The failure of Big Science, by which I mean large group efforts by multiple institutions, etc. (once called Program Project grants) is well-known to anyone who has participated in these efforts. Huge sums of money are squandered to forced artificial interactions, in stark contrast to the spontaneous and meaningful collaborations that occur when real scientists find they need to collaborate to make the next step in their research.

To summarize:
1) More funding for the NIH and NSF. American research is in its death throes, losing ground to China and other countries wise enough to support science, and the continuity required to sustain technological expertise teeters on the brink.
2) Greatly reduce the funding for large "Program" grants. These are fine in RARE cases like the Human Genome Project, but as a rule they fail miserably at great cost.
3) Support BASIC research, not Disease-Directed research. It sounds good to politicians to direct research toward curing a specific disease, but this is not how reality works. We have to stop lying to politicians, and ask them to accept the way the real world works.

Thank you for the opportunity to speak. I hope someone eventually will listen.

Keith Dredge
Progen Pharmaceuticals
Director of Drug Development

Dear Sir/Madam,

Please find below some comment which are relevant to the irreproducibility of preclinical data. Althought the comments are focused on cancer research, they would also apply to other areas of research.

The following is NOT published and my original comments.

Challenges to improving the reliability of preclinical cancer research

Cancer researchers would be prudent to heed the recent recommendations proposed by Begley and Ellis [1] as several scientist-level recommendations are designed to improve the quality of preclinical data and concerns relating to basic errors in peer-reviewed published articles. However, there is an overarching question that remains which is whether the culture of cancer research groups and other stakeholders can adapt to effectively implement these guidances and promote a new approach to the conduct of oncology research and preclinical experiments. Having spent seven years in both academia and the biotech industry, I offer some insights into the complexity of the issue whilst attempting to compare and contrast academic and industry cancer research where appropriate. This is a very significant challenge with multiple stakeholders so quick-fix solutions are unlikely and but cancer researchers need to acknowledge and accept their individual role in resolving these problems and government, funding agencies and host institutions/companies also need to understand their respective roles in acknowledging the challenge. Below are some additional points for consideration on the steps the scientific community needs to acknowledge if a change is to occur – and some initial steps to resolve the challenge ahead.

Culture

The need for a change in culture and the recommendation how to implement such change has been previously discussed by Begley and Ellis. Since the article, readers interested the culture of cancer research are encouraged to read Clinton Leaf's 'The Truth in Small Doses' [2].

The urgency culture that exists in daily life is not helping the effort as social media or sites like Research gate (or H-index metrics etc) encourage scientists to watch their 'scores' increase.

Intrinsic Bias

In academia

The proposals by Begley and Ellis are effective ways to eliminate or reduce bias at the experimental level and blinding studies and/or analyses of data is a critical component of such an approach. As a PhD student in a behavioural pharmacology laboratory (Prof Brian Leonard, NUI Galway, Ireland), blinding was common practice but as a discipline, scientists were frequently required to work on their peers' experimental work – sometimes for weeks at a time – which built a strong team culture over many years. Each PhD student or post-doc researcher was indebted to their peers for substantial contributions to each other's projects during their tenure. In cancer research, blinding isn't always possible and where it is (e.g. asking other personnel to administer mice with a putative anti-cancer agent), delegation of work to junior staff in particular needs the nurturing environment without fear of retribution as previously advised by Begley and Ellis. Any staff member or student willing raise a potential concern must first feel self-assured in their finding and appropriate training is one method to attain an environment of good practical skills.

The other form of bias may be more controversial. This is because it relates to passion. Every professor I've ever met is passionate about their work. This is not confined just to academia. Of course senior scientists in industry often feel a strong sense of ownership having worked on a project for perhaps several years and wants the project to succeed because they believe in the project! The intrinsic interest in a scientific paradigm or a drug program is unlikely to have the inherent passion within members new to the team or those in junior positions. However, given the rights senior academics retain within academia – rights that allow them the freedom to pursue their own interests and projects without the threat of instant termination of projects – they are very drive towards outcomes which will agree with their hypothesis. In contrast, scientists in industry may be more focussed on processes (drug discovery, preclinical or clinical development) rather than projects/scientific hypotheses and are less inclined to have bias to a specific dataset (of course it still happens).

But academia continues to reward individual behaviour and not teams so in order to attain such high positions, would-be professors need that intrinsic or inherent drive (passion). The demands of such positions then drive professors away from day-to-day laboratory life in order to spend time writing grants, teaching, attending conferences etc. It is only natural that over time, personnel producing positive data become well-regarded and cross-checking data is a significant, unrewarding task. Passion doesn't' typically make a good bedfellow with a prescribed operating style which is basis for quality systems. But in the rush for publications, there is a time when scientists should think 'inside the box' and ensure that the raw data reflects the final datasets and subsequent interpretation in the manuscript. It is acknowledged that the co-authors typically ensure this during the preparation of manuscripts but incentivising lab members not directly involved in the work to cross-check the data could be encouraged. But again this needs a culture of nurturing and acceptance, not one of fear or retribution. Alternatively, an independent reviewer at an institutional level may be considered (see solutions). Big pharma companies utilise publication managers and even some academic institutes have hired grant writers. Perhaps an institute-level review by a senior independent scientist (employed outside any specific departments to improve publication quality might help to catch potential issues (at least query anomalies, statistics etc) in articles?

In industry

Industry scientists of course are also guilty of bias but there are some differences between the bias in industry and academic research. First, industry tends to have a more holisitic approach. For example, as part of a drug development program, scientists with expertise in PK/PD/tox are typically utilised and this aids the design of initial proof-of-concept (PoC) studies. Moreover, many of these PoC studies are outsourced to contract research organisations (CROs) and the personnel in these organisations have no bias towards the project, often will blind the test items and usually insist on positive and negative controls in order to demonstrate effectively to the client that the experiment itself worked. Second, industry also likes to publish peer-reviewed scientific articles but this is not considered its 'end product'. Publications are often in conjunction with academic labs but it is difficult for industry to control all the data which is associated with publishing when conducted at academic institutes (see "The politics of collaboration"). But for the data that industry has control of, these need to be well documented once the reported science is included in other documents such as Investigators' Brochures and/or regulatory dossiers (IND annual reports) which will be inspected by regulatory authorities such as the FDA so it is critical for industry scientists to provide signed reports of scientific reports containing this information. In fact, such signed reports are generally considered more reliable that the inclusion of academic publications into regulatory dossiers. Although this does not excuse the industry scientist from appropriate review of academic publications, it perhaps points to the advantage of maintaining data that is well-documented and available for peer review.

Whether in academia or industry, the pressure to perform and generate positive data will always risk shortcuts or biased experiments. In contrast, the requirement for 'Good Laboratory Practice' (GLP) in the conduct of nonclinical safety studies ensure experiments are well planned, performed, monitored, reported and archived. Moreover, these experiments have well defined timeframes (depending on resource availability) to produce the end product (the study report). The outcome of the study (in some part, thanks to GLP) is typically not biased and reproducibility (while not perfect, Gottmann et al 2001 estimated a concordance of 57% between the overall rodent carcinogenicity classifications but these studies had differences in protocol design etc) is far improved compared to cancer research studies. I am not advocating that GLP be extended to academic facilities conducting cancer research. The cost, time and expertise required to be GLP-compliant is very significant. However, those interested in translational studies of cellular and gene therapy products should note that the FDA have recommended (although not required) that efficacy studies be performed within the scope of GLP if possible (Preclinical Assessment of Investigational Cellular and Gene Therapy Products – Draft FDA Guidance Nov 2012). Thus, in years to come, GLP compliance of in vitro and in vivo pharmacology/POC studies with GLP may become commonplace. This could have massive implications for the future of medical institutes moving such therapies from bench to bedside. As a result, either academic laboratories will need to transfer the intellectual property of complex efficacy models to CROs, or academic facilities may need to establish GLP compliance programs in-house – a significant cost and resource issue. As a consequence, it may enhance reproducibility of cancer research data but it comes at a significant cost to the taxpayer.

Extrinsic bias

The scientific literature itself leads to a form of bias. However, the sheer number of publications now easily available increases the pressure to (a) keep up with the literature and (b) amend projects accordingly. Scientists 'power-browse' leading to reductions in the time taken to actually read articles [1]. Given the reproducibility concerns, the assumption to believe published data is 'true' without due diligence and launching into new studies based on such brief reviews is of concern.

Granting agencies, university and government policies. Scientists' projects shift towards where they can achieve the greatest potential to secure grants. For example, cancer researchers studying basic biology need to identify translational relevance which is seldom achievable within the timeframe of the grant and so the focus should be on the science and not the potential application. Another example the probability of grant success for those willing to investigate novel hypotheses with limited experimental data. Researchers know their grant submission will fail without strong publication history in a specific area so that innovation becomes stifled.

Metrics for Career Advancement & Publications

The end product for academic cancer researchers is considered to be primarily peer-reviewed journal articles. Industry scientists also wish to see their efforts in top journals as scientific justification for projects to move forward. While loathe to admit it, as a community we need to acknowledge that publications are a form of advertisement and by association, influences others with interests in the 'product'. Apart from the scientist who subsequently chase new projects based in irreproducible data, this also applies to university deans, grant agencies, governments, corporate and business development departments of industry. As industry's primary metric is commercial success in development of a technology, the publication as a metric for success becomes more important for academic researchers. So apart from the efforts that we needs to make as scientists to improve data quality, we also need those with the capacity to fund scientists to better understand the design, execution and ramifications of research and to appreciate the need for understanding science and not just future technological/commercial success. Metrics to better award team efforts (perhaps supplying a % of each author which could be used to create a new type of index?) is important and grant agencies also need to consider how to ensure science is well conducted and reported (maybe not always pushing for commercial outcomes when basic science is not always able to realistically identify commercial opportunities).

Communication & Transparency

Just some general points

1. Storage of electronic data. Data stored on personal drives only should be a warning flag. Journals should request key raw data to be displayed in the web (for a limited time, say 6-12 mo after publication) so that peers can see the real data……….it will limit people submitting data without appropriate checking of sample size, statistics, show replicates etc)

2. Influence of sites like Research gate (in addition to H-index metrics etc)

3. Cancer researchers should take care when explaining their findings to lay audience and media. Industry for its part is also guilty of misleading scientific data. For example, I have read several press releases from small biotech companies with inclusion of some key preclinical experiment (e.g. anti-tumour effect) that is actually meaningless but has been ‘dumbed down’ for a lay audience.

4. Journalists should also ensure accurate reporting. I recently read a report of a report on a Phase I trial which suggested that the journalist didn’t appreciate the difference between pharmacokinetics and pharmacodynamics.

The politics of collaboration

Increasing collaboration is good for science. It can help to synergise projects, achieve outcomes in faster times and create teams of inter-disciplinary scientists, engineers, mathematics etc to better understand cancer and science in general. However, there remains some challenges with collaborations which are seldom acknowledged. First, inter-disciplinary teams by nature cannot fully appreciate each other’s data. Building trust is critical in these scenarios as cross-checking is not necessarily helpful and individual institutes may choose not to share all the raw data with other institutes.

Material transfer agreements (MTA) are commonplace between industry and academia and typically involve the transfer of a technology platform, reagent or compound developed within industry for academic researchers to test in their models. In a collaborative setting, such projects may lead to publications with both industry and academic scientists as co-authors. It is seldom the case that industry scientists have access to the raw data or lab books as these are the property of the academic institute so again trust is important. In the author’s experience, it is typical under MTA agreements that academic investigators have the right to publish any data arising from the project and although it would be subject to review by an industry representative, it is seldom possible to review all the raw data and make major modifications to the manuscript (this in some cases of course can be a good thing for the truth but challenging if investigations are not willing to share raw data). This is perhaps one reason why industry sometime raises concerns with the distribution of its proprietary technologies under MTAs.

Requesting full disclosure of all data from collaborators (whether they be academic or industry scientists) would be advantageous but politics play a role in such conversations. One other approach to achieve greater transparency is to ensure formal agreements in place at an institutional level. However, this is cumbersome for legal departments involved and delays collaborative efforts.

Acceptance that this phenomena happens in every lab

Cancer researchers should acknowledge that bias isn’t necessarily a conscious decision as such and accept that data is generated and published which retrospectively may have been analysed or presented in a somewhat bias environment. Pointing the finger at others isn’t appropriate and will not resolve the issue. Professors and senior scientists have argued that younger scientists lack core subjects such as biochemistry, point to other labs for suspicious data, or ask can't journals employ statisticians to review submitted data but placing the onus on others will not resolve the deficiencies – we each have a responsibility to ensure we extend our passion of science into a passion for accurate presentation.

Additional Recommendations

1. Training. As a new M.Sc./Ph.D. student enter the Department of Pharmacology in NUI, Galway we spent the first three months leaning basic techniques, informal seminars, and a statistics course totalling at least 40 hours. Managing a GLP-certified laboratory at The University of Queensland, the quality system ensures each individual must achieve three levels of training for each technique (observation, competent with supervision/assistance, competent/independent). At a basic level, some form of training needs to be implemented for cancer researcher especially those involved in preclinical studies.

2. Introduce team-based metrics - but how?

3. Institute level review of data and statistics. This is only feasible by employing a highly experienced scientist with good statistical knowledge to review manuscripts, perhaps cross-check data and engage with academic scientists to ensure reliability of the data prior to submission. This position would need to be independent and possibly permanent within the research offices of such institutions to act as an internal form of quality assurance. There are some institutes that already employ such scientifically-trained staff for grant writing. Industry scientists also need to avail of appropriate expertise if not an in-house capability. CROs that conduct such work also tend to have toxicology capabilities and it is due to the prescriptive use of study design and statistics in toxicology (eg OECD 407 & 116) that tumours models tend to have adequate design and statistical tests applied to the data.

4. Cancer researchers conducting tumour models are advised to read OECD Draft Guidance Document 116 - Section 4 (April 2012).

5. Journals could consider more detailed guidances on statistics and/or design of studies (for example, utilising aspects of OECD 116 as a template)

6. Lab managers to ensure appropriate reagent labelling and expiry dates. This is commonplace in GLP laboratories and isn't too challenging for individual scientists in academia or industry research labs to label preparations appropriately yet it is not done routinely.

7. Documentation, not to the level of GLP but appropriate design, execution, archiving and access to data is important.

8. Agreements between collaborators to include a need for each party to get access to copies of raw data generated in the project.

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I hope some of these point are useful and would appreciate any feedback should any specific topics be discussed in more detail.

Bob Dvorak

Riffyn, Inc

Director Commercial Development

Given the recent emphasis on the need to improve reproducibility (question 11) in research and development, the federal government should start to dedicate resources to developing greater infrastructure to enforce and enable reproducibility. Reproducibility not only costs companies time, but it lowers the overall knowledgebase of our R&D infrastructure by making knowledge difficult to access and by reducing our ability to stand efficiently and effectively on the history of information already in place in the areas where we are looking to develop and innovate. The key starting point would be funding and initiatives focused on creating and supporting a distributed cloud-based architecture supported with open applications and open data structures which would enable faster movement to the edges of innovation. Companies developing combined collaborative innovation tools should be given the opportunity to access funds dedicated to driving the development of innovation tools (for example, through targeted SBIR funds specifically targeted to innovation tools developers). Standards organizations should be put in place to facilitate the development of the common components on which those tools would reside. The government could help accelerate the creation of those standards bodies to push innovation to the front of the queue.

This culture of shared innovation and focus on the edge of innovation would help drive greater progress by transforming the current models that focus more on hiding innovation in order to preserve intellectual property. This would require a reconsideration of the way intellectual property rights (question 21) are assigned to help reduce barriers to innovation, but also ensure profitability for the companies who are driving innovation. Intellectual property should be preserved at the edge of innovation to enable the market to reward innovation, but the boundaries of property and the rights attached will need to be redefined by Congress to enable innovation to occur faster than the current cycle of patents and subsequent patent suits allows.

The key element of addressing skilled workforce (question 12) Innovation is including a baseline implementation of open-source innovation collaboration tools at the university level, where they would create a common shared architecture for innovation and information they could be leveraged as those individuals move out into the workforce. Students learn to collaborate, but university tools for collaboration are primarily focused on communication rather than on shared tools and better access to knowledge bases around market and product information. Knowledge between students and between students and markets are as important as the dissemination of knowledge in the classroom, but the infrastructure does not exist to prepare students to drop into a technical collaborative environment of innovation. Focus on curriculum changes to ensure that innovation, development of products, and the path of taking them to market are considered as essential to discipline as its core science and technology would help drive this forward. Educational grants to support these changes and a focus on infrastructure are required here. A national program of post-baccalaureate positions for innovators (not driven back from industry, but forward from the universities and technical schools) with loan forgiveness or loan payment credits (such as exists with AmeriCorps) would help facilitate the transition from school to workforce, helping focus on innovating fields ahead of landing jobs—which providing better preparation for long-term careers in innovative spaces. These should be designed to leverage the collaboration tools used in the schools to transfer the theoretical collaboration to real collaboration in the market as quickly as possible.

Innovation districts (20) while regional should be coordinated and highly collaborative. Otherwise we will break down the existing silos between research organizations and companies and replace it with regional silos between the individual regional elements. While regionalization and direct in-person communication within the region are important, a focus on creating a set of interconnected centers of excellence that coordinate with industries and research universities would help erase those silos. The goal is a truly collaborative culture that can be built on physical centers that bring together knowledge, but that are part of well-structured national communities so that collaboration is as broad as it is deep. Common tools established for all of the regional centers would go a long way toward creating that connectivity.

At the root of innovation is making it possible for the vast chaos of open tools, widgets, and data sources to be brought into a space where they can facilitate innovation. Innovative companies right now spend too much time trying to fill in the gaps that the existing tools create just to be able to leverage those tools to properly innovate. This would require cloud-based access, market and technical information around the tools, and some reconsiderations of intellectual property to help allow companies to get to market faster and still preserve their economic rights to the innovations they build atop those tools. This investment by the government would spread out the costs so that companies don't have to absorb the overhead of finding and leveraging the tools. This would accelerate innovation and reduce cost to innovation, opening up opportunities for smaller companies to leverage well-vetted tools for their products.

In the end, it really all comes down to design quality and changing the culture of innovation (question 6). The tools, the collaboration, the education, and the communities have as their goal the improvement of the process of innovation. Just as we spent the latter half the last century improving manufacturing, we must move to improve the process of research & development and establish the same efficiency and focus on quality. This starts with reproducibility, which is currently the greatest barrier to our ability to advance our knowledge to market quickly and effectively. The federal government should have as its goal the lowering of the cost of innovation and building a sustainable culture of innovation through our education system and into our markets. Each of those goals has at its heart the need to dramatically improve the reproducibility of our work.

Charles Ebersole

Issue #11 is one of great importance to me, and I think it should be for the OSTP as well. The federal government has a role to play in encouraging replicable science. First, the government can incentivize or require experimental materials and data to be open access upon the completion of a study. This will help others to accurately replicate original work as well as encourage best practices among researchers. Furthermore, the government should help fund projects that focus on replicating research. At the moment, there is little incentive for researchers to spend their time and resources replicating past work, since funding and publications tend to reward novel work. However, replication is an important part of the scientific process, and must be encouraged.

Roy J. Epstein
Boston College
Adjunct Professor of Finance

Dear Sir/Madam:

Very often there is just a handful of large data sets, or only a single data set, to study important policy questions in health, the social sciences, the environment, and other areas. Because these data sets are generally very expensive to create, they are typically funded by public agencies.

The data are therefore a scarce and valuable resource. Yet even when funded by public money, the data are seldom available for use by the general community of researchers. This greatly impedes the ability of scientists in a given field to evaluate the reliability of findings that often have great importance for guiding public debate and policy decisions.

Critical scrutiny of empirical studies, starting at a minimum with verifying reproducibility of the results, is critical for avoiding costly policy errors. But when the data sets are treated as proprietary and the de facto property of the original investigators, the quality and integrity of scientific work is needlessly diminished. Vigorous, healthy, and rational debate based on actual data should be a paramount public policy goal. The current system of restricting effective independent review of major research findings by limiting access to the underlying publicly funded data should be revised to better promote the public interest.

The ostp memorandum of Feb 2013 is an important step in the right direction. It should be followed up with all government agencies.

Thank you.

Timothy Errington

Comment on item 11:"Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?"

Promote sharing of ALL data and research materials. This can be accomplished through supporting the development of tools, such as openly accessible software, to increase discoverability of all research, whether it was published or not.

Promote transparency and open practices throughout the entire research lifecycle, including preregistration of hypothesis, protocols, and analysis before data collection. This is especially important for confirmatory experiments, such as testing of novel drugs.

Dedicate a small portion of research dollars towards independent replication of important findings.

Promote and support training of methodology (including, but not limited to, proper statistical approaches) and reproducibility practices.

Lloyd S. Etheredge
Policy Sciences Center
Project Director

Dear Dr. Handelsman (and Tom Kalil and Jason Miller):

I enclose ideas for three projects that OSTP might organize to accelerate scientific innovation in many fields - for example, genetics-based agricultural research to meet the "zero hunger" goal discussed by Dr. Swaminathan in Science (August 1, 2014).

The projects, in part, build on ideas developed by Joshua Lederberg and a working group in the 1990s that have helped to accelerate biomedical research using Internet technology and NIH applications. They also include a MOOC and STEM-education development strategy.

with best wishes in your new position,
Lloyd Etheredge

Three Projects to Accelerate Scientific Innovation in Agriculture (& Other Fields)

by

Lloyd S. Etheredge *

It should be possible, with a light touch of leadership, to accelerate scientific innovation in many fields. The compelling human agenda articulated by M. S. Swaminathan ("Zero Hunger") in Science[1] to support 500 million family farms by scientific innovation (e.g., biofortification of food crops) and other initiatives suggests three projects that can use Internet technology to accelerate the scientific creative process in new ways.

1.) Provide a http://www.videocast.nih.gov service for agricultural research (and for each scientific field that we want to accelerate). The National Institutes of Health/National Library of Medicine system has pioneered extraordinary resources to support basic and applied biomedical research and innovation. Their videocast.nih.gov service efficiently uses NIH's 27 Institutes and Centers and their lectures and conferences as a capture point to provide a selection of the best and latest ideas, 1-2 years before print publication and without charge, to the desktops of researchers in academic settings and the private sector worldwide.[2] A Director's Series gives high visibility to boundary-crossing scientific ideas.

The remarkable NIH service (now, with an archive of 7,300+ events) provides biomedical research with a fast, cross-breeding information system for leading edge ideas. It allows policymakers (and agenda-building discussions of NIH advisory committees) to reach wide audiences quickly. The service builds culture and it creates an online reality that extends the excitement of scientific discovery in biomedical research to wider networks.[3]

2.) An "Inventions Wanted . . . " Weekly Colloquium Series to Engage the World's Scientific Brainpower. Often, today's scientific creativity involves a combinatorial process, connecting ideas from different fields in new ways. A brilliantly-designed, high visibility global webinar series would be ideally suited to support this process. A weekly "Inventions Wanted . . . " webinar can brief, and stimulate creative thinking by, a wide universe of interested scientists and students, in all fields and countries, and in academic and for-profit settings.

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* Director, International Scientific Networks Project, Policy Sciences Center. URL: http://www.policyscience.net; [redacted] (301)-[redacted] DRAFT (9/3/2014). Comments welcome.

Scientists love challenging problems. The “Inventions Wanted . . . “ weekly brownbag would be an event that nobody would miss. It could produce, within months or years, innovation that might otherwise require decades if the world relies upon print media (expensive for many users, and with limited circulation) and a limited number of researchers without access to the full range of ideas that might usefully be connected. A key breakthrough might come from a current graduate student in China, listening to a Webinar challenge, who begins to think about a problem.

- For example, the first “Inventions Wanted . . .” project could organize a series of weekly briefings by senior researchers about a.) the challenge to improve biological nitrogen fixation (and reduce the need for commercial fertilizers), what is known about plants that can do this, the theoretical and technical challenges of genetic upgrades, what people are trying, and where they are stuck.[4] The project’s planners might include a large-scale collaboration system to capture new ideas and suggestions from participants and provide online access to articles and papers.[5]

A first step might be to organize a working group to survey the challenges for breakthrough agricultural research that can be structured for the “Inventions Wanted . . . “ global system; and to give thought to the best way to organize creativity-stimulating presentations, manage, and learn lessons about the global innovation process.

3.) A (Full) Global MOOC Curriculum. New, affordable global online courses (MOOCs) make it possible to provide students in all countries with a curriculum, in all fields, equal to the best in the world. Now, a key step for a strategic plan to accelerate global scientific innovation and economic benefit in agriculture (or any field), is to decide what MOOC packages should be organized and underwritten, by whom, to support a full range of jobs, business opportunities, and leading-edge science?

A first step would be to organize a working group, with leading research scientists and educators, potential underwriters, and specialists in government services to agriculture, and starting new companies. The task of the working group would be to identify the full package of basic STEM (science, technology, and mathematics) and specialized courses and advanced global webinars that leaders in these fields want to have available for agricultural science.[6] Additional Fast Track conferences might accelerate plans in selected countries or regions (e.g., India, Spain, Brazil, Eastern Europe) to use new MOOC technology and this new curriculum to support family farms and create business opportunities.[7]

Notes

1. August 1, 2014, 345:6196, p. 481, attached.

2. An original justification is that the service allows NIH researchers to use their time more efficiently and to view more presentations (that they could not attend physically). Beyond simple videocasting, the New York Academy of Sciences (www.nyas.org) has experimented with an ebriefing option, with indexing and enhancements for skimming and accessing parts of lectures for 100 events/year. The NYAS system also supports the Scientists Without Borders initiative, https://www.scientistswithoutborders.org/

3. It also enriches the flow of leading edge ideas/speakers series at every individual four-year college and university. It also provides national and global access to researchers and students with limited resources to attend scientific conferences in person.

4. E.g., S. C. Wagner, "Biological Nitrogen Fixation," online at http://www.nature.com/scitable/knowledge/library/biological-nitrogen-fixation-23570419

5. Dr. Swaminathan's goal suggests a large potential agenda for an "Inventions Wanted . . . " project, including: b.) biofortification. Other challenges might include c.) creating food crops that can grow in sea water, allowing oceans to be planted or irrigation by sea water; d.) Improved efficiency of photosynthesis and - since some plants grow faster than others - otherwise discovering ways to accelerate their growth process; or to enhance growth at winter temperatures with winter sunlight; e.) Inventing new bio-fertilizers that can allow a powder, with a collection of microbes, to enrich different soils and substitute for commercial petroleum-based fertilizer or otherwise improve growth and health of crops; f.) Evaluating the potential for large N databases and *in silico* research. Agricultural science primarily has relied upon experimental methods but a scientific strategy for breakthrough discoveries could be designed to include (as it is emerging for biomedical research and health) large online genetic databases, possible individualized records for large N's of plants of each species, and free online supercomputing and analysis tools for academic researchers and students, and startup companies, in all countries; g.) Thinking more widely: the physicist Freeman Dyson has proposed the invention of "carbon-eating trees" as a solution to global warming. He forecasts that the scientific discoveries might take several decades, but the new system for agricultural research might produce discoveries and global benefits more quickly. (Freeman Dyson, "The Question of Global Warming," The New York Review of Books, 55:10 (June 12, 2008). Online at www.nybooks.com. See also the letters and exchanges in issues of 7/17, 9/25, and 10/9, *ibid*.

6. A pioneering step has been taken by MIT, where Dr. Eric Lander and his associates now offer the genetics-oriented Introduction to Biology course (7.00x) to shift undergraduate curriculum (and assist secondary school biology teachers) to build capabilities for the new era of genetics-based research and applications. Online, without charge, through www.edx.org.

7. See the planning work of a World University Consortium: http://www.wunicon.org/

Lloyd S. Etheredge
Policy Sciences Center
Project Director

Dear Jason Miller and Tom Kalil:

In further response to your request for new strategies to accelerate scientific innovation and economic prosperity, I enclose a proposal to develop a rapid learning system for macroeconomics. There is a growing recognition that there are missing variables in economic science, and the forecasting models do not work as well, across the G-20, as we would like. We do not have a national R&D system that is designed, led, or funded for these challenges and Big Data opportunities: The enclosed proposal illustrates what one social scientist, as a Principal Investigator, could do in 3 years.

However, in addition, we also can draw upon lessons from the rapid learning system for physical health to move more boldly, and quickly, for economic health. Appendices are online at www.policyscience.net at I. A. We ought to move quickly to organize behavioral economics working groups at the G-20 meeting: everybody needs comparative data because coefficients in US models that are interpreted as rational choice may include components of culture and psychology with other pathways relevant to policy, just as there are proving to be multiple pathways that affect how we classify medical conditions and treatment options.

Yours truly,
Lloyd S. Etheredge

Proposal

A Rapid Learning System for G-20 Macroeconomics:

From Greenspan to Shiller and Big Data

by

Lloyd S. Etheredge

March 6, 2014
(Draft)

Proposal

A Rapid Learning System for G-20 Macroeconomics: From Greenspan to Shiller and Big Data

by
Lloyd S. Etheredge[1]

Abstract

There is a growing agreement that there are missing variables in economic science. Robert Shiller (2014) believes that needed progress can be achieved by creating, and then drawing upon, an inclusive behavioral science framework that "accounts for actual human behavior." [2] Independently, Alan Greenspan has started to build this expansion. He draws upon a lifetime of experience, and reflections on the recent economic crisis and recovery, to recommend the behavioral variables that, with appropriate metrics, should be added to the world's data systems and forecasting equations.[3] The purpose of this project is to build upon Greenspan's outline and Shiller's vision and use them as a stimulus for expanded, multi-disciplinary, and inclusive R&D data systems that can be deployed internationally to create a rapid learning system for macroeconomics. [4] [5]

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[1] Lloyd Etheredge is Director, Government Learning Project, at the Policy Sciences Center, Inc., a public foundation; URL: http://www.policyscience.net. Contact: (301)-[redacted] This is a draft grant proposal. Comments welcome: Please do not circulate without permission.

[2] Robert Shiller, "The Rationality Debate: Simmering in Stockholm," The New York Times, January 14, 2014.

[3] Alan Greenspan, The Map and the Territory: Risk, Human Nature, and the Future of Forecasting (New York: The Penguin Press, 2013).

[4] The columnist Robert Samuelson reported a disciplinary pessimism about finding new and better policy ideas in current models and data systems at the invitation-only IMF summit last year: Robert J. Samuelson, "The End of Macro Magic," Washington Post, April 21, 2013. Concerning new variables, see also Lawrence Summers, "Lessons Can be Learned from Reinhart-Rogoff Error." Washington Post. May 5, 2013: "In retrospect, it was folly to believe that with data on about 30 countries it was possible to estimate a threshold beyond which debt became dangerous. Even if such a threshold existed, why should it be the same in countries with

The project is timely. Global economic recovery is lagging and established models and data systems have not worked reliably. The addition of new variables (each, likely influenced by several pathways) raises the possibility of a new set of effective policy tools (for example, to restore confidence and accelerate economic recovery). There is exciting and creative thinking among economists that will be captured by the project (i.e., and these upgrade ideas can disappear unless they evolve into metrics and are included in new R&D data systems of the G-20). There are very few problems in the world that cannot be made better by a speedier return to economic health and adding another 1%/year to long-term GDP/capita growth. And in February 2014 the G-20 governments made a public commitment to better results. They promised to *"develop ambitious but realistic policies with the aim to lift our collective GDP by more than 2 percent above the trajectory implied by current policies over the coming five years."* [6] More inclusive economic models and data systems should help to improve economic science and get these results for the G-20 and other nations.

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and without their own currency, with very different financial systems, cultures, degrees of openness and growth experiences?" Summers also recommends surrendering the comfortable dream of "returning to normal" and a world already charted by established equations and data systems: "the presumption that normal economic and policy conditions will return at some point cannot be maintained." ("Economic Stagnation is Not Our Fate - Unless We Let It Be," Washington Post, December 18, 2013). A consulting project for China, with leadership by the Nobelist Michael Spence, concludes that the ideas that must guide China's next phase of growth "step outside well-known economic models" and require tasks of adding metrics and variables into formal models that are "very much on economist's 'to do' list:" Jonathan Schleferfeb, "Nobel Winner's Frank Advice to China's Leadership." The New York Times, February 17, 2014.

[5] The commitment of the policy sciences tradition is to develop inclusive frameworks to guide democratic decision making. See Harold D. Lasswell and Abraham Kaplan, Power and Society: A Framework for Political Inquiry (1950) (New Brunswick, NJ: Transaction Publishers, 2013), reprint with an Introduction by Ronald Brunner; the behavioral sciences made impressive steps toward this goal, even several decades ago: Lloyd S. Etheredge, The Case of the Unreturned Cafeteria Trays (Washington, DC, 1976) and the "Map" (attached as an Appendix to this proposal) and *idem.*, "Wisdom in Public Policy" in Robert Sternberg and Jennifer Jordan (Eds.) A Handbook of Wisdom: Psychological Perspectives (New York: Cambridge University Press, 2005), pp. 257-328; William Ascher, Bringing in the Future: Strategies for Farsightedness and Sustainability in Developing Countries (Chicago: University of Chicago Press, 2009).

[6] Jamie Smyth, "G20 Aims to Add $2 Trillion to Global Economy," Financial Times, February 23, 2014.

Table of Contents

I. <u>Scientific Plan</u>

A Project Director and an Advisory Group will identify specific topics to be addressed in three steps and invite leading researchers to participate in a planning group (N=12-14) for each step. The planning groups will be asked to do justice to the thinking of Greenspan and other theorists. To bring their own creativity to the task. And to assure that the new variables and metrics will, in the spirit of the Michelson-Morley experiment in physics, be politically fair and support the competitive evaluation of variables, pathways, and claims that are civically relevant.

The three steps will be:

1.) <u>Greenspan's List</u> of (known or suspected) missing variables and recommended metrics;

2.) <u>Inclusive Social Science Lists</u> to capture (known or suspected) missing variables and metrics from other theorists and researchers;

3.) <u>Finding Unknown Variables and Organizing Rapid Learning Systems</u>.

- Greenspan is a professional economist and a libertarian. [His mentor and lifelong friend was Ayn Rand (author of <u>Atlas Shrugged</u>, an entry pathway to these policy views for many college students.)] He has taken the unusual step of recommending rapid scientific evaluation of his new economic ideas and these (what others would call) ideological beliefs. He expects these new scientific equations will improve economic forecasts *and*, in the competition of ideas in the political marketplace, prove that libertarians are right.

The Project Director will prepare an initial outline of issues for each planning group, meet with each member for a discussion, prepare a draft paper for a 1 ½ day group meeting, and author a summary report of recommended variables and metrics and next steps from each group. Each of the three Reports will address:

1.) Recommended variables and metrics that are on the shelf and that can be deployed immediately;

2.) Recommended metrics that can become available soon, with additional work;

3.) Important areas where further R&D is needed before metrics can be recommended.

Here (for the three steps, and with three examples for each step) are new variables and clusters of metrics that will be addressed, with my initial commentary about how I believe the discussions of social science advisers will develop and refine the analysis.[7]

A. Greenspan's List

> "We are driven by a whole array of propensities - most prominent, fear, euphoria, and herd behavior."
>
> \- Alan Greenspan [8]

Greenspan recommends adding variables to provide a more inclusive account of human nature. Thinking internationally, he also recommends including cultural variables in the new equations because he believes that cultures exert (often) fixed causal forces on economic behavior.

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[7] Greenspan suggests "an apparently inbred upper limit to human IQ" may limit productivity growth in America and other advanced economies to 3%/year (pp. 165-166, 296). The phenomenon is worth investigating and forecasting, but I am skeptical about this explanation.

[8] Also, a capacity for human rationality should be measured in the new equations: The new behavioral variables (fear, euphoria, and herd behavior) can be "broadly subject to reasoned confirmation," *op. cit.*, p. 299. [Including different (and sometimes opposing) logics and mechanisms (like rationality) in different parts of the human brain may seem logically contradictory and unacceptable but an emerging view of human nature, informed by neuroscience, is comfortable with this theoretical upgrade.]

Greenspan adds that "much of animal spirits are heavily tempered by rational oversight. Markets, even in their most euphoric or fear-driven state, do not expect global stock market averages to double or triple overnight, or wheat prices to fall to five cents a barrel" *op. cit.*, p. 35.

1.) Motivation 1 - Fear, Confidence, "Animal Spirits"

> "[T]he world economy is pregnant with multiple equilibria - self-fulfilling outcomes of pessimism or optimism."
>
> - Olivier Blanchard [9]

a.) Fear. An early, simplified mathematics of economics assumed human motivation to be fixed and seeking maximum economic profit, and that knowledge of the world was limited to economic variables (e.g., the prices and other current behavior of markets). Greenspan begins by adding an instinct for survival, risk-aversion, and a hardwired, fast, and compelling response to fear: "fear induces a far greater response than euphoria."[10] [Thus the boom phase of economic crises build across several years while the financial collapses will be sudden panics as these primitive, "fast" brain mechanisms are activated.] [11]

b.) Restoring confidence has emerged as one of the high policy priorities for economic recovery. Greenspan's wider model (discussed below, based on Keynes), includes the genetic endowment of human nature with natural "animal spirits" and a non-rational optimism about the

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[9] Dr. Olivier is Chief Economist at the International Monetary Fund and, for many years, was a member of the MIT Economics Department. Olivier Blanchard, "2011 in Review: Four Hard Truths." Online at http://blog-imfdirect.imf.org/2011/12/21/2011-in-review-four-hard-truths/

[10] *op. cit.*, p. 280.

[11] To psychologists, pain is a physical sensation with specific measurements. Thus, pain-avoidance can be different than risk-avoidance. [Greenspan probably means to include pain-avoidance in his theory: he discusses "the propensity of policy makers to seek the least politically painful solution to a problem . . . We see it everywhere." (p. 224).] The distinction between pain and risk will sometimes be nit-picking, but it helps to distinguish which brain pathways actually might be involved, for whom. While a new breed of Wall Street financiers may instinctively wish to avoid pain, they might be thrilled by the excitement of high risk gambling.

future.[12] [Thus, human nature is on the side of economic health, which will return as soon as we can understand the fear mechanisms and reduce or remove the fear and restore confidence.]

What are the pathways and metrics to model the neuroscience of fear and confidence? The fast "fight/flight" panic mechanism appears, at this point, to be linked to other mechanisms that continue to suppress or inhibit animal spirits and economic confidence. The actual combinations will have different implications for optimal recovery policies.

For example: The conventional remedy of economic pump-priming imagines that 1.) economic reality must be changed and become reliably reassuring (e.g., by reducing interest rates to stimulate investment and by increased government (deficit) spending). As flows of income increase to individuals and businesses, and as they slowly and repeatedly test the waters, confidence gradually is restored, their own spending and/or hiring increases, and the recovery process becomes self-sustaining. Another possibility is 2.) calendar time may be required for healing and recovery, and this might also require outreach steps (recognizing the additional psychological mechanisms involved) for people who have been injured personally or become discouraged. Or 3.) if the fear was activated in the context of a perceived catastrophic failure of trust and/or betrayal by governments and financial institutions who had a moral obligation to be trustworthy, these institutions may be required to restore confidence in themselves and have not done so. [These psychological ideas are consequential: the Federal Reserve systems of the world can spend hundreds of billions of dollars believing that there is a Liquidity Trap and they must keep interest rates low. Yet they will waste the money if the current problem is a Confidence Trap linked to deficient trust in major institutions and guarantors, and a dispiriting anomie.] [13]

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[12] Kahneman agrees with Greenspan and Keynes: "the optimistic bias may well be the most significant of the cognitive biases." Quoted in Greenspan, *op. cit.*, p. 32.

[13] Adding new and direct confidence metrics about governments and political systems is an innovation implied by Olivier Blanchard: "Markets have become more skeptical about the ability of governments to stabilize their public debt" in his "Strong Policy Action - The Essence of Restoring Global Economic Hope" blog, September 20, 2011. Online at http://blog-imfdirect.imf.org/2011/09/20/strong-policy-action-the-essence-of-restoring-global-economic-hope/

Alternatively, there may be 4.) a news-media perpetuation of fear and anger by (for profit) companies (like Fox News) or (with huge campaign contributions) by the Tea Party. [Once, three centrist television networks and sober, professional journalists (NBC, ABC, CBS) conveyed reality to, and constructed reality for, the American people.][14]

A wider set of metrics may allow other confidence-restoring or -building variables, possible brain mechanisms, and policy options to come into focus. For example, leadership-induced confidence: 5.) Experiments by McClelland and Winter found that videos of dramatizing leaders, with speeches rich in achievement images (like President Kennedy), energized people for economic achievement. [Thus: new metrics may show that President Obama and a world of rationalist economists and prosaic politicians are contributing to the current slow rates of economic recovery by the uninspiring public drama that they create.] [15] Or 6.) FDR used yet another set of (*de facto*) psychological theories of fear and brain mechanisms: Declaring that "the only thing we have to fear is fear itself," he presented himself as a confident, cheerful, and even jaunty role model (in a scary and troubled time); and, by using his position as a leader, and new mass communications technology, to *name* emotions he may have created new brain pathways in his listeners that helped them to be self-starting in an internal world that began to bracket fear.[16]

c.) "Animal Spirits." Greenspan's (psychological, political, and economic) theory of

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[14] New capabilities for quantitative analysis of communication flows would provide an interesting cross-national set of metrics. See Robert Harris, The Fear Index (NY: Vintage, 2012). Reprint; Ithiel de Sola Pool, "Content Analysis and the Intelligence Function," reprinted on Lloyd S. Etheredge (Ed.), Humane Politics and Methods of Inquiry: Selected Papers of Ithiel de Sola Pool, vol. 2 (New Brunswick, NJ: Transaction Publications, 2000), chapter 2.

[15] David McClelland and David Winter, Motivating Economic Achievement: Accelerating Economic Development Through Psychological Training (New York: Free Press, 1969).

[16] The G-20 appear to be using, at this point, 7.) a straightforward goal-setting theory of leadership and induced motivation. However the degree of repetition that is needed may be under-estimated. It may be necessary for leaders to communicate goals a hundred times more than they initially believe should be necessary

"animal spirits," borrowed from Keynes, imagines that the success of the capitalist system is the expression of this restless and even joyful human energy and natural optimism (that is not derived from cold, rational calculations), typically channeled into activities with others. Keynes' phrase was used of British students in boarding schools in late Victorian and Edwardian England: the "animal spirits" find natural expression in the freedom of the playing field and, sometimes, in an irreverent, youthful independence and instinct for challenging the rules that enjoined vigilance by headmasters. [17]

Greenspan's theory is a strategic move on a political chessboard. The "animal spirits" of human beings - not the profit-seeking of economic robots programmed for maximum rationality - drive capitalism and economic growth.[18] However these human "animal spirits" are suppressed by regulations and Greenspan's scientific prediction is that the new equations will prove libertarian claims: If we want the capitalist package to work, we should limit government and its regulation and other interference. The *laissez-faire* freedom from regulation that is required for the animal spirits of capitalism to create a better future [and also for the growth of strong, healthy, self-starting entrepreneurs as they move from competition on the playing fields to the

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[17] For further discussion: George Akerlof and Robert Shiller, Animal Spirits: How Human Psychology Drives the Economy, and Why it Matters for Global Capitalism (Princeton, NJ: Princeton University Press, 2009) and Robert Shiller, "Animal Spirits Depend on Trust: The Proposed Stimulus Isn't Enough to Restore Confidence," Wall Street Journal, January 27, 2009.

[18] As a side issue: Greenspan believes that *"To the extent that any human action is at least partially driven by 'spirits,' the material outcomes are less satisfactory in purely economic terms than they would be under the hypothetical presumption that animal spirits did not exist and that human beings' economic behavior was wholly rational."* Greenspan, *op. cit.*, p. 35. However computer simulations may show Greenspan's view to be untrue: a sociobiology theory might predict that, while irrational over-confidence may increase death rates of individuals or many entrepreneurial firms, this trait could, when there is random variation and changing environments, facilitate adaptation and success of the species. In the study of emerging infectious diseases, for example, millions of individual virus particles may die in the continuing assaults on new antibiotics but, with random variation, the continuing assaults eventually include breakthroughs by resistant mutations and survival and new population growth for the species.

corporate offices - LE] also means that political systems should accept that cycles of boom and bust are an inevitable part of the global capitalist system.

Greenspan's political deductions mandate a careful attention to measurement. There is a distinction between subjectivity (how reality is perceived, interpreted and wired-up in the brain) and Greenspan's almost definitional theory that regulations restrict freedom. There will be abundant challenges for the scientific planning groups to sort out but (to make the points briefly): 1.) actually, the youthful athletic contests on the playing fields of Eton, with their genuine and energetic freedom and competition, also are exquisitely created and affected by rules and regulations, depend upon honest and competent referees and agreed-upon penalties, and the activities are sustained by a moral universe of respect, fairness, and sportsmanship, and norms that distinguish acceptable competitive strategies (e.g., of misdirection) from cheating. Thus, it is not obvious that indexes of financial or environmental regulations *necessarily* will show inhibiting brain/psychological impacts on businessmen that erode their economic motivation and lower the growth rate of GDP. [However, 2.) once the new subjectivity-recognizing metrics are created, Greenspan might be right. In part, the truth depends upon the subjectivity of capitalists - although complaining about government regulations is not compelling evidence that regulations actually do inhibit their economic motivation: some of the most regulated and supervised industries in the world (e.g., the pharmaceutical industry) are the most profitable and innovative.] [19]

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[19] Economists are accustomed to use the hard numbers of conventional economic data. This methodological point about including measures of subjectivity (more easily accepted in other social sciences) is one of the "four hard (*sic*) truths" to improve econometric forecasting recommended in 2011 by Blanchard: "*Perception molds reality*." *op. cit.* A second-level measurement issue for a planning group, also flagged by Blanchard, is that perceptions can change: "[F]inancial investors are schizophrenic . . . they react positively to news of fiscal consolidation but then react negatively later. . ." *ibid*. A related measurement issue is the contextual principle in behavioral science - i.e., the effect of a variable can depend upon the context in which it occurs. Thus President Kennedy's tax cut may have produced an unusually strong effect on economic growth because it occurred in the frame of his achievement-oriented (N-Ach in the technical language of psychologists) rhetoric and leadership. If so, the Reagan-era

Also, *pace* Greenspan and Keynes, 3.) Social scientists might discover that actual economic motivation can be much greater than the baseline animal spirits of human nature. For example, motivation might be increased by (external) political leadership (see above) or by a non-rational manipulation that, via the visual cortex, activates long-term motivation with vivid images of vast, guaranteed profit. Greenspan's *laissez-faire* utopia of natural, animal spirits may actually achieve only a fraction of what psychologically astute G-20 policies (to design a fully incentivized global capitalist system) could empower capitalism to achieve in the future. [20]

2.) Motivation 2 - The Herd Instinct

"Euphoria will always periodically produce extended bull markets that feed off

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tax cuts would have produced a diminished effect because his Presidential rhetoric was low on N-Ach imagery. For a further discussion: Lloyd S. Etheredge, "President Reagan's Counseling" in Political Psychology, 5:4 (1984), pp. 737-40, online at www.policyscience.net at II. C.

Political combat in the Ayn Rand tradition has used her Objectivist philosophy which (i.e., it is a somewhat closed system) can interpret other people's differing perceptions as a "false consciousness." Greenspan may not readily accept a political philosophy or economic policy based on people's "unthinking" subjective experience of whether they are regulated.

[20] To secure the benefits of new technologies, the American government energized the national capitalist system and built a trans-continental railway system in the 19th century, very quickly, by offering government payments and bonuses (and vivid, high profits) of $16,000, $32,000 or $48,000/mile and assuring land grants, to competing companies who started building westward, and another that started eastward from California.

Similarly, the actual "herd instincts" motivations of Wall Street portrayed in the Academy Award-winning Inside Job and The Wolf of Wall Street appear to have been fueled by vivid images of fabulous profits and cocaine-like drug addiction and pleasure centers in the brain. Greenspan's partly exculpatory theory of human nature notwithstanding, only a very small percentage of self-selecting human beings may actually become involved in high-stakes gambling addictions.

> herd behavior, followed by rapid fear-induced deflation of the consequent bubbles."
>
> - Alan Greenspan [21]

> "I see no way of removing periodic irrational exuberances without at the same time significantly diminishing the average rate of economic growth and standards of living."[22]
>
> - Alan Greenspan [23]

Greenspan's new "herd instinct" variable moves economic analysis beyond the mathematical assumption that the motivation of human beings is only to maximize selfish economic profits. The herd ("social") instincts have their own aims, expressions and rewards (including contributing to the lives of others).[24] They are expressed in a nonprofit sector of the economy that is capable of astonishing gains in productivity and human benefit (e.g., MOOCs that can make a curriculum equal to the best in the world available to everyone on the planet, without charge) and, also, stunning and baffling inefficiency (e.g., the American health care system). The American media focus on the quarterly performance metrics of the for-profit economy but Greenspan's conceptual and pro-metrics upgrade will engage a planning group to think about

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[21] *op. cit.*, p. 292.

[22] Greenspan predicts that periodic irrational exuberances may grow worse as a result of social media, *op. cit.*, p. 25: "fear and euphoria . . . are contagious processes exaggerated by herding." It is an important prediction, made possible by including the herd instinct set of variables, that should be evaluated for G-20 forecasting.

[23] *op. cit.*, p. 301.

[24] Greenspan includes a propensity to compete in games and for status (p. 26) and power (p. 34).

equivalent quarterly performance metrics for the nonprofit sector.[25]

Adding a "herd instinct" variable also is a strategic move on a political chessboard. Here is the background: The term was introduced (with cross-species examples) by the social psychologist (and neurosurgeon) Wilfred Trotter in 1908.[26] It refers to many human phenomena, including altruism and compassion, standards of fairness, marriage and friendship, the nonprofit sector, all social and mass movement participation - including financial bubbles (and skewing risk-aversion judgments to the mean of a group) - and enlisting in wars, seeking status and power, conformity and followership, the quests for self-esteem, copycat behavior exploited by advertising and marketers, etc. During the 1930s and the Cold War, "herd instinct" became a pejorative term. Alan Greenspan, Ayn Rand, and many allies believed that the herd instinct dangerously drew political supporters to the seductions of collectivism, with the reality of a soul-crushing tyranny (and mistaken economic ideas) of America's mortal enemy, Russia and a global

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[25] I am not sure how far this initial project can go to develop metrics and forecasting equations for the nonprofit sector of the G-20 economies. However, the economics profession and society may benefit in several ways from Greenspan's conceptual upgrade. Typically, doctrinaire economic analysts recommend improving nonprofit institutions by turning them into for-profit hospitals, for-profit public schools, universities with Profit Centers, outsourcing the work of government agencies to the private sector, etc. Greenspan's "herd instinct" variable allows there to be legitimate, different, and important motive instincts that sustain the nonprofit sector and that can used and organized for the common good. (A motivation to maximize economic profit is not required for efficiency: the management consultant Peter Drucker thought that the Girl Scouts of America, with their commitment to "help each girl reach her own highest potential," was better run than Fortune 500 companies.) See also the variables affecting productivity in well-managed public sector and nonprofit institutions identified by the Baldrige awards, www.apqc.org. A discussion of conceptual implications of allowing different motives in models of human nature is Howard Margolis, Selfishness, Altruism and Rationality (Chicago, IL: University of Chicago Press, 1984).

[26] His later popular book influenced the application of scientific method to develop modern advertising and analyze the mass movements of the 1930s, accelerated by the new mass media technologies. W. Trotter, Instincts of the Herd in Peace and War (London: T. F. Unwin, 1916).

Communist movement. In Greenspan's tradition the "herd" (social) instincts also contribute to the well-intentioned, spiritually-eroding, collectivist welfare state (eroding the personality of 47% of Americans, according to the Republican-individualist Presidential candidate, Mitt Romney). The mass psychology of society and human imagination are zero-sum: even when governments enlarge their prominence and hold the high ground as benevolent planners of welfare states (and *de facto* regulators), they restrict and erode the open spaces and zones of freedom that are required for the full development of strong, healthy, self-starting individuals (who become entrepreneurs). [27]

Again, these are moves on a political chessboard and two measurement cautions are in order: a.) Political, educational, social, spiritual, and psychological theorists since Plato's analogy of the Cave and Buddha's teaching of a path to Enlightenment have thought about issues of freedom, liberation, and growth. Many psychologists have researched causal ideas about the growth of healthy, strong, free, responsible, self-starting, enlightened individuals who can become the "entrepreneurs of their own lives" and ethical, civic and business leaders and organizers.[28] Thus, there are likely to be different pathways and coefficients and a package of societal metrics that need to be put on the table; b.) As I indicated above, the Honest Broker scientific refereeing of ideological political arguments requires the measuring of subjectivities: a society with a psychology of "entitlements" *might* be unhealthy, but the appropriate metrics for Sweden may show that "entitlements" are healthy when they are wired-up differently and express and strengthen mutual respect and democracy and provide resources for the genuine personal freedom to grow and prosper. Similarly, constructing a "dependency index" for macroeconomics

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[27] I.e., rather than become victims, or pawns, or the drone employees of others, or people who look to governments and vote for a welfare state.

[28] Etheredge, "Wisdom . . . ," *op. cit.*. E.g., Lawrence Kohlberg, The Philosophy of Moral Development: Moral Stages and the Idea of Justice (San Francisco: Harper and Row, 1981); Jane Loevinger, Ego Development: Conceptions and Theories (San Francisco: Jossey Bass, 1976); see also David Winter, David McClelland, and Abigail Stewart, A New Case for the Liberal Arts (San Francisco: Jossey Bass, 1981).

(as some libertarian think tanks have proposed), equating (almost by definition) the public sources of individual income with an unhealthy, hierarchical, psychological relationship, begs an important measurement question; and c.) Once we see the numbers for a particular culture or subgroup, Greenspan and other libertarians may nevertheless be right.

3.) <u>Culture</u>

> "A specific brand of culture - populism - has been particularly debilitating to economic progress. . . . Capitalism and socialism are specific about the conditions they deem necessary for the creation of wealth and rising standards of living. Populism [for example, in 20th and 21st century Latin America] is not. It is a shout of pain."
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> "For those economies that seek maximum economic growth, it appears that abstinence and prudence are necessary (although not sufficient) virtues for prosperity."
>
> - Alan Greenspan [29] [30]

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[29] *op. cit.*, pp. 226-227.

[30] Abstinence and prudence are used by Greenspan as economic terms to refer to the percentage of income that is saved and invested for future returns, although there may be other behavioral (e.g., Puritan) correlates that he has in mind.

Concerning other variables, Greenspan writes: "Producing a fully detailed model is beyond the scope of this book. But such a model would include a number of variables reflecting those verities of human nature [or culture - LE] that reveal long-term economic stabilities. Among them are time preference (and interest rates), equity premiums, corporate earnings-price yields, and, since the 19th century, the private savings rate. They reflect the outer limits to fear and euphoria that define the dynamics of the business cycle. For forecasting purposes they can be assumed to continue trendless [unchanged - LE] in the future. . . . In addition there are those stabilities that are not inbred, such as the sum of social benefits and gross domestic savings as a percent of

"Innovative (thinking outside the box) entrepreneurship and prudence are largely, if not wholly, culturally-driven traits."[31]

- Alan Greenspan [32]

Greenspan recommends cultural characteristics and metrics be included in the new era of 21st century economic forecasting models.[33] His relatively brief and topical discussion includes savings and investment rates (abstinence, forbearance and prudence), cultural differences in entrepreneurial risk-taking, and in the rule of law and corruption.[34] His primary examples are Euro-North countries v. Euro-South countries: Greenspan believes that "becoming more like Germany" (e.g., forbearance, prudence, a work ethic, a commitment to legal economic activity and paying taxes) is (in the abstract) the cultural solution to improve economic forecasts for Greece, Italy, Spain, and Portugal. [35]

Since Greenspan's book went to press there is growing agreement that national and cultural differences must be included in forecasting models. Although these still are, to a degree, a "black

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GDP. Other forecast stabilities include the size of the workforce - those potentially in the workforce have already been born - and average hours worked." p. 292.

[31] China and Japan are cited as cultures that restrict innovation (p. 231).

[32] *op. cit.*, p. 231.

[33] Adherence to the rule of law can be proxied by the share of illegal activity in GDP. Other national/cultural characteristics include social harmony and communications and a functional political system. (p. 231).

[34] Note that there are opposite elements in Greenspan's model of economic growth - prudence (for savings) and risk-taking entrepreneurs.

[35] See also Lewis's observations that include Ireland and Iceland (different peoples with different reasons) that took the cheap credit to the point of disaster: Michael Lewis, Boomerang: Travels in the New Third World (New York: W. W. Norton, 2011).

box," the scientific failure to include them apparently has led to serious policy mistakes during the recent recovery, with (sometimes) opposite national effects of austerity from those that were forecast by economists. [36]

- Again, Greenspan may be right in his list, but there are political implications to these equations and the social science package will need to be robust. For example, a.) Asian cultures with traditions of hierarchy, combined with obligations for moral, benevolent, responsible and competent leadership, may develop a group-based psychology that is a source of competitive economic strength. In Japan, a psychology of dependency within firms (a hated characteristic, in the terms of Ayn Rand or Governor Romney's analysis of American economic performance) may be consistent with a highly competitive global automobile industry; [37] b.) Porter's work on

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[36] Howard Schneider, "An Amazing *Mea Culpa* from the IMF's Chief Economist on Austerity" Washington Post, January 3, 2013 concerning a (still, somewhat mysterious) set of differences that imposed remarkable damage on the Greek recovery and that can change over time. For European recovery, pro-austerity recommendations were based on a forecast of a fiscal multiplier of 0.5 when the actual multiplier sometimes was 1.5, meaning that a dollar reduction in government expenditures actually produced a $1.5 dollar reduction in GDP. Concerning other national/cultural variables that have emerged on the "to do" list to include in forecasting equations, see also Lawrence Summers, "Lessons Can be Learned from Reinhart-Rogoff Error." Washington Post. May 5, 2013 (discussed at footnote 4 above): ". . . [W]hy should it be the same in countries with and without their own currency, with very different financial systems, cultures, degrees of openness and growth experiences?"

[37] Concerning dependency inside a benevolent hierarchy: The allegedly growing American trait cited by Governor Romney as dysfunctional and true of 47% of Americans in a "too generous" welfare state may, as part of a package, be a successful feature of Japanese culture and many of its economic organizations: see Frank Johnson, Dependency and Japanese Socialization: Psychoanalytic and Anthropological Investigations of *Amae* (New York: NYU Press, 1995). The possibilities of cross-cultural learning and of culturally appropriate public policies are explored in Nicolas Berggruen and Nathan Gardels, Intelligent Governance in the 21st Century: A Middle Way Between West and East (New York: Polity, 2012).

international competitiveness suggests a wider set of nation-state metrics.[38]

There are many new cultural and sub-cultural groupings (e.g., c.) the economic behavior and causal dynamics of youth cultures) that might be the units of analysis, especially in countries with high and uncorrected rates of prolonged youth unemployment. Concerning the psychology of lower status individuals and their cultures: There may be d.) a Primate Subordination Syndrome that - even in objectively similar circumstances - reduces motivation, affects stress and endocrine levels and health, inhibits educational achievement, and is pervasively destructive of lower status primates.[39] The comparative neuroscience of lower status cultures may reveal a new universe of unrecognized causes (via the visual cortex and hierarchical imagination) of limitations in human economic potential. e.) The changing (post-deregulation) cultures (supported by changed recruitment and self-recruitment) of Wall Street and the financial world may be critical variables for economic forecasting.[40] f.) There are important (known) sub-cultural differences in

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[38] Michael Porter, Competitive Advantage (New York: Free Press, 1985).

[39] Studies of the Primate Subordination Syndrome may clarify a parallel inhibiting factor in regulations - i.e., if they also are perceived as establishing a status and dominance hierarchy. Subjectivities are important in the measurement of the inhibition of economic motivation by status ranking: Sub-cultures may provide inoculating effects (e.g., strong religious identities with the vividly experienced assurance of love and respect from a Supreme Deity and social support) and perceptions of economic opportunity also may mitigate these effects. See Lloyd S. Etheredge, "Neuropsychology and Rapid Learning Systems About Social Problems," unpublished, January 2010 and October 25, 2012 (online at www.policyscience.net at II. A. For some of the emerging correlates of subjective inequality on health and economic and social participation and (possibly) social problems see Moises Velasquez-Manoff, "Status and Stress," The New York Times, July 27, 2013.

[40] Tom Wolfe, The Bonfire of the Vanities (New York: Picador, 2008), reprint. The new "Masters of the Universe" status psychology may view members of Congress and political leaders (by judging their annual salaries) as (at best) hired middle management. The global political manipulation and exploitation of tax laws and regulations reflect a subjective change. In the 1960s most American businessmen felt poorly informed about the world beyond the water's edge

the motivation for economic achievement, and problems of structural discrimination and limited economic opportunities for different groups, that effect economic performance. (Euro-South and other cultures that discriminate against women or that limit access to good schools and higher education for their youth (to cite obvious examples) may inhibit their own economic growth). [41]

B.) Inclusive Social Science Lists

In Step 2 a planning group will reach out to include known (or suspected) R&D variables and metrics from other economists and disciplines. These ideas, like Greenspan's, are at risk of disappearing unless they evolve into metrics and their contribution can be evaluated by inclusion in R&D data systems.[42] At this point, we can measure almost any variable once we agree what they are.

4.) Behavioral Economics and Neuroscience

Researchers in behavioral economics often complain (rightly) that they are constrained to use small N experimental studies and do not yet have national data systems to allow the relevance of

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and were hesitant to become involved in political lobbying: Raymond Bauer, Ithiel de Sola Pool, and Lewis Dexter, American Business and Public Policy: The Politics of Foreign Trade (New York: Atherton, 1963). For the historic evolution of accounting and legal departments (from "just pay what we owe") into major profit centers with global strategic plans and lobbying see, for example, David Kocieniewski, "GE's Strategies Let It Avoid Taxes Altogether," The New York Times, March 24, 2011.

[41] Max Weber, The Protestant Ethic and the Spirit of Capitalism (New York: Penguin Classic, 2002) reprint; David McClelland, Human Motivation (New York: Cambridge University Press, 1988), Charles Murray, Human Accomplishment (New York: Harper Collins, 2009), and the work of Dean Keith Simonton.

[42] For a range of emerging diagnoses about missing variables see the IMF Rethinking Macro Policy II: First Steps and Early Lessons conference of April 2013, with papers online: http://www.imf.org/external/np/seminars/eng/2013/macro2/

their discoveries to be evaluated. This planning project will be their chance. [43] [44] [45]

Among other theorists, David Brooks has started to map a universe of fresh thinking about social and economic policy based on neuroscience discoveries. There is a new Society for Neuroeconomics (neuroeconomics.org) and emerging doctoral programs in neuroeconomics, and neurobiology and social science, whose members might suggest metrics for panel studies with genetics and brain data.[46] Full genomic mapping has fallen to $1,000 per individual and is heading toward $100 per individual: already genetic data (with some behavioral, social, and environmental data and electronic health records) are available in research databases (e.g., N=500,000 for the www.rpgeh.kaiser.org project).

An exciting challenge for this fourth task is to evaluate the possibility of genetic diversity in

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[43] Daniel Kahneman, Thinking, Fast and Slow (New York: Farrar, Straus, and Giroux, 2011). The growth of behavioral economics with support from the Sloan and Russell Sage Foundations is addressed in Floris Heukelom, Behavioral Economics: A History (New York: Cambridge University Press, 2014).

[44] This step also will include metrics to explain and forecast innovation rates. Greenspan believes that it is the role of the financial sector to assemble and channel needed funds. However, a wider list of metrics is needed: innovation systems are much wider than a financial system. See Robert D. Atkinson and Stephen J. Ezell, Innovation Economics: The Race for Global Advantage (New Haven: Yale University Press, 2012).

[45] Olivier Blanchard posits a new behavioral variable: “adjustment fatigue . . .which is leading to maybe less reforms than would be desirable.” Transcript of a Press Briefing World Economic Outlook, October 8, 2013. International Monetary Fund, online.

[46] Concerning new funding, metrics and data systems: James Gorman, “The Brain’s Inner Language,” The New York Times, February 24, 2014. Investments include the EU’s decade-long $1 billion Human Brain Project and the Obama Administration’s $100 million startup.

the most important aspects of human nature relevant to economic behavior.[47] Only a very small number of people participate in creating financial booms and catastrophes and they may be atypical.

5.) Human and Social Capital

At the beginning of the 21st century most of the world has decided that market capitalism is the best engine for the future. There is a powerful and reciprocal relationship between the human and social capital of a society and the performance and outcomes (intended and unintended) of the economic system.

a.) Education. Especially in an emerging age of information technology and skills, investments in human beings are probably the most powerful contributions to economic growth. An exciting cluster of measurements can help to understand new, transformative opportunities for MOOCs and global education. We can bring a curriculum, equal to the best in the world, to the desktops of everybody in the world, virtually without charge. There is much experimentation to be done, and many additional investments required to turn online resources into a truly powerful education.[48] The second planning group will be asked to address the question: What should we measure?

STEM education has been proposed as a global metric, but one of the best areas for R&D research may be the psychological package of attainments that allows individuals to flourish as

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[47] Greenspan believes that human nature is homogenous with respect to the major characteristics affecting economic behavior and performance. However high IQ is an exception: higher IQ increases capacities for abstraction and forethought, self-control, and delayed gratification, and thereby supports successful entrepreneurship and capitalism.

[48] U.S. President's Council of Advisers on Science and Technology (PCAST), Memorandum to President Obama concerning economic mobility, higher education, and MOOCs. December 2013. Online at www.whitehouse.gov.

“entrepreneurs” in their own lives and in the freer and more individualist societies implied by the system of market capitalism.[49] [50] A neuroscience snapshot of this larger “future-imagining-and-realization” or ”taking responsibility for projects” cluster might include developing: 1.) capacities to be self-starting; and 2.) to create clear goals in which there is a genuine personal stake and that call forth commitment; 3.) to relate to aspects of realities as socially- and personally- created and changeable; 4.) learning how to identify or create alternatives; and 5.) how to decide upon and develop plans of action, assemble resources and enroll people and support (sometimes, including coaching); 6.) new brain mechanisms linking together abstraction, foresight and self-management (to achieve goals); 7.) a growing capacity to persevere (for short periods in doing elementary school assignments to several years when writing a Ph. D. thesis or book, and, then, even decades; 8.) growing cognitive capacities to manage integrated complexity and live and work with uncertainties and open-ended lines of thinking; 9.) capacities to persevere through a possible roller coaster of emotions along a path; 10.) to be self-reflective and able to think honestly and with integrity about what is working or not working; 11.) to be responsible about outcomes and breakdowns; and 12.) bring self-initiated projects to completion at a level of excellence.

In many areas of the world, formal educational systems (K-12 and college- even formal business schools) are not focused on doing the best job that they can to support this cluster and the future health that they imply for the world’s economic systems. STEM education may support this growth, but it is a narrow idea and, in the wrong hands, any content-specific curriculum and testing program can become the use of authority and peer pressure to motivate

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[49] This educational cluster also will work for nonprofit institutions. The achievement/competitive drive for market capitalism is a separate psychological dimension: see McClelland and Winter, *op. cit.*

[50] The sociology of the G-20 education system and its relationship to G-20 economics involves a much wider set of issues. Mass production technologies may only have required mass production classrooms, with the goal of producing socialized students who were certified as willing to sit at desks for long periods and perform tasks assigned by authority, to reasonable standards, even if these were boring. Unless there are the right G-20 measurements, STEM education also can develop in this model.

behavior and produce diligent and mechanistic equation-solving or memorization. In truth, thoughtful measurement will be required from a planning group because the "being the entrepreneur and organizer of your own future" cluster might grow in many ways and from different sources: learning how to write academic papers and plan research, how to go step by step in your head to solve an algebra or geometry problem, practicing and achieving excellence in a competitive sport or playing the cello, or being a leader in student government, or (perhaps) an evolution of MOOCs, capstone projects, and new ways of teaching.[51]

b.) Moral breakdowns of institutions (including moral betrayal) may slow economic recovery, even if the issues are not discussed in public. David Brooks writes: "Moreover, it is harder to accept that psychological factors like uncertainty and anxiety really are a mirage . . . It has been harder to dismiss morality as a phantom concern, too. Maybe in a nation of [economic] robots the government can run a policy that offends the morality of the citizenry, but not in a nation of human beings."[52]

c.) The possibility that we are destroying social capital (without being fully aware of the

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[51] Comparative metrics for the performance of educational systems may be revealing: Greenspan's (Euro-South) cultural critique of Italy, Greece, Spain and Portugal suggests that serious limitations of their authority-oriented and conventional K-12 educational systems also may exist. Public policy research in the US has found that first-rate schools (and graduation from high school) works. Good K-12 schools is emerging as one of the best societal investments for the economic and personal success of individuals. See Ron Haskins and Isabel Sawhill, Creating an Opportunity Society (Washington, DC: Brookings, 2009).

[52] David Brooks, "The Two Cultures," The New York Times, November 15, 2010. Online. See also Robert Fogel's AEA Presidential Address "Catching Up with the Economy," American Economic Review, 89:1 March, 1999), pp. 1-21 about "commodities that lack material form" and his The Fourth Great Awakening and the Future of Egalitarianism (Chicago: University of Chicago Press, 2000). Anomie in the former Soviet Union (a case that Greenspan does not discuss) is a striking example of perceived moral breakdowns that illustrates their devastating effects on many aspects of life.

process) is raised by Charles Murray and other writers.[53] 1.) High divorce rates and single parent families may (especially without compensating investments) be a bad idea for children with long term costs to themselves and to society. 2.) There may be a vital degree of now-eroding social capital, and trust, that depend upon the experience of people that good values and hard work and social responsibility are appreciated and rewarded. Politicians across the US political spectrum now run for office and address a perception that "playing by the rules" is not working in America. 3.) In Europe, astonishing and uncorrected rates of youth unemployment are accompanied by a politically dangerous and demoralizing public discussion of "a lost generation" that ultimately may not accept its fate.[54] 4.) The expectation (and reality) of social mobility may be part of social capital: variables associated with social mobility, across regions in the US and abroad, are likely to be revealing of partial blockage in causal pathways for economic health.[55] 5.) The Spence *et al.* consultation process addressing Chinese economic growth predicts that greater inequality in society is corrosive and becomes dysfunctional: inequality creates different interests and erodes a political process; it also fuels political combat and redirects energies that could be used more productively.[56]

- d.)<u>The Psychological Economy</u>. The broader agenda for the planning group will be to

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[53] Charles Murray, <u>Coming Apart: The State of White America, 1960-2010</u>. (New York: Crown Forum, 2012).

[54] For forecasting equations illustrating potential destabilizing effects of prolonged high unemployment for different groups, see Alan de Bromhead *et al.*, "Right-wing Political Extremism in the Great Depression." Unpublished working paper online at www.voxeu.org.

[55] See the geographic variations in social mobility within the US and new variables identified by by Raj Chetty and his associates: http://www.equality-of-opportunity.org/

[56] Edwin Lim, Ian Porter, Paul Romer, and Michael Spence, "Medium and Long Term Development and Transformation of the Chinese Economy: A Synthesis Report." March 2011 (online at www.cairncrossfund.org): "If not addressed such disparities risk fueling greater social conflict and instability," p. 69. See also their lesson for new models: "social policymaking must be tightly integrated with economic policymaking," *op. cit.*, p. 71.

advance the sensitive and respectful measurement of the “psychological economy” - which I define (following Fogel) as all aspects of the economy - its input and functioning, and its “commodity” outputs and effects - that lack a material form. Coming from the metrics and the limited concerns of national income accounting (and independent and dependent variables defined by accountants and the tax code) and the physical realities of nation-state, steel plant economies, these new metrics will help us to grasp a changing world of complex, sometimes interdependent, systems and subsystems whose outputs shape the quality of our lives and the material-form economy.[57] One of the leading edge questions (likely to be flagged as “important, but needing further research before metrics can be recommended”) is a refined understanding of the social recognition and status economy and the production systems that societies link to what Greenspan calls the “herd' (social) instincts. Competition for recognition and status can be as important as competition for economic rewards. And institutions and societies create status scarcities and competitions that function as motivators. (Arguably, one of the most important reforms that Margaret Thatcher brought to the UK was to make it socially acceptable for higher status people to become successful entrepreneurs.)

6.) Political Variables

> “Shadow banking is a form of financial intermediation whose funding is not supported by the traditional banking safety nets . . . the shadow banking system remained slightly more than half the size of the regular banking system throughout the 2002 to 2011 period . . . In the United States alone, shadow banking constituted $23 trillion in assets at the end of 2011, by far the largest constituent of the global network of

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[57] See, *inter alia*, Lasswell and Kaplan, *op. cit*.; Robert E. Lane's pioneering The Market Experience (New York: Cambridge University Press, 1991) and The Loss of Happiness in Market Democracies (New Haven: Yale University Press, 2001); Robert Putnam, Bowling Alone: The Collapse and Revival of American Community (New York: Simon and Schuster, 2001); Fogel, “Catching Up” and The Fourth . . ., *op. cit.*

nonbank credit intermediaries."

-Alan Greenspan [58]

"Institutional flaws are best prevented, because they are hard to fix. Once an institutional structure is in place, people quickly acquire a vested interest in its preservation. The flawed structure then becomes surprisingly resistant to reform, as the US health-care system clearly demonstrates."

- Lim, Porter, Romer and Spence [59]

"Our highest priority going forward is to fix our broken political system."

- Alan Greenspan [60]

Every societal goal has a production function: most desired outcomes can be produced several ways and by different mixes of inputs. In turn, politically, each input mix may allocate new economic income, status, power and control differently, to different beneficiaries and constituencies. To improve scientific knowledge and (with a genuine Honest Broker intent) to build political support, step six also will seek input from a full range of think tanks, activists, and others to expand upon Greenspan's list.

Greenspan has a wide range of personal observations about dysfunctional political systems, ranging from a theory that an *angst* caused by American political schism and conflict is reducing long-term business investments and slowing recovery, to genuine puzzlement about why Washington leaders cannot sit down (as they did in earlier days) for drinks after hours and reach

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[58] *op. cit.*, pp. 40-41.

[59] Edwin Lim, Ian Porter, Paul Romer, and Michael Spence, "Medium and Long Term Development and Transformation of the Chinese Economy: A Synthesis Report." March 2011 (online at www.cairncrossfund.org), p. 71. Discussed in footnote 4.

[60] *op. cit.*, p. 302.

compromises.[61] This initial project cannot do full justice to the range of these conceptual, theoretic, and measurement issues, which have extensive literatures in several social science disciplines. However, several key political system issues can be reviewed by the second planning group.

a.) Is "Human Nature" a Political Misdirection?

Social scientists will instinctively ask whether Greenspan's ("it's human nature!") ideas are a political misdirection and *mea culpa* that focus attention away from the real (political) variables that should be included in the world's macroeconomic prediction equations. Yes, the Tulip Mania of the 1630s and many of the financial bubbles and panics of history may have been produced by primitive emotions and people who stumbled through history to a catastrophe and did not understand the eventual behavior of the system and their fate.[62] However, the world's "shadow" banking systems [whose size is indicated by Greenspan in the quotation at the beginning of this section] and their international lobbying expenditures and political largesse did not arise by accident.[63] And the first edition of Kindleberger's Manias, Panics, and Crashes: A History of Financial Crises (now in its sixth edition) was published in 1978.[64] Of course Kindleberger did not intend to write a handbook, but subgroups in generations of financial analysts, by now, may have gone to school on the amounts of money that they can make if they

[61] Greenspan has a list of observations about how the American political system (and the Latin American political systems, and the Chinese political system, and the Euro-South political systems, etc.) are dysfunctional. Some of the problems might benefit from a greater degree of agreement in economic science: Greenspan may be right that Latin American Populism is a "shout of pain" and can be shown to lack a coherent and effective economic theory.

[62] However see CW and AJKD, "Was Tulipmania Irrational?" The Economist, October 13, 2013.

[63] See also Sebastian Mallaby, More Money Than God: Hedge Funds and the Making of a New Elite (New York: Penguin Press, 2011).

[64] (New York: Basic Books, 1978).

activate asset bubbles, and then manipulate the irrationalities and deceive the trust of others and, thus, outsmart the system. In the recent crisis, brilliant hedge fund managers hyped asset bubbles, falsified or obscured credit ratings, and also bought insurance (e.g., through AIG) to cover themselves when the asset bubbles finally burst. *Pace* Greenspan, perhaps the instincts that society has to blame, or worry about, are not homogenous endowments of animal spirits or shared herd (social) instincts of people drawn into the irrational exuberance of competitive games, but brilliantly rational, realistic, strategic (gratification-deferring) predators at the atypical upper tail of statistical distributions? In a phrase of the psychologist William James, "the beaked and taloned predators," with an absence of social instincts?

b.) <u>Politics can be the continuation of economic competition by another name</u>. The news media can draw audiences by creating a drama that implies, ultimately, that governments are in charge of societies. However some businessmen do not live inside this media-created drama. The possibility that some wealthy entrepreneurs might relate to national government and politics as dependent variables (to be manipulated and managed) is a possibility that may be especially important to explore for G-20 nations since assertive (and, ultimately, poorly regulated) actors in a subset of G-20 countries may collude and act across national boundaries. There is indirect evidence to suggest that growing asymmetries of brainpower and concentrations of wealth are deployed against (penetrated) political systems to induce deregulation and achieve other benefits. Specifically, the world had, from the late 1970s through 2003 (according to IMF data) 117 crises of banking systems in 93 countries in which much or all of the capital of the system was exhausted. In Martin Wolf's assessment of these cases, the banking industries developed strategies of privatizing their gains during the upside of financial bubbles, then secured government bailouts from taxpayers as losses during the crisis phase became large enough to wipe-out remaining bank equity and destroy the economy. In 27 of the earlier crises, taxpayers were stuck with added public debt equal to, or greater than, 10% of GDP, often much more. When similar, highly strategic people continue to win ["privatize the gains"], with a similar *modus operandi*, the better, new forecasting models might be based on the classic dynamics of predator-prey ecosystems described by the Lotka-Volterra equations.[65] If this theory proves to be correct, and the G-20 nations want to improve economic forecasting, the best question suggested by upgraded social science forecasting could be: "What are *they* [the alpha predators] planning next?" And every chief of state might ask that the best (public) economic forecasting models be accompanied by secret reports and forecasts from his intelligence agencies based on massive penetration of the national and global financial sectors and especially the "shadow" sector.

By contrast with Greenspan, it is interesting to consider the perspective of David Stockman, a former OMB Director for President Reagan who later made a fortune on Wall Street. In Stockman's view, the major players always are trying to outsmart each other - and the same instincts are directed against governments as on the economic playing fields; in his analysis, few governments, including the American government, can play in this new game and win.[66]

C. Finding Unknown Variables and Organizing Rapid Learning Systems

> "We are confronted with . . . 'unknown unknowns' . . . "
>
> \- Olivier Blanchard [67]

The third planning step will develop methods to find unknown variables and causal relationships and organize rapid learning systems.

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[65] Martin Wolf, Fixing Global Finance (Baltimore, MD: Johns Hopkins University Press, 2008), pp. 32-33. Lloyd S. Etheredge, "Predator-Prey Models: Forecasting a Global Financial System with Asymmetries of Brainpower and Money," Memorandum # 17 for the Fischhoff (NRC) Committee on Behavioral and Social Science Research to Improve Intelligence Analysis for National Security. Online at www.policyscience.net at II. D.

[66] David Stockman, The Great Deformation: The Corruption of Capitalism in America (New York: Public Affairs, 2013).

[67] David Wessel, "Olivier Blanchard's Five Lessons for Economists from the Financial Crisis," Wall Street Journal, April 1, 2013.

The model for Step 3 will be the new rapid learning systems of international biomedical research that use “Everything Included,” large N, curated databases partly underwritten at public expense. Until recently, cancers were classified by their site of occurrence (e.g., breast cancer, lung cancer). Now, with “Everything Included” databases (100,000++ variables per patient, and tens of millions of patients and their genetic information and electronic health records being linked in international networks), new machine learning algorithms have established themselves as a disruptive, breakthrough technology. They brilliantly help human researchers to replace old paradigms more quickly than traditional systems of single investigator awards. An investigator is not limited to imagine (ahead of time) the specific hypothesis to be tested and, then, fated to discover unknown variables only by accident.

With this powerful investment in new scientific technology, the biomedical world is changing. It now appears that there may be 10 or more different types of cancer that appear in the breast or the lung (etc.), each with its own complex causal pathway (linked to the genetics of the specific individual). Each type has its own universe of newly emerging treatment possibilities and the exciting future that humanity is facing is a new *precision* medicine also tied to genetic and other unique characteristics of each patient. [68]

Discovering unknown variables and relationships is becoming an automated science. This could be G-20 macroeconomics!

For this third planning group I think that the challenges to develop “Everything Included” research strategies are: What constitutes Everything? (For example, when you include psychology and neuroscience and when the social sciences do not yet have the equivalent of the periodic table and the human genome?) How fast do we want to learn? And what G-20 priorities to recommend? It is an open-ended question, and the powerful machine-learning Big Data, paradigm-busting methods may be sensitive to initial omissions of variables or error rates in

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[68] B. Vogelstein *et al.*, “Cancer Genome Landscapes,” Science, March 29, 2013, pp. 1546 - 1558, attached to this proposal.

metrics.

7.) Big Data and Private Sector Partnerships

The seventh planning project will map how the startup of "Everything Included" R&D economic data systems can be linked together in international partnerships with the private sector. A useful initial global project might be data mining and rapid, cumulative learning concerning consumer/household behavior and marketing.[69] Just as 11,000 individual Walmart store managers in 27 countries are currently expected to run three to five experiments each week, so a R&D consortium of interested global corporations could be linked with leading business schools in rapid learning systems.

For example, it might be easy for these partnerships to organize large N, randomized cross-cultural experiments of advertising and marketing for all demographic groups and all nations and cultures.[70] Companies like Mastercard or Google would have incentives to contribute data to an initial R&D data system, since discoveries of how their data can be combined with other data make the business case for why their future data should be purchased to improve economic models and forecasting, worldwide.[71]

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[69] See Liran Einav and Jonathan Levin, "The Data Revolution and Economic Analysis." Unpublished manuscript, May 1, 2013 prepared for the NBER Innovation Policy and the Economy conference.

[70] Concerning steep cost reductions by designing collaborative global rapid learning systems, see Michael S. Lauer and Ralph D'Agostino, "The Randomized Registry Trial - The Next Disruptive Technology in Clinical Practice?" The New England Journal of Medicine, October 24, 2013, pp. 1579 - 1581.

[71] Academic social science might benefit from this project. American social psychologists typically have used their undergraduates as experimental subjects, and there are sparse discussions in standard textbooks about how human beings in other cultures might behave differently than American undergraduates in the late 20th and early 21st centuries. A discovery by American

8.) New Methods

> "How reliable are these tools? . . . They work but they don't work great. People and institutions find ways around them."
>
> - Olivier Blanchard [72]

The third planning group also will consider recommendations for faster and better learning cycles in the US and G-20 nations. For example:

a.) Data collection and analysis should be faster and supplemented by new methods to estimate coefficients. Traditional forecasting uses quarterly time series data and regression equations, but this clearly is too slow and unable to detect changing coefficients in a timely fashion. A new universe of real-time sampling and monitoring will be useful: Walmart has global data on sales, by store and product, online within 24 hours and the global banking system clears most of the transactions of the world economy within several days. Soon, it could be possible to monitor economic behavior and track the effects of economic policies in real time.

b.) To work through, and master, the integrated complexity that economic science must face requires new methods for modeling and display. These are large, living, complex and (sometimes) adaptive systems composed of large, living, complex and (sometimes) adaptive subsystems that may be loosely or tightly coupled or even partly inconsistent with each other. The biomedi-

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Express [informal communication] that social media effects (e.g., knowledge of a friend's purchase) have 3- to 5- times greater impact to influence purchasing decisions of Egyptian teenagers (compared to American teenagers) may stimulate thinking for a wider universe of new and informative discoveries about cross-cultural social psychology.

[72] Wessel, *op. cit.*. Blanchard's five lessons emphasize the need for analytic tools with much more "plumbing" detail: "We do macro on the assumption that we can look at aggregates in some way and then just have them interact in simple models. I still think that's the way to go, but [experience] shows the limits of that approach. When it comes to the financial system, it's very clear that the details of the plumbing matter."

cal world has been evolving new and sophisticated computer simulation models of the human body (beginning at the molecular level) - with extensions to medical practice decisions, public health and government policy - that will be worth evaluating for their applications to macroeconomics and G-20 forecasting.[73]

c.) Cross-walking past economic policy mistakes and forecasting errors in G-20 countries may be useful: A new, meta-learning strategy in biomedical research is to analyze the eventual discovery of lethal side-effects of approved drugs and to calculate how much larger new rapid-learning data systems should become if we want to catch such types of mistakes in the future in three months, or six months, or two years (etc.).[74]

d.) Panel studies are another useful innovation, especially to achieve the “Everything Included” vision for R&D. [Traditionally, economists have correlated independent and dependent variables (defined by accountants or tax laws) and told (without an independent examination of the mechanisms) a rational choice, profit-maximizing story to explain the links. Now, with alternative explanations and pathways, panel studies can, using multiple methods, provide much more information, and in depth, to compare different theories.] Especially with compensation, many people might be willing participants. In addition to formal guarantees of privacy, the panel membership could be limited to several years and, thereby, reduce concerns about broader invasions of privacy. There are multiple groups of actors in economies, and a diverse range of these panels are likely to be recommended by the planning group.

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[73] For example David Eddy's Archimedes Project originally developed for Kaiser Permanente: http://archimedesmodel.com/ . The model and its mathematical methods recently have been acquired for international medical practice, pharmaceutical research, and public health advising by STG, a global venture capital company.

[74] See Larry Norton's overview of the wider rapid learning system for cancer, https://www.ecri.org/Video/2013_TA_Conf/4-Session-1-Norton.mov. See Blanchard (2011) *op. cit.*

e.) Computer-assisted content analysis (discussed in footnote 14) may help to understand public moods and the emotional component of recovery processes.

f.) Empirically-defined variables (rather than accounting-defined variables) might be useful experiments. Greenspan's forecasting ideas place great weight on the (alleged) very high rate of consumption (and low savings) in American households, but most families may view many of their expenditures differently, as investments contributing long-term benefits to their lives and the lives of their children.

g.) To libertarians, except for the contributions of a minimal government (e.g., national defense), most public sector expenditures can be just political shell games and "theft" (transfer payments). Greenspan does not use this term: However a current lack of analysis methods skews his analysis into a story of how the financial sector, securing private savings, plays the leading role in the economy by assembling and allocating funds for the new investments that increase productivity and the possibility of higher standards of living. Yet all sectors (including governments) actually make investments. The broader measurement challenge for forecasting equations is to measure what investments are good investments, not who makes them. Whether society is "investing enough" cannot be calculated, as Greenspan does, by the percentage of the average household income that is saved: the public sector investments (paid through taxes or deficits) also must be measured and evaluated.

h.) Weighted scenarios and game-theoretic methods (even war games) may be useful to forecast the emerging national and global financial systems with asymmetries of wealth and brainpower. In testimony to draft laws and regulations, some economists already systematically analyze loopholes and vulnerabilities and forecast how these will be exploited.[75]

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[75] Charles Calomoris and Alan Meltzer, "How Dodd-Frank Doubles-Down on 'Too Big to Fail,'" Wall Street Journal, February 12, 2014. See also Sheila Blair's answer to the questions: "Can regulators ever be as nimble as the regulatees?" and "Given the cat and mouse game between regulators and regulatees, do we have to live with regulatory uncertainty?" In her "Everything the IMF Wanted to Know About Monetary Regulation and Wasn't Afraid to Ask"

9.) Rapid Learning Systems

> "With a century and half of clear, detailed information on crisis after crisis, the burning question is not How did this happen? but How did we ignore that long history, and think that we had solved the problems with the business cycle?"
>
> - Joseph Stiglitz [76]

An evolving design of a global rapid learning system for macroeconomics needs a self-reflective theory of itself - and metrics. The practical realities of the system, and the speed of its learning cycles in the G-20 (and beyond), will depend upon the evolving design of a complex (sometimes) adaptive system composed of complex (sometimes adaptive) subsystems. Once, the focus of philosophers was to discover how a single individual could become wise: Today, we recognize wider problems, especially in democratic systems: How, in Stiglitz's terms (in the quotation above) do we get *other* people (and systems) to listen and to remember?[77]

Creating a rapid learning system also will depend upon recognizing that it is in the self-interest of each G-20 nation, in a world of globalizing economies, that other nations (and private sector decision makers) adopt realistic and evidence-based policies and that everybody prospers. Upon a news media that support the system. And upon funding, honesty and reliability, and institutional homes, and much else. What are the variables to measure, the theories to test, who are the allies, where is the funding, what are the disruptive technologies to deploy?

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online at http://www.imf.org/external/np/seminars/eng/2013/macro2/pdf/sb.pdf

[76] Joseph Stiglitz, "The Lessons of the North Atlantic Crisis for Economic Theory and Policy," http://blog-imfdirect.imf.org/2013/05/03/the-lessons-of-the-north-atlantic-crisis-for-economic-theory-and-policy/

[77] See also Etheredge, "Wisdom . . ." *op. cit.*; Ascher, *op cit.*

II. Work Plan – May 1, 2014 – June 30, 2017

The project will organize an Advisory Committee to develop initial plans. Next, it will complete three steps in three years (each step taking about a year, with three areas of focus). Each step will have a planning group (N=12-14 members, with a degree of overlap) and will produce a Report.

Each planning group will produce a report (i.e., the grant will deliver three Reports) to the sponsors with recommendations of variables and metrics to produce a state-of-the-art international rapid learning system for macroeconomics. Each of the three Reports will address: 1.) Recommended variables and metrics that are on the shelf and that can be deployed immediately; 2.) Recommended metrics that can become available soon, with additional work; 3.) Important areas where further R&D is needed before metrics can be recommended.[78]

The budget supports a full time Principal Investigator with part-time assistance and expenses. Expenses include honoraria and travel for Advisory Committee and planning group members, initial discussions between the PI and each working group member, and a 1 ½ day meeting of each planning group.

The Advisory Committee (five members) will be the joint responsibility of the PI and [the home institution for the project]. The project is envisioned as part of a long term research program at [the home institution] devoted to achieving a rapid learning (international) system for macroeconomics. [The home institution] may seek additional funds for Fellowships, research to analyze new data, and additional, concurrent conferences and lecture series.

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[78] This initial project will focus on macroeconomics of the G-20 system. Additional data systems and better forecasting equations may benefit all countries.

III. Budget and Budget Narrative (to be added)

IV. Attachments

Bert Vogelstein *et al.*, "Cancer Genome Landscapes," Science, March 29, 2013, pp. 1546 - 1558.

Lloyd S. Etheredge, The Case of the Unreturned Cafeteria Trays (Washington, DC: American Political Science Association, 1976).

Lloyd S. Etheredge, Brief Biography and *Curriculum Vitae.*

Lloyd S. Etheredge
Policy Sciences Center
Project Director

"Re: An Experiment to Accelerate Biomedical Discovery and Economic Growth

Via: innovationstrategy@ostp.gov

Dear Deputy Director Jason Miller and Associate Director Tom Kalil:

This memorandum responds to your request (July 28,2014) for new strategies to accelerate scientific innovation and economic growth. I suggest an experiment to crowdsource the analysis of the new, huge NIH genetic databases. This initial experiment could be a spectacular success. Change how we think about the entire organization, division of labor, and potential speed of this new era of biomedical research. And discover new business opportunities for drug development and decision making tools for both physicians and consumers.

Crowdsourcing Big Data Analysis to Assist NIH

Scientific crowdsourcing allows us to multiply, by thousands of times,. the number of investigators who can analyze, test new hypotheses, and discover clues irr the new genetic databases for the universe of health problems. The method can save the government a great deal of money and time. The cost of cloud computing has dropped to the point where it is easier, much faster, and more cost-effective to conduct any proposed analysis of Reference Databases -and discover the answer -rather than waste the time to pre-screen hypotheses (i.e., and allocate once-scarce computer resources) by a peer-review process.

Rather than wait for individual grant applications -and to get started and learn lessons -I suggest that NIH and Amazon Web Services draw from the new, huge genetic and Electronic Health Record (EHR) databases to create a Reference Database for the study ofpeanut allergies.1 The Reference Database will exist in the Cloud, along with online analysis tools. The experiment will allow 24x7 online access to the Reference Database and computer resources, without charge, and will include online tutorials and a prototype discussion forum and large-scale collaboration system. The experiment will have an advisory panel to assist the design and draw lessons and a staff to develop the NIH!AWS online tutorials, an online reference library, and help users to learn the system. Eventually, the Reference Database will be archived for citation in publications and to allow reanalysis of earlier discoveries. Initial discoveries and better questions might evolve the experiment with a Reference Database 2.0 (see below).

Accelerating Scientific Innovation and Discovery

-There is an exciting flood of new data and a huge amount of important scientific work that should be done as quickly as possible. As a nation -and worldwide -we are blessed with an extraordinary number of educated people who might welcome this opportunity to participate in scientific discovery from their desktops: Current or retired physicians and biomedical researchers, science-trained individuals -perhaps with family members with these medical issues.2 And students, ranging from advanced medical students to bright undergraduates and even high school students who might be thrilled and drawn to STEM careers by the excitement of tackling leading-edge scientific problems with real data, and participation in an online collaboration process in which real science is being done.

Benefits to NIH

-The creative process, accelerated by scientific crowdsourcing, is likely to sharpen questions and accelerate NIH feedback loops for the acquisition of new data and a new Reference Database 2.0 .. [For example: peanut allergies may be several conditions that require new and more specific data about the different types and severity of symptoms, and different organ systems affected, from each patient. And the comparative efficacy of different treatments. Biome and ""gut bacteria"" data may be relevant. Individual differences in brain characteristics and emotional wiring may be relevant. The global collaboration framework can begin to explore reported cultural differences and accelerate the international expansion of the Reference Database system. The early age of onset may be an important clue, leading to an expanded Reference Database 2.0 with larger samples of children. Biobank data and analysis of additional proteins that were not originally encoded in the Reference Database 1.0 might emerge as worthwhile.]

Yours truly,
Lloyd S. Etheredge

Lloyd S. Etheredge
Policy Sciences Center
Project Director

[copy to innovationstrategy@ostp.gov]

Dear Dr. Handelsman and Dr. Chandler (NSB):

There is an exciting neuroscience hypothesis, outlined in the enclosed communication with the NIH Council of Councils, that could transform how we think about causal mechanisms affecting behavior and health in lower status populations - e.g., problems of STEM education attainment, unsolved societal problems within the purview of federal, state, and local governments, and the disproportional health costs of the "dual eligible" (Medicaid + Medicare) populations.<1>

This line of investigation needs your help: For emerging genetics-based research systems, the key federal/national challenge is to assure that we identify, and include, exploratory measures of social status, social relationships, and a full range of other (epigenetic) behavioral science variables in key genetics/EHR Reference Datasets for fast discovery research about these brain and health mechanisms. If we add these variable sets now, it will save us many years to play catch-up later. Kaiser/UCSF and VA are making forward steps, but only limited, to leverage genetics and EHR databases with social and psychological epigenetic hypotheses and variables.

This could be one of the most important, transformative discoveries for the social sciences and public policy in many years.

Re OSTP current projects: Breakthroughs along this dimension would be extraordinary discoveries of business opportunities for the pharmaceutical industry.

with best regards,
Lloyd Etheredge

<1. These "dual eligible" poor and elderly populations have an unusually high rate of societal problems, including alcohol and drug abuse, poverty and employment difficulties, serious mental illness, broken marriages and spousal abuse and account for a large share of federal and state health expenditures. Social marginalization and defeat can begin early; most people are resistant and recover but a syndrome, once established, can limit an individual's own resources and affect many areas of life.

Dr. Lloyd S. Etheredge - Project Director
Policy Sciences Center
c/o 7106 Bells Mill Rd.
Bethesda, MD 20817-1204
URL: www.policyscience.net; [redacted] (o)

Please reply to: [redacted]

[The Policy Sciences Center, Inc. is a public foundation that develops and integrates knowledge and practice to advance human dignity. It was founded by Harold Lasswell, Myres McDougal, and their associates in 1948 in New Haven, CT. Further information about the Policy Sciences Center and its projects, Society, and journal is available at www.policysciences.org.]

Lloyd S. Etheredge
Policy Sciences Center
Project Director

Re: 1.) Rapid Population of a new Global Data Net for the Pharmaceutical Industry and 500 Million Rarer Disease Patients.

Dear Jason Miller and Tom Kalil:

I am responding to OSTP's solicitation for ideas to accelerate innovation, economic growth, and competitiveness.

I suggest that the Obama Administration provide high level leadership to populate, quickly, a global data network for the pharmaceutical industry, academic researchers, and the 5%-7% of the world's people who suffer from the "rarer" diseases and conditions. These 6,500+ "orphan" diseases and conditions, defined as less than 200,000 in the US population, have not been of sufficient size to pay for the development of targeted pharmceuticals, including the cost of finding enough patients, readily, for clinical trials. Typically the symptoms are treated by guesswork and off-label use of drugs for other conditions. No physician sees enough patients with any one condition to cumulate experience. Worldwide, the total of sufferers is estimated to be about 500 million. The exciting possibility is that a new data net can create a new world of hope and innovation for these patients, with a creative partnership of governments, the pharmaceutical industry, and academic researchers.

The G-20 Summit and a High-Level Strategy Working Group

The first step already has been taken by NIH - investing in the software and infrastructure to support a global patient registry network and rapid learning system. The next step, that OSTP and the White House can take, is to work with the Australian government to organize a high-level strategy working group, at the fall G-20 summit in Australia, to get the word out to national health plans and medical practitioners in all countries, create metrics and milestones, and populate the data sharing system quickly. <1> <2>

These registry systems are not just for researchers: They give immediate benefits to health care providers and patients: they cumulate simple statistics about what is being tried and what works best to manage symptoms. They revolutionize costs and help researchers and pharmaceutical companies to recruit patients, at a very low cost, for clinical trials. They steeply reduce marketing costs for the pharmaceutical industry because news of new and approved drugs, or combinations of drugs, can be brought immediately to the desktops of personal physicians, worldwide, via the data network. NIH also is developing partnerships to pay costs for biobanks and genetic analysis that will be openly available to researchers and the pharmaceutical industry. The NIH registry net can protect privacy to US standards (and the standards of national health system).

There will be a new, shared data resource, a global playing field, and American companies are well-positioned.

Fast population is the key step: the goal is 500 million. OSTP can make the basic connections this fall. Once the high-level strategy working groups meet with a political blessing from their governments, and build relationships and a shared strategy to populate the data net, they will carry the ball and move quickly.

I am enclose a copy of the exciting strategy article that appeared in Lancet in 2010. **The Administration listened!** NIH followed-up and built the capability that - now - can be brought fully to life with help from OSTP, and a light touch of further leadership, to populate the system and give the critical mass that the pharmaceutical industry and academic researchers need for fast discovery and innovation.

One of the co-authors of the article is Dr. Yaffa Rubinstein at NIH, who has played a leading and visionary role - I will send her a copy of this message about possible high-level strategic assistance to get to the 500 million mark quickly. They have created a Website.

Lloyd Etheredge

<1> When there are national health systems, a pop-up box can appear whenever a rarer disease diagnosis code is entered and a physician (typically, a pediatrician - these conditions are first seen in childhood) can learn about the new resource and evaluate the benefits for his decisions and his patient.

<2>Australia has designated the goal of the summit as assembling ideas to raise GDP/capita growth 2% above projected baselines. As host, it has the lead to invite heads of state to bring senior delegations to develop options for strategic plans and build personal relationships for follow-ups.

[The Policy Sciences Center, Inc. is a public foundation that develops and integrates knowledge and practice to advance human dignity. It was founded by Harold Lasswell, Myres McDougal, and their associates in 1948 in New Haven, CT. Further information about the Policy Sciences Center and its projects, Society, and journal is available at www.policysciences.org.]

Lloyd S. Etheredge
Policy Sciences Center
Project Director

Dear Jason Miller and Tom Kalil:

I enclose a further submission, in response to your request of July 28, 2014. The innovation, described in the enclosed letter, also will be a catalyst to support several other Administration objectives, including STEM education.

with my best regards,
Lloyd Etheredge

THE POLICY SCIENCES CENTER, INC.

Project Director: DR. LLOYD ETHEREDGE
7106 Bells Mill Rd.
Bethesda, MD 20817-1204
Tel: (301)-[redacted]
E-mail: [redacted]

August 4, 2014

Mr. Jason Miller, Deputy Director, National Economic Council
Mr. Tom Kalil, Associate Director for Technology and Innovation, OSTP
The White House
1600 PA Ave., NW
Washington, DC 20500

Re: An Experiment to Accelerate Biomedical Discovery and Economic Growth
Via: innovationstrategy@ostp.gov

Dear Deputy Director Jason Miller and Associate Director Tom Kalil:

This memorandum responds to your request (July 28, 2014) for new strategies to accelerate scientific innovation and economic growth. I suggest an experiment to crowdsource the analysis of the new, huge NIH genetic databases. This initial experiment could be a spectacular success. Change how we think about the entire organization, division of labor, and potential speed of this new era of biomedical research. And discover new business opportunities for drug development and decision making tools for both physicians and consumers.

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Rather than wait for individual grant applications - and to get started and learn lessons - I suggest that NIH and Amazon Web Services draw from the new, huge genetic and Electronic Health Record (EHR) databases to create a Reference Database for the study of peanut allergies.[1] The Reference Database will exist in the Cloud, along with online analysis tools. The experiment will allow 24x7 online access to the Reference Database and computer resources, without charge, and will include online tutorials and a prototype discussion forum and large-scale collaboration system. The experiment will have an advisory panel to assist the design and draw lessons and a staff to develop the NIH/AWS online tutorials, an online reference library, and help users to learn the system. Eventually, the Reference Database will be archived for citation in publications and to allow reanalysis of earlier discoveries. Initial discoveries and better questions might evolve the experiment with a Reference Database 2.0 (see below).

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- There is an exciting flood of new data and a huge amount of important scientific work that should be done as quickly as possible. As a nation - and worldwide - we are blessed with an extraordinary number of educated people who might welcome this opportunity to participate in scientific discovery from their desktops: Current or retired physicians and biomedical researchers, science-trained individuals - perhaps with family members with these medical issues.[2] And students, ranging from advanced medical students to bright undergraduates and even high school students who might be thrilled and drawn to STEM careers by the excitement of tackling leading-edge scientific problems with real data, and participation in an online collaboration process in which real science is being done.[3] [4]

Benefits to NIH

- The creative process, accelerated by scientific crowdsourcing, is likely to sharpen questions and accelerate NIH feedback loops for the acquisition of new data and a new Reference Database 2.0.. [For example: peanut allergies may be several conditions that require new and more specific data about the different types and severity of symptoms, and different organ systems affected, from each patient. And the comparative efficacy of different treatments. Biome and "gut bacteria" data may be relevant. Individual differences in brain characteristics and emotional wiring may be relevant. The global collaboration framework can begin to explore reported cultural differences and accelerate the international expansion of the Reference Database system. The early age of onset may be an important clue, leading to an expanded Reference Database 2.0 with larger samples of children. Biobank data and analysis of additional proteins that were not originally encoded in the Reference Database 1.0 might emerge as worthwhile.]

Yours truly,

Lloyd Etheredge

Dr. Lloyd S. Etheredge

Notes

1. Peanut allergies are a relatively well-defined medical condition for crowdsourcing analysis, compared to such broad diagnoses as asthma. About 1.5 - 3 million Americans appear to be affected (0.6% - 1%) and the problem may be growing (for unknown reasons). For an overview: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC154188/

2. The Cochrane Collaboration (http://www.cochrane.org/) has been a remarkable success in organizing science-trained individuals to support evidence-based medicine. They might have suggestions about how to structure an experiment that allow interested and knowledgeable members of their networks, in 120 countries, to participate in the analysis and interpretation of these new databases.

3. Eric Lander at MIT, co-chair of President Obama's Council of Advisers on Science and Technology, offers an online Introduction to Biology MOOC that includes support for upgrading (to a genomics orientation) high school and undergraduate biology courses worldwide. His team might offer a module to educate teachers and students - using this Reference Database 1.0 for peanut allergies - about how to use these new online analysis tools and interpret results.

4. This resource could be used more widely: the Obama Administration does not yet have a national, system-upgrade strategy to use these new databases and analysis technologies, at maximum velocity, for economic growth and new functionalities for the American people. Harlan M. Krumholz "Big Data and New Knowledge in Medicine: The Thinking, Training, and Tools Needed for a Learning Health System, Health Affairs, July, 2014, 33:7, pp. 1163-1170 suggests that many groups, including almost all of the currently practicing physicians and medical students in the US (and the world), also may benefit from opportunities to use an initial Reference Database 1.0 to learn these new rapid learning technologies.

Lynn Etheredge

Rapid Learning Project

To: OSTP & NEC
Re: Rapid Learning Systems for Innovation

I am responding to your request for information about how to accelerate innovation. I have been actively involved
in this area since 2005 as head of the Rapid-Learning Project to produce better national systems for generating and
using new knowledge (innovation). In a government career, I headed the professional health staff at the Office of Management and Budget and served there as a fiscal economist.

Much of my recent project's focus has been to design and support national policies for a "rapid-learning health system"
and to offer lessons for similar initiatives in education, sciences and technology, and the economy.

It's been a successful venture, stimulating widespread changes in US health policy, $ billions of US public investments, and UK and EU collaborations to create an international"rapid-learning health system". I attach a recent Health Affairs overview piece, along with a listing of more than 70 developments that have been part of this national strategy (2007-2014).
As an Institute of Medicine consensus study concluded, the success of a learning health system is critical our nation's health and to our economic future, reflecting the importance of health care costs for worker compensation, corporate profits, and government spending. But the point of this response is not to seek your support for a rapid-learning health system, but to offer it as a model for a general strategy to accelerate American innovation.

From this work, I offer two suggestions:

1). Use high-speed computational power, "big data", and learning networks to speed the generation and use of new knowledge (innovation). This will be a creative, wide-scale, public-private, and long-term national strategy. While "big data" is a new potential resource everywhere, the RL health system work has recognized that, in itself, massive amounts of new data do not do anything - but they can create new capabilities to take on "big issues", "big problems", and "big opportunities".

It is important to design, pre-position, and pre-populate new "big data" investments in the context of learning systems and networks that create communities, institutions, and processes that can collaborate in identifying questions, designing and building databases, and generating, testing, and rolling-out useful knowledge and innovations on an organized national scale. In RL, we have come to see the production and application of new knowledge (innovation) as a national "production process", from basic science to innovation user(s), and to apply concepts and models of "systems engineering" and "use case" specifications to identify gaps, delays, and opportunities for better performance. The RL work is not only intended to speed science, new products, and clinical innovations (e.g. NIH's Big Data to Knowledge (BD2K) initiatives), but also to learn as much as possible, as soon as possible, about their best uses (e.g. the FDA's new Sentinel Network that accesses 100 M patient records, and comparative effectiveness research by the new Patient-Centered Outcomes Research Institute and its PCORnet of learning systems to include 100 million patients), and then to design and implement national demonstrations and roll-out strategies (e.g. the new $10 billion CMS Innovation Center).

The National Science Foundation has recognized that our "learning health system" work offers important lessons for how "big data" and the nation's high-speed computing power can be turned into rapid learning and innovation in other areas, and supported a national conference of 55 scientists from 10 disciplines and a workshop report Toward A Science of Learning Systems.

With the US health sector at 17% of GDP -- and already one of our most innovative sectors -- I am confident that there are many lessons that are applicable for broader national strategies.

2). Identify and adapt lessons from the world's most successful "rapid-learning systems" for a national innovation strategy.

In the NSF-related work, I started research on the world's best "learning system" models for successful innovation. One of my suggestions - tho' it's likely to surprise you -- is that OSTP and NEC consider agriculture as (one of) the world's most successful models for accelerating innovation. The "Green Revolution" from half a century ago, led by US scientists and philanthropies, alone has been credited with saving more than a billion lives. Successful innovation ! Let's take on innovations of that scale and importance in many areas !!

The attached brief lays out a case for this view, reviewing more than a century of developments and evidence, and suggests that agriculture offers four major lessons that can be applied to national economic and innovation strategies in the areas of: (1) an overall learning systems & systems engineering strategy; (2) rapid-learning for assessing and disseminating workable innovations; (3) life-long workforce education; and (4) "feedback systems" for measuring and speeding up progress.
Thank you for the invitation to offer suggestions for your report. I realize these proposals raise many issues and that much of this information may not yet be well known. I would be glad to talk by phone [redacted] or (since I am based in the Washington DC area) come by for further discussions on these matters that are of great interest to PCAST, NEC, and myself.

Accelerating Progress – Rapid Learning Systems

by

Lynn Etheredge

How do we build "rapid learning" systems that inspire changemakers and entrepreneurs – and take their best ideas and successes quickly to scale?

This is a fundamental and widespread problem. Many sectors – such as health and education– are slow to adopt best practices. Economic growth is anemic.

Last year, the National Science Foundation convened a workshop to discuss how to create *a new science of learning systems*. Such a science could offer key lessons for accelerating progress everywhere.

For stimulating thinking about these topics, I suggest that we consider agriculture as a candidate for the world's best learning system. In America, farm productivity increases have been so great that farm employment has gone from 50% of employment in 1870 to less than 2% today.

We might think of agriculture as not having much to teach about how to build a modern science-based economy. In reality, agriculture has been a leader in developing and applying science and technology. The US built a system of Land-Grant (public) universities, starting in the late 1800's, to support practical agriculture research and education, engineering and other studies. Modern statistics and research design owe much to RA Fisher's work at a British agricultural research station in the 1920s. Hybrid corn production took off in the 1930s. Starting in the mid-20th century, the Green Revolution – with important leadership from American Nobel prize winner Norman Borlaug and the Ford and Rockefeller foundations -- is credited with saving more than a billion lives through initiatives using hybrid grains (e.g. wheat and rice), fertilizer, pesticides, irrigation, and new farming equipment and techniques. Modern agriculture is now advanced by an international network of agricultural research centers, advanced technology industries, and an international market economy.

I do not suggest that everything about agriculture development has been right (it hasn't been) or that it can simply be copied (it can't). But four key elements in the US agricultural sector's stellar record offer a checklist for diagnosing what may be missing today in less well-performing sectors and ideas for their upgrade paths.

First, agriculture shows that *a fundamental driver of economic growth is the rate at which we develop and apply new, useful knowledge – our learning systems*. The agriculture sector's successes did not happen from relying on status quo knowledge and methods or wishful thinking. For much of the last century, many national (and international) initiatives -- engaging scientists, farmers, governments, foundations, universities, and technology companies -- have collaborated to advance knowledge and worked to translate it into innovations and improved productivity of the individual farmer.

Second, in agricultural research government and foundations have strongly supported *applied science* that can be used by individual farmers. What are the comparative advantages of different seeds, fertilizers, irrigation, pesticides, and farming techniques in local growing conditions? What will happen if variables are changed? These have been subjects for organized, collective learning. The federal government began support for state agricultural experiment stations in the late 1800's. In contrast, our national network for studying the comparative effectiveness of medical treatments is just now getting launched (www.pcori.org); one can imagine agriculture research pioneers, such as RA Fisher and Norman Borlaug, asking, "What took you so long?"

Third, the agriculture education system aims for *lifelong learning of new knowledge and best practices for every farmer*. The national agricultural extension service, with support for county agents, was started in 1914. Education of the workforce, in farming, doesn't end with a school diploma. Using these lessons, a future national learning system could support all workers with life-long education, using methods that can now include MOOCs and online learning, electronic textbooks, community colleges, apps, and much else.

Finally, a key element in the agriculture sector's successful learning system is that it has built-in *"feedback loops" – aka harvests*. Each farmer learns how well he/she has done with each crop, each year -- and his/her learning is directly reinforced by economic profits and losses. The profits/losses for each harvest create unavoidable incentives for every farmer to learn about, match or exceed the improving practices of others. Where such plant-harvest cycles do not exist, e.g. government programs and large organizations, our society needs to create learning systems with feedback loops. Much future work in learning systems will involve building in practices that create inspiring goals, identify current processes, plan and implement change, and measure results – then repeat (e.g. www.apqc.org, www.ihi.org, www.carnegiefoundation.org).

Lynn Etheredge directs the Rapid-Learning Project. He helped to plan the NSF workshop on a new science of learning systems. Previously, he headed the professional health staff of the US Office of Management and Budget.

A Rapid-Learning Health System –

Selected Highlights

2007-2014

<u>Rapid-learning concepts and proposals</u>:

Health Affairs special issue on a rapid-learning health system (2007) and follow-on proposals [1];

19 IOM reports on elements of a learning health system and a consensus report (2007-2013) [2];

National Cancer Policy Forum (IOM) report on a rapid-learning cancer system (2010) [3];

National Research Council *Precision Medicine* report (2012); NIH – Francis Collins proposal for 20-30 M new patient database system [4];

National Science Foundation funded report *Toward A Science of Learning Systems* (2013) [5]

IOM report on *Improving Genetic Science Translation;*[6]

NIH (BD2K) report on *Enabling Research Use of Clinical Data;* [7]

Presentations by Francis Collins, Joe Selby, and Philip Bourne presentations on *New Models for Data-sharing and Collaboration*; [8]

President's Council of Advisers on Science and Technology, report on *Systems Engineering* for accelerating healthcare improvements*;* [9]

Health Affairs theme issue on *Using Big Data to Transform Health Care* July, 2014. Includes L. Etheredge "*Rapid Learning: A Breakthrough Agenda*" [10]

Initial issue of *The Kanter Journal* July, 2014. Includes interviews with Joe Selby, Allen Lichter, Lynn Etheredge;[11]

<u>Rapid-learning research investments</u>

Patient Centered Outcomes Research Institute (PCORI) created for comparative effectiveness research. $650 M/yr provided 2014-2019 [12];

CMS Innovation Center created to test and roll out improved care models, $10 B appropriated; [13]

HMO Research Network creates a virtual data warehouse for distributed database EHR research; (18 members, 14M patients) [14];

FDA creates Sentinel Network for rapid drug safety studies (100 M patients) [15];

NIH creates a national biobank (500,000 patients w/ genome and environment data) with Kaiser[16], and an eMERGE genetics research network [17]; a Collaboratory to facilitate research with organized delivery systems with electronic health records[18]; a new NIH institute for accelerating translational science (NCATS) [19]; a Big Data To Knowledge (BD2K) "centers of excellence" initiative and a chief data science officer.[20]

NIH and AHRQ start new research networks in cardiovascular, cancer, diabetes, mental health, exposures in pregnancy, multiple chronic diseases [21] and rare diseases. [22]

NCI launches an international "data cloud" for cancer genome database(s) and a cancer genomics data commons [23];

VA starts a Million Veterans biobank[24];

PCORI and NIH start PCORnet -- 29 data research networks, coordinated with NIH's Collaboratory and FDA's Sentinel initiatives via a common data coordinating center; potential for 100 million patients. [25] Initiatives include a National Pediatric Learning Health System (PEDSNet).;[26]

Flatiron (with Google Ventures) launches national OncologyCloud initiative; [27]

CMS announces $100M Medicaid "Innovation Accelerator" initiative; [28]

<u>International initiatives:</u>

UK launches a biobank (500,000 lives) [29], a Clinical Practice Research Datalink, [30], and a national cancer database and learning system [31], and an integrated health-social services database (care.gov); [32]

Global Alliance agreement announced for sharing genomic and clinical data (70 organizations, including NIH, 41 countries);[33]

EU TRANSFoRm initiative to create a rapid learning healthcare system in Europe (10 countries, 21 collaborators); [34]

<u>Health Information Technology</u>

US initiative – electronic health records for all Americans $28 B [35]

HHS's HIT Strategic Plan – goal V [36]

Harvard SMART platform architecture & Apps [37]

Blue Button – patient access to EHR data [38]

Other international initiatives

EHR4CR (33 European universities and industry partners) [39];

Cancer Genome Atlas data-sharing studies (150+ authors, on genetic bases of colon, lung, and breast cancer); [40]

EU Human Brain Project. [41]

Professional society learning networks

Cancer rapid-learning network (ASCO's CancerLinQ) [42]

Cardiovascular research registries (cardiologists) [43];

Pediatrics collaborative improvement networks; [44]

National surgical quality improvement program (NSQIP); [45]

Patient-powered research networks

Cystic fibrosis foundation presentation on building a successful patient-led research network and culture of research; [46]

New statistical and research methods:

MIC/MINE statistics; [47]

VA adaptive point-of-care trials; [48]

Accelerated multi-cohort experiments, randomized cluster designs; [49]

Data-driven prediction of drug effects and interactions [50]

N-of-1 clinical trials; [51]

Rapid-cycle learning ; [52]

How medical know-how progresses (model that highlights important role of learning in clinical practice) [53]

FDA "standing trials" infrastructure for new technologies; [54]

National Research Council report: *Frontiers of Massive Data Analysis;* [55]

Analyses of registry data to show it can emulate randomized clinical trials results;[56]

New collaborative clinical trial design using a "master protocol" for simultaneous study of multiple targeted therapies (lung cancer) including 200 medical centers in NCI's new National Clinical Trials Network); [57]

New approaches to patient protections/privacy:

Ethical oversight of learning health systems [58]

Predictive models for personalized healthcare:

Archimedes-ARCHeS (desktop version) to personalize health care decisions, 16 diseases; [59]

Progress in cancer genetics

MD Anderson ($3B for rapid-learning, 8 cancers); [60]

Cancer drivers and signaling pathways (Vogelstein); [61]

Four subtypes of stomach cancer identified; [62]

Alzheimer's disease

NIA national Alzheimer's coordinating center, data-sharing network among 27 Alzheimer's disease centers [63]

Alzheimer's disease neuroimaging initiative, 55 research centers, through NIH Foundation [64]

G8 summit agreement on international data-sharing and research collaboration on Alzheimer's disease, hosted by UK [65]

European Medicines Agency

New policy on disclosure of patient-level trial data [66]

Other advances

Kaiser-UCSF, RWJF supported, biobank data for 78,000 persons on-line via NIH's dbGaP;[67]

Genetic factors identified for autism (Swedish databases); [68]

Genetic factors identified for schizophrenia; [69]

NIH primer for physicians use of genome and exome sequencing; [70]

Genetic factors identified for Parkinson's disease; [71]

[1] Etheredge, L. "A Rapid-Learning Health System" http://content.healthaffairs.org/content/26/2/w107.full.html; Etheredge LM. Medicare's future: cancer care. Health Aff January/February 2009 28:148-159. Etheredge LM. Creating a high performance system for comparative effectiveness research. Health Aff October 2010 29:1761-1767

[2] http://www.iom.edu/Activities/Quality/VSRT.aspx

[3] http://www.iom.edu/Reports/2010/A-Foundation-for-Evidence-Driven-Practice-A-Rapid-Learning-System-for-Cancer-Care.aspx

[4] http://www.nap.edu/catalog.php?record_id=13284. Francis Collins's proposal: http://www.pcori.org/assets/2-Collins-Slides-Network.pdf

[5] Available at: http://healthinformatics.umich.edu/lhs/nsfworkshop, L. Etheredge, "A Rapid Learning Health System: A Behavioral Science-Economics-Public Policy Perspective, April 2013 and other materials on the site.

[6] http://www.iom.edu/reports/2014/improving-the-efficiency-and-effectiveness-of-genomic-science-translation.aspx

[7] http://bd2k.nih.gov/pdf/ClinicalDataWorkshopReport_March2014.pdf

[8] http://www.pcori.org/events/from-research-to-practice

[9] http://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_systems_engineering_in_healthcare_-_may_2014.pdf

[10] http://www.healthaffairs.org Vol. 33, No. 7 July 2014; http://content.healthaffairs.org/content/33/7/1155.full.pdf+html

[11] http://www.kanterhealth.org

[12] http://www.pcori.org; http://effectivehealthcare.ahrq.gov/index.cfm

[13] http://www.innovations.cms.gov

[14] http://www.hmoresearchnetwork.org/about.htm

[15] http://www.fda.gov/Safety/FDAsSentinelInitiative/default.htm

[16] http://www.dor.kaiser.org/external/DORExternal/rpgeh/index.aspx

[17] http://www.ncbi.nlm.nih.gov/pubmed/21269473

[18] http://commonfund.nih.gov/hcscollaboratory/

[19] http://www.ncats.nih.gov

[20] http://www.whitehouse.gov/blog/2013/04/23/big-data-big-deal-biomedical-research; http://videocast.nih.gov/summary.asp?Live=12155&bhcp=1 (starting minute 10); http://www.nih.gov/news/health/jul2013/nih-22.htm

[21] http://www.hmoresearchnetwork.org/projects.htm

[22] http://www.grdr.info

[23] http://videocast.nih.gov/summary.asp?Live=12906; final session, starting at 5:58; http://ocg.cancer.gov/news/genomics-data-commons

[24] http://www.research.va.gov/mvp/

[25] http://www.pcori.org/funding-opportunities/pcornet-national-patient-centered-clinical-research-network/

[26] http://pfaawards.pcori.org/node/20/datavizwiz/detail/1556; https://www.abp.org/abpwebsite/moc/collabimp.htm
[27] http://www.flatiron.com/about/
[28] http://www.medicaid.gov/State-Resource-Center/Innovation-Accelerator-Program/Innovation-Accelerator-Program.html
[29] http://www.ukbiobank.ac.uk
[30] http://www.cprd.com/intro.asp
[31] http://www.bbc.co.uk/news/health-22870352
[32] http://www.england.nhs.uk/ourwork/tsd/care-data/
[33] http://www.broadinstitute.org/files/news/pdfs/GAWhitePaperJune3.pdf
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[35] http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__home/1204
[36] http://www.healthit.gov/sites/default/files/utility/final-federal-health-it-strategic-plan-0911.pdf
[37] http://smartplatforms.org/about/
[38] http://www.healthit.gov/sites/default/files/blue-button-fact-sheet-2014-feb_0.pdf
[39] http://www.ehr4cr.eu
[40] http://cancergenome.nih.gov
[41] https://www.humanbrainproject.eu
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[44] http://pediatrics.aappublications.org/content/131/Supplement_4/S189.abstract
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[49] http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/chapter_16/16_3_cluster_randomized_trials.htm
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[53] Nelson RR, Buterbaugh K, Perl M, Gelijns A. How medical know-how progresses. Research Policy 2011:40;1339-1344
[54] http://www.brookings.edu/events/2013/07/16-biomedical-innovation (Janet Woodcock, starting at 1:04)
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[58] http://www.thehastingscenter.org/LearningHealthCareSystems/

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[60]http://online.wsj.com/article/SB10000872396390443890304578008562044709472.html?KEYWORDS=md+anderson+cancer+center

[61] http://www.sciencemag.org/content/339/6127/1546.full.pdf?sid=b9f70096-d4aa-4ee5-be72-df8a22cf9e1d

[62] http://www.nih.gov/news/health/jul2014/nci-23.htm

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[64] www.adni-info.org

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[70] http://www.nih.gov/news/health/jun2014/nhgri-18.htm

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Lynn Etheredge

Rapid Learning Project

I hope that you will consider this same kind of initiative to accelerate progress in all areas of science, technology, agriculture, education & economics. LE

Subject: NIH's draft for "The Commons" of a rapid-learning health system
Date: September 19, 2014 at 1:02:05 PM EDT

In case you missed it, NIH has recently posted its draft for the national data "Commons" for discussion, http://tinyurl.com/1pf59xv Video of briefing/adv mtg at http://videocast.nih.gov/summary.asp?Live=14643&bhcp=1
Tho with about 5 min of George Kormatsoulis at about 2:00 you could get the sense of their thinking,

As the adv cte noted, the draft is still quite abstract and missing "use cases" and "human beings", i.e. still a "cyber" rather than "cyber-social" blueprint, not clear what it is supposed to do, for whom, who has to do what that they aren't yet doing. At least they are thinking about "credits" from NIH and others that would be used to pay the (conformant) "data clouds" for use and analysis, as well as including funding for curation and access to data in the original study funding -- so financial viability is on the radar scope.

I suspect plans will be for most of the $30 B annually of NIH research projects to put data in The Commons, plus PCORnet, Sentinel, NCI's new "data clouds", etc. etc.

NIH is going to announce its 12 BD2K (Big Data To Knowledge) "centers of excellence" awards later this month. Quite possible that these "centers" will be associated with one (or more) of the new "data clouds", i.e. they will hold huge chunks of data, as well as analyze.

Lynn
Lynn Etheredge
Rapid Learning Project

Lynn Etheredge

Rapid Learning Project

update & addenum to 8/2/2014 submission

CGIAR (http://www.cgiar.org) is the international consortium of agricultural research networks & is now in the midst of "development dialogues" -- what we would likely see as how to develop rapid-learning systems for agriculture. I'm linking them into our work. LE

Lynn Etheredge
Rapid Learning Project

a second addendum to 8/2/14 suggestion.

This new book, by Nobel Laureate Joseph Stiglitz, advances the case to top-level economists for "rapid learning" -- involving many new institutions and policies -- to become a major strategy for innovation and economic growth.

Thank you. Lynn Etheredge

Subject: Rapid-Learning Economics: Creating A Learning Society by Joseph Stiglitz & Bruce Greenwald;

--Creating A Learning Society: A New Approach to Growth, Development, and Social Progress by Nobel prize economist Joseph Stiglitz and Bruce Greenwald is an important contribution to bringing "learning" toward a central focus of the economics profession (Columbia University Press, 2014)

The book (an expanded lecture) focuses mostly on how a "learning society" can accelerate economic growth in less-developed countries, and its authors find fresh insights for public policies such as taxes, investments, intellectual property law, competition, trade and exchange rates, and more.

The authors also view their contribution is: "to show the potential that the economics of learning and innovation has for revolutionizing both economic theory and practice".

"This book, then, is an attempt to study the economics of "learning societies", focusing especially on the role of government in promoting growth through the creation or strengthening of a learning society"; and, conclude that

"the entire economic regime needs to be re-examined and reevaluated through the prism of learning"

Lynn Etheredge
Rapid Learning Project

an addendum to 8/2/14 suggestion

Many of the key initiatives for a rapid-learning health system feature learning networks that share data.
Here's a slide on why data-sharing
is such a high pay-off strategy.

Economics of Data-Sharing

- If 10 institutions each share 100 cases
  - Database = 1,000 cases
  - *Every* institution gets 900 added cases for a contribution of 100 = 9:1
- If 100 institutions each share 1,000 cases
  - Database = 100,000 cases
  - *Every* institution gets 99,000 added cases for a contribution of 1,000 = 99:1
- Data-sharing is a high pay-off strategy. More data-sharing multiplies benefits.

Ferric Fang

University of Washington School of Medicine

Professor of Laboratory Medicine and Microbiology; Adjunct Professor of Medicine (Infectious Diseases)

(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a scientific funder of scientific research to most effectively address the problem?

I am a physician-scientist with more than twenty-five years' experience and over one-hundred eighty peer-reviewed publications. I have also served as a scientific journal editor and editor-in-chief for twelve years and have published studies and commentaries on the state of the scientific enterprise, sources of error, and research misconduct (e.g., Casadevall & Fang. Infect Immun 78:4972, 2010; Casadevall & Fang. Infect Immun 80:891, 2012; Fang & Casadevall. Infect Immun 80:897, 2012; Fang et al. PNAS 109:17028, 2012; Casadevall et al. FASEB J 2014 Jun 13 epub ahead of print; Stern et al. eLife 3:e02956).

In my view, the single most important measure to improve the reliability and reproducibility of scientific research is to increase overall research funding and thereby alleviate the current hyper-competition for grants and jobs. The intense and unrelenting pressure on scientists to publish high-impact papers is creating a perverse incentive for haste and misrepresentation. Reducing targeted funding and instead dedicating more funding to investigator-initiated projects would also help to reduce bias, which contributes to the reproducibility problem. Many other things can be done, such as improving training in statistics and providing support for the replication of particularly crucial studies, but all will come to naught if the funding situation does not improve.

Cailey Fitzgerald

One way to support reproducibility and encourage open scientific practices is to require the sharing of data. If the purpose of science really is to gain information about the world, it makes sense that we should encourage sharing of data.

Norman H. Gaffin

Sirs:

Germany has succeeded in improving the manufacturing sector of the economy by using Fraunhofer to research potential product needs. Decision to proceed is a coordinated, combined effort, by Industry, colleges & government. Sufficient viable companies has resulted in manufacturing accounting for nearly 21% of the German economy vs 13% US & 12% UK. German exports rose 11% in 1910 to more than $1.3 trillion.

A time worn cliché is " Reduction in tax on corporations increases jobs". In 2002, corporate tax rate was reduced by 10%. By 2007, employment increased by 0.9%, corporate profit by 10.8%. Corporations today sit on approximetly $1 trillion,used largely in various financial transactions.

Fraunhofer or a similar research organizition could accomplish results similar to those of Germany. I understand the herculian challenge to convince the potential investors to plan for "long term" return. Manufacturing jobs benefit the 75% middle income & consequently increase TAX REVENUE.

Majid Ghoddusi

Ensigna Biosystems, Inc.

Vice President

Greetings!

United States leadership in innovative science and technology has been hampered by lack of proper validation of experiments, instrumentation and reagents, thus resulting in lack of reproducibility. This needs to be addressed at the National level through collaborations with institutes, organizations and private enterprises. In the field of biotechnology and pharmaceutical research and development, we have started a private enterprise with great emphasis on validation and reproducibility. We validate the specificity, sensitivity and reproducibility of our reagent by having appropriate controls for assays and careful examination of results. I believe our model of validation process sets some of the highest standard in the industry. We will need help and assistance from Federal and local government to continue this trend.

Rick Gilmore

Pennsylvania State University

I believe that the Federal government has a key role to play in ensuring that public investments in scientific research have the maximum benefit. I speak to these issues as the grateful recipient of Federal support for my research from the National Science Foundation and the National Institutes of Health.

I believe the following would help increase transparency and reproducibility in the scientific enterprise:

1. Make all data and materials collected with Federal support, whether published or unpublished, available to the public to the maximum extent possible.

Some data or materials may contain sensitive or identifiable information, and so may not be easily shared with the public. However, there are new approaches to the sharing of identifiable research data that may make some of these materials eligible for sharing with other researchers (http://databrary.org) under special circumstances.

2. Set aside a portion of Federal research dollars for replication studies of important findings.

3. Set aside a portion of Federal research dollars for the curation and preservation of research data and materials in open data and material archives.

4. Direct Federal agencies involved in the support of research to examine legislative, regulatory, or policy barriers to data sharing and open scientific practices among their awardees and to reduce or eliminate them.

Steven Goodman

Stanford University School of Medicine

Associate Dean for Clinical and Translational Research; Professor of Medicine & Health Research and Policy; Co-Director, Meta-research Innovation Center at Stanford (METRICS); Chief, Division of Epidemiology

To the OSTP -

We welcome the opportunity to comment on the OSTP's recently released RFI seeking comments on how to strengthen America's strategy for scientific innovation. In particular, we would like to focus on point number 11, which asks:

"Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?"

We believe that the OSTP is correct to highlight this as an important feature in enhancing America's competitiveness in science, as study results that point us in the wrong direction represent not just a waste of resources from the initial funder, but it can have a multiplier effect of spurring unneeded follow-on research that leads to dead-ends, as well as improper or unneeded patient treatments.

We write as the directors of two recently established centers to investigate the causes of and promote policies designed to improve non-reproducibility in scientific studies. Dr. Nosek is the director of the Center for Open Science (COS), and Drs. Goodman and Ioannidis co-direct the Meta-Research Innovation Center at Stanford (METRICS).

The production of science is achieved through a very complex ecosystem involving funders, academia, professional bodies, industry, market needs, the media, and of course the public. The federal government cannot solve problems in all of these domains, but it can adopt or incentivize the adoption of policies that have a profound influence on what is done in virtually every sector responsible for science production.

We propose four actions that could help address this important problem. One of the most important goals of such steps is to help produce a system that rewards research results that are shown to be valid, as opposed to simply the production of research results.

1.) Require all federal agencies funding scientific research to support a "culture of replication" through:

a. Funding studies that seek to rigorously replicate important scientific findings.

b. Developing policies that use evidence for replication of prior work by the grantee, research group, center, or program as a criterion for grant awards.

c. Requiring funders to develop and enforce policies for transparency in data and methodology so that independent replication is possible.

2.) Make transparency of data and research materials (e.g., protocols, code, identity and source of research materials) the default, through various actions:

a. Have federal research funders require a commitment of grantees to share relevant research materials and data as a condition for grant awards.

b. Require funders to define and elaborate criteria for when NOT sharing data or materials is justified.

c. Require funders to define procedures for monitoring and enforcing commitments by grantees to share of data and deposit relevant materials in public repositories. This includes all the relevant meta-data, statistical code and study protocol information to allow full understanding of the data files and analytic results. This is critical not just for the purposes of replicating the study, but for enabling data-reuse and combination, which can produce new scientific findings.

c. As part of this effort, it is also critical that the results of all federally funded research be accessible, and that granting agencies make it more further funding difficult if the results from prior funded research are either not published or not reported in accessible repositories. In the world of clinical trials, this is being achieved in great part to the mandatory registration of all clinical trials at inception, and mandatory reporting of trial results on CT.gov within one year of the completion of the funded study, per FDAAA. Trials that are registered but not published can be tracked, as can those that do not report their results. Similar procedures could be adapted and adopted in other scientific fields for hypothesis-testing research, and there are a variety of organized efforts to produce the necessary infrastructure to support that (e.g., http://osf.io/). Ct.gov has made it possible to track non-published trials, and research using CT.gov data has also highlighted discrepancies between planned and reported study results and procedures.

d. The federal government can also play a key role in facilitating connections among those creating a technical infrastructure for data deposition and sharing. These exist in highly fragmentary and diverse forms throughout the federal government, but the coverage of such platforms is grievously incomplete, as are their technical capabilities. A major informatics effort needs to be made to create scientific data platforms that are not merely repositories for unsearchable documents, where some of the extra effort needed for data sharing is taken off the hands of individual investigators, including those of long-term storage and access. Such repositories also need to include policies and procedures for controlling data access, when that is appropriate.

3.) Fund the development of curricula and training programs related to the procedures necessary to maximize reproducibility of both research processes and research results. These would include both teaching in the fundamentals of experimental design, data gathering and curation, data management and proper statistical analysis and study reporting. These should be aimed not just at researchers in academia, but for those in research contexts outside of academic settings, and importantly, support staff who are often primarily in charge of implementing these procedures.

4.) Fund research on research practices so as to identify which practices can be improved and how, using rigorous methods.

Thank you very much for this opportunity to comment on this important issue.

Sincerely,

Steven Goodman, MD, MHS, PhD
Associate Dean for Clinical and Translational Research
Professor of Medicine & Health Research and Policy
Co-Director, Meta-research Innovation Center at Stanford (METRICS)
Chief, Division of Epidemiology
Stanford University School of Medicine

John P.A. Ioannidis, MD, DSc
C.F. Rehnborg Professor in Disease Prevention
Professor of Medicine and Professor of Health Research and Policy
Co-Director, Meta-Research Innovation Center at Stanford (METRICS)
Director, Stanford Prevention Research Center (SPRC)
Stanford University School of Medicine

Brian Nosek, PhD
Professor of Psychology, University of Virginia
Founder and Director, Center for Open Science (COS)

James Gover

1. Because the quantitative correlations among domestic job creation, innovation and R&D are not well understood today, there is a critical need for innovation economists to develop a validated and quantitative framework by which they can establish the relationships among public investments in R&D infrastructures, innovation, and domestic job creation.

2. Companies, universities, government labs and FFRDCs that perform mission-driven federal R&D must expand the scope of their work and bring private sector job creation to the top of their agenda while concurrently satisfying agency need for mission driven outcomes.

It is imperative that the productivity and quality of government, healthcare and education be increased so that these are lower fractions of GDP.

3. Cutting federal spending to 18-20 percent of GDP should provide incentives for government to make productivity improvements. Healthcare quality would likely be increased and costs reduced if HHS would allocate 10 percent of its R&D budget to emphasizing how to increase quality and reduce cost. If the US Department of Education were to spend its entire budget on finding ways to improve the quality of K-12 education and reduce the cost of college, perhaps education would be improved and its costs reduced.

4. If colleges and universities would offer education options that can be pursued for no more than $10,000 for a four-year education, then many students that are being shut out of college for economic reasons could attend college and those that do attend can graduate in four years.

5. If any educational institution receiving federal R&D funds were permitted to use some fraction of those funds to emphasize entrepreneurship in all phases of its technical and business education programs, it would encourage more students to become entrepreneurs upon graduation.

6. If Master's thesis projects and PhD dissertation projects funded by federal R&D were selected based on potential to spin-off start-up companies, the rate of spinning-off companies from university R&D would increase.

Few dispute the historical role engineers have played in innovation; a disproportional fraction of innovation-driven job creation as well as job destruction has been made by electrical engineers, computer engineers and computer scientists. It is imperative that our universities graduate more students in these disciplines who are prepared to contribute immediately to industrial work.

7. If companies employing electrical or computer engineering or computer science students in co-op or intern positions were permitted to pay one term of these students' tuition for each term of work and take that tuition payment as a tax credit, it would increase the number of US citizens who pursued degrees in these fields.

8. If government-owned laboratories employed 1 percent of their total workforce as electrical or computer engineering or computer science students in co-op or intern positions and paid one term of each student's college tuition for each term of work, it would likely increase the number of US citizens who pursued degrees in these fields and it would likely lead to an increase in the quality of government-owned laboratory employees conducting R&D.

9. If universities, companies, government laboratories and federally funded research and development centers were permitted to use 10 percent of their federal R&D to aid their employees in spinning-off companies that would not need federal funding, then perhaps innovation leading to private sector job growth could be stimulated.

10. It is reasonable to select two of the highest performing government-owned laboratories, transform

these from solely mission-driven to mission- and economic-outcome driven and use the knowledge gained from that experience to transform other laboratories. The intent is to explore ways to make the federal R&D investment at a government laboratory or FFRDC have three to five times as much economic impact as a federal investment in highway construction of the same amount.

11. If a special category for immigrant entrepreneurs called H1BE were established and open to all foreign-born scientists, business-people or engineers who meet H1B requirements and wish to come to the US to start a new company, the US rate of starting new companies would be accelerated without discouraging US citizens from STEM studies. If after 5 years an H1BE immigrant had not started a new company that employs 20 or more people, their H1BE visa could be revoked.

Jeremy Gray
Michigan State University

I strongly urge the OSTP to adopt as a default position that scientific data and research materials should be freely available to other scientists. Some sensible exceptions should be possible, but quite rare.

Yaroslav Halchenko

Dartmouth College

short one since I only now discovered about this call, so here is just one.

In sciences related to human subjects research (e.g. neuroscience), governmental agencies should compile CLEAR guidelines for ethics norms (e.g. templates of consent forms) which could be used by researchers collecting human data to ease its open sharing later on. At this point different IRB committees have different stands at how such forms should be composed, which disclaimers must be mentioned, and what data "de-identification" must be done. Those recommendations heavily vary among different committees. Some of them being overly too cautious. Some others overly too "relaxed" e.g. considering "private" data only be a SSN, name, while in reality facial features stored in anatomical images could be considered sufficient for identification and thus requiring additional consent from the subjects on release of such data in pristine form, or stating that images would be defaced before release. Thus I think it would be great if there were clear guidelines and consent forms templates (if not stricter policy) enabling more efficient and safe (for researchers and their subjects) sharing of the collected neuroimaging and other data. Making "default" consent forms for studies contain explicit public data sharing (where possible/applicable) would simplify data sharing, thus would potentially increase utility of collected data.

Jeff Harford

Reproducibility in science should be a major priority for all scientists. Any given publication should easily be able to be reproduced, just like a recipe. Why are they not reproducible?

1) There are inconsistent standards for citation of products/cell lines/techniques used; journals need to have standardized and complete documentation of methods and materials.
2) Methods used are often fraught with error (e.g. Western blotting with chemiluminescence and/or film often leads to misinterpretation and if quantifying, absolutely irreproducible)
3) Researchers are not rewarded for reproducing their research, rather it is a publish or perish mentality
4) Funding does not account for reproducibility requirements; In any given grant, a certain amount should be allocated for the reproducing of studies by independent researchers

Please take some time to establish standards in this area to ensure science is productively moving forward.

Seth Harkins

SeraCare

Principal Scientist, New Product Development

Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

Irreproducibility in scientific data is not so much are issue of misconduct but rather an overt focus on justifying one's own importance in their field of study. From my prospective, today too much emphasis is placed on introductory statements and forwarding looking remarks. Its seems these days that a chemistry paper cannot be published if it doesn't promise to solve the worlds energy problem, nor a life science article that doesn't elude to a world free of cancer or disease. In the 1920's, the first sentence of a scientific paper immediately address the results of the study. Today papers are mired in such useless wastes of words as "The Placenta plays a pivotal roles in orchestrating maternal adoption of pregnancy…….." We knew this 100 years ago, yet it still needs to reiterated in the first sentence of a paper published in a major journal.

A mentor of mine once told me that all you can is report the data as you find it. Interpretations change over the years but the observation that resulted from the described methods should be enduring. With this, we need a greater focus on the reporting of methods and results. These are the features which will stand the test of time and drive science forward. Today, results that do not fit the author's agenda are frequently omitted/not report in a paper and key experimental features are obscured to limit competition. The responsibility for this is centered squarely on the editors of journals. High impact journals should be the bastion for the most technical complex experiments and ground breaking results which are immediately actionable by the community. I personally no longer read Science or Nature because their experimental reporting is so weak compared to so-called second-tier journals that publish the back-bone science today. Scientists are now rewarded for being the best salesman of science rather than the best experimentalists. I believe that if we can work our way back to strengthening the practice of experimental science rather than the practice of over bloated pontification and strategic grant writing, the field would be propelled forward and irreproducibility issues would be attenuated.

Helene Hill

(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

Attempts to repeat experiments are probably a waste of time and money. It should be up to the Universities, companies, publishers and granting agencies to police their own. This can be accomplished by requiring of all submitted documents for funding and/or publication that images be scrutinized for inconsistencies and falsifications, software be used to analyze for numerical discrepancies, and plagiarism tests be applied. Granting agencies and publishers should require demonstration of such scrutiny before accepting grant applications or papers. Stopping any cheating at the source should go a long way to addressing the irreproducibility problem.

Hans Ijzerman

Tilburg University

In regards to reproducibility of research. This is not an easy equation. Irreproducibility can point to a number of things:

1. context sensitivity of the findings
2. expertise of the researcher (original or replicator)
3. effect being non-existent

Basically, it means we need to 1) intensify our research practices, and 2) improve the archiving of data. Concretely, we should make sharing data and research materials the default. Furthermore, federal agencies should dedicate a small portion of their research dollars toward replication of important results. Importantly, the infrastructure for this needs to developed. Finally, funding should also focus on promoting and supporting training of methodology and reproducibility practices.

Elizabeth Iorns

Science Exchange

Co-Founder

(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

The most important thing that the Federal Government can do to effectively address the problem of irreproducibility is to fund replication studies. Despite reproducibility being a defining feature of the scientific method, it is more an assumption than a practice in the present scientific ecosystem. A literature review in psychological science, for example, estimated that only 0.15% of the published results were direct replications of prior published results (Makel et al., 2012). This is because incentives for scientific achievement prioritize innovation over replication and careers are made by producing exciting new results at the frontiers of knowledge, not by verifying prior discoveries. The lack of incentive to perform replication studies is compounded by the lack of grant support available from funding agencies to support replication research. If all published results were true, then a singular focus on innovation over verification might be inconsequential. In such a context, the most efficient means of knowledge accumulation would be to spend all resources on discovery and trust that each published result provided an accurate estimate of effects on which to build or extend. However, the small amount of direct evidence about reproducibility currently available suggests that most published results are not reproducible. A survey of faculty and trainees at MD Anderson Cancer Center found half of those researchers reported an inability to reproduce data on at least one occasion (Mobley et al., 2013). More dramatically, two industrial laboratories, Bayer and Amgen, reported reproducibility rates of 11% and 25% in two independent efforts to reproduce findings from dozens of groundbreaking basic science studies in oncology and related life science domains (Begley & Ellis, 2011; Prinz et al., 2011). Therefore, it is vital that the Federal Government invests in replication studies so that important potential breakthroughs are validated and can be effectively built upon by the scientific community. Replication studies are the only way to properly validate an important result because it is not possible to interpret failed replications when the experimental conditions are not the same. By funding replication studies, the Federal Government can initiate a cultural shift that rewards high quality reproducible research from its' fundees. By assessing and rewarding reproducible research, major additional benefits are gained - for example protocol, data and reagent sharing from original authors are incentivized as mechanisms to improve the likelihood of a successful replication. Overall, there is a major need for investment in replication studies to effectively leverage the enormous investment made into original research that is currently never validated. The Federal Government has the opportunity to lead this new approach to ensure the generation of high quality reproducible research.

Martin Ivancic

J. Iverson Riddle Developmental Center

Replication is the hallmark of science. The most careful replications occur in behavior analysis where group designs are abandoned in favor of repeated effects with individuals. Single-subject designs have built a powerful (inductive) technology of behavior. Concerns about generalizability are de-empasized in favor of results that are shown to replicate within the single subject design. Murray Sidman's Tactics of Scientific Research (1960, NY: Basic Books, Inc) suggests "systematic replication" where various aspects of the original treatment are varied and produce the same effect help show the general power of these treatments. This approach builds a treatment and a science with very little wasted effort. It is slower and less grandiose, but very little of what is learned cannot be used to support the future knowledge base. Very little of what is learned is completely unreplicable and thrown out. Very little tax money is wasted. There is, of course, room for group designs in science, but single-subject designs have not been given enough credit for their ability to build a science. Every clinician could conduct AB studies which, if coordinated, could demonstrate powerful (nonconcurrent) multiple-baseline effects.

Robert Ivey

Perhaps no innovative project could rival the benefits of support for research into liquid fluoride thorium reactors (LFTRs) for small modular reactor based public grid energy. The impact of dense, safe, dispatchable energy at low cost solves many pressing needs of the United States. By contrast, the historical support of other "so-called" renewable energy sources only produces low density, higher priced, subsidized, intermittent energy and requires backup power plants that emit more, rather than less, CO2 as our societal demand grows.

So, to help the economy, provide a more competitive US business climate and serve the needs of the entire range of citizens, especially the lower economic segments, nothing could compare with harnessing a safe LFTR based public electrical grid. China is developing thorium based energy, I wish we were. Finally we could turn those neutrons in spent nuclear fuel from a liability into something immensely valuable. We have a SNF problem only because we have elected not to use this resource. LFTRs could surely help solve this issue.

PROMOTING INNOVATION IN THE USA

Pitch Johnson

September 15, 2014

Conditions

It is critical to economic and social future of the United States of that the flow of innovative ideas to serve existing markets, and to serve new markets enabled by new technologies, be increased. The concept of the market to be served is an essential part of the innovation. It is important to differentiate between science and technology, although the line between the two cannot be sharply defined. Science is the development of new knowledge, while technology is used to apply science to human needs. Innovators understand what markets can be served and what engineering is required to create a product to serve that market. The innovation usually does not come directly from science, but from further development of previous engineering or recognition of further markets to be served.

The federal government has a primary role in encouraging and financing fundamental research. New scientific knowledge is vital, and when research is undertaken it is done to increase knowledge with the ultimate use, if any, being unclear. Examples of this were the early scientists working on genetics, the nature of electrical materials, atomic structure and the rules of logic. The present effects of that and other research on modern life are enormous, but it took innovative people and organizations to conceive the markets and do the engineering to bring the idea into use. Much other research went on and goes on to discover nature, but human knowledge is increased as a benefit of its own.

While innovation goes on in existing and large companies, entrepreneurs have been in the forefront of innovation. Entrepreneurs have played a vital role the economic growth of our country. In 1979 a study by David Birch of MIT found that all the net new jobs in the US were being created by companies less than ten years old. I think that is probably true today. The federal government can play a role in the furtherance of entrepreneurship, but it must be shared with state and local governments. In my own paper of 1984, The Entrepreneurial Climate, written while I was teaching a course at GSB Stanford and published by Harvard Business School , I pointed out several things necessary in any country to have thriving entrepreneurship. They were: minimal regulations for starting new companies, low tax rates on income and capital gains for young companies, a pool of talent and knowledge, availability of capital, bank lending for young companies, availability of professional services and an appreciation in society for the role of the entrepreneur. These conditions still apply, and the underlying environment has changed, but the federal government can provide positive conditions in some of the areas.

The regulations involved with starting new companies is a state and local government matter as is the availability of professional help. The taxes are primarily a federal matter, however with some local influence, especially in California, where taxes are high. The pool of talent and knowledge refers primarily to education and science, with science being primarily federal, and education primarily local. The availability of capital suited to new business depends now on angel investors as well as venture capital, and bank lending has become very much subject to a federal regulation. The desirability of entrepreneurs and the ability to fail is not an issue now our country.

Actions

There are some action items suited to federal government which are probably are politically viable and will work if instituted. Many of these require expenditures and lower taxes in some case. The source of the revenue will depend on the economy continuing to grow and other tax policy.

While regulations for starting companies are a state and local matter, the federal government has the major influence on taxes. A major new factor in new-company financing is the “angel” investor, and there are many people now who have made money as part of successful start-ups. It would be advisable to have very low capital gains taxes on investments in start-ups which are devoted to serving markets with new technology in order to get money from “angels.” The same should apply to the partners of venture capital firms which invest in such start-ups. Venture firms, however, have pressure to show results within their typical ten-year lives, and they invest after the fund is founded for few years. In this present hot market companies often get liquid quickly, but this cycle will slow as always, and more patience will be required for the typical five to seven-year time frame often needed by young companies to get profitable and growing. A good policy to encourage investment in young companies with long development cycles would be to make the very low capital gains rate to apply only to new-company investments held by investors and founders for five years. Normal capital gains should also be lower than at present. It would help to lower corporate taxes as well, especially for small companies, since our corporate tax rates are high by international standards.

The pool of talent and knowledge is a function of support for research and education. An increase in research support in universities from the federal government, and in certain government laboratories, is vital to increase the knowledge base from which innovative technology can be drawn to serve new markets. Support of education, without interfering too much in state and local activities, is also important. It is important that we keep economic opportunity open essentially to everyone, and that depends on education. This implies that, while the major universities continue to be important, the state colleges and community colleges are open to a much broader section of the population and emphasis needs to be given to support for them and the students who attend them. This means scholarships for many students and support for the faculty, especially those likely to foster the marketing, production and technical skills for innovative companies. The borrowing now required for many students to go to school is untenable, but it should be continued with limits.

The availability of capital to innovative companies should be helped by tax changes, since there is so much capital around these days. The SBIC program needs a new look, however, since when the inevitable down-turn comes, it will good for the federal government to make additional capital available as long as there are private investors at risk ahead of government money and the private investors make the investment decisions, within broad guidelines. If bank regulations are inhibiting otherwise good lending decisions to small innovative companies, the regulations need to be examined. I do not favor loan guarantees by the government to the banks.

The availability to new companies of professional services such as lawyers and accountants is a state and local matter. The desirability of entrepreneurs in the society and the ability to fail and try again has long been established in the United States, and needs no federal government action.

It is clear that federal action on immigration is necessary, although not listed by me in my earlier paper on the entrepreneurial climate. The issues are well known, but it is clear, from the point of view of innovative companies, that we need to stop making people leave the country after getting degrees from American universities in the subjects needed in innovative companies, and we need to attract foreign talent.

Large companies often have innovative activity, and set up sections to bring products using new technologies to markets. The investment tax credit needs to be looked at to see if it is influencing the actions of such companies, or if it can make other companies more interested in innovation.

In summary, I believe the federal government needs to further support research in university labs, find greater ways to help students of any economic level find educational opportunity, have a very low capital gains tax rate for founders and investors in innovative companies who hold their investments for five years, and develop the SBIC program to further to add government capital to investments by private capital.

Franklin Pitcher Johnson
Asset Management Company
Palo Alto, California
[redacted]

Geoffrey Kabat

Albert Einstein College of Medicine

Dept. of Epidemiology and Population Health

I am a cancer epidemiologist at the Albert Einstein College of Medicine in New York City, and am writing to stress the vital importance of data transparency in the regulatory process.

It is extremely difficult to evaluate the scientific data on issues confronting society, such as hydraulic fracturing or â□œendocrine disrupting chemicalsâ□□ â□“ to take just two examples. Different experts and advocates can put greater weight on different scientific studies and come to very different judgments. Furthermore, all studies have their limitations. Given these facts, it is of the utmost importance to evaluate all the data and determine which are the highest-quality and most informative studies.

In order to be able to take all of the pertinent evidence into account, qualified scientists, regulators, and the interested public need to be able to examine the underlying data. There are situations in which the underlying are not provided to scientists, regulators and the public. At times the refusal to make important data public has been justified by the need to protect the privacy of participants in a study. However, this should not be an obstacle to making the data available, since datasets can easily be stripped of identifiers.

The process of coming to a rational assessment of difficult questions involving factors affecting health and the environment must be based on two principles: first, that of open data and, second, that the assessment of the science must be kept separate from political agendas and pressures.

Below are two links to articles where I discuss issues relevant to the need for transparency and a non-political approach to evaluating the evidence on a given question.

http://www.forbes.com/sites/geoffreykabat/2013/09/23/what-is-really-at-stake-in-the-republican-partys-subpoena-of-epa-data/

http://www.forbes.com/sites/geoffreykabat/2014/09/04/the-raging-controversy-over-bpa-shows-no-signs-of-abating/

A book dealing with these issues is here:

http://www.amazon.com/Hyping-Health-Risks-Environmental-Epidemiology/dp/0231141491

Kathryn Kaiser

University of Alabama at Birmingham

Office of Energetics, Dean's Office, School of Public Health

To whom it may concern:

I am writing to add my support for the efforts to increase our national leadership role in the global scientific community that are alluded to in the plan, notably this item:

“Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?”

By specifically funding and requiring adherence to better (more specific and transparent) disclosure of a priori research plans and methods (to include long term data management and sharing) to those scientists funded by US federal dollars, I believe we can begin to provide the needed incentives to elevate our scientific processes to the level of quality we should aspire to, both in the US and globally. I perform research on the research of others in the form of systematic reviews and meta-analyses, and I am especially disappointed on a regular bases at the failures of my scientific peers to provide needed data to inform these works that are often the basis of policy making for health. Please provide funding to build the infrastructure needed to improve the quality of science we fund.

Neil Kane

Illinois Partners

Founder and President

Re: Intellectual Property/Antitrust, Question 21

The federal government has tens of thousands of patents in its portfolio that have no commercial value. Maintaining this large portfolio is not only costly, but it also adds a huge drag to the innovation economy because time and money are spent evaluating these patents, in light of new innovations, and at times new projects are not undertaken because of these patents (concerns about enforcement, freedom to operate, etc.). The challenge, however, is identifying those that have little to no commercial promise.

My recommendation is that for any patents owned by the federal government that have not been licensed within seven years of their issuance, they be offered for license via a Dutch auction. A Dutch auction is the same mechanism under which the Treasury Dept. raises money through the sale of T-Notes and is a very mature and well-understood mechanism for finding the market clearing price of assets.

In a Dutch auction, terms of sale are set (in this case, terms of offer for an exclusive license) and then the price is systematically lowered until a market clearing price is reached. In a typical auction things of marginal value don't always sell, but in a Dutch auction things always sell—the only uncertainty is the final price. My thesis is that if these patents get licensed for a low price, then that provides confirmation that they had little value and were not worth the expense of additional protection.

To avoid these patents being held by non-practicing entities and creating the opposite problem of the one intended to be solved, they would have to be licensed with stringent diligence milestones to ensure successful commercialization. My hypothesis remains that a great many of them won't be licensed with commercialization milestones because they have dubious value and aren't even worth the cost of maintain—except by speculators. If and when they get licensed late in their patent life it is not because people are innovating…it's because people need the patents for defensive reasons.

And here's the important policy piece—if they are not licensed by a Dutch auction process, then they should be abandoned.

Universities and other large research organizations that generate a lot of new IP and maintain portfolios of occasionally unproductive patents would be free to adopt this policy if they chose to.

This is the most authentic market-based system for the federal government to stand behind. It will stimulate the commercialization of those patents that have commercial value (because in a Dutch auction the competitive dynamic is to want to keep the patents out of someone else's hands) and get rid of a lot of detritus that creates a negative drag on the economy.

In the long run, the existence of this system may even influence the decision of what to protect by patent in the first place.

I wrote an article about this topic for Forbes in May, 2014:
http://www.forbes.com/sites/neilkane/2014/05/22/a-modest-proposal-for-licensing-patents/

Heather Kappes

Encourage funding proposals to be based on studying important questions rather than proving that an idea is right or wrong. That is, encourage and fund research where no matter which way the results look, it would be interested and publishable. Dedicate a small portion of research funding to replicating important results. Promote and support training in research methodology that will help researchers use appropriate methods and disseminate their findings - regardless of the results - widely.

Kenneth Kellar

I am writing regarding the reproducibility of published work American science.

If possible, I would like to suggest that, at the very least, once a publication has been found by an appropriate panel of experts to contain one or more major flaws, it should either be removed from the National Library of Medicine's PubMed files or flagged to alert people who find it that there was a major question about the paper. A similar procedure could be urged to instituted by publishers on their own journal web sites where searches are sometimes begun. This could help to prevent unsuspecting investigators in the future from propagating misinformation by citing the flawed work.

Richard Klein

Specifically relating to item 11 regarding reproducibility:

Although the current replicability crisis may seem like a threat to science it may actually be a great opportunity. Up until now, it is entirely possible that we have been basing our theories on results that may often have been contradictory simply because up to HALF of those results may have been false positives. Increasing replicability may have the greatest potential to increase the rate of scientific progress.

Perhaps the two biggest Ways the federal government can encourage reproducible research:
1. Make sharing of FULL datasets (except sensitive data), materials, and procedures the default. This encourages full peer review and facilitates replication.

2. Allocate a portion of federal funding to replicability efforts, rather than insisting on novel research as a requirement for funding. Ensuring the results we have are reproducible is a key to scientific progress and without incentive researchers will not undertake these projects. Furthermore, once replicability becomes a norm researchers will have an incentive to produce replicable research in the first place.

Naomi Kleitman

Craig H. Neilsen Foundation

VP for Research

The issues of reproducibility in science reflect the complexity of much of the work going on today as well as the commonly cited publication pressures faculty are under. I applaud your attention to this issue, but urge you to be sure that it is discussed in the context of making good science better rather than what may be perceived incorrectly as fraudulent behavior. The very important thing in approaching this issue is the nature and message to the public about why things are either not repeated or not repeatable. They vary greatly, and I believe in very, very few cases are due to outright dishonesty. Errors also are facilitated by short, incompletely supported papers in major journals that undervalue careful documentation of methodological descriptions and documentation with high quality anatomical photographs, in favor of first-time descriptions of what appear to be "scientifically sexy" results. In other cases, the low review quality in lesser journals means that someone somewhere can always find a way to publish their studies.

I speak from experience as a former Program Director at NINDS/NIH, who served not only as the Research Integrity Officer for that Institute but also as the COTR on an NIH/NINDS contract to support replication studies in spinal cord injury. Disease and injury models are difficult to manage well and our efforts to support replication studies of what were thought to be very high quality studies via a contract (as they could not be done under the existing grant mechanisms) led to a number of reported failures to replicate findings in the reported injury models. As part of that contract, we required that the contractors publish all findings, positive or negative, and in fact we published an entire special issue in the journal Experimental Neurology including an introductory editorial describing the experience to both explain the nature of the difficulties we encountered, plus the context and limitations of each and every paper with a failure to replicate the original studies. In no case did we find any evidence of scientific misconduct, but we did manage to uncover a number of methodological booby-traps that were unknown at the time (leakage of tracer through a compromised blood-spinal barrier, baseline heterogeneity between groups, batch differences between peptide preparations, etc.). Our overall conclusion was a very careful statement relating to the "readiness to translate findings from animal to human studies," not a condemnation of the field or laboratories involved.

It would be outstanding if NIH and other agencies that fund such research developed dedicated, or at least protected funding to support replication studies. This involves selection of which key studies are at a stage where verification is actually a worthwhile investment. To be successful, it also requires acknowledgement that high quality replication studies are neither easy nor inexpensive (which was certainly a surprise to NINDS when they tried to support such studies by small supplements). Reviewers routinely find replicative components of applications to be "not innovative" or "something NIH doesn't fund." Moreover, such studies would best be carried out by experienced technical staff, not students or postdocs whose career advancement depends on original, independent new findings. Such staff are more and more not available in sufficient number to support any but the most critical studies in most labs. Universities are unlikely to support such staff efforts unless they are directly and completely reimbursed by federal funds. Anything less could lead to trivial and unsupportable negativity and potentially targeted attempts to undermine others in the field. A negative finding should be check and rechecked, and publishable if and only if it is found to be a sound interpretation of comparative methodologies.

Traditionally, science has depended on other types of "verification" through similar but not identical studies that build on reported findings and depend on the hypotheses on which they are based to be true. This type of indirect verification is often sufficient, given time. It also is easier done in fundamental studies than in those directly testing a preclinical drug, etc., where perpetuation of a nonrobust therapeutic strategy could lead to immediate harm to patients in expensive trials. The current emphasis on speeding up the rate of translation of studies from the bench to the bedside makes the need for independent testing of potentially risky interventions more needed than ever. It would behoove an agency dedicated to funding such translational efforts to also support sufficient quality control.

Once again, thank you for OSTP’s interest in this topic,

Calvin Lai

It is often difficult to replicate others' results without in-depth knowledge of the original research materials and data. Sending individualized requests for materials and data can often be time consuming, beset with delays, and even complete non-response. Making data and research materials open for everyone should be the default across the sciences and scientific journals.

September 23, 2014

To: Dan Correa,
Office of Science and Technology Policy,
1650 Pennsylvania Ave NW.,
Washington, DC 20504
By email: innovationstrategy@ostp.gov

Re: **Strategy for American Innovation**.

As an innovation executive, inventor and an entrepreneur, I hereby provide only one comments in response to the Request for Information at 79 *Fed. Reg.* 44064 (the "Notice"):

The Notice propounds the following as Question 11:

> "Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?" 79 FR 44066.

My answer is:

The Federal Government can readily address the problem by ***starting at the top***: first it must stop generating ***its own irreproducible findings***, such as those assembled and disseminated by the White House in its June 4, 2013 report entitled "*Patent Assertion and U.S. Innovation.*"[1] This report violates the Information Quality Act[2] ("IQA") in several ways and a specific request for correction under the IQA is filed separately with this Office and will be available in full at http://j.mp/OSTP-IQA.

Respectfully submitted,

Ron D. Katznelson, Ph.D.
Encinitas, CA.

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[1] www.whitehouse.gov/sites/default/files/docs/patent_report.pdf

[2] 44 U.S.C. § 3516 note, Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A–153–154 (2000).

September 23, 2014

Dear Mr. Correa,

My name is Peter Lee, and I am a professor at UC Davis School of Law, where I specialize in intellectual property law. I have written extensively on patent doctrine, patents in biomedical science, university-industry technology transfer, and social innovation. I am writing in response to the Notice of Request for Information for the *Strategy for American Innovation*.

(1): Policies and Initiatives Aimed at Spreading the Benefits of Innovation

The current *Strategy for American Innovation* focuses on promoting overall innovative output, which is a worthy policy objective. In addition, the next *Strategy* should also emphasize enhancing access to and widely distributing the benefits of the U.S. innovation system, including serving the innovation needs of low-income populations. After all, an innovation infrastructure that generates sophisticated technologies may be of little benefit to those who cannot afford those technologies and have no equity stake in the companies that produce them. The *Strategy* should operationalize this commitment through three sets of specific policy actions.

First, the *Strategy* should promote wider access to vital technologies derived from federal funds. In particular, the National Institutes of Health (NIH) should consider greater use of its march-in rights and paid-up licenses under the Bayh-Dole Act to enhance access to patented diagnostics and therapeutics. The recent litigation over Myriad Genetics' "gene patents" provides an illustrative case study. Myriad Genetics attracted significant criticism because it utilized patents on genes related to breast and ovarian cancer to charge supracompetitive prices for clinical genetic diagnostic testing. Ultimately, such criticism motivated a lawsuit, recently decided by the Supreme Court, which invalidated Myriad's isolated DNA patents. Overlooked in the debate was the fact that NIH had partially funded the research leading to Myriad's gene patents, thus raising the question of why the public was paying patent-inflated prices for diagnostics that arose in part from public funding. Although NIH retains march-in rights under the Bayh-Dole Act, it has only considered four petitions to exercise those rights, rejecting all of them. It may be advisable for Congress and agencies to revise the statutory text and implementing regulations of the Bayh-Dole Act, as they currently establish rather high barriers to exercise march-in rights. Policy refinements can help agencies judiciously increase access to federally-funded technologies while still ensuring that patents provide robust incentives to develop new innovations.

Second, the *Strategy* should promote opportunities for low-income and underrepresented individuals to participate in inventive, innovative, and entrepreneurial activities. Such improvements would be consistent with the *Strategy*'s broad, market-based approach to innovation; to the extent that policy intervention can decrease barriers to entry for underrepresented individuals and small businesses, innovation markets will operate more efficiently and productively. Two specific sets of policy interventions can enhance participation. First, reforms to the patent system can widen opportunities for low-income inventors to protect their work. Along these lines, refinements and extensions of the micro-entity designation, which lowers patent fees for certain entities, as well as greater technical assistance to nonprofessional inventors, can increase participation in the patent system by a broader class of inventors. Furthermore, Congress and the USPTO should build upon the America Invents Act's provisions to study the diversity of patent applicants and grantees to ensure low barriers of entry by all inventors.

Second, the federal government can directly increase participation in the innovation ecosystem by expanding funding for the Small Business Innovation Research and Small Business Technology Transfer programs. These programs provide valuable funding for small, innovative enterprises that may be neglected by mainstream capital markets. Through increasing participation by all kinds of inventors and companies, the *Strategy* can help strengthen the United States' overall innovation system.

Third, the *Strategy* should adopt a more expansive notion of "innovation" to serve a broader set of interests, values, and constituencies relative to current approaches. The present *Strategy* reflects a traditional view of innovation as indelibly intertwined with technology and generating market value. However, many innovations are not "technological" in nature and possess social value that far exceeds their market value. For instance, "social innovations" such as microfinance, novel strategies to reduce homelessness, and techniques for reducing hospital-based infections, may not be "technological" in nature, yet they immensely benefit social welfare. Furthermore, such innovations tend to have a distributive character, serving the needs of society's least privileged populations. Although innovations such as improved touchscreens for smartphones are certainly valuable and deserving of public support, so are innovations such as methods of providing free voicemail accounts to homeless individuals so that they can receive messages from social service agencies. In other contexts, the Obama Administration has already supported such innovation by establishing a Social Innovation Fund. However, the separation from this initiative from the *Strategy* suggests a rather crabbed and particularistic conception of innovation. A more holistic view of innovation policy—as well as the constituencies it can serve—counsels greater coordination between the Office of Science and Technology Policy and the Corporation for National & Community Service. Ultimately, innovation policy is bigger than promoting technology and should serve interests beyond maximizing market value.

(8) and (11): Institutional Innovations and Promoting the Reproducibility of Scientific Findings

Institutional and infrastructural innovations that enhance the disclosure of data, particularly from federally-funded research, can greatly accelerate collective innovation. Such an approach has several components. First, regulations and policy should tie federal funds to more robust requirements for data disclosure. Currently, NIH requires researchers receiving at least $500,000 in federal grants to make any research-related data available to the public. While this is a laudable policy, the $500,000 threshold is rather high, and NIH should consider a lower threshold. More substantively, officials should consider expanding the policy to require not just disclosing data, but also disclosing the particular methods and algorithms used to analyze those data. Oftentimes, these "back-end" analytical techniques remain opaque to the public, thus preventing other scientists from reproducing original findings. Once data and methodological disclosure requirements have been expanded, other science funding agencies, such as NSF, should adopt similar policies. Among other benefits, widespread access to data and methodologies will greatly facilitate the reproduction (and falsification) of research findings, thus driving scientific progress.

Second, in addition to emphasizing greater data and methodological disclosure, the *Strategy* should seek to improve data infrastructure. One promising target for improvement is GenBank, a centralized database of nucleotide sequence and related information operated by the National Center for Biotechnology Information (NCBI). Along with policies requiring rapid disclosure of sequence data, GenBank has been an indispensable resource in advancing genomic science. However, it features a rather centralized and inflexible data architecture. GenBank is currently structured so that only original data contributors can update data records (which they rarely do). As such, GenBank does not fully capture the power of community-based wikification, in which members of the scientific community can modify existing nucleotide data based on more accurate sequencing, assembly, and annotation. Although NCBI also maintains a Third Party Annotation (TPA) database that allows for external modification of existing data records in GenBank, currently there is only one TPA record for every 12,000 GenBank records. The *Strategy* should provide greater support for community-based wikification through increasing federal funds for parallel sequencing, assembly, and annotation of known nucleotide fragments. Furthermore, NCBI should actively encourage genome scientists to contribute to the TPA by standardizing attribution and scientific credit offered for such contributions. In this manner, federal agencies can both promote the reproduction and verification of existing work as well as ensure that new insights arising from such research are widely available to the scientific community.

(16) and (20) Knowledge Exchange Centers as Conduits for University-Industry Technology Transfer

One of the key priorities of the *Strategy* should be to enhance the transfer of technology and technical knowledge from universities to industry. After all, universities have enormous innovative potential, and one of the objectives (among many) of federal funding of academic research is to spur the development of new goods and services that enhance social welfare. Mechanisms that promote technology transfer from universities to industry will also facilitate proof of manufacturability as well as the creation of vibrant innovation districts. To accelerate such activities, the *Strategy* should support the creation of "Knowledge Exchange Centers" on university campuses whereby academic and industrial scientists can work side-by-side on commercializing university discoveries.

Although universities are eager to patent academic inventions, empirical research shows that patents and licenses are rarely sufficient to fully transfer an academic technology from a university to a private company for commercialization. Among other challenges, even when a patent disclosure satisfies the enablement and description requirements of 35 U.S.C. § 112, a significant amount of "tacit" technical knowledge remains personal and undisclosed by the faculty inventor. This tacit knowledge can relate to the basic operation of an invention or, more relevantly, to adapting or modifying that invention for downstream, commercial purposes. The inability of patents and licenses to convey tacit technical knowledge represents a significant challenge to effective technology transfer between universities and industry.

Because tacit knowledge is personally retained by a faculty inventor, interpersonal interaction between that faculty member and an industrial scientists is often necessary to transfer such knowledge. Side-by-side experimentation and shared "muddling through" technical challenges of commercialization are sometimes the only way to unlock the tacit knowledge in the faculty inventor's mind, even when an invention is fully "disclosed" in a patent. Reflecting this insight, many companies licensing university intellectual property insist on licensing the faculty inventor's "know-how" as well, usually in the form of engaging the faculty member as a consultant on commercialization projects. Ultimately, companies often value people (human capital) more than the patents that they license from universities.

To facilitate the transfer of tacit technical knowledge from universities to industry, the *Strategy* should consider establishing Knowledge Exchange Centers on university campuses. Such center would be spaces—both physical and virtual—where academic inventors could work alongside industry scientists to refine, develop, and ultimately commercialize university inventions. These Knowledge Exchange Centers would represent "estuaries" that would bridge the gap between upstream academic research and downstream commercial application. Dedicated laboratory space on university campuses whereby faculty inventors and industry scientists could work on development projects together would greatly accelerate proof of manufacturability of embryonic academic discoveries and help transcend the "Valley of Death" that so often prevents university inventions from becoming useful products and services. In addition, Knowledge Exchange Centers can serve as cores around which broader innovation districts, such as Silicon Valley or Research Triangle, can coalesce. Federal funding for Knowledge Exchange Centers would promote technology transfer and the introduction of new goods and services to society.

Of course, developing Knowledge Exchange Centers faces several challenges. Due to the (valuable) strictures of academic freedom, participation by faculty inventors in Knowledge Exchange Centers would have to be strictly voluntary. Faculty members are not "employees" of universities in a conventional sense, and universities cannot force faculty members to participate in commercialization efforts. Furthermore, there are delicate questions regarding who would own intellectual property arising from academic-industrial research conducted at Knowledge Exchange Centers. In addition, there are broader normative questions of whether it is desirable for faculty inventors to divert time and energy away from their traditional research, teaching, and service activities, and whether encouraging commercialization work would skew academic agendas and research inquiries. Ultimately, however, a carefully calibrated approach to Knowledge Exchange Centers can help accelerate the transfer of technical knowledge from universities to the private sector, thus helping to realize the innovative potential of both universities and significant federal investments in academic research.

I hope that these suggestions are helpful in contributing to a stronger *Strategy for American Innovation*. I would be happy to answer any questions or provide any additional assistance regarding these recommendations.

Sincerely,

Peter Lee
Professor of Law
Chancellor's Fellow
UC Davis School of Law
[redacted]

Randall J. LeVeque

University of Washington

Professor of Applied Mathematics;   Senior Data Science Fellow, eScience Institute

I would like to comment on paragraph (11) of the Strategy for American Innovation Request for Information.

Reproducibility of scientific findings is an essential component of the scientific method and it should be expected that published work provides the information required for other scientists to attempt to reproduce the work. The shift towards digital data and computational techniques should make it easier to meet this goal, but too often the data and computer code are not made available to readers of an article. Federal agencies can help encourage greater sharing of data and code through requirements that data to accompany publications resulting from funded research be deposited in suitable public repositories, along with the computer code used for analysis or simulation. Of course exceptions must be made for certain types of data, e.g. due to privacy concerns, but I believe the default should be open data and code or some explanation of why this is infeasible.

Huw Llewelyn
Aberystwyth University (UK)
Honorary fellow in mathematics

The reader of a scientific paper asks: "If I repeated this study in my lab or clinic or locality, what is the probability that I would replicate the result?" If the probability of such replication is very high, I would not bother to repeat it and accept its findings. If it were very low, I would ignore the paper (such a paper should not have been published anyway for that type of reader). If it was neither very high nor very low and I found the idea very interesting, I would repeat it. There are two issues:

1. The current reasoning regarding the probability of replication is incomplete: In order that the probability of replication is very high, then the probability of non-replication for all the reasons that we can think of must be very low. The most well known reason is statistical e.g. if the P value is low (or the 95% or 99% confidence limits or Bayesian credible intervals are narrow) then the probability of non-replication due to the number of observations made will be low. However, this is only the start of the reasoning. We must also consider that the probability of non-replication due to poor methods, differences in subjects (patient or animals used), other local factors (e.g. reagents used), the presence of contradictory results in other published studies and other unpublished studies, dishonesty (e.g. due to desperate need to publish an interesting paper for employment reasons or commercial profit) etc. must all also be very low. It is clearly very difficult to even estimate these probabilities in order to satisfy the requirement to get a very high probability of replication. The basis for reasoning legitimately in this way is a probability theorem that is also used for differential diagnosis and is described in detail in the 3rd edition of Oxford Handbook of Clinical Diagnosis (Oxford University Press, Oxford, 2014) published this week.

2. Replication is difficult: one way around this is for every grant giving body or journal to nominate another scientific group to repeat a study to see if the result can be replicated before it is published. It is possible of course that the group repeating the study may not do things properly or get an aberrant chance result so blame should not be attached for failure of replication. A contradictory result might have to be investigated further by using a bigger study if this was deemed important. A research grant could allocate funds in advance for this to be done. In medical settings a partial form of replication for RCTs could be done much more cheaply by using a 'cut-off' study during day to day clinical practice and on a far larger number of patients than is possible in RCTs. A similar approach could be used for arriving at diagnostic criteria and optimising differential diagnosis using diagnostic tests. This is also explained in the 3rd edition of Oxford Handbook of Clinical Diagnosis (Oxford University Press, Oxford, 2014) published this week.

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September 1, 2014

Mr. Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building,
1650 Pennsylvania Ave., NW
Washington, DC 20504

Dear Mr. Correa:

Thank you for the opportunity to provide input to the upcoming update of the *Strategy for American Innovation*. My perspectives are informed by my experiences of the last twenty years interacting with students, faculty, entrepreneurs, and industry. First as an educator, having led one of the first biotechnology programs in the country, as a faculty member in biotechnology and entrepreneurship at the Kellogg School of Management and, most recently as the head of the Innovation and New Ventures Office at Northwestern University where I am in charge of multiple educational, translational, technology transfer, and startup activities.

In the last five years Northwestern University has experienced unprecedented growth in innovation and entrepreneurship driven in large part by students and faculty, while supported by institutional, community, and Federal programs. Today, Northwestern is well recognized for its success in commercializing research and for its student-led startup achievements. This rapid transformation has provided us with a vibrant laboratory to teach us how to best nurture an energetic, adaptive, and continuously disruptive ecosystem.

Below I will address some of the overreaching questions requested by the Council. I will start by outlining some of the "key innovation trends" of the 21st century followed by a partial response to the question of, "What specific actions can the Federal government take to build and sustain US strengths including its entrepreneurial culture, world-class universities, strong regional ecosystems and large share of global venture capital investments?"

Innovation Trends

For the last thirty years the United States has maintained a dominant position in innovation as measured by the number of publications, patents, startups, people employed in entrepreneurial activities, and venture investments. However, in more recent years, there has been increasing evidence that innovation is becoming a global activity. We can no longer take our lead for granted.

NORTHWESTERN UNIVERSITY

The globalization of innovation, as opposed to the globalization of established industries such as traditional manufacturing, reflects an attempt to compete "head-to-head" with the US in the creation of new knowledge. Knowledge is the 21st century currency and as such it has become a strategic focus of governments and policy-makers. In fact, many governments approach innovation as an economic development activity and are pouring substantial investments in the creation of "clusters by design."

While it is true that innovation often becomes a clustered economic activity, the evidence suggests that government-designed clusters are not always sustainable. Innovation clusters usually sprout from top research universities with significant fundamental research activity. They require a very specialized skill set, and entail an organically grown entrepreneurial environment with supportive policies in which workers are shielded from failures.

Given this unique set of conditions, many of the global clusters remain small and are highly dispersed across the world. In addition, although there are scores of activities worldwide, most of the value creation (product development, commercialization, and capitalization) still remains centered in the US. This highly dispersed topology opens the opportunity for one of the more subtle dynamics of clusters: hubbing.

While the globalization of innovation is often seen as a threat to the relative preeminence in the US and as an indication of the US "falling behind" in the world, it also provides a historical opportunity for the US to establish a long-term position as a global "hub" for innovation and entrepreneurship.

Specifically, the US has an opportunity to become a "magnet" for international entrepreneurial activity. Given the central role that universities play in the development of clusters, it is not surprising that they should be the best poised to act as magnets for: knowledge, entrepreneurial, and commercial "know-how." However, progressive actions and policies are needed to seize this opportunity.

Below are some specific suggestions, on needs, opportunities, and steps the Federal government could take to ensure the US strength in innovation. Success will need multiple solutions at different levels. Due to space limitations, I will discuss only two general steps: (i) Increase the spanning of organizational and international boundaries, and (ii) Strengthen US core capabilities in research, intellectual property, and entrepreneurship. These steps contain several specific actions that are described within, including: policies that encourage international research and commercialization collaborations, a strong intellectual property policy that facilitates the exchange of knowledge, reshaping graduate education, and funding.

Becoming a Global Hub of Innovation

In order to become a global hub of innovation, boundaries need to be porous to allow the free-flow of people, resources, and capital. At the same time, policies should be supportive and our core strengths in research, intellectual property, people, and funding need to be secured and adroit.

1. Increase the spanning of organizational and international boundaries

It is well known that innovation occurs at the intersection of disciplines, organizations, and cultures. If the US is to become a global hub of innovation, collaborations across institutions and nations should be promoted. Innovators, research, and capital need to freely move across organizational and cultural boundaries. Understandably, immigration and export control issues are complex and we must find ways to simplify the processes without compromising the security of the country. However, some small and specific actions can be taken in related areas that could significantly benefit interactions among institutions.

- **Review Conflict of Interest Regulations**
  While it is vital for leaders to ensure that all activities meet the highest standards of ethics and integrity, overly stringent regulations on Conflict of Interest (COI) also discourage our researchers and entrepreneurs from collaborating with industry to develop innovative technologies. Risk cannot be looked at in isolation without assessing the potential benefits. The administrative burden on entrepreneurs and universities discourages promising young faculty members to consider collaborations with industry or entrepreneurial options. The paperwork has become overwhelming. A clear example of the chilling effect that these regulations have on innovation has been in the slower rate of (disruptive) innovation in medical device area. Device innovations are an iterative process between engineers, clinicians, and commercial developers. These interactions have diminished in the last few years partially due to potential COI concerns. It is of great importance to add some flexibility to the current Conflict of Interest and Conflict of Effort guidelines established by Federal agencies to reduce the administrative burden and to encourage more vibrant industry-academic collaborations.

- **Encourage international research and technology transfer collaborations – Review restrictions on manufacturing**
  Policies need to be adapted to the highly connected world of the 21st century. The Bayh-Dole act of 1980, together with its amendments of 1984 and 1986, is perhaps the most enlightened and impactful legislation in support of research translation and innovation in the US. This legislation propelled new industries in sectors such as information technology, biotechnology, clean energy, and nanotechnology. While this legislation is

insightful and inspiring, it might be time to reassess whether it is poised to address our globalization needs. The Bayh-Dole provision requirement that breakthroughs from US university-based research are manufactured substantially in the United States, is not only limiting potentially fruitful collaborations but also is not consistent with new economic realities. While waivers could be allowed upon petitions, on a one-to-one basis, the process is cumbersome and unpredictable. Predictability and speed are the key ingredients for partnership building.

2. Strengthen US core capabilities in intellectual property, research, graduate education and entrepreneurship

As we attract more global innovations, we concurrently need to make sure that our core capabilities remain strong, relevant, and highly adaptable. Some examples of small actionable steps that will strengthen our position are:

- **Maintain an IP policy friendly to innovation and startups**

The US IP policy has been the bedrock of innovation and commercialization in the US. Intellectual property promotes clear transactions and collaborations by encouraging disclosure rather than secrecy. IP is powerful as long as it is enforceable. While we have seen many abusive patent litigation practices in the past and many attempts for reform are underway, we should be cautious not to create reforms that would seriously undermine the ability of universities and startups to legitimately enforce their patent rights. Over-reaction is a real risk. While it is important to address the concerns about "patent trolls" and their abusive practices, we also need to make sure that the proposed reform and the "loser pays" provisions do not end up having a chilling effect on academic and startup innovation.

- **Build strong intellectual property positions**

Filing and maintaining strong patent portfolios at universities is usually the responsibility of the Technology Transfer offices. These offices are generally under-resourced and under-funded. Technically, universities may charge the cost of patenting to their administrative cost pools or F&A. But the administrative components of F&A are capped by the Federal government at 26 percent, which means these costs effectively do not get reimbursed. In addition, patent costs are unallowable as a direct cost. This makes it almost impossible for these offices to adequately support filings for many disruptive inventions. It is also very rare for universities to do foreign filings, which are essential in today's global economy. It is important to explore ways for the Federal funding agencies to search options that will allow the support of patent costs.

- **Reassess research funding**
  We must realize that the landscape is shifting, and what worked yesterday may not be as effective today, nor be the best approach in the future. The US and universities should continually reevaluate and redesign the traditional research funding mechanisms in order to prepare for the changing world of innovation. Some investments are key to strengthen the US leadership: basic research, funding to attack the "big" problems (energy, climate control, cancer), and non-dilutive proof-of-concept seed capital. Other investments may be controlled experiments that need frequent evaluation (regional cluster, etc.).

  ✓ *Increase Basic Research Funding*
  It is impossible to underestimate the importance of having vigorous and predictable funding in fundamental sciences and engineering. Without basic research there will be no innovation pipeline. No other Federal funding programs should come at the expense of fundamental research. Entire industries can be traced back to fundamental discoveries at universities that had "no commercial value" at the time of funding - the internet, semiconductors, and genetic engineering, just to mention a few. More than 70% of all the patents are traced back to university discoveries. We need to make sure that funding for truly disruptive research programs such as NIH's Transformative Research Awards, NSF's EAGER awards, and DARPA and ARPA-E awards more generally are not only sustained but their budgets are also increased. Yet federally funded research is but a part of a complex innovation ecosystem. It produces maximum value to society only when it interacts with other programs capable of exploiting the scientific opportunities it creates such as the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

  ✓ *Support and Review SBIR and STTR Requirements to Meet the New Landscape Needs*
  Funding programs need to be nimble to quickly adapt to technology and market shifts, SBIR and STTR programs are powerful programs that dovetail on research grants to provide non-dilutive seed capital and encourage entrepreneurship. These programs are becoming even more powerful when coordinated with supporting policies such as state matching funds and refundable tax credits on angel group investments. SBIRs and STTRs also need to be continually redesigned to become even more effective in incentivizing the blurring of organizational and international borders. Some potential actionable steps could include; (i) making programs available, on a highly selected basis, to international teams, (ii) consider removing the SBIR requirement to have the primary researcher employed by the company receiving the grant, (iii) facilitate the presence of startups on campus by creating an IRS exemption for

university-industry collaborations built around university-owned intellectual property that is conducted in university buildings.

✓ *Review Investments Made in Support of Regional Clusters*
Federal agencies have also made significant efforts in programs supporting the creation of innovation regional clusters such as i-Corps, Engineering Research Centers (ERC), Industry University Cooperative Research Centers (I/UCRC), Partnerships for Innovation (PFI), or NIH's Research Evaluation and Commercialization Hub (REACH) programs. These models may be too formulaic to inspire innovation. As opposed to the organically grown clusters from the past, these clusters are created "by design" with an economic development mission, following a similar model as the European clusters. It is too early to know whether these efforts will result in sustainable and vibrant clusters but we know that they require enormous administrative infrastructure and resources to set up. Some of the best people are shying away from these programs. I know of cases where people withdrew after having obtained a grant due to the high cost of administration. These programs are long-term bets on translation and given the complex structure they might be difficult to adapt. It will be important to continually evaluate the efficiency and impact of these awards in the future.

- **Create Doctoral/Entrepreneurial Fellowships**

As an alternative to the cluster investments, one could consider other, simpler, and nimbler investments that will support entrepreneurship, collaboration, work-force development, and at the same time increase commercialization efficiencies, i.e., the development of Doctoral translation/entrepreneurial fellows that would spend an additional year after receiving their Ph.Ds to validate, prove-the-concept, and pursue an entrepreneurial path.

Our graduate system has been drifting for the last few decades. Students are trained to be researchers, not innovators. The job market for Ph.D graduates has been declining and life-long postdoctoral positions are becoming common. At the same time, the US invests great resources into developing Ph.Ds. Almost all science and technology graduate students are supported by either the NSF or NIH funding, but the US is not able to capture their full potential value.

The demand for research results, the rigid need for effort compliance, and the need to meet the funding program goals creates a vicious closed system for the doctoral students with no time to spend exploring, validating results, and proving the technology they work so hard to create for five years. US undergraduate program are flexible with opportunities for customization. PhD programs are rigid. Many students born and bred in flexible undergraduate programs shy away from Ph.D programs that limit flexibility.

By creating large hurdles for graduate students, we are limiting the effectiveness of the newest generation of innovators we have invested so heavily to foster -- a wasteful loss of opportunity for career development, innovation, and commercialization.

Why not create a prestigious fellowship option to allow selected Ph.D graduates spend a year after graduation exploring entrepreneurial options, validating the technology, and moving the research towards commercialization? Last year, Northwestern piloted this concept with philanthropic funding. While the scale was small, it produced impressive results with two validated startups led by recent PhD graduates. One could only imagine the tremendous impact that a program could have if implemented nationwide.

We have an historic opportunity today to leverage the flurry of innovation and establish a long-term position for the US as a global "magnet" for innovation. In order to do seize this opportunity we need to strengthen our research and educational capabilities and adapt our policies and institutions to make sure they are aligned to the innovation needs of the 21st century.

Thank you again for the opportunity to comment on the upcoming update of the Strategy for American Innovation. I will be happy to discuss these issues in greater detail.

Best regards,

Alicia Löffler
Associate Provost for Innovation and New Ventures
Associate Vice President for Research
Executive Director, INVO

Raymond A. Mar

York University

Associate Professor, Department of Psychology

Hello,

In response to the recent call for information regarding reproducibility, I would recommend that a task force be set up in order to examine whether the published research in various topics within psychology and other disciplines hold evidential value. This can be achieved by using a p-curve analysis. For more details on this analysis please see:

Simonsohn, Nelson, Simmons, (2014) ""P-curve: A Key to the File Drawer,""

Journal of Experimental Psychology: General, V143(2), p.534-547.

p-curve.com

Experts from each field should be tasked with forming committees to conduct a p-curve analysis on the major topics in the field. Those topics for which ample research exists, but these studies fail to demonstrate an evidence for the true effect, should no longer be funded or taught.

Thomas Martin

Biotechnology is currently a growing field of science that is on the cusp of revolutionizing the way we live our lives, similarly to how our lives are now being changed by the computer revolution that started 40-50 years ago. With PCR and genetic sequencing becoming ever cheaper and more prevalent, we're beginning to start a new era in medicine and technology that solves problems with genetic methods. The power of genetic research can make our food supply resistant to the effects of climate change, invent new and cheaper methods of curing disease, and even teach us more about ourselves. A good example of this is how we've changed life for diabetics: through genetic modification, we've been able to make E. coli produce massive quantities of human insulin, rather than the more inefficient and expensive porcine and bovine insulin. More recently, genetic modification technology has resulted in a tobacco plant that produces antibodies against Ebola.

The federal government needs to recognize the importance of biotechnology and its role in creating our future world. The Human Genome Project was a huge success, and this kind of success must continue in the future. Without proper research funding and government support, the United States will fall behind the rest of the world in biotech.

Saroj Mathupala

Wayne State University

There have been numerous reports on irreproducibility of scientific research, including recent complaints from pharmaceutical companies indicating that 90% of the biomedical research cannot be replicated by them (http://www.nature.com/nature/journal/v483/n7391/full/483531a.html) during their efforts to translate the findings to develop new drugs for the benefit of the US tax payer. Broadly stated, this translates into the waste of approximately 27 billion of the 30 billion dollars that Congress and Senate earmarks each year for extramural research funded by the National Institutes of Health.

Most editorials and article on this problem downplay the primary reason behind the issue; misconduct by researchers who are either forced to produce research data by their supervisors, or their own willingness to take short-cuts in biomedical research (including data fabrication, data manipulation) to increase their research productivity – which is broadly measured by the scientific community by the number of research publications produced by a particular scientist. In other words, it has become a "numbers game" with more publication translating to greater chance of securing federal funding. This quantity-over-quality issue has deeply undermined the scientific process with unscrupulous scientists slowly winning over the limited federal funds that are available; by pushing and selling their sub-standard science to the scientific community and NIH, NSF and DOE review panels, over and above their more peers who are more ethics conscious and civic minded.

There are several avenues available to attack the problem;

1] Enhance research integrity: provide more funding and authority to Office for Research Integrity (ORI) under Health and Human Services Dept. (HHS) to investigate, pursue and punish dishonest researchers. At present, the ORI is under equipped, under staffed with no clear mandate and authority to investigate; the scientific misconduct reported to them in turn, is turned-over to individual universities or research institutes to investigate. These institutions never want "bad press" and routinely plough-under the investigations – and only pursue the issues if it has surfaced in popular press. Thus, the research misconduct reported in the Federal Register comprises only the "tip-of-the-iceberg". If possible, such and investigative unit should be staffed by scientists who have had immediate family members who have suffered from the disease phenotype that is being funded by the government. It is well-known in the scientific community that some of the best clinically applicable research is being conducted by scientists who have had a personal stake in finding a cure for the specific disease being studied, for example, cancer, cystic fibrosis, Alzheimer's, multiple-sclerosis etc.

2] Provide "more-teeth" to the online community (blogs) that is pursuing research misconduct: Either provide more Federal support for such "blogs" or establish federally maintained "blogs" along the lines of Retraction Watch (retractionwatch.com) or PubPeer (pubpeer.com) where civic minded scientists, students, researchers and public citizens can "out" questionable science published by the "unscrupulous" among the scientific community. These blog sites have provided yeoman service in raising awareness of the corruption that permeates current scientific enterprise, not only in the USA but the world-over. But, they are constantly under attack with legal threats leveled at them by the scientists exposed of committing misconduct. If a federal blog is established along the lines of Retraction Watch or PubPeer it should be manned by experienced science writers or correspondents and not by scientists themselves, in order to impart a sense of impartiality.

3] Enhance quality of scientific publications: Establish a more valid yardstick for measuring scientific productivity, and the contribution of the science to enhance the health of the federal tax-payer: First and foremost, this should be based on quality and not quantity of publications. One area to consider is the impact factor of each of the publications by the researchers that are listed in PubMed, Medline, Thompson-Reuters Web of Knowledge Database, and how often the research is cited in patent database (for example patents.gov; if f the researcher's studies have been useful to the pharmaceutical industry, then it will be reflected by being references in patent applications). The impact factor of individual journals where the research is published should not be taken into consideration). However, none of the current schema are not perfect; a better parameter needs to be established by the scientific community to tackle the "productivity-measurement" problem.

4] Enhance public-based peer-review of research: In awarding federally-funded grants, the NIH (and NSF, DOE) should consider not only the above mentioned impact factor parameters, but also whether the principal investigator's publications have been flagged by peers on the public peer-review blogs such as PubPeer and Retraction Watch. If so, that should raise a "red-flag" for the federal review committees. Such investigators should be banned from receiving more federal funds. If such a mandate is followed, it will seriously curtail the current problems with insufficient federal funds for research, and the research that will be funded will have a direct impact in enhancing the health of the tax payer.

5] Minimize waste of tax payer funded research dollars: Funds are currently allowed for investigators to attend national and international scientific conferences. This practice needs to be eliminated for all funding mechanisms. In this age of instant communications, such expenditure is unnecessary, and the funds can be better utilized towards actual research. If the investigator finds it necessary to attend such meetings, then the respective employer (university or research institute) can provide the funds through their indirect cost mechanisms).

Kevin McCarthy

To Whom it May Concern,

Regarding the reproducibility problem in science, I would encourage the federal government to FUND groups who just reproduce significant research... especially research in medicine, biotechnology, and advanced technology. There's not a lot of incentive to fudge research in paleontology, but there is significant financial incentive to fudge results in major research areas.

By encouraging researchers who otherwise wouldn't get funding, you 1) get research money spread over a wider area. 2) Get researchers some funds and potentially allow them access to equipment and processes that they wouldn't otherwise have. This will make them better researchers and prevent the problem that seems to be occurring where 10% of all research scientists are getting 90% of the funds and publishing 90% of the papers. 3) You have significant evidence that the work is reproducible. 4) You encourage people to publish research that disagrees with top names, knowing that it will be confirmed.

I would also suggest that the US Government, as part of it's various research programs produce a peer-reviewed journal that specializes in confirmation experiments AND negative results. This would help scientists who work for years on a project only to get a negative result. Their work will never be published in a leading journal, even if many people repeat the same mistakes, because no one knows that it's already been done and failed.

Thanks
Kevin McCarthy

Dennis McQuerry

Pacific Northwest National Lab

Senior Research Scientist

I am a scientist at the Pacific Northwest National Lab. One of my projects involves creating a visualization-based navigation system for all the DOE's patents and patent applications. Take a look at http://techportal.eere.energy.gov/VPS/index.html to see the current state of this work. DOE has approximately 18,000 patent applications and current patents available for licensing. I'm sure there are patents assigned to other gov't organizations as well, which could be served up in a similar way. We need to expand the work on tools such as the Visual Patent Search tool, in order to provide a means for corporations and start-ups to quickly and easily navigate this sea of intellectual property in order to identify possible licensing opportunities. The intent of the current project is to enable a user to locate a patent of interest with just a few mouse clicks using a simple interactive visual representation of the data. Ideally, all patents assigned to US Government agencies would be served up in the same interface. So far, we are only doing this for DOE patents. The work has been paid for as part of NREL's Energy Innovation Portal for EERE/DOE.

Maartje Meijs
Tilburg University

I think it is very important to promote and support training of methodology and statistical practices in order to ensure reproducibility of scientific findings. Methods and statistics are essential in understanding how to design research, to analyze the data, and to draw wise conclusions.

Hendrik J. Monkhorst

University of Florida

Professor Emeritus

Modern innovation, advances in technologies and trans-formative breakthroughs in both are deeply rooted in understanding the underlying physics, chemistry, or biology of the area of progress sought. This requires a workforce that is well prepared, open-minded, and broadly aware of global activities in their area of expertise. In short, they must be well-educated in a rather all-round fashion.

The "Strategy for American Innovation" sorely lacks the realization of this requirement. And the foundation for the required workforce is laid at the most elementary level, i.e., K-12 education. As long as the US is way behind in this education relative to most advanced countries, we will continue to fall behind in the quality and quantity of US-educated workforce. Reliance on immigration to fill this shortage is no option anymore, they will not come as employment opportunities in their home countries keeps improving.

Capitalism works its wonders of entrepreneurial successes, once a good workforce is in place to carry out the innovations and advances in technologies. But it detrimental in under-appreciating the teaching professions, unfettered research pursuits without immediate pay-offs, and giving time to a full and all-around education. Many developed countries do a much better job at these aspects, and they surge ahead.

In my judgement, very much effort must go in

1) greatly raising teachers' salaries;
2) greatly improving teaching environments for all, and not only minorities and women;
3) greatly increase basic research funding at Universities, simplifying rather than the current rising bureaucratic overload, and extension of funding periods, rather than the current one-year like cycles.

Without these trends we will not make any headway with SAI; indeed, we might very well stagnate or fall behind, and any other expenditures toward the SAI will go wasted.

Alisa Murray

11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

Irreproducible data is holding scientific research back. There needs to be validation studies and validation grants to stop the wasted NIH grant money that are chasing results that can not be replicated by other labs. This is frightening given the fact that science builds upon the prior work of others. More needs to be done to ensure the relevant information on experimental design is captured in protocols and the replicate data is reported.

9 September 2014
Palo Alto, California 94306

SIR/MADAM:

Please accept this response to the Notice of Request for Information (re Strategy for American Innovation), online at

https://www.federalregister.gov/articles/2014/07/29/2014-17761/strategy-for-american-innovation

I address some of the Overarching Questions as follows:

(5) Re innovative practices and policies:

Three words in response: *Lower Corporate Taxes*.

(7) Re emerging areas of scientific and technological innovation:

See the response to (24), below.

(8) Re needs or opportunities for institutional innovation:

See (11), below.

Note also that the United States maintains an ongoing overemphasis on university degrees as a mark of “higher learning”, despite decades of shortages of skilled craftsmen (tool-and-die makers, skilled machinists, aircraft mechanics, and the like). Note in contrast that Germany, for example, has far less of this problem, as they have emphasized trade schools and polytechnics as viable and respectable alternatives to a university education.

The solution: instead of expanding university campuses, invest instead in building trade schools at the high-school and polytechnic levels, as well as art-and-design schools (as done in Europe). Let’s not be too proud to admit that the Europeans have done some things right.

(11) Re the irreproducibility of scientific findings:

To quote a Wall Street analyst during the Bernie Madoff inquiry: when you pay peanuts, you get monkeys. To clarify: a blatant fact that my academic colleagues are loath to admit is that much of the lack of reproducibility of scientific findings is caused by those findings being *false*. The falsehood of the findings springs from the culture in which they are made. That is, a remarkably high percentage of known academic misconduct, and retractions of published papers, directly involves foreign graduate students and foreign postdoctoral research fellows as culprits. By 'foreign", I do not mean Canadian. Or British. Or German.

The United States of America has developed a chronic dependence on scientific research done by desperate PhDs and pre-PhDs from China, India, Korea and Japan. These individuals are highly motivated to remain in the United States at any cost, in order to have American children, as well as to avoid having to return to lower living standards and/or lower financial research support in their native countries. Add to this the present hyper-supply of such individuals, and you have the present situation: underpaid and overambitious foreign employees embedded in a laboratory culture in which publication equals advancement and in which lab heads are too overworked filling publication quotas to properly supervise their understudies. The lab heads themselves are poorly supervised. The entire situation is ripe for cheating. China and India in particular are notorious for student cheating even at home; why should any rational person assume that they behave any differently here?

Part of the problem is psychological. American lad heads are gullible. They rarely check the credentials of hired scholars. Further, they choose to believe that the "remarkable" advances found by their foreign workers are genuine, although their American workers fail to make such advances. Worse still, their American workers demand better pay and better working conditions; some even have the nerve to expect that the large research universities where they work should at least offer them a medical plan. Foreign workers, in contrast, will take whatever they can get. So we pay peanuts – and we get monkeys.

There is no good excuse for the continuing dependence on Asian immigrant personnel. The United States alone generates more PhDs every year than this country's universities can employ. That is, America's own PhDs do not all become postdocs, and only a few become professors. In my own time, the best graduate students who spoke English as their native language left academia entirely, for lack of adequate reward and advancement. That is, the issue is not that *foreign workers* are paid poorly; they will cheat regardless of what they are paid. Rather, the issue is that American and European workers, who have far less motivation to cheat, likewise have far less motivation to accept unfair working conditions, such as insultingly poor salaries. Here in Palo Alto where I live, a postdoc is lucky to get $50,000/year, which is $30,000year less than what some local police constables, with only high-school educations, get paid to patrol one of America's safest beats. Is this fair?

The solution to the problem is straightforward, in principle: pay better salaries to postdocs and grad students, while simultaneously emphasizing the hiring of American and European personnel, rather than Asians. Otherwise, we will continue to pay peanuts, and we will continue to get monkeys. And we will continue to get the irreproducible results to be expected from desperadoes. *Please note* that no amount of "ethical training" for faculty and students will solve this problem, which is inherent to the students themselves and to the nations from which they originate.

(24) Re national priorities:

A coming technology that will, by its very nature, significantly impact national security as well as living standards is Quantum Computing. However, papers published in recent years in *Science* and *Nature* indicate that the United States is far behind some other nations in developing this technology. Some nations that have evidently made Quantum Computing a priority are Switzerland, Germany, and Austria. The one quantum computer presently being practically tested is made in Canada. We can rest assured that China, also, is pursuing this technology, albeit in secret. Do we wish to be purchasing all of our future computers from Austria or China?

Yours Sincerely –

Dr. Lance Nizami BSc (Physics) MSc (Physiology) PhD (Sensory Psychology)
Independent Research Scholar

Sometime member of the Acoustical Society of America, the American Psychological Society, the Society for Neuroscience, and 11 other recognized scholarly organizations

Some publications listed on GoogleScholar under "Nizami L"

Simon Noble

CHDI Management/CHDI Foundation

Please see the attached Commentary that we published recently in Nature Biotechnology on this vital topic. My fellow authors and I contend that quality control throughout all stages of the scientific process is essential, not simply a matter of reproducibility - career advancement incentives should be closely aligned with scientific rigor to maximize scientific enterprise.

Robert Obenchain

Risk Benefit Statistics LLC

Principal Consultant

Dear Sir/Madam:

Too many current researchers blindly use traditional statistical methods developed almost 100 years ago to analyze data that severely violate the basic assumptions underlying those methods. The findings from unreported "number crunching" within such analyses cannot be subsequently reproduced (validated) because they were wrong and/or misleading in the first place.

These sorts of analysis snafus can be ultimately detected / corrected only if publication of findings in reputable journals is made contingent upon archiving a copy of the final data set for reanalysis by all interested, credentialed researchers ...including information on which numerical values were imputed because they were originally missing.

The OSTP memorandum of Feb 2013 should be vigorously promoted by all government agencies.

Thank you for soliciting opinions; I assure you that mine is well-informed.

Colleen Parks

Regarding: "Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?"

There needs to be a way to publish research that produces null results in all scientific disciplines. Currently, publication bias makes it nearly impossible to publish null results. Since we can't make private companies publish null results, we need new journals that are dedicated to publishing studies regardless of outcomes. As suggested by Neuroskeptic, one means of doing this would be to have journals review research protocols and commit to publishing the results prior to conducting the study. This is ideal for federally funded research and such journals could be incorporated into the missions of federally funded science organizations (e.g., NIMH and NSF). Note that this would have a beneficial side effect; if these turned into high-impact journals, the culture would start to change and other privately-owned publishers would start to feel pressure to address publication bias.

Thomas O'Neal

University of Central Florida

Associate Vice President for the Office of Research & Commercialization

OVERARCHING QUESTIONS:

1. **What specific policies or initiatives should the Administration consider prioritizing in the next version of the *Strategy for American Innovation?***

- America needs to lead the world in cutting edge research.
- Overall K-12 educational system such that schools, parents, students, and teachers are incentivized to excel in core STEM subject areas, and to pursue post-secondary education in science or engineering. See #10 below.
- Complete revision of tax code for corporations to reduce migration of American companies to other countries, and to provide incentives for establishing innovative manufacturing facilities for products/materials that spin-out of U.S. R&D investment
- Fast-track immigration process for immigrant applicants that have STEM degrees, especially those that earned their degree from a U.S. college. See #3 below
- Reduce/eliminate capital gains tax for investors that provide early funding in early-stage companies (for both individual investors and corporate investment). See #3 below
- Opportunities are great to start new companies and counties like China are providing significant incentives for ex-patriots trained in the US to start them in China. We need to lead the world in being a fertile place to start new innovation based companies

2. **What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?**

CHALLENGES:

- The US faces aggressive competition abroad, especially from China and Korea. The US needs to address its diminished global position in terms of innovation, entrepreneurship, and manufacturing .

- Shortage of American STEM labor pool. This is due to the combination of 1) reduction in American students earning STEM degrees (due to U.S. education policy) and 2) high barriers to earning U.S. citizenship by foreign engineers and scientist (many of whom attended US colleges, and then go back to their countries to compete against U.S. innovation)

- Lack of smart early-stage capital focused directly on moving technology from the lab bench prototypes (researcher-driven) into commercial viable prototypes (intrapreneur/entrepreneur-driven)

OPPORTUNITIES:

- America is still highly coveted as a country that highly educated people with advanced engineering/science degrees want to live in. The U.S. needs to leverage this in order to bring top talent to the U.S. to drive innovation.

- The U.S. model of investment in R&D has been the key driver for America's ability to innovate. There is incredible economic opportunity in finding ways to expand the reach of these investments across the entire country, and to enable entrepreneurs/innovators in every state to commercialize and exploit this investment.

3. **What specific actions can the Federal government take to build and sustain U.S. strengths including its entrepreneurial culture, flexible labor markets, world-class research universities, strong regional innovation ecosystems, and large share of global venture capital investment?**

Innovation capacity:

- There should be a significant increase in US investments in competitive research programs. The ROI has long been established for this and other countries have figured it out as well.

- Doubling the funding for the SBIR / STTR program. This is a proven asset of the US.

- Work with Universities to create commercialization sabbaticals for faculty to promote effective technology transfer

- Provide commercialization add-on's to Federally funded research to provide validation, market research, prototype development, etc for commercially promising technologies

- The US has proven innovation and research assets and strengths that need to be resourced at levels that keep us in a leading position

STEM Talent:

- Provide financial incentives (scholarships) for college students that pursue relevant STEM degrees that align with innovative economic growth, independent of their financial need. For low-income students pursing a STEM degree, provide free college education. This will address both poverty and innovation talent issues in U.S.
- Streamline the immigration process for foreign engineers or scientists that have urgently needed skills or that have graduated from a U.S. college or university. These folks currently have to compete with immigrants that do not bring STEM skills to the U.S., and they should be provided with a fast-track/exception over under-skilled immigrants.
- Allow foreign students that earn STEM degrees at a U.S. university remain in the U.S. and either conduct research or obtain a tech job after graduation.

CAPITAL:

- Consider financing accelerator funds in addition to funding accelerator program labor/operations costs. Accelerators receiving funds should be targeting a STEM domain that aligns with U.S. Strategy for American Innovation. Federal funds will go directly to early-stage companies led by STEM entrepreneurs (grant mechanism similar to SBIR), with the additional requirement of being selected by the accelerator. For example, a regional university may have strong research expertise in biomedical, and starts a biomed accelerator that is managed by an experienced business team (ideally successful biotech entrepreneurs). Federal funds can be used for both program costs and for the accelerator to provide milestone-driven seed grants to the most promising companies in the accelerator program.

- Consider creating guaranteed venture capital funds targeting early stage companies. These funds have been successful in states as a way to get private investment flowing into early stage companies and is similar to the SBA small business guaranteed loan program.

- Modify Qualified Small Business Stock (QSBS) Section 1202 (100% capital gains exclusion for ROI on angel investments) as follows:
    - Increase the roll over period from 60 days to one year

- Reduce the required 5-year holding period to 2-years (or less). Many exits in tech happen earlier than 5 years.
- Allow LLCs, warrants and options to qualify for exemption

4. How can the Federal government augment its overall capacity for analysis of both the forces that determine the competitiveness of specific sectors and the impact of Federal policies – including, but not limited to, science, technology and innovation policies – on sector-specific productivity and competitiveness? What are the most important outstanding questions about innovation policy and process, and how might government promote systematic research and program evaluation in those areas?

- Provide competitive funding to conduct research necessary to understand the phenomena as is common with other sciences. Elevate the importance of this at all level and specifically at the National Science Foundation. The important questions include:
  - The effects of policy on investment in startups
  - Understanding innovation eco-systems
  - Understanding why some eco-systems are effective and others are not
  - Understanding and identifying gaps in eco-systems
  - Creating the culture that ignites innovation and entrepreneurship
  - Increasing the number of STEM workers
  - How to create engineers and scientist that are entrepreneurial

5. What innovation practices and policies have other countries adopted that deserve further consideration in the U.S.? What innovation practices and policies have been adopted at the state or local level that should be piloted by the Federal Government?

- K-12 Education: Korea and Finland have turned the economic status of their countries around with tough overhauls of their K-12 systems.

- Advanced Manufacturing: Germany has been able to maintain both R&D and manufacturing capabilities. Both are also related to strong K-12 educational system that results in formidable native engineering labor force.

- Germany's Fraunhofer institute with its strong industry and academic partnerships

- The SEMATECH model in New York and Austin should be expanded nationwide

INNOVATION TRENDS:

6. **How has the nature of the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?**

AGILE / Lean Startup INNOVATION METHODOLOGY:
Innovation in the private sector has rapidly migrated towards Agile/Lean Startup methodologies, which have proven to significantly reduce risk and cost of failure. Agile innovation entails a cycle of build-test-revise-pivot:

- Build the most fundamental working prototype that can be customer-tested at the lowest cost
- Have early-adopter customers evaluate prototype and provide feedback
- Revise the prototype based on customer-driven feedback
- Run through build-test-revise again. If customer approval continues to improve, keep going. If not, consider pivoting to a new model or scrapping the project

Agile or Lean startup-based financing (both for innovation and manufacturing) requires a series of milestone-driven smaller investments that align with the cyclical agile process. In recent years, technology accelerator models have aligned with agile innovation, and this model could be replicated for any technology sector as well as for "proof of manufacturing" models. Federal funding for both research and commercial purposes could be greatly optimized if it took an Agile approach. The SBIR program follows this model to a certain degree (with three-phased funding), but proactive confirmation of progression towards true commercialization (ie: building something a customer will buy) would greatly improve the longer-term sustainability of SBIR-funded products, and thus create more job-creating innovation.

OPEN SOURCE MODELS CAN DRIVE OPEN/COMBINATORIAL INNOVATION:
In software development, open source models have become a critical engine for rapid advancements in software, communications and big data innovation. Open Source software projects start with a software code base for a specific project or application. The designers then post the source code in an open forum (usually on GitBit – another open source application for managing software revisions). Other software engineers can access the source code to use in other projects, and are expected to add bug fixes or new feature sets back to the original code base, which are available to anyone. The result is global collaboration on software sets, which results in "best in class" software products. Today some of the most popular (and profitable) software products on the market are open source.

Open source models would be very applicable in other scientific domains – especially IP intensive sectors such as biotech and advanced materials. The pharmaceutical sector is struggling to finance R&D for new drugs, and global health would greatly benefit if both big pharma and early stage biotech startups could have access to foundational IP developed at leading research institutions. This model would flip traditional tech transfer models. Instead of institutions trying to identify licensees for specific patents, they could elect to submit Federally funded IP to a Federal "open source" IP database available to both corporations and entrepreneurs. IP selected by the private sector to be deployed in commercial products could optionally have a flat royalty. Royalty funds could partially flow back to the university, with the rest going into a Federal fund that is used to fund patent fees (a huge expense for universities today) or strategically innovative research projects that enhance licensed IP (ie: an open source IP/innovation enhancement model).

7. **What emerging areas of scientific and technological innovation merit greater Federal investment, and how can that investment be structured for maximum impact?**

- Artificial intelligence based on machine learning and predictive analytics in big data sets.
- Advanced cyber-security to protect big data sets.
- Optics and photonics
- Advanced materials for semiconductor, automotive, energy and other critical sectors
- Advanced Manufacturing, rapid prototyping/manufacturing automation
- Biomedical innovation, especially around global health issues. Subtopics would include stem-cell, genetic and viral epidemic cures (e.g.: Ebola)
- Advanced sensors and other devices that will drive the next generation of the internet
- Nanoscience

Investment should be competitive but also should have a goal of establishing new centers of excellence across the US. Investing in only known, trusted areas and investigators and institutions puts the emerging areas at a significant disadvantage. Program managers should get out of their offices and familiarize themselves with the incredible work being done a lesser known regions of the country.

8. **What are important needs or opportunities for institutional innovation and what steps can the Federal government take to support these innovations?**

Federal funding of a large, distributed network of prototype/research labs based on institutional expertise. These "Maker Labs" will be maintained by a research institution, but can be used by regional innovators in the private sector that have a need to prototype innovations or conduct innovative research. For example, advanced materials, rapid prototyping, and biomedical labs are too expensive for an early-stage company to fund, and may not provide the ROI required by a larger corporation. Currently Federal funding of research labs tends to be in large funding amounts to a small set of institutions. This results in relatively few U.S. regions/researchers/entrepreneurs having access to these types of labs, which reduces the opportunity for both research and commercial innovation.

These facilities should have significant industry input into the scope, direction, and operations of the facility to maximize the effectiveness of the center and getting things into the commercial market.

SCIENCE, TECHNOLOGY and R&D PRIORITIES

9. **What additional opportunities exist to develop high-impact platform technologies that reduce the time and cost associated with the "design, build, test" cycle for important classes of materials, products and systems?**

Program that is focused on advanced manufacturing/rapid prototyping models and technologies. The mission is to use innovation to reduce manufacturing overheard, and thus help bring high tech manufacturing back to the U.S. Need to study how China and Korea are innovating in manufacturing as a model.

10. **Where are there gaps in the Federal government's science, technology, and innovation portfolios with respect to important national challenges, and what are the appropriate investment and R&D models through which these gaps might be addressed?**

The U.S. is rapidly falling behind in the quality of our K-12 education system (ranked 26th), and there is extensive room for both policy and innovation to return the U.S. to the top. With respect to encouraging innovation by our youth, we need to give them the tools and knowledge to innovate, even in elementary school, and even in the poorest school districts. Some areas in innovation for Federal funding to address the U.S. crisis in education:

- Scholarships for middle and high school students in poor school districts to participate in high tech summer programs or internships.
- Funding for regional technology centers that provide public access to creative and digital resources (computer labs, digital media creation centers, access to tutors to teach programming/computer skills, etc.)
- Funding universities to create programs that provide high school students with opportunities to intern in research labs or innovate under a mentor
- Early remediation in basic STEM skills in grades K-6, including after school programs that specifically focus on STEM skills

Current US ITAR policy should be revamped. It doesn't appear to be providing security and is providing protected markets for key competitors abroad. Open work environments increase innovation and the US is keeping some of the brightest people in the world from solving the US's biggest challenges.

11. Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

- Place a higher level of importance on the quality of research and less on the uniqueness.
- Scientific findings based on federally funded research should be validated. Nothing as elaborate as an FDA approval but a requirement that the results must be validated by an independent validator should be explored.

SKILLED WORKFORCE DEVELOPMENT

12. What novel mechanisms or models might facilitate matching skilled STEM workers with employers and helping individuals identify what additional skills they may need to transition successfully to new roles?

There are existing platforms such as LinkedIn that do this quite well and most STEM workers use it. Other on-line and more transparent apps or other databases could be developed or tapped into as well. It's not clear that government should have a large role in this.

13. What emerging areas of skills are needed in order to keep pace with emerging innovations or technologies? What are successful models for training workers with these skills to keep up with emerging innovations?

For Big Data, there is an urgent demand for data scientists. These folks require a unique blended understanding of computer science, statistics, market research/business understanding, and domain expertise for their specific market sector. There has been a recent growth in Data Scientist Masters degree offerings across the country, but they are very expensive ($40K minimum) and take 2 years. Most folks entering this domain already have one or more of the needed skills, so an online curriculum/certificate program that enables participants to focus on areas they are deficient in, followed by a certification test, would optimize the process of developing this labor pool.

Generally speaking, students should receive a high quality, solid education. Skills change rapidly and by the time you identify a new area, the need is well known.

14. What mechanisms or programs can effectively increase the supply of workers with technical training, from industry-recognized credentials and post-secondary certificates to two-and-four year degrees?

For biomedical skills, experienced bio-lab technicians might be offered a 1-year researcher credential certificate, or a 2-year Tech-to-B.S. degree option that is similar to nursing R.N to B.S.N programs. These could be a collaborative degree offering between community colleges and 4-year research institutions. Students could take foundational courses in areas of deficiency at regional community colleges before enrolling in higher level biomedical courses at an accredited 4-year research institution.

MANUFACTURING AND ENTREPRENEURSHIP

15. What new or existing investment models should be explored to support entrepreneurship in new geographies, as well as in technologies and sectors that are capital intensive, relatively high-risk, and require substantial investment over long periods of time?

For capital-intensive sectors: Implement a highly distributed network of innovation labs across the U.S. Regional labs will each be designed to leverage the domain expertise of local universities/research institutions. Larger states (CA, TX, FL, NY) will have a minimum of five labs, and will cross-share state/regional resources. The mission of this lab network is to commercialize peer-vetted research conducted at universities/research labs, or to provide a venue for qualified innovators to commercialize their own inventions. In other words, it will also support innovators that may not have direct ties to local universities. The innovation lab network will be co-funded by Federal, State and Regional dollars. Lab facilities should be managed by regional research institutions, and will encourage collaborative innovation projects that partner academic researchers with entrepreneurs, student-innovators or corporate intrapreneurs. The Federal government should take care to ensure labs are located in every state to maximize ROI that comes from collaboration and shared knowledge-networks, and to provide opportunities for any American entrepreneur or innovator.

This network of innovation labs will be overlaid with a network of regional accelerators that provide the following services to innovator-participants.

- A national network of scientists available to provide domain expertise for project teams (no matter which lab the team is using). Part of the Federal funds for these accelerators goes towards paying for these experts' time.

- A national network of corporate sponsors that provide commercialization expertise, beta testing, and possible acquisition of technologies or spin-out companies from the labs. Corporations receive tax credits in exchange for their commitment to working with accelerator project teams.
- Regional network of entrepreneurial business veterans that understand what it takes to launch, finance and grow technology startups, and agree to mentor 1-2 project teams each year.
- A national network of contract manufacturing organizations (ideally U.S. based) that are "on call" to assist with agile-based manufacturing test runs (see question #16 for further details on CMO need)
- Additional networking through professional organizations should be encouraged.
- A sustainable fund that provides seed grants to qualified projects. Funds are incrementally provided in agile-based milestones of commercialization progression. Funding progression typically follows a $50K, $100K, $250K iteration. Funds can be provided as either grants or equity investments (common stock format that is common in business accelerators).
- A national network of investors (angels and VCs) with domain expertise that agree to review business plans and provide investor-level feedback on progression required to received Series A funding. Federal government could partner with Angel Capital Association and NVCA
- Corporate sponsors would be another source of funding for the most promising innovations/spin-outs in capital-intensive sectors. Tax incentives (federal and state) could help encourage corporate investment.
- Student interns to assist with lab activities and business plan development

Many existing labs such as the NSF's Engineering Research Centers are excellent models that should be expanded and include focused commercialization and entrepreneurship support.

16. For new technologies and product, how might "proof of manufacturability" be gauged sooner, and what entities would most appropriately provide the necessary resources and facilities? What sectors represent the most promising opportunities for the application of such models?

Agile "lean innovation" methodologies, which were described above for optimizing innovation and commercialization processes, can also be implemented to show "proof of manufacturability". NSF's iCorps program could be expanded. However, instead of iterating on product development and customer viability, iterations will incorporate a set of highly targeted steps, each meant to reduce time and costs associated with designing manufacture-grade products.

a) Iterations of early designs using rapid prototyping/3-D modeling best practices.
b) If needed, leverage contract manufacturing organizations with domain-specific product design expertise (ideally through innovation labs/accelerator network). This will reduce labor costs for manufacturing expertise during early product design stage.
c) Setup a small run of devices, ideally using actual materials designed into final model. For medical devices, this run should be viable for Phase II clinical trials. For non-medical products, use this run to test sustainability (how long do devices last, identify weak spots in design, etc.)
d) Based on findings, repeat steps a-c until a design that passes quality tests is completed before moving into scaled up manufacturing of device

17. What tools, business model innovations, financial innovations, or other developments hold promise for reducing the cost of starting and scaling a business in capital intensive sectors like the life sciences, advanced materials, and clean energy? What can the federal government do to accelerate these trends?

See #15

18. What investments, strategies, or technological advancements, across both public and private sectors, are needed to rebuild the U.S. "industrial commons" and ensure the latest technologies can be produced here?

The long-term competitive advantage for the U.S. lies in our ability to invent and deploy highly innovative products. As such, the largest ROI for both public and private sector entities interested in reviving America's manufacturing excellence lies in the most innovative sectors. Today those include biotech/medical devices, advanced materials (including semi-conductor and advanced composite materials), and other high tech products that directly result from American R&D and innovation.

It is critical for the long-term economic health of the U.S. to maintain control over the interface between advanced R&D and the manufacturing of innovative products that arise from our investment in R&D. This means both the public and private sectors need to step up to provide needed resources and facilities. For the Federal government, continued investment in R&D is critical. In addition, the U.S. education system (both K-12 and Higher Ed) need put policies and curriculums in place that strongly encourage American students to pursue STEM-related careers, as well as curriculums specifically focusing on manufacturing process expertise. Korea has transformed their national economic positioning with this strategy, and Germany has maintained both their R&D/innovation capabilities and control of critical manufacturing sectors based on their engineering expertise.

For the private sector, there needs to be motivation to invest in native manufacturing facilities, which can be encouraged with a revision of tax and labor cost incentives. These are both policy areas that the Federal government should urgently focus on to entice both American and foreign corporations to consider establishing state-of-the-art manufacturing facilities in the U.S.

REGIONAL INNOVATION ECOSYSTEMS

19. **What partnerships or novel models for collaboration between the Federal government and regions should the Administration consider in order to promote innovation and the development of regional innovation ecosystems?**

The Federal government might consider an open-topic annual funding mechanism for states and regions. In this model, every state would develop a unique innovation plan that addresses the unique economic issues, labor demographics and market sector expertise for the state, or for specific regions within the state. The states should be required to follow a general framework (e.g.: innovation lab creation, K-12 STEM improvements, etc.), the state has the ability to specific the tactics for deploying funding that are specific to the state or a regions unique challenges or strengths.

Programs such as the Florida High Tech Corridors, matching grants research program should be deployed across the US. Industry partnering with University's would be eligible to receive matching grants from State and Federal sources to expand their research project. This mechanism helps steer faculty research to areas that are important to industry and acts as a catalyst for collaboration.

20. **How should the federal government promote the development of metropolitan "innovation districts" where large research institutions, companies, startups and business accelerators congregate to facilitate the knowledge flows that sustain innovation?**

The EDA's i6 Challenge grant model is an excellent example of the Federal government funding these sorts of collaborative innovation networks. One caveat to the i6 funding model, as well as most other Federal funding vehicles, is that certain requirements may prevent some regions from being able to receive the funds (e.g.: requirement for manufacturing partner, when there may not be such an entity in a region). In order to enable every state or region to have the opportunity to develop "innovation districts", funding opportunities should be as open as possible, and avoid requirements that often reduce regional abilities to receive needed funding.

INTELLECTUAL PROPERTY/ANTITRUST

21. **What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation (including e.g. through the growing use of open innovation, combinatorial innovation, user innovation, internet-enabled innovation, and big data-driven innovation)?**

See Question #6 – Open Innovation.

NOVEL GOVERNMENT TOOLS FOR PROMOTING INNOVATION

22. **What are specific areas where a greater capacity for experimentation in law, policy, and regulation at the Federal level is likely to have large benefits? Are there useful models of experimental platforms in the public or private sectors that the Federal government can adopt? How might the Federal government encourage state and local experimentation?**

    - Corporate tax policy designed to reduce export of companies and manufacturing to foreign countries, and to invest in regional innovation ecosystems. States could be encouraged to follow tax revisions as a method for encouraging establishment of manufacturing facilities and/or innovation centers locally.
    - Open source options for IP for federally funded R&D IP – follows highly successful model of open source software
    - Distributed innovation lab network – while not a direct model, distributed networks have drastically improved energy distribution and big data analysis. The scientific theory behind local distribution of resources resulting in very high efficiency returns is well-vetted.

23. **Beyond current Federal efforts to promote open data and open application programming interfaces (APIs), what other opportunities exist to open up access to Federal assets (such as data, tools, equipment, facilities, and intellectual property from Federally-funded research) in order to spark private sector innovation?**

- Open source IP
- Open up research labs and enhance with regional innovation labs

NATIONAL PRIORITIES

24. **Which new areas should be identified as "national priorities" either because they address important challenges confronting U.S. security or**

living standards, or they present an opportunity for public investments to catalyze advancements, bring about key breakthroughs and establish U.S. leadership faster than what might be possible otherwise?

The US must establish itself as the world leader in manufacturing.

We must also protect our way of life so people can conduct business without fear from external attached. We need to be leaders in Cyber Security to protect our personal, business, and national data.

25. What Federal policies or initiatives could unleash additional corporate and philanthropic investment for critical national priorities, such as energy innovation?

Deploy a matching grants program modeled after the Florida High Tech Corridor's program nationally. Universities and industry would in collaborate in meaningful ways to address relevant needs that are commercially driven.

A national energy policy could help move states to sustainable energy programs.

Response to:

Notice of Request For Information regarding the
Strategy for American Innovation
by the Science and Technology Policy Office and the National Economic Council
(Federal Register 07/29/2014; https://www.federalregister.gov/articles/2014/07/29/2014-17761/strategy-for-american-innovation)

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Associate Vice President – Science, Engineering and Technology
Arizona State University
Phone: [redacted]

September 23, 2014

Innovation Trends:

6. How has the nature of the innovation process itself changed in recent years and what new models for science and technology investment and innovation policy, if any, do these changes require?
7. What emerging areas of scientific and technological innovation merit greater Federal investment, and how can that investment be structured for maximum impact?
8. What are important needs or opportunities for institutional innovation and what steps can the Federal Government take to support these innovations?

Flexible electronics, advanced materials, synthetic biology, and understanding the microbiome are key areas of innovation that warrant greater federal investment.

Flexible electronics has reached a tipping point and is poised to advance rapidly. We lack a standardized infrastructure of enabling components/materials, toolsets and protocols for the manufacturing supply chain. These barriers prevent companies from satisfying the market needs for flexible systems. An investment in a national Institute that would provide both a shared industrial commons for establishing standards for manufacturing and design tools would position the technology to grow and flourish.

Advanced materials: The very nature of advanced materials and their applications is in its intentional design and integration into devices and complex systems. Current research and development methods, however, still rely on serendipitous approaches in the laboratory in terms of discovery, synthesis, fabrication and development. Materials engineering has not yet evolved to a level of sophistication like mechanical, electrical and structural engineering, that rely heavily on computational and modelling design approaches prior to the building of an object. The predictive capabilities of these fields have not yet been reliably achieved for materials engineering, although it could. The challenge now is to combine all of the computational, modelling, characterization and fabrication tools available into closely integrated and interactive methodologies. The infrastructure needed requires a combination of developing shared regional facilities for materials fabrication and characterization and distributed computational and database resources.

Synthetic biology is an incredibly diverse arena with impacts to human health, food, energy, defense, and environmental applications. Funding for traditional approaches using Genetically Modified Organisms (GMOs) has demonstrated great impact. In recent years, next generation approaches using synthetic alternatives to DNA monomers (the XNAs) have advanced toward xenobiology, where synthetic genetic materials are encoded within living organisms. Synthetic biology, and more specifically xenobiology are poised for rapid advancement and would benefit from increased funding and targeted calls through traditional funding mechanisms.

Microbiome: Understanding the microbiome is a relatively new undertaking that has been enabled by technology advances in areas such as high throughput, low cost genetic sequencing. Activities have focused on understanding diversity within the microbial communities and within the host-community interactions in the gut and/or in community interactions within environmental ecosystems. New methods must be developed and once developed applied at scale to understand the microbiome. A mixture of funding approaches, using traditional mechanisms to develop new technologies for characterizing the microbiome and host system interactions, and larger center-level funding to advance these discoveries to engineered solutions and ultimately for the high throughput application of those tools within centers of excellence across human, animal, and ecological systems.

Science, Technology, and R&D Priorities:

9. What additional opportunities exist to develop high-impact platform technologies that reduce the time and cost associated with the ''design, build, test'' cycle for important classes of materials, products, and systems?
10. Where are there gaps in the Federal Government's science, technology, and innovation portfolios with respect to important national challenges, and what are the appropriate investment and R&D models through which these gaps might be addressed?
11. Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?
12. What novel mechanisms or models might facilitate matching skilled STEM workers with employers and helping individuals identify what additional skills they may need to transition successfully to new roles?
13. What emerging areas of skills are needed in order to keep pace with emerging innovations or technologies? What are successful models for training workers with these skills to keep up with emerging innovations?
14. What mechanisms or programs can effectively increase the supply of workers with technical training, from industry-recognized credentials and postsecondary certificates to two- and four- year degrees?

Flexible Electronics: In the FlexTech Alliance Industry Potential User Survey[i] in February 2014, an overwhelming response from a significant majority of companies surveyed revealed that: "The adoption of flexible electronics by Fortune 500 companies is inevitable and an impressive array of its representatives have made that clear. The technologies are poised to make huge inroads into the marketplace once devices are produced in quantity and standards are written to guide manufacturing and integration, which will enable the purchase of meaningful volumes." Federal funding of a Flexible Electronics Center (perhaps as an NNMI with significant industry engagement) would provide a shared industrial commons for establishing standard manufacturing processes and approaches as well as standardized design architectures and TCAD design tools. These developments would reduce the time and cost associated with the ''design, build, test'' cycle for flexible electronics and would importantly provide US manufactures with a leadership position as competitors in Asia have focused primarily on flexible display manufacturing. Flexible electronics as a platform technology would enable a new generation of electronics. Potential domestic and global product markets pervade nearly all aspects of human life and our economy, and include (SEE figure below):

- On-body / in-body (wearable) sensors for human health and performance monitoring
- Smart bandages for wound healing
- Large area conformable structural health monitors (SHM) for physical infrastructure, mechanical infrastructure, and aircraft
- Environmental sensors and detectors (bio and chem)
- Flexible displays for portable and wearable smart phones and other personal IT devices
- Conformable high efficiency solar cells for building integrated photo-voltaics (BIPV) or unmanned aerial vehicles (UAVs)
- Conformable high efficiency solid state lighting (SSL)
- Flexible digital x-ray detectors for hospitals, first responders, and security personnel
- Large area multi-modal stand off sensors and detectors for port security
- Communications, energy harvesting, and SHM built in to expandable structures for space exploration and colonization

Strategies to establish and maintain U.S. leadership include a continuing focus on; (i) high-value, high performance technologies and system solutions, (ii) manufacturing approaches that leverage our established strengths and enable rapid advances towards commercialization, and (iii) workforce development that leverages our historical leadership position in the high tech industry.

<u>Advanced Materials:</u> In meeting the objective of speeding the discovery and application of new materials, a necessary step will be the extensive integration of computation and modeling with experimentation. Later in the development cycle, computation and modeling would be used for

optimizing synthesis and fabrication. The combination of both would require extensive development of hierarchical modeling, from the atomic, molecular, polycrystalline and to the macroscopic scales. Moreover, materials are a combination of fundamental domains atom/molecular networks and interfaces between those domains. Because he physical and chemical behavior of matter at interfaces and within those domains are often different, this means that comprehensive modeling methodologies will be needed for both individually for bulk materials and interfaces and these entities interactively. To accomplish this, extensive investment will be needed in database development. This would include databases for a broad range fundamental physical and thermochemical properties corresponding to vast ranges of materials differing by the connectivity patterns of atoms and molecules within the bulk and at the interfaces . Reliable information will require standardized approaches for the gathering of information from experiment and computation. To speed this process, combined, self-consistent experimental and computational methodologies should be identified and recommended, and the results collected in central databases that are regularly reviewed and evaluated. This will require dedicating investments into networks of regional facilities that are easily accessible and comprehensive in capabilities.

Materials characterization facilities are also becoming quite expensive to purchase and manage. This is especially true of nanostructural and nanochemical characterization equipment. However, it is often this equipment that reveals the most information relevant to new materials in the shortest time. This equipment should be routine for researchers, however, are limited by availability. To overcome this, a network of regional facilities should be constructed to provide greater access.

There is also a need for regional facilities that support the local research communities in materials synthesis and fabrication and device manufacturing. Often, it is such facilities that control the rate of materials research. The challenge with this is that such facilities are quite diverse dependent on the material and application. Like with characterization facilities, a network of shared synthesis and fabrication facilities would provide benefits of convenience and professional management, which should speed the progress of research.

<u>Synthetic Biology:</u> Funding is needed to establish biochemical systems for coding and decoding genetic information in XNA polymers. This would require the development of polymerases that can copy DNA into XNA, replicate XNA, and transcribe XNA into RNA. In addition, xenobiology will require engineered kinases that can convert XNA nucleosides into nucleotides, which are the substrates for XNA polymerases. This would lay the foundation to enable the application of xenobiology into cellular systems. Protein expression would be induced at a defined time so that information contained in an XNA chromosome would be transcribed into RNA and converted into a functional protein with an observable phenotype using the normal ribosomal machinery inside the cell. In this model, the flow of genetic information from XNA to RNA to protein represents a redesign of the central dogma of biology.

As laboratories strive to engineer enzymes for xenobiology, immediate practical applications have become apparent where functional XNA molecules with ligand binding (aptamers) and catalytic activity can be developed. While similar efforts have been reported for DNA and RNA, XNA is a superior polymer for this purpose due to its inherent stability. Funding should be applied to develop XNA molecules as diagnostics and therapeutics, as well as drug delivery and cell imaging agents. In addition, enzymes developed for xenobiology would have practical applications beyond their use in aptamer and catalyst development. XNA kinases, for example, could provide green alternatives to chemical synthesis by avoiding the need for harsh chemicals and organic solvents.

<u>Microbiome:</u> New technology platforms and associated tools for bridging the gap between microbiomic historical correlations to biological causation are needed. Such tools will enable functional systems research, rational ecosystem design/management, and subsequent environmental and economic impact

analysis. Tools and techniques that enable a holistic analysis of functional microbiomes within their respective environmental niches are also needed. Achieving this capability will require new empirical methods and theoretical modeling, as well as data infrastructure specifically targeted to capture functional behavior and metadata of microbiota in physically isolated and interconnected ecosystems.

Federal investment in technology platform/tool development and the application of those tools at scale in centers of excellence will rapidly advance our understanding of the microbiome and our impacts on it. Integration of centers of excellence will ensure that quality assurance practices are applied so that high quality, reproducible data is output. Establishment of these multidisciplinary centers will also produce a highly trained workforce within a shared framework for understanding human and veterinary medicine, and diverse natural ecosystems.

Workforce development: The Arizona Advanced Manufacturing Institute at Mesa Community College (AZ-AMI) is designed to meet the growing and changing needs of the manufacturing business sector. Its multi-faceted and holistic approach to the learning environment allows the Institute to be flexible to the needs of industry. Input from industry partners helps faculty provide current and relevant content in the classrooms and laboratories. Through internships and apprenticeships AZ-AMI offers earn-as-you-learn opportunities. Current partnerships include: Arizona Manufacturing Partnership; American Welding Society; Arizona Tooling and Machining Association; East Valley Partnership Aerospace and Aviation Alliance; Federal Aviation Administration; Microchip Academic Partnership; and National Institute of Metal Working Skills. Program and Career Opportunities focus on: Automation and Robotics Technology; Aerospace Manufacturing technology; Manufacturing Engineering; Machinist Apprenticeship; Electronics Technology; Electrical/Mechanical Drafting; Industrial Maintenance (machine & facilities) and Welding Technology. Populations to be served include TAA-eligible workers, veterans, the unemployed, incumbent workers and other college bound adults. The projected job growth for the targeted industries in the project is an additional 10,149 jobs in the metro Phoenix area from 2010 to 2020 (EMSI, 2013).

Manufacturing and Entrepreneurship

15. What new or existing investment models should be explored to support entrepreneurship in new geographies, as well as in technologies and sectors that are capital-intensive, relatively high risk, and require sustained investment over long periods of time?
16. For new technologies and products, how might ''proof of manufacturability'' be gauged sooner, and what entities would most appropriately provide the necessary resources and facilities? What sectors represent the most promising opportunities for the application of such models?
17. What tools, business model innovations, financial innovations, or other developments hold promise for reducing the cost of starting and scaling a business in capital intensive sectors like the life sciences, advanced materials, and clean energy? What can the Federal Government do to accelerate these trends?
18. What investments, strategies, or technological advancements, across both the public and private sectors, are needed to rebuild the U.S. ''industrial commons'' and ensure the latest technologies can be produced here?

The Flexible Electronics and Display Center (FEDC) at Arizona State University (http://flexdisplay.asu.edu) is an exemplary federally-funded public-private investment model to be emulated for establishing manufacturing capabilities for new technologies. Since its establishment in 2004 with a federal investment of more than $100M and a similar investment from ASU and its industry partners, the FEDC has grown to become an international leader in lightweight, flexible electronics manufacturing, including materials R&D and supply chain development. The FEDC incorporates vertically-integrated backplane electronics design, fabrication, testing and assembly capabilities and operates dedicated pilot line toolsets for technology development and technology demonstrator production. This powerful innovation asset has attracted companies to co-locate with the Center and has attracted significant foreign direct investment from European countries.

Through their dynamic partnership model, the Center has collaborated with over 45 for-profit companies from the smallest startups to the largest multinationals. Although there are a significant number of partners in the Phoenix metro area and southwest region, including Boeing, Honeywell, Raytheon, BAE Systems, General Dynamics, Intel, Apple, Jabil, Amkor, and AGI, and the FEDC has served as a magnet for corporate co-location by OEMs (e.g., EV Group, Soitec, Ito America, GTAT), the consortium includes companies that span the nation from coast-to-coast, including such companies as GE, Applied Materials, UDC, E Ink, and DuPont Teijin Films. Hence the desire by many to create regional centers of excellence must be tempered by the reality that to be successful engagement must be national and global in scope to drive the industry standardization that is required.

While standard models should be applied for research investment in the basic sciences underlying synthetic genetics and technologies underlying the microbiome research, the scale of the microbiome characterization will require sustained investment over long periods of time for centers of excellence to evaluate humans, animals, and diverse ecosystems. The scale of the characterization efforts and of the data output necessitates a new model for engaging with industry and entrepreneurs. Access to data and metadata will enable larger industrial firms to leverage results of the microbiome activities. Smaller firms and entrepreneurs who may not have computational expertise or infrastructure will require access to data as well as the computational resources and analytical expertise to tackle this big data problem and to leverage data into innovation.

Microbiome models will play a key role in accelerating time to market for products in healthcare, animal production, agriculture, and environmental management. Models and tools will be peer-reviewed by the scientific community, to demonstrate their predictive power, and ability to inform product developers on outcomes, and policy decision makers on best available courses of action (and the consequences of one choice over another).

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[i] FlexTech Alliance Industry Potential User Survey, February 2014. http://flextech.org/au-news-detail.aspx?item=30393

Michael Pitts

Reed College

Related to item #11, it would be very helpful if federal agencies dedicated some small amount of research funding to support studies that aim to replicate important findings. The overall trend of only funding novel, innovative, and ground-breaking research can have serious side-effects. At least some portion of federal funding could be well spent on verifying whether the results found in ""innovative"" research are actually true. The best way to do this is to repeat experiments in independent laboratories. These replication experiments may also provide a unique training opportunity for young scientists.

Jonathan Plucker

University of Connecticut

I applaud OSTP for addressing innovation issues. However, many of these initiatives tend to focus on what I call "downstream innovation" - creating systems and supports that foster innovation among adults. Although these systems and supports are critically important, the sole focus on innovation among adults overlooks the fact that creativity and innovation can be taught and fostered among children.

I suspect that the traditional neglect of childhood creativity and innovation is largely due to the bias that we just don't know that much about enhancing creativity, especially among children. Yet a huge body of research and interventions exists, to the point that Newsweek ran a story a few years ago about the "science of creativity." Since that story ran, we've seen exponential growth in research on creativity, especially within educational settings, and in a number of countries (but most notably, in the U.S. and U.K.).

Any comprehensive, long-term innovation policy must include educational and childhood components. We have the necessary research to support such efforts, and the members of that research community would enthusiastically participate in any efforts in this area.

Jud Ready

Georgia Tech Research Institute

Principal Research Engineer & Adj. Professor

Using Biologically Inspired Design to accelerate innovation and increase creativity

The complexity of today's global issues requires a capability to collaborate across disciplines. Not only must our next generation have a deep understanding in a discipline about which they are passionate and confident, they must feel comfortable delving into unfamiliar territory. To accomplish this goal and to add a new tool in their toolset, the field of bio inspired design serves as an education platform for teaching the language of interdisciplinarity to communicate between disciplines (essential!) and as a means to accelerate innovation in design. The rise in bio inspired patents is exponential. Supporting interdisciplinary hubs and centers that bring people from different specialties, especially from the biological sciences, is essential.

As Vest says: We're going to see in surprisingly short order that biological inspiration and biological processes will become central to engineering real systems. It's going to lead to a new era in engineering." - Charles Vest, President, National Academy of Engineering & President Emeritus of MIT (from <http://www.nytimes.com/interactive/2010/11/09/science/>).

To teach a new language requires cognitive and learning scientists. To engage in bio inspired design requires integrating expertise in biology and the sciences with engineering and design. To become cognitively flexible, analogical reasoning is a key element: bio inspired design necessarily makes analogs between biology and technology, e.g. stick like a gecko teaches us not only why the gecko survived by evading land-bound predators but how it sticks to ceilings via multiple asymmetric tiny toe hairs that generate van der Waal's forces. To develop the dry adhesive polymer and apply it to robots that can climb glass walls takes the innovator from the biology of gecko locomotion -to evolution via comparative analysis between species -to polymer science and the manufacture of nanostructures -to robotics that don't need gravity to stick to any orientation of a surface as on the space station. This is STEM education.

Nature is all around us and is accessible: it is easy to introduce any age group to consider the delicate spider's web and provoke them by saying: spider silk is as strong as steel. This apparent mismatch challenges them to learn more, and enables an entry into a. the biology of the spider: how it integrates its web with the environment and the rules of complex web building in the DNA blueprint, b. a consideration of mass of spider silk when comparing to the strength of steel, c. the exploration of the changes in molecular architecture of the alpha helices to H-bonded beta sheet when put under tension, d. the small changes in amino acid composition to cause material property changes.

Bio inspired design can accelerate innovation in two key ways:
1. Over evolutionary time, Nature has down-selected from many possibilities so that existing species represent successful solutions to earthly challenges. This increases the rate of innovation by presenting likely starting points, already selected in nature, instead of trying all starting points.
2. Nature provides the physical prototyping. Each species is a successful prototype. This reduced the physical experimentation but opens up research in the biology and its application to technology and design.

THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Suggested Approach to Revising *Strategy for American Innovation*

Andrew Reamer, Research Professor
September 23, 2014

The 2011 version of *A Strategy for American Innovation* is structured around a set of beliefs about the contribution of innovation to the nation's economic well-being and the factors that bring innovation about. Upfront, the report states "Innovation . . . is the foundation of American economic growth and national competitiveness." It then identifies policy and programmatic actions the Obama Administration is taking to enhance three sets of factors that stimulate innovation:

- Building blocks – education, scientific research, physical infrastructure, and information technology
- Market mechanisms – Research and Experimentation Tax Credit, intellectual property policy, entrepreneurship, antitrust, regulatory review, open Internet, and export promotion
- Sectoral investments – clean energy, biotechnology, nanotechnology, advanced manufacturing, space applications, health care technology, and educational technologies.

The 2011 strategy indicates a recipe of various policy and program ingredients that, collectively, would serve to catalyze American innovation and, therefore, competitiveness. As a well-articulated recipe, the strategy by need was fixed in a moment of time, late 2010-early 2011. Essentially, the document appears to be a reporting of the types of efforts the Administration was undertaking four years ago and how and why they were all tied together. Beyond its educational value, its post-release use seems to be primarily as a reference document, less so providing day-to-day guidance or principles for Administration decision-makers.

I wish to suggest an approach to U.S. innovation strategy that differs in several aspects from the prior effort. As I'll discuss later, I can offer resources and ideas for implementing this approach.

1) As a general principle, I suggest that OSTP and the NEC develop and implement a U.S. innovation strategy that mirrors the innovative processes it aims to stimulate, i.e., one that is entrepreneurial, information-based, flexible, adaptive, collaborative, and responsive.
2) To provide the public with a better understanding of the importance of innovation, I would like to see the rationale for an innovation strategy grounded in an in-depth,

literature-based discussion of the role of innovation in national economic development and competitiveness. The 2011 report simply asserts the relationship.

3) To guide and justify the component parts of the strategy, I would like to see discussion of current understandings of the innovation process, the important role of general purpose technologies (GPTs), and the various factors that affect the rate and nature of innovation. Recent academic research has done much to advance understanding of these dynamics. The 2011 report asserts a set of beliefs regarding the connection between various factors and innovation. While I share these beliefs, I believe that a review of the literature will yield a broader, more nuanced, and more justifiable framework for action.

4) I suggest the U.S. innovation strategy be derived, to the extent possible, from an understanding of:

   a) U.S. capacity for innovation relative to other nations;
   b) global markets and U.S. competitive positions in those markets, particularly regarding research and development;
   c) the nature and characteristics of U.S. private and public organizations that carry out innovation;
   d) the current U.S. policy infrastructure, including:
      - the parts of the U.S. Code that set forth congressional findings, mandates, priorities, principles, and reporting requirements regarding innovation and competitiveness;
      - the units of the federal government now actively involved in promoting innovation—including agencies, federal advisory committees, and congressional committees and caucuses; and
      - findings regarding the efficacy of various federal efforts to promote innovation; and
   e) other nations' policy and programmatic efforts to stimulate innovation.

   My experience is that strategic plans are most effective when they target specific issues and opportunities based on a detailed understanding of real-world conditions.

5) As the federal government currently isn't organized to produce and integrate such research and analysis, I'd like to see the strategy document describe how the government plans to organize such capacity.

6) I suggest that the document make full and appropriate use of all policy tools, including facilitation and information, not only the traditional ones of money programs (grants, tax credits and subsidies) and regulation. As each policy tool is

appropriate in particular circumstances, and some policy tools tend to be much less expensive and flexible than others (e.g., information and facilitation as compared to grants and regulation), I further suggest that the document take care to choose the most cost-effective tool for each issue or opportunity.

7) I encourage the document to emphasize the role of the Office of Science and Technology Policy and the National Economic Council in engaging and coordinating a network of public, nonprofit, and private sector actors in the strategic planning and implementation process. I believe that leveraging the work and interests of other organizations would serve to multiply the effectiveness of a relatively small strategic planning process by several orders of magnitude.

8) I suggest that the document emphasize an ongoing process for strategy development and implementation in light of ever-changing global conditions of competitiveness, distinct from providing a fixed strategy. The speed of change in global markets outstrips the ability of any government to produce a formal list of strategic actions that remains complete and fully pertinent for several years.

9) I encourage the document to place the Administration's strategy in historical context by providing a brief summary of the federal government's efforts to stimulate innovation from George Washington and Alexander Hamilton through the present. Some assert that the federal government should not concern itself with making intelligent choices about investing the nation's resources to promote innovation. I believe the Administration can make an effective counterargument on the basis of both Schumpeterian economic theory and historical precedent.

I can offer the following resources and ideas for carrying out the approach suggested above:

- "The Impacts of Technological Invention on Economic Growth – A Review of the Literature" provides an overview of research findings regarding the role of invention in economic growth and the factors that drive invention. The paper is organized by six realms--economic history, innovation accounting, macroeconomic analysis, microeconomic analysis, economic theory and models, and future scenarios.
  - For present purposes, I think this analysis would be helpful in terms of items 2 and 3 above.
  - OSTP and the NEC could regularly update their understanding of the field by engaging the academic community through such means as RFIs, roundtables, and communication with academic associations.

- "Indicators of the Capacity for Invention in the United States" looks at the standing of the U.S. relative to other nations regarding invention/innovation outcomes and the building blocks of invention capacity (per the literature review)—including R&D, human capital, patent policies, free trade, entrepreneurship, labor market churning, societal values and attitudes, and national innovation agency and strategy.
    - This analysis could be used for item 4a above and could be updated annually.
- "Efforts to Measure Trade in Value-Added and Map Global Value Chains: A Guide" (attached) provides an overview of fast-moving international efforts to map global value chains (GVCs) and measure trade in value-added (TiVA) so that, for the first time, U.S. firms and policy-makers can see the place and competitive role of U.S.-based establishments in the global economy, by industry and business function, including R&D.
    - This is pertinent to item 4b above.
    - While U.S. representatives have participated in these international efforts, at present its primary statistical agencies are not actively pursuing collection and publication of such information.
    - Consequently, I encourage OSTP and the NEC to discuss with the Commerce Department's Economics and Statistics Administration options for the preparation of this form of data.
- Businesses involved in research, development, and innovation—I encourage OSTP and the NEC to speak with the Center for Economic Studies (CES) at the Census Bureau regarding opportunities for fruitful analysis of the CES Longitudinal Business Database (LBD) to better understand the nature of and factors influencing R&D and innovation in U.S. business establishments. The LBD combines firm-specific data from all Census business surveys, including the Business R&D and Innovation Survey carried out on behalf of the National Science Foundation.
    - This is pertinent to item 4c above.
    - As part of such an effort, I believe it'd be useful to determine, to the extent possible, the influence of participation in NSF cooperative R&D programs (e.g., the Industry & University Cooperative Research Program) and business R&D consortia registered with the Justice Department Antitrust Division under the National Cooperative Research and Production Act (see attached list of consortia examples).

- U.S. Code sections relevant to federal innovation policy—Earlier this year, I asked my research assistants to comb through the U.S. Code to identify congressional findings, priorities, mandates, principles, and reporting requirements regarding federal competitiveness and innovation efforts. We found a very large number of pertinent sections and it's clear there's very little coordination and integration among them. As the U.S. Code is a primary vehicle for federal innovation policy, it seems to me that OSTP and the NEC should have a complete understanding of relevant existing statutes so that they can respond to the Administration's current legal responsibilities and are in position to propose useful revisions, additions, and deletions.
    - ➢ This proposed effort is pertinent to item 4d above.
    - ➢ I'd be pleased to provide OSTP and the NEC with examples from our database and share the full database once review is complete.
- Federal innovation efforts—I have a draft set of profiles of over 50 federal programs in the executive branch and working lists of federal advisory committees and congressional caucuses.
    - ➢ This is pertinent to item 4d above.
    - ➢ I'd be pleased to share these documents with OSTP and the NEC. They can be easily updated on a regular basis.
- Other nations' strategies for promoting competitiveness and innovation—Earlier this year, I asked my research assistants to use the Internet to identify other nation's current strategies for promoting competitiveness and innovation.
    - ➢ This is pertinent to item 4e above.
    - ➢ I'd be pleased to share this work, which is rough at present, with OSTP and the NEC.
- Federal capacity for research and analysis—In item 4, I suggest that the U.S. innovation strategy be created on the basis of in-depth knowledge of innovation processes, global markets and value chains, U.S. research organizations and innovative capacity, and federal innovation policies and programs. While this is a substantial amount of knowledge, I believe the federal government's capacity to obtain and maintain it can be carried out through a network of existing offices of federal economists, facilitated by the Science and Technology Policy Institute (STPI).
- Federal statistical system—I suggest that the OSTP/NEC innovation strategy document emphasize the importance of modest investments in the federal

statistical system to provide the types of data useful to businesses, students, workers, education and training institutions, and governments in making decisions that influence the nation's capacity for innovation and competitiveness. As data are a public good, improved statistics can be a low-cost, high-impact means of positively influencing millions of decisions on a regular basis.

- Advances in information technology are enabling statistical agencies to explore opportunities to increase the value and lower the cost of federal statistics through using non-traditional sources of data, including webscraping, matched datasets, administrative records, modeling, and synthetic data. (See recent presentations by senior staff from the Bureau of Labor Statistics and the Census Bureau.)
- Since 1998, the Secretary of Labor has been mandated by Congress (29 USC 49l-2) to create and maintain a national system of employment and occupational statistics so that students, workers, and educators can make effective labor market decisions. However, the Labor Department has yet to fully fulfill this mandate, which was just reaffirmed with the passage of the Workforce Innovation and Opportunity Act (WIOA), section 308. Full implementation of Section 49l-2 would do much to promote the development of the U.S. STEM workforce.
- Opportunities exist for judicious investments in new federal statistics gathered through the traditional means of surveys, particularly in the realms of trade, prices, and occupations.
- I suggest that the strategy emphasize the importance of maintaining and advancing U.S. statistical strengths relevant to innovation, particularly with regard to
  - the Economic Census;
  - the Business R&D and Innovation Survey;
  - the new Microbusiness Innovation Science and Technology Survey;
  - other surveys of the National Center for Science and Engineering Statistics;
  - Occupational Employment Statistics;
  - the Occupational Information Network (O*NET);
  - the Competency Model Clearinghouse;
  - the American Community Survey;
  - the Local Employment Dynamics Program;
  - BEA's Industry Economic Accounts, including the Innovation Account; and
  - the Statewide Longitudinal Data Systems Grant Program.

- I'd be pleased to discuss specific opportunities for maintaining and improving federal statistics pertinent to innovation and STEM workforce.

- "National Nonprofit Organizations that Inspire and Enable Invention and Invention-based Enterprises" provides profiles of 59 organizations in six categories--young inventor encouragement, independent inventor encouragement, invention development and commercialization, inventor recognition, intellectual property, and invention and innovation policy.
    - This is pertinent to item 7 above.
    - As the documents suggests, I believe that federal convenings of these various groups could have a significant positive effect on the nation's capacity for innovation.
- U.S. innovation strategy in historical context—To provide political justification and demonstrate options for action, I strongly suggest that the innovation strategy document ground present-day activity in the context of history. Innovation strategy has been an explicit part of federal policy since George Washington's first term. Examples include:
    - Treasury Secretary Alexander Hamilton's famous 1791 report on manufactures, prepared due to President Washington's interest in encouraging manufacturing, domestic inventions, and the transfer of new technologies from abroad.
    - The U.S. Army initiative's, begun in 1815, to develop a "uniformity system" for manufacturing standardized, interchangeable parts.
    - Creation of the National Bureau of Standards in 1901 to create standards, carry out materials research, and serve as a source of state-of-the-art technical information for manufacturers and engineers.
    - In the 1910s and 1920s, federal-business R&D collaborations in the aeronautics, steel, ceramics, glass, and petroleum industries.
    - In 1919, the Navy Department's effort to have General Electric, Westinghouse, and AT&T join forces to create the Radio Corporation of America, which soon dominated radio manufacturing worldwide.
        - This is pertinent to item 9 above.
        - I'd be pleased to provide historical examples for possible use in the strategy document.

In conclusion, I hope OSTP and NEC staff find the above suggestions and information of value. I'd be pleased to discuss any aspect of this memorandum with staff at their convenience. I may be reached at [redacted] and [redacted]

David Reinhard

It would be great if federal agencies could give a small portion of their research dollars toward replication of important results. Specifically, provide funding to allow multiple labs to collaborate on replicating important findings.

Joseph S. Ross

Yale University School of Medicine

General Internal Medicine

To whom it may concern,

I was delighted to read that the Office of Science and Technology Policy and the National Economic Council were requesting public comments to provide input into an upcoming update of the Strategy for American Innovation. I believe that it is imperative that this initiative address the dissemination and reproducibility of biomedical and clinical research in the United States, particularly research funded by the U.S. government. Currently, only two-thirds of clinical research studies funded by the National Institutes of Health are disseminated through the peer-reviewed biomedical literature after the research is complete. There should be requirements that all U.S. government funded clinical research be registered in a clinical trial registry (such as ClinicalTrials.gov, even if the study is not focused on FDA-approved products) and report results on said registry to ensure the complete dissemination of publicly-funded clinical research findings. Moreover, investment in clinical research by the U.S. government should be viewed as a public good and the data that are derived from these studies should be shared widely across the research community. Sharing clinical research data maximizes its value to the broader research community and honors the participation of individuals who had volunteered for these studies. It allows additional investigators to utilize the data to address secondary research questions, validate the findings of other investigators, examine additional endpoints by combining multiple data sources, and leverage the data for uses others may not even have considered. So long as the data can be de-identified to protect patient confidentiality, there should be requirements that all U.S. government funded clinical research should be deposited in a research repository for access by other investigators in the spirit of promoting open science.

Many thanks for the consideration of my suggestions,
Joseph S. Ross, MD, MHS
General Internal Medicine, Yale University School of Medicine
Robert Wood Johnson Foundation Clinical Scholars Program
Center for Outcomes Research and Evaluation, Yale-New Haven Hospital
Health Policy and Management, Yale University School of Public Health

Robert Ryan

Kutztown University

Pre-registration is key. Journals should require studies to be pre-registered, evaluate them on the basis of the importance of the research question and the soundness of the methodology, not on the results, and then commit to publish the results whatever they may be. That, and registered replication studies will go a long way to solving the irreproducibility problem. The Federal Government should support the development of infrastructure for pre-registration and replication studies and support training of methodology and reproducibility practices.

Karla Sainz

To whom it may concern,

Reproducibility should be a critically important issue for our Federal government.

We need:
1. Higher standards in what we fund;
2. data should be shared and code should be more routine for scientific research; and
3. pre-registration should be used more often.

This matters for our future and our childrens future! please make sure we have evidence of what works for our future!

Please make sure that this (item number 11) in the President's strategic concerns makes it into our budgetary priorities next year.

September 23, 2014

Via electronic mail to: innovationstrategy@ostp.gov

Mr. Dan Correa
Office of Science and Technology Policy
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504
Re: Comments Regarding Strategy for American Innovation

Dear Mr. Correa:

We, the undersigned, are two law professors who specialize in intellectual property ("IP") law and information policy, with a particular emphasis on trade secret law. We write today to provide comments and 17 concrete proposals (numbered consecutively below) in connection with your efforts to update the *2011 Strategy for American Innovation.* Pursuant to the directions that are set forth in the Notice of Request For Information (RFI) which was issued on July 29, 2014, the following comments are numbered in accordance with the numbering set forth in the RFI and will address only some of the numbered issues.

(2) What are the biggest challenges to, and opportunities for, innovation in the United States that will generate long-term economic growth, increased productivity, sustained leadership in knowledge-intensive sectors, job creation, entrepreneurship, and rising standards of living for more Americans?

To us, the biggest challenge facing the United States with respect to the foregoing issues (and the overriding theme of our comments) concerns the need for balance in US intellectual property laws so that (a) the information and knowledge that is needed to spur innovation and creativity is not unduly constrained and (b) small businesses and innovation entrepreneurs are not subjected to the over-assertion of intellectual property rights.

With regard to the foregoing, although it has long been the policy of the United States to encourage the free flow of ideas and knowledge, including the fundamental building blocks of innovation and creativity (see *e.g.*, language in the U.S. Supreme Court's recent decision in *Alice Corp. v. CLS Bank*), we worry that the incessant drumbeat for ever greater intellectual property protection threatens to quell more innovation and creativity than it promotes, particularly among small and emerging businesses that cannot afford to defend themselves against unfounded or weak infringement claims.

While the *2011 Strategy for American Innovation* recognizes in several places (and with respect to various suggested initiatives) that education and the diffusion of knowledge are essential components of any innovation strategy, it does not explicitly state in the section labeled "Promote ingenuity through effective intellectual property policy" that US intellectual property laws should be appropriately balanced so that they do not impede the diffusion and appropriate use of knowledge and information. In our opinion, more attention should be paid to (as President Thomas Jefferson said) what society gets for "the embarrassment of exclusivity."

In the case of patent protection, society is supposed to receive a fully-enabled disclosure of the invention from which others can learn, further innovate, and ultimately use. This is the "quid pro quo" that we teach in a basic IP Survey course. There is a risk, however, that some patent related "know-how" will not be fully disclosed and will be protected as a trade secret instead. Also for some inventions in some fields (e.g., biologics), even a full disclosure of the invention for patent purposes may not allow follow-on competitors to make competitive products due to the secret nature of associated manufacturing processes and know-how. In other words, there is a technology transfer problem.

With respect to copyrights, there used to be an explicit disclosure of creative works because copyright protection did not attach until a work was either published (publicly disseminated) or registered. Since January 1, 1978, however, neither publication nor registration is necessary for copyright protection to attach to an original work of authorship. Thus, it is possible under copyright law for an author to receive the benefit of copyright protection without any corresponding benefit to the public in the form of information or knowledge diffusion. The same can be said of trade secret laws since, by definition, they require valuable commercial information to be kept secret, or relatively so. In that sense, trade secrecy "teaches" the least of our IP doctrines, by far.

While admittedly with respect to patents, copyrights, and trade secrets there are other benefits besides knowledge diffusion that society receives in exchange for the IP rights provided (principally, more creativity and innovation), because education and the diffusion of knowledge is essential to further innovation and creativity, it is short-sighted to look at only one side of the IP equation (how to strengthen protection) without carefully considering how to appropriately limit such protection and thereby improve technology transfer and the flow of information that is needed for ever greater invention and creativity.

A related tension, and one that is only indirectly expressed in the *2011 Strategy,* concerns the potential use of intellectual property rights in anti-competitive ways. In the section of the *2011 Strategy* labeled "Promote Innovative, open, and competitive markets," the importance of free competition is recognized as a key driver of innovation, but no mention is made to how intellectual property rights often restrict free competition and employee mobility. This is in stark contrast to traditional pronouncements by U.S. judges and policymakers that recognized that "free competition is the rule, and intellectual property protection is the exception." Somewhere in our shift from the agrarian and industrial ages to the information age, we seem to have lost sight of this very important concept which, when applied, dictates that appropriate limits be placed on the scope of all intellectual property rights.

Suggestions:

1. All intellectual property laws that currently exist and that might be added in the future should be carefully designed and tailored to ensure that they are properly balanced (a) so that society gets a sufficient return for the rights granted and (b) to prevent such laws from unduly restricting access to and diffusion of information and knowledge, free competition, and employee mobility.

2. An examination should be made to determine if the disclosure purpose of patent protection is being fulfilled and whether new rules and procedures should be put in place to facilitate greater disclosure and diffusion of knowledge with respect to patented inventions, including their associated know-how and processes. Requiring the use of simple, common English in patent applications might help.

3. In order to enhance the public availability of copyrighted works, particularly those that do not currently enjoy copyright protection and may be out of print, the US government should consider taking the deposit requirement seriously and putting the works currently maintained in the Library of Congress in digital form. With respect to new works, the U.S. Copyright Office can start this process by requiring that a digital copy of each work be deposited upon registration of the work.

4. Currently, civil trade secret law in the U.S. is governed by state law which has developed over the past 160+ years to include a number of important limitations on the scope of trade secret rights. Some of these limits are in laws that are ancillary to trade secret doctrine itself, for instance the legal principles governing the ownership of employee-created inventions and the enforceability of non-compete agreements. While we are opposed to a federal law to create a civil cause of action from trade secret misappropriation because we think it will create more problems than it solves, if such a law is enacted, it should include provisions that effectively limit its scope so that it cannot be used to unduly limit the dissemination of knowledge, free competition, and employee mobility.

5. Specific attention should be given to the impact of trade secrecy on access to knowledge, both as an exemption under state freedom of information laws, as well as broader concerns about access to proprietary information. Carve outs might be warranted based upon the public's legitimate interest in access to information of vital public concern (like, for example, the chemical composition and formula for hydraulic fracturing).

(3) What specific actions can the Federal Government take to build and sustain U.S. strengths including of an entrepreneurial culture, flexible labor markets, world-class research universities, strong regional innovation ecosystems, and large share of global venture capital investment?

The assumption of a lot of U.S. and international intellectual property policies is that if the U.S. and other countries build a stronger intellectual property protection system, then innovation, investment and economic development will naturally follow. However, when the assertion of weak or non-existent intellectual property rights is made against fledgling entrepreneurs, mobile employees, research scientists, and their investors, the result is quite the opposite. As recent experience with patent assertion entities has shown, individuals and companies with great ideas and hopeful spirits can be sued out of existence before their great ideas even reach the marketplace. Sometimes these weak claims are brought innocently out of ignorance of the scope and limits of applicable IP rights. Other times, they are brought for anti-competitive reasons because a larger company with an investment in incumbent technology values its own profits over the importance of innovation and competition. Whatever the reason, there is a great need to limit such claims so that only legitimate IP rights are asserted.

Suggestions:

6. Provide better information and education about the scope and importance of the limits that are placed on intellectual property rights.

7. Amend U.S. law as necessary to clarify the limits that are placed on intellectual property rights.

8. Consider adopting "safe-harbors" that would allow for the limited use of IP rights for research purposes and expand the experimental use exception of patent law. Perhaps one such safe harbor could be granted to new businesses under specified situations?

9. Amend U.S. law to explicitly provide for attorney's fees or other sanctions against plaintiffs who bring unfounded intellectual property infringement claims. Also consider whether a private civil cause of action for bad faith assertion of IP rights should be created to address harmful cease and desist letter and licensing practices by the owners of weak or non-existent IP rights.

(4) How can the Federal Government augment its overall capacity for analysis of both the forces that determine the competitiveness of specific sectors and the impact of Federal policies – including, but not limited to, science, technology, and innovation policies – on sector-specific productivity and competitiveness?

This RFI process is a great way to hear from a broad cross-section of individuals, companies, and associations that are interested in innovation policy, but we fear that the voices of small businesses and fledgling entrepreneurs are not being heard. If and when they are, we are certain that there will be many stories of aspirations quashed by the over-assertion of IP rights and statements of general confusion about the meaning and scope of intellectual property rights. Unfortunately, many of these fledgling entrepreneurs are not able to afford legal counsel at critical times and may be taken advantage of by those that see the benefits of claiming ownership of their ideas, including unscrupulous patent promotion companies. Also, without adequate knowledge of the meaning and scope of intellectual property rights, these individuals and small businesses may invest too much of their limited resources in intellectual property protection efforts that are not worthwhile.

With respect to sector-specific information, a lot of great work is being done by academics across the country to examine the levels and types of incentives that are needed to spur innovation in various industries. This work could be better identified, distributed, and supported, much like the federal government funds health research.

Suggestions:

10. Increase efforts to hear from individual inventors, small businesses, and fledgling entrepreneurs in order to better understand the challenges they face in pursuing their ideas and securing IP protection.

11. Fund legal clinics that are designed to assist individuals and small companies to protect and promote their ideas and launch their businesses.

12. Develop a grant program to better utilize the talents of U.S. academics to further study U.S. innovation and information policy.

(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address this problem?

As noted above, part of the problem concerns the limited scope of disclosure in patent applications and the risk that some "know-how" or "best-modes" will be held back and protected as trade secrets. A related problem concerns the scope of disclosures that are required under the Bayh-Dole Act. If the federal government paid for the creation of information, arguably it should be fully disclosed for the benefit of the public, although the timing of such disclosures might be debated.

Suggestion:

13. Amend the Bayh-Dole Act to require the disclosure of all information related to the federally-funded research, not just information regarding patentable inventions. This should include information commonly described as "know-how," negative information, confidential information, proprietary information, and trade secret information.

(21) What new challenges and opportunities for intellectual property and competition policy are posed by the increasing diversity of models of innovation (including, e.g., through the growing use of open innovation, combinatorial innovation, user innovation, internet-enabled innovation, and big data-driven innovation)?

What many of the new models of innovation have in common is the free and open sharing of ideas and information among individuals and companies – what Prof. Henry Chesbrough calls "open innovation." At some stages of a business and in many industries, the applicable norms are to share information without much concern for the disclosure of potential trade secrets or the waiver of patent rights. For instance, the norm among venture capital firms that are asked to fund start-ups is not to agree to any formal duty of confidentiality. The same is true in the publishing and entertainment industries where individuals must often pitch their ideas without any express or implied promise of confidentiality.

The foregoing suggests at least three things. First, the need for secrecy and intellectual property rights to encourage innovation, creativity, and investment can be overblown. Second, in thinking about policies to protect innovation and creativity, one-size does not fit all, particularly if the policies prefer secrecy and the assertion of property rights in information over open-innovation. Third, sometimes it is better to let the norms of a particular industry govern a situation instead of enacting federal laws; Or, at the very least, there are often benefits to waiting to see if effective norms develop before enacting laws to govern a situation.

The Open Software movement can provide some clues as to potential problems and solutions for the broader open innovation movement. Among other issues, the Open Software movement has given rise to issues regarding the ownership and intellectual property status of the software and how it can be used and modified.

Suggestion:

14. Default rules concerning the intellectual property status and ownership of inventions and works of creativity that are created as part of an open-innovation model could lower associated transaction costs and, thereby, facilitate more open innovation. In keeping with the general theme of this letter, these default rules should be designed to encourage the exchange of knowledge and information, perhaps in exchange for limited exclusivity.

(25) What Federal policies or initiatives could unleash additional corporate and philanthropic investment for critical national priorities, such as energy innovation?

We address this issue in a recent joint work to be published later this year titled: "Trade Secrets and Climate Change: Uncovering Secret Solutions to the Problem of Greenhouse Gas Emissions." Like this letter, the theme of that work is that a lot of problems related to innovation (or the lack thereof) can be solved if we recognize the limited scope or intellectual property rights and allow information to flow more easily. In that work, we make ten suggestions, many of which have already been mentioned above. Additional suggestions applicable to the question of energy innovation include the following:

Suggestions:

15. Create a centralized and searchable database of public information regarding energy efficient and low carbon technologies that is easily accessible by those innovating in the field. An added benefit of such a database would be to enhance patent examination with respect to such innovations.

16. Drive inventors toward patent protection because society benefits from patent disclosures.

17. Consider sector-by-sector analysis of the best bundle of IP rights needed to encourage innovation.

We appreciate the opportunity to provide the foregoing commentary and suggestions. Should additional information or insights be needed, we can be reached at the email addresses listed below.

Sincerely,

Sharon K. Sandeen
Professor of Law
Hamline University School of Law
[redacted]

David S. Levine
Visiting Research Collaborator
Princeton University Center
Information Technology Policy
Associate Professor
Elon University School of Law
[redacted]

Rebecca Saxe

Massachusetts Institute of Technology

It is critical for the Federal government to continue to support basic research. This research leads directly to innovations, through it's results, and also indirectly, by training the next generation of scientists, engineers and innovators. Funds for training new scientists should therefore be a top priority of continued government support. Another priority should be to focus on producing true and replicable (rather than immediately "translatable" research). It is easier to evaluate whether results are true, reliable and replicable than whether they are "high impact" -- and more important, since often our vision is too myopic to truly identify the results that will have the biggest impact in a decade or a century. The recent emphasis on "translation" and "impact" has often led to distorting and even perverse incentives, for scientists to overstate the known implications of results and to under-test their reliability. Funding should focus on curiosity driven science, and on maintaining the highest standards for truth and reliability, and trust to the future to determine the application of the results. These are the standards that drove the first century of American leadership in science and innovation, and the same standards must be at the center of the next one.

Kathleen Schmidt

In response to item 11, the Federal Government could encourage sharing research materials and data, generally promoting the transparency of research in the Sciences. Additionally, federal grants for replication could provide incentives to create and confirm reproducibility in Science. Finally, infrastructures that provide means for research transparency and dissemination would benefit from governmental support.

Mike Schmidt

I believe that one of the major challenges facing all of research today is keeping tabs on the overwhelming amount of information available. The solution is twofold. First, we need to continue supporting tools that mine existing information. Second, we need to rethink and modernize the way we publish our results with an eye to making them easily searchable.

The top-down approach is progressing fairly well with "big data" approaches using machine learning to mine more and more effective results to searches. Google Scholar, The Neuroscience Information Framework, and many tools under the NCBI umbrella do a terrific job and will hopefully continue to grow and receive support.

The bottom-up approach seems to be working well with genetic data, feeding annotation databases for more effective searching later. Those annotations also enrich the dataset with meaning. But most research is reported purely as publications, where every journal has a different format and every author a different style. It becomes impossible to read all of the publications even in a small niche. Several interesting ideas have come to my attention, and I'm sure there are many more I'm unaware of. The NIF is working to help scientists store and share data in formats that are easily searchable by their engine. This has allowed me on several occasions to find the targeted data I'm looking for without having to read through dozens of semi-relevant papers. Those kinds of approaches will make the top-down work easier, and keep us more productive while we await more powerful data mining tools. Another example of smarter bottom-up information management is "Research Maps," proposed by Alcino Silva and John Bickle. Their approach is to document in simple graphs of relationships each cause and effect relationship discovered. Over time, it would generate a rich web of information suggesting gaps to be filled by experiment and saving students time in consolidating established facts. I would urge the federal government to invest in these approaches because their broad impact can positively influence all of science.

These projects that make it much easier to disseminate information in a structured way are essential to efficient progress. Thank you for taking the time to read my suggestions.

fuentek
a fountain of possibilities

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Change the "Private Use in Bonded Facilities" Regulation (Section 6.02 of Revenue Procedure 2007-47)

A Response to OSTP/NEC Request for Information:
Strategy for American Innovation | 79 FR 44064 | Doc. No.: 2014-17761

My name is Laura A. Schoppe, and I offer this Public Submission in response to the "Strategy for American Innovation: Request for Information" notice issued July 29, 2014, by the Office of Science and Technology Policy (OSTP) and the National Economic Council (NEC) and published in the *Federal Register*, volume 79, number 145, pages 44064-44068.

I am the founder and president of Fuentek, LLC, one of the world's leading intellectual property management and technology transfer consulting firms. Founded in 2001, Fuentek is a trusted advisor to a wide range of U.S. and international clients in government, academia, and industry. Having worked in the technology transfer and commercialization industry for nearly 20 years, I bring significant experience and insights to this Public Submission:

- I am on the advisory board for the Electrical and Computer Engineering Department at North Carolina State University.
- I am a member of the N.C. governor's Innovation-to-Jobs Task Force.
- I served on the White House Lab-to-Market Cross-Agency Summit in 2013.
- I served on the board of the Association of University Technology Managers (2011–2013).
- I participated in a roundtable discussion held by the President's Council on Jobs and Competitiveness in Durham, North Carolina, in June 2011.
- I have supported the technology transfer and commercialization efforts of more than a dozen public universities in the United States as well as academic institutions around the world.
- I earned an MBA from the University of North Carolina–Chapel Hill and mechanical and aerospace engineering degrees from Carnegie Mellon University and Princeton University.

It is from this background that I wish to offer an answer to the RFI's third Overarching Question: What specific actions can the Federal Government take to build and sustain U.S. strengths including its entrepreneurial culture, flexible labor markets, world-class research universities, strong regional innovation ecosystems, and large share of global venture capital investment?

My answer: **Change Section 6.02 of Revenue Procedure 2007-47** (from IRB 2007-29 issued on July 16, 2007) regarding corporate-sponsored research so as to better ensure that such innovative R&D occurs in U.S. universities rather than overseas. This change can serve as **a no-cost solution** that can have a positive impact on local/regional economies without creating a financial burden on the federal government or on U.S. taxpayers.

This RFI response provides an overview of the current regulations and the deleterious effect they are having on innovation.

The Current Regulation

The regulation—which is referred to as "private use in bonded facilities"—reads as follows:

> **Internal Revenue Bulletin: 2007-29 | Revenue Procedure 2007-47**
>
> *Section 6.02 Corporate-sponsored research.* A research agreement relating to property used for basic research supported or sponsored by a sponsor is described in this section 6.02 if any license or other use of resulting technology by the sponsor is permitted **only on the same terms as the recipient would permit that use by any unrelated, non-sponsoring party** (that is, the sponsor must pay a competitive price for its use), and the price paid for that use must be determined **at the time the license or other resulting technology is available for use**. Although the recipient need not permit persons other than the sponsor to use any license or other resulting technology, the price paid by the sponsor must be no less than the price that would be paid by any non-sponsoring party for those same rights. *[emphasis mine]*

In other words, public universities cannot accept funding contracts that have pre-negotiated royalty rates. A company that pays a public university to conduct R&D cannot know in advance the price they will need to pay to license the outcomes of that R&D. Despite the fact that it risked its own resources to have the university conduct cutting-edge R&D that ultimately may yield nothing patentable or commercializable, the company must pay the same rate that would be paid by any party, **including one that did not pay for the research**.

This is problematic for companies that understandably want some assurances on ownership of the intellectual property (IP) that might emerge from the research they are funding. The sponsored research agreement (SRA) can include a "first right of refusal" provision, whereby the company can pay to acquire the IP if they want it (and if they do not, the university can license it to anyone). However, the company will want to minimize the risk associated with the IP-ownership acquisition. If the company were hiring another business to do the R&D, the parties would pre-negotiate the license fees or enter a work-for-hire arrangement where IP ownership automatically goes to the funder. But in the case of a public university, **research sponsors cannot pre-negotiate the license fees because to do so would jeopardize the university's tax-exempt status**, according to Rev. Proc. 2007-47§6.02.

A Regulation Out of Synch with Reality

The intention of the "private use in bonded facilities" regulation was to prevent companies from receiving what essentially amounted to a subsidy by having their R&D conducted in a building funded through publicly issued bonds. This avoidance of "corporate welfare" may have made some sense in an era when public universities were flush with government funding that was not tied to any specific research, when full-cost accounting was not the norm, and when academic researchers had the time and money to do what they wanted in their labs.

Ask any researcher in a public university and he or she will tell you that things have changed:

- Public universities are not receiving as much support from the state as they used to. Therefore, researchers are fighting for every dollar, whether it comes from dwindling federal funds or from private companies.
- Corporate research is funded by companies, and companies pay fair market value for that research. (If they didn't, the researcher would pursue R&D funding from another source.)

- Universities are performing full-cost accounting, including overhead fees associated with the facilities in which the sponsored R&D is conducted. Therefore, the company is paying for the use of any publicly funded facilities used in conducting the R&D.
- Research projects are not untargeted, and universities cannot do R&D without money being provided from some source. This research leads to future innovations for this country.

In short, the “private use in bonded facilities” regulation is outdated and no longer aligned with the reality of R&D in public universities. Not only is it mitigating a non-existent risk, the regulation is being recognized more and more as a problem, as noted by Dr. Elizabeth Hart-Wells during the July 24, 2013, hearing of the U.S. House Subcommittee on Research and Technology on “Improving Technology Transfer at Universities, Research Institutes and National Laboratories.” Dr. Hart-Wells is Assistant Vice President for Research as well as Associate Director of the Burton D. Morgan Center for Entrepreneurship at Purdue University. She said the following in response to a question from Rep. Ami Bera about the tax code issues associated with university partnerships with entrepreneurs/industry:

> We run into this and we have this conversation—actually more vigorous conversations more recently…. There is a prohibition on basically for-profit activities in those spaces [i.e., private use in bonded facilities]. So that is actually an input in the analysis that is often not considered… in the dialogue on the outside but is a critical go/no-go of whether a university can even undertake a partnership, whether it wishes to or not. It would be very appropriate in the context of all of the conversations about realizing the value of federally funded research through products and services, where appropriate, to consider and take up the question of “private use” and its impact—positive and negative—on this whole ecosystem.

The Damages from the Current Regulation

The negative impact of the “private use in bonded facilities” regulation is real, measurable, and far-reaching:

- **A Tracking Burden for Universities:** Because of this regulation, public universities have to track which buildings—or portions thereof—were funded by public bonds and how much of the research in those buildings is corporate sponsored versus federally funded. This not only is difficult but also leads to the inefficient use of resources. For example, one U.S. public university uses different colored carpeting in buildings to virtually “tape off” areas that can and cannot be used for corporate sponsored research. As this example demonstrates, the IRS rule creates a logistical burden that universities would not have to suffer if the regulation were changed.
- **Sharing Across Campuses Is Impossible:** Section 2.01 of Rev. Proc. 2007-47 specifies that up to 10 percent of a public bond can be used for any private business use. However, this attempt to be generous becomes an administrative nightmare for multi-campus universities, such as the 17-campus system of the University of North Carolina. The rule allows the 10 percent to be shared across the system, which in theory would be useful if some campuses do not need their full 10 percent. In reality, private business use is so difficult to track that most universities do not even bother to try for fear of running afoul of the IRS and therefore hold back on fully reaping the benefits of the 10 percent exception.
- **Companies Perceive Universities as Hard to Work with:** Most corporations do not know about this IRS rule and therefore do not understand why universities are not willing to pre-negotiate a license for research they are paying for (and when it is explained to them, they surely don’t like it). With

federal research dollars being reduced, universities are forced to obtain more funding from corporations. However, this IRS rule makes it more difficult for them to secure the corporate funding needed to continue valuable research that has benefits beyond just the company's interests (e.g., progressing science, funding graduate students, discovering an enabling capability). This is in direct conflict with the Administration's growing emphasis on cooperation and collaboration between universities and industry.

- **Companies Perceive Universities as Greedy and Adversarial:** Under the current IRS regulation, companies can pay to have research done at a public university, but they essentially have to do it as a grant. If any IP results from the R&D, they cannot lay claim to it any more than anyone else can, even though they funded it. Without a guarantee, companies understandably become suspicious that the university will later hold the IP hostage. This is by no means the reality, but it is what companies fear. And their concern is understandable.
- **Companies Are Taking Their R&D Dollars Overseas:** If a company has $500,000 to invest in R&D and can choose between a university that will guarantee a specific licensing fee and one that will not, it stands to reason that they will choose the former. And they are doing so, directing their R&D dollars to non-U.S. universities. (***Note:*** I have been told point-blank by representatives of at least three companies that, rather than deal with the limitations that the IRS rule placed on their SRAs with U.S. universities, they are now having the R&D performed overseas.) Furthermore, universities in Europe understand this problem and are starting to take advantage of it, emphasizing the IRS issue when they market their R&D labs to U.S. companies.

If the OSTP and NEC want to ensure that cutting-edge research will be conducted in the U.S., that our nation's universities continue to be deemed world-class by all, that our historical investments in science and engineering reap economic benefits for our citizens, then I urge you to **change IRS Revenue Procedure 2007-47§6.02 so that companies funding research at public universities can pre-negotiate their license rates.**

Thank you for your consideration. If you would like to discuss this topic further, feel free to contact me at [redacted] or [redacted]

LASchoppe

Laura A. Schoppe
President
Fuentek, LLC

Will Schroeder

Kitware

President & CEO

Dear Mr. Dan Correa, Office of Science and Technology Policy-

Thank you for providing us with the opportunity to provide input to the development of a Strategy for American Innovation. We would particularly like to address issue (11) below:

Science, Technology, and R&D Priorities
(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

As you have pointed out, there is growing evidence that too many scientific findings are not reproducible, meaning that the foundations of science, and hence innovation, are at significant risk.

We recommend a very simple and easy to communicate solution: all the products of government-funded research must be open. This includes data, source code, and publications. Such an approach will ensure that others can reproduce and hence validate scientific findings. It also represents the interests of taxpayers who are the ultimate investors in government research.

We understand that during the research process there may occasionally be the need to withhold information while research is proceeding; however it is imperative that the products of research are quickly released once the research comes to a close. Preferably, the entire process should be initiated and run in the open.

Another initiative that the government can pursue is to support open data and software repositories. In a similar vein, supporting grand challenges and reference datasets also encourages innovation. That is, collecting data and encouraging competitive analysis on it. For example, gather digital pathology images and challenge companies to discover cancerous cells from these images (compared to what experts can find). Then publicly disclose the results of the challenges.

We wish you well in this very important endeavor.

Axel Schultze

Society6 Accelerator

CEO

Thank you Thomas Kalil for the amazing initiative. Leading nations come and go. When they go under all had the same issue: They invested more resources in protecting what they had unwilling to let go and building a new future.

However, there has always been a FIRST

The birth place of a structured society was around 3,500 BC in Africa. The birth place of the industrial revolution was around 1800 AD in Europe. The birth place of a self actuating society that creates more wealth than ever before imaginable has its greatest opportunity in the US.

However the US has to make almost impossible shifts of seismic proportions in its inner structure and architecture to make it happen. From a 30,000 feet point of view:

1) Monopolized Economy
The current economic structure has evolved to a monopolized economy where a few monster organizations control the entire nation - not so different than the collapsed eastern block economy.
EVIDENCE:
The food industry, the car industry, the energy industry, the telecom industry is in the hands of less than 5 player and crashing any up and coming business with weapons that are not based on competitive advantage but by leveraging rules, rights, patents, law... to maintain their status - even though they no longer create the value necessary to lead.
NEEDED CHANGE:
Stimulating competition by removing many of the inadequate legal requirements when doing business including the insane situation that all the "manufactured" residential home areas DO NOT ALLOW businesses to be integrated other than again manufactured shopping centers and both controlled by a small hand full of massive construction companies. How cool would it be to have a bakery within a residential area? How cool would it by to have a little cafe or restaurant with a nice outdoor seating in a residential area that serves beer outside and not protecting the one alcoholic at a price where 300 Million others have to suffer. How cool would it be if any telco could sell any service in any area and not been bound and arranged based on capacity and other Russian business model like plans and structures?
ECONOMIC IMPACT
Small business can provide an added value to 60 Million homes in structured residential areas creating an incremental 500 Billion in combines revenue. Innovative telcos providing the much wanted customer experience and service could possible double the revenue of the entire industry.

2) Protectionism
The US has grown into a protectionism that allows a small group protecting their interests and prevents change and innovation.
EVIDENCE: The 99/1% issue is rather inconvenient and mostly ignored. And the 99% are so terribly bad educated that they don't even have a chance to intelligently articulate what goes on "down there". Leading to a slowly but steadily growing risk of "inner explosion" - But definitely an inability to contribute to innovation and economic growth.
NEEDED CHANGE
Taking down those protecting walls where some businesses can protect themselves from competition - which usually grows by innovation. Why should a car maker like Tesla obey a "LAW" that dictates how to sell a car? Why should Uber be restricted to do business that many want to deal with just because some

Taxi union is protecting an old and outdated business model?
ECONOMIC IMPACT
The free flow of innovation would force aging companies be more agile and allow the innovative challenger to grow faster. Both together would put the US not only locally but also globally in a way more competitive position and increase the export volume significantly.

3) Overloaded LAW
Slowly but steadily and over generations the US law has turned into a self serving structure at an unbearable cost and slowing down innovation, growth and most importantly competitiveness.
EVIDENCE: The US Law has not seen any disruption and most of the rules, rights and regulations are bolt on - all too often with the help of influential people who rather act in their own or their business interest but not in the interest of a society as a whole.
NEEDED CHANGE
Restructuring the US LAW which is bound to a centuries old British law structure. Not only it became so complicated that a lawyer is needed in almost any situation, sentences have grown so outrageous that insurances grew outrageous and the cost of doing business is actually affected by the law that should rule and protect but now requires added functions and reserves that puts the business into a competitive disadvantage.
ECONOMIC IMPACT
Easier law, avoidance of inadequate risks and cost would accelerate many businesses by having less to worry from a legal side that is too complicated for a business to understand or act on and no real aspect of protecting or guiding anything.

4) Endangered Political Freedom
Intolerance that suppresses critics as "un-american" and does not allow to work on structural problem like the above.
EVIDENCE: some, even influential people, decide to rather not speak up as they want to keep their comfortable position and just don't care what happens in the next 20 years.
NEEDED CHANGE
Constructive criticism, meaning providing a critic with an accompanied suggestion for improvement should be stimulated. Schools need to educate kids at all social levels about the meaning and importance of politic and law in a way they can understand and become contributing democrats.
ECONOMIC EFFECT
Even moderately educated but contributing citizen have a much higher chance to also become entrepreneurs and even if it is just opening a small shop providing a service and added value to our society. Widening the business horizon and stimulating small businesses to grow without even expecting them to turn into giants would strengthen the mod market and further stabilize the overall economy.

5) Lack of vision
Duct tape mentality that ignores the underlying problems and just fixes holes on the surface until the surface is only tape.
RISK: Hoping to find interesting and smart economic innovation without building the necessary foundation to let those economic innovations actually flourish. In the end all those quick and dirty programs would not solve the problem and possibly make the solution impossible.
NEEDED CHANGE
Creating awareness for holistic thinking in all aspects of our daily lives including our social and business structures.
ECONOMIC IMPACT
Many people will see things in a bigger picture and come up with solutions faster and more motivated. In the end with more and faster solutions, more businesses get created and added wealth can be distributed.

Political Influence & Responsibility
Innovation, creativity, entrepreneurship, or growth can not be politically created or demanded but a great government can provide the best possible seeding ground. Usually up and coming nations which have little to change and nothing to loose have the best chances to become the next leading society. Yet a

nation like the US with a culture that still is way ahead any other, a spirit that seem to be unbreakable and intellectual assets like no other nation has the chance to break all the rules - even the political ones.

Democratization of influence
Publicly posting the issue of the nation and asking for feedback is a significant first step. Guidance for collaboration and support is certainly the next big challenge.

Thanks - an immigrant of the same fabric like the ones who built that nation in the first place

Dylan Selterman

University of Maryland

1. Make sharing of data and research materials the default.

2. Ask federal agencies to dedicate a small portion of their research dollars toward replication of important results.

3. Promote transparency across the entire research lifecycle, including preregistration.

4. Support the development of infrastructure to increase discoverability of research, regardless of whether it was published.

5. Promote and support training of methodology and reproducibility practices.

Daniel Sheltraw

UC Berkeley

Researcher

Dear Mr. President
In response to the recent concerns over reproducibility in science I offer the following concise critique and suggestion.

Publications are the currency of science and the review of publications is the nexus where all forces promoting bad science meet. Therefore any solution to the problem of reproducibility will be best directed at this nexus.

In my opinion the best solution is to move away from the 50 year old model of pre-publication review to a post-publication review of scientific publications. This will give all scientists a say in the value of a publication rather than leaving that determination in the hands of a few with vested interests that are too often greater than their scientific interests.

Barbara Spellman

University of Virginia School of Law, APS (Association for Psychological Science)

Regarding:(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings, how can the Federal Government leverage its role as a significant funder of scientific research to most effectively address the problem?

The problem is that too much information about science is lost -- and that happens at two points in the research process.

(I am a psychology journal editor who has published a lot about reproducibility and a co-founder of http://www.psychfiledrawer.org/ -- a website where psychology researchers can post results of replications.)

First, researchers run many studies that they don't report.
We need repositories for "research that doesn't work" because scientists learn a lot from such 'failures'. At http://www.psychfiledrawer.org/ psychology researchers can post results of replications -- be they successes or failures. But even studies that 'fail' that are not replication attempts should be recorded.
Doing studies that COULD lead to interesting/important results should be encouraged and rewarded, regardless of actual outcome. Funded researchers should have to report all that they tried.

Second, information is lost because research is not well-connected or well-archived. Science needs something like what law has for cases -- a record of how often studies and results have been followed, overturned, etc. This needs a (funded) group or organization to create and oversee. (See attached for description -- suggestions 3 and 4.)

Brandon Steelman

Clear Gene, Inc.

CEO

I'm writing to express my support for increasing the federal government's role in the reproducibility of research.

Francis Collins, among other, has cited increased training as a key element of the solution. Reproducibility requires three technical elements: design, execution, and articulation. In addition, reproducibility requires both a culture of scientific ethics and training new scientists in ethical standards. In my experience, scientists collectively and individually hold themselves to high ethical standards. An educational initiative should therefore focus on the technical elements of reproducibility.

As tempting as it is to design targeted initiatives for emerging challenges, I encourage you to ask whether this is a symptom of a more systemic problem. I believe unreproducible science is the result of problems with scientific training that the federal government has previously failed to address.

When I was a postdoc, I represented ~2,000 postdocs as Co-Chair of the Stanford Postdoc Association (the nation's oldest, and one of the nation's largest postdoc associations). Training was our primary issue. Advanced scientific training in the United States is outstanding for some aspects (creativity, leading techniques), but dismal in many aspects. I would argue that unreproducible science one of the expected side-effect of our current system. The need to address scientific training is perhaps most acutely presented in the preface to a National Academy of Sciences report. The NAS was asked to review the NIH Training Grants administered under the NRSA program. The NAS responded with an indictment of the current scientific training system. They said in part that these grants support a labor workforce, not training. They noted that the majority of the biomedical workforce in the US are graduate students and postdocs. They also noted that most of these students are trained to join the academic professorate. However, for example, the number of postdoctoral fellows doubled at Stanford University School of Medicine over the past decade, while the number of new tenure-track faculty positions is now capped. There is single-digit growth of tenure-track academic positions nationwide. Some programs within the NIH continue to define success as a trainee who obtains an academic position. Society needs scientists in diverse roles: journal editors, policy advisors, teachers. I work in the field of translational medicine, where we bring scientific discoveries to patients' lives. Translation of scientific discoveries into patient care occurs almost exclusively outside of academia. Yet graduate students and postdocs are not trained for a wide range careers. In fact, and in line with NIH definitions, most trainees feel like failures if they do not pursue academic careers. In the current environment, the majority of research is being performed by trainees (often after decades of advanced training), whose primary focus is advancing their careers. Designing, executing, and articulating reproducible experiments will never be a priority in a system that appears to an observer as a pyramid labor scheme.

I applaud your efforts to address reproducibility, and encourage you to focus on scientific training. Democratic administrations pushed for more advanced scientific training, and rightly so, but I believe that this system can only be addressed by a Democratic administration. Please don't hesitate to contact me if I can be of assistance.

Victoria Stodden

This comment is directed at point 11, requesting input on the reproducibility of scientific findings. I believe there are two threads: a traditional problem whose longstanding solution has been the methods section in the scientific publication; secondly, a new issue that has arisen over the last twenty years as computation has assumed a central role in scientific research. This new element is not yet accommodated in scientific publication, and introduces serious consequences for reproducibility. Putting aside the first issue of traditional reproducibility, for which longstanding solutions exist, I encourage the federal government in concert with the scientific community, to consider how the current set of laws and funding agency practices do not support the production of reproducible computational science. In all research that utilizes a computer, instructions for the research are stored in software and scientific data are stored digitally. The complexity of the data generation mechanism and the computational instructions is typically very large, too large to capture in a traditional scientific publication. Hence when computers are involved in the research process, scientific publication must shift from a scientific article alone to the triple of scientific paper, software, and data from which the findings were generated. This triple has been referred to as a â□œresearch compendiaâ□□ and its aim is to transmit research findings that others in the field will be able to reproduce by running the software on the data. There are two primary laws come to bear on this idea of computational reproducibility (data and code availability in support of published results). The first is copyright law, which adheres to software and to some degree to data. Software (source code) and data from scientific research should be made openly available by default (rather than closed by copyright law by default) with attribution for the creators. Secondly, the Bayh-Dole Act from 1980 no longer has the effect of creating transparency and technology transfer due to the use of the computer in scientific research. Bayh-Dole charges the institutions that support research, such as universities, to use the patent system for inventions that derive under its auspices. Since software may be patentable, this introduces a barrier to knowledge transfer and reproducibility. A research compendia would include code and would be made openly available, where as Bayh-Dole adds an incentive to create a barrier by introducing the option to patent software. Rather than openly available software, a request to license patented software would need to submitted to the University and appropriate rates negotiated. For the scientific community, this is equivalent to closed unusable code. I encourage you to rethink the legal environment that attends to the digital objects produced by scientific research in support of openly available research findings: the software; the data; and the digital article. Science, as a rule, aims to make these openly available to society but they are frequently captured by external third parties, using copyright transfer and patents, that restrict access to knowledge and information that has arisen from federal funding. This retards American innovation and competitiveness. Federal funding agencies and other government entities must financially support the open sharing, broad access, and long term archiving of research data and code that supports published results. With guiding principles from the federal government, scientific communities should implement infrastructure solutions that support openly available reproducible computational research. There are best practices in most communities regarding data and code release for reproducibility. Federal action is needed since the scientific community faces a collection action problem: producing research compendia, as opposed to a published article alone, is historically unrewarded. In order to change this practice, the scientific community must move in concert. The levers exerted by the federal funding agencies are key to breaking this collective action problem. Finally, I suggest a different wording for point 11 in your request. Scientific findings are not the level at which to think about reproducibility, it is better to think about enabling the replication of the research process that is associated with published results, rather than the findings themselves. This is what provides for research that is reproducible and reliable. When different processes are compared, whether or not they produce the same result, the availability of code and data will enable the reconciliation of differences in methods. Open data and code permit reproducibility in this sense and increase the reliability of the scholarly record by permitting error detection and correction. I have written extensively on all these issues. I encourage you to look at http://stodden.net , especially the papers and talks.

Fraser Tan

Science Exchange

Science Solutions Manager

To the White House Office of Science and Technology Policy,

My name is Fraser Tan; I'm a Stanford PhD and postdoc trained scientist. I am currently a core member of the Reproducibility Project: Cancer Biology (http://validation.scienceexchange.com/#/cancer-biology). As you can no doubt tell by the fact that I've chosen to work directly on this issue, I strongly believe that reproducibility is a key issue that a needs to be addressed in the scientific research community.

Working on the RP:CB for a year now has given me some key insight into how the research field currently responds to reproducibility. While some may embrace it and some may reject it, the major obstacle that all researchers face in implementing reproducibility-related measures is funding. As the largest single funder of biomedical research, the federal government holds enormous influence to help implement changes that address reproducibility that will ultimately help increase the efficiency of both basic science research and drug development.

I would urge the White House to consider how the federal government, through the NIH, could add measures to ensure evaluation of reproducibility and increased standards in data sharing for all investigators who use federal funds for their research.

Caner Uguz

I am currently finishing up my PhD at the University of Virginia and I work with large and small research efforts. I also have a significant interest in the development of technology and web services. One of the major take aways for me from having exposure to both these fields is how in technology improvements are made quickly, ideas spread and there is a wider conversation about what improvements and directions need to be made. This efficiency I think is partly due to the open nature of the web and there is a lot that practice of science research can learn from it. We need research process (not just the results) to be accesible and as open as possible. Having a good sense of where research is heading and being able to access the data and information required to replicate studies will democratize the process and allow the conversation to include wider communities. The US has lead the effort on technology innovation for decades but academic research is going to be left behind if sensible measures are not taken.

David L. Vaux

The Walter and Eliza Hall Institute

Head, Cell Signalling and Cell Death Division

The biggest cause of the lack of reproducibility in science is corruption of the journals' peer review process.

The single measure that would do the most to improve the integrity of the peer review process would be to implement double-blind peer review.

Double-blind clinical trial are mandatory before drugs are approved, and they work by reducing bias. Double-blind peer review is just as important for determining which papers are published.

It is only with double-blind peer review that submitted papers must be judged on the quality of the science they contain, rather than on who the authors are and where they come from.

Charles Weiss

Georgetown University

1. There is no academic focus for research on the ensemble of excellent questions posed in this Request for Information. I am not aware of a source of money specifically intended to support such research. Nor is there a really good journal or professional society devoted to addressing these questions as they cut across the different sectors of the economy, especially the ones devoted to the impact of broad policies on innovation, overall and in specific sectors. Even OTA did not take as broad a view as some of the questions on the OSTP list, and OTA unfortunately failed to establish an academic base from which these questions could be systematically pursued across the economy and that would have survived its unfortunate demise.
2. Innovation in 'Legacy" sectors like energy, the electric grid, health delivery systems, and sustainable agriculture requires attention not only to R&D, but also to the incentives that favor existing technology and the numerous obstacles to the introduction and scale-up of disruptive innovation that would match innovation to human needs like efficiency, sustainability and public health. This in turn requires attention to all stages of the innovation process, not just research, development and the "valley of death," which are the prime foci of US innovation policy. The sum of these sectors adds up to a significant proportion of the US economy and the obstacles to disruptive innovation in these sectors are major hobbles on US growth and competitiveness.
3. Stovepiping at the NIH makes it difficult to fund cross-cutting areas, especially those involving engineering, such as medical instruments and devices. There are analogous problems in energy and other sectors.
4. Finland has a number of innovative institutions, including an institute for the future that serves as a focus for long-range planning. Congress has abolished the OTA, but the Executive could use an official locus with an explicit mandate for long-range planning and research on innovation, beyond the consultant reports produced by IDA. Such an institute could point out areas where incentives to producers are inconsistent with efficiency and sustainability, and highlight obstacles to introducing innovation, even if the political difficulties are insuperable for the moment.
5. Restoring an Innovation culture in manufacturing is particularly challenging. The MIT study points to the need to reestablish the "industrial ecosystem" of consultants, technical services, university curricula, applied research labs, etc. There is a need for a change agent that can orchestrate and press for such a thoroughgoing change.
6. Support is needed for training science students to communicate with the public, and for introducing science and technology into the discipline and curricula in international relations, which is deeply enmeshed in technology but is notoriously technophobic.

Natasha Welcher

Center for Open Science

Promote reproducibility in the sciences, but also support the training of methodology and reproducibility practices.

Shalom Wertsberger

Saltamar Innovations

Sir,

My name is Shalom Wertsberger; I am an individual inventor, an angel investor, and a registered patent agent with the United States patent office.

Below are my comments and suggestions for enhancing American Innovations. I allowed myself to provide my comments not in the order they were presented, as I believe that the comments to other items will provide the background and support to my conclusions and proposed steps.

I. Observations and background

1) Innovation trends:

a. As an inventor and angel investor I witness the lack of access to necessary resources both in capital and in knowledge by small, individual inventors and small businesses. I also witness the greatness and weaknesses of institutional innovation, primarily lackluster motivation and disconnect from the business climate. While I am aware that academics identified institutional innovation ass critical, I would submit that the conclusion ignores the glut of researchers in academic institutions, and the amazing potential of small industry and individual inventors driven by necessity and thinking out of the box. While institutional innovation is of course highly important and should be encouraged, the individual and small inventors have been pushed to the side. Later on I will propose some steps to alleviate that problem.

b. Historically, some of the largest, groundbreaking technologies came from individuals, whether in products or in methods. Individuals like Edison, Tesla, Ford, and others all operated outside of academic institutions. Many of the greatest inventions of our times came from privately held research laboratories, a trend that now has gone the way of the dinosaurs. I would like to propose that abandoning the innovation by the small inventors and the destruction of private research laboratories is a step in the wrong direction, and steps may be taken by the Federal Government to provide support for both the academic environment and the private sector.

c. The high particularity of science nowadays makes an advanced academic degree a necessity for any funding of research. However, thinking out of the box often requires some ‘fuzzy knowledge’ that is not bound by the ‘mathematical model’, and the ability to look at the phenomenon or problem itself, and innovate in thinking. Then comes the reality of things, the identifications of problems, required knowledge, and often a solution for those problems. While the highly advanced professional will place higher trust on the known, the innovative individual who is less trained in the field often may bring the initial idea as a seed. There is no question that science demands the highly trained individual for all high tech inventions, this is often a second step, rather than a first,

d. DARPA and other government institutions became more and more politicized. Additionally I urge looking at the record to see how many items were funded lately by DARPA, even at low funding levels, without a PhD with strong record of accomplishment. This attitude is understandable to reduce failure risk, but in innovation, it is counterproductive.

e. SBIR similarly requires the individual to ‘bring’ the academician. In my experience this is a chicken and egg problem: the inventor first has to identify the right academician willing to work on the project. The academician (and the institution) has little time and sends the inventor to bring money. The inventor

– likely experienced at problem solving – is the absolute wrong person to fight the bureaucratic maze. The academia is too busy. The idea is dead.

f. Therefore, I submit that the Federal Government should foster easier access to match ideas with the right institutional research, providing incentives for the institution, the scientists, and the inventors. In my opinion the existing framework does not meet the needs due to strong bias towards institutions and high level academic degree.

2) Entrepreneurship

a. I am an angel investor, and in meeting with other investors learned quite a bit of the chilling effect that the latest anti-patent legislation created. It is not hard to see that the numerous opportunities an infringer has to attempt patent invalidation, and even to exhaust all resources of a small patent owner, has a strong chilling effect on the willingness of investors to invest and on the willingness of inventors to begin a business.

b. In my other role as a patent agent I often talk to inventors who would not continue with a promising product because of a realization how badly the intellectual property field is tilted on behalf of the large, often multi-national corporations. The America Invent had a strong and chilling effect on many inventors that see little reason to invest their life saving for the benefit of the infringers. This causes those inventors who can to rely on trade secretes, and others avoid innovating at all. By way of example, a growing trend which is in response to the continued devaluation of software patents deals with renting algorithms for processing data without providing any information about the algorithm, which is kept secret. The knowledge of how such algorithms operate will likely die with the businesses that developed them. This is in direct contravention to the constitution and the spirit that guided the founding fathers of allowing inventors AND society to benefit from innovation.

c. On the other hand it is quite clear that true patent trolls are not deterred by any of enacted and proposed legislations.

d. It is clear therefore that while the patent allowance rate has increased, the value of patents have been severely degraded, and continue to be degraded by the continued legislative attempts to get small inventors out of the innovation arena, by one guise or another.

3) The US 'industrial Commons' was build by much small business that grew, and competed, even as medium size businesses. The American automobile industry grew by a very large number of brands, that competed, got intellectual property protection, and created the best vehicles in the world. It failed with consolidation and the concept of 'too big to fail'. The US electronics industry innovated and grew when many small and medium companies flourished, and while the companies became multi-national, the benefit to the US economy grew weaker as consolidation took place. So happened din so many other fields: Consolidation has short term efficiency benefits, creates a behemoth, which fails after relatively short time, destroying the field.

therefore, I believe that it is a strategic interest of the US to prevent growth of mega corporations. This can be done by tax legislation and by regulatory oversight. A mega-corporation should be viewed as undesired and suffer significant consequences that would encourage the creation of many smaller corporations.

4) Rebuilding manufacturing is, amongst others, requires having excellent supporting professionals. The fact that almost every job nowadays requires a college degree is counter productive to the US economy. The Federal Government should support trade schools, and direct efforts to having graduates of such school be well compensated. While I do not believe that the US can or wants to compete based on simple labor wages, creating automated manufacturing will require local, small innovation of the local machinist, welder, model maker, electronic technician, and machine operator. To that end the Federal Government should encourage states to create vocational schools, and promote the perception of trades

people. Easing transformation of experienced tradesperson to the university would likely also increase innovation. Therefore, I propose to raise eligibility to more favorable university loans at a later age, say for people in their 30's. Doing so would a) make the students better motivated, and b) allow the universities benefit from real life expertise.

5) The present intellectual property arena is challenging: more and more the small inventor is removed from effective patent protection, while the larger player use their patent protection to crush small innovators. This trend must be reversed, lest the US economy and would become a hostage of the multi-national corporations.

II. Proposed concrete steps to improve innovations in the United States

In order to improve innovation and better the US economy in the long run I believe the Federal Government should:

1) To improve innovation, the Federal Government should

a. increase the ease of innovation to small, non-institutional inventors as well as for the institutions by creating bodies, either federal or by federal encouragement local and private, that will do an initial evaluation of ideas submitted by individuals, and if those ideas show promise, direct the inventors and facilitate connection between the inventor and academic personnel Cooperation resulting from such initial review/referral will enjoy faster track to funding, to provide added incentives to inventors, academicians, and institutions. Referrals and cooperation with industrial partners should also be encouraged and supported, after an initial review.

b. If cooperation as described above seem successful or gets support from several academicians, the Federal Government should facilitate connection to industry and inventors, at a relatively early stage.

2) In the area of patent law

a. Strengthen protection of true experimental and research use of bona-fide innovators (except where thee nature of the invention is for research/experiments)

b. Limit real patent trolls operations by

i. Presenting meaningful limitations in patent litigation, based on plaintiff real party of interest size and plaintiff real party of interest legislative history in patents involving more than one invention and/or field.

ii. change the structure of protection if at least one of the original inventors/applicant owns a majority share in the patent and proceeds, and qualifies as small entity

iii. iii) Strengthen the exhaustion of rights doctrine for individual and small users.

c. Support patenting, and patent enforcement by small entities:

i. Repeal, revoke and reverse most if not all of the provisions of the America Stop Inventing Act. Most importantly the post grant review, third party reexamination, and willful infringement provisions, and strengthen the protection for one's own disclosure ("grace period").

ii. strengthen the small entity provisions of the patent office by providing preferential prosecution

iii. Bring back software patents, perhaps with shorter time to live, but with accelerated examination

iv. Discourage and if possible stop all current legislative efforts to weaken the US Patent System, in the guise of dealing with 'patent trolls' Define precisely what a patent troll is and deal with it on a singular basis

v. Limit steps which may be taken by a large infringer litigated by small and medium entity plaintiff, to prevent outspending, instead of justice

d. Provide legislative provisions for inexpensive elective mediation in patent cases. Mediation will be carried out by persons experienced in both the technical and patent law, the selection of mediators being done either by agreement between the sides, or by assistance from an administrative authority. While the results of mediation are not necessarily final, the courts will consider the results of such mediation as impartial expert opinion, and consider such opinion in determining the outcome of such dispute.

e. Provide clear legislative and judicial guidelines to increase patentability and incentive for pioneering inventions

f. In order to increase efficiency in the USPTO, enact a system where quality of both patent allowances AND REJECTIONS are scrutinized, and offer examiners compensation by number of claims. Furthermore, allow and encourage multiple dependent claims at many levels , while allowing the Examiner to elect a single interpretation of multiple dependent paths. This will speed up prosecution and provide a more comprehensive protection.

g. Offer limited time stay of action in a patent application

3) To recreate the 'Industrial Commons', the Federal Government should consider any permanent corporation that can dominate a field of endeavor a strategic threat, and a major impediment to US innovation. to deal with it the Federal Government should

a. Establish a field of endeavour dependent maximum desirable size, expressed by annual income, and optionally certain other parameters.

b. Tax rates for corporations exceeding such size would double for each multiple of the size.

c. Corporations may be formed for specific projects, on a temporary and annually renewable after review basis, which will be exempt for that duration.

d. Definition of a corporation as too large shall be made with an average of two-three years.

I believe that the results will be that mega-corporations will break themselves up to smaller, independent divisions (as otherwise monopoly laws will be triggered). The economy will gain from having additional jobs, corporate owners will now spread their risk over many entities, competition will gain, innovation will flourish, and the US will rid itself from the risks of corporations that are "too big to fail". It will also limit the exposure of the US to imported money taking over a complete field. Clearly this is more than asked, but as part of innovation I dare offer that solution to bring

4) To bring manufacturing back to the US the Federal Government should begin a strong program to qualify high level tradespersons – machinists, welders, programmers, etc., such that when manufacturing, and more specifically automated manufacturing attempts a comeback it has the required infrastructure.

5) While I believe student loans are a great tool to improve general education, special favorable and preferential loans should be made available in STEM, and more specifically for persons who have selected real world work or certain military experience prior to commencing academic training.

Julian Wills

I strongly advocate the following suggestions:

1. Make sharing of data and research materials the default

2. Ask federal agencies to dedicate a small portion of their research dollars toward replication of important results

3. Promote transparency across the entire research lifecycle, including preregistration

4. Support the development of infrastructure to increase discoverability of research, regardless of whether it was published

5. Promote and support training of methodology and reproducibility practices

Pamela Young

Texas Foreign Language Association

Please consider that languages are essential to a well-rounded education and global citizenship. The process of learning another language allows students to approach the world from different perspectives not reflected in their culture at home. It allows them to process information outside the confines of the society in which they live. It helps them understand that their opinions are not the only opinions, and not always the right ones. The study of languages breaks down barriers between people and countries by allowing them to appreciate differences in perspectives and opinions that could help them develop diplomatic and business relationships that can lead to peace and profitable business relationships.

Beyond diplomacy and business, science and technology can benefit from the improved communication between scientists and technologists from various countries. The contributions from various sources aided by an improved ability to communicate in more than one language can lead to the development of vaccines and medicines, for example, in a more timely fashion. It can also lead to great leaps in technology that could benefit the human race.

If this is not enough to convince one of the necessity of learning a second or third language, consider how important it is to national security. Without the ability to understand what is being said by another person, one must rely on a third party to translate. Depending on that personâ™s intentions, many things can be lost in translation. How much better it would be to be able to communicate directly with the person, or at least be able to understand what the interpreter is saying, instead of simply trusting that what is said in one language, is what is being communicated in the other.

In order to make that happen, we must start educating our students at a much younger age for a much longer sequence of study. Language proficiency does not occur overnight and requires a sizeable investment of effort on the part of the student and the teacher. Not only does it require class time, but study abroad. Obviously, the latter requires money to cover the expenses of travel, lodging, and tuition. The money for salaries for teachers for the younger students needs to be made available, as well as scholarships for study abroad for older students and teachers. Since language evolves over time, refresher courses are a must for teachers so they can remain current in the latest terminology in that particular country.

Stan Young

National Institute of Statistical Sciences

Dear Sir/Madam:

It has been noted that 80-90% of research claims can not be reproduced.
There is essentially no effective oversight.

Science would be more reproducible if whenever research results are published that the data used in the research is placed in a data repository such as Dryadd.com. Also from the very beginning of the federally funded research process, the work should be done so that the data "can" made public.

The ostp memorandum of Feb 2013 should be vigorously followed up with all government agencies.

With public access to data, other scientists can carefully examine papers that are important to their work and "normal science" can operate to provide some level of oversight.

Jianlu Yuan
Center for Open Science

The government should require that scientists share their data and research materials, or at least those scientists who conduct research through federal grants. America cannot continue to innovate and collaborate on science if certain researchers are secretive and protective with their results.

Bill

Figure out a way to give inventors a real incentive to invent!

ROYALTIES!

If song writers can get royalties for every time a song is performed or played on the radio, SURELY we could figure out a way to do the same for inventors.

Anonymous

The advancement and innovation of nowadays technology had naturally brought forth a plethora of interests and passions of many young adults and the exuberance and the enthusiasm of younger generation. This natural flow of engagement had trended and foraged the skills and the capacities of many brilliant minds.

The strong connections between science and innovative technology had undoubtedly essential to the trends of economic market and the manufacturing industries. It is fascinating and wonderful we live in this day to appreciate the development and the advancement of the current economic growth. The work force had intricately motivated the intrinsic learning and the development of functional skills to adapt and to adjust to the demand and the task force. Strategies were to deployed to ensure and sustain the pacing status and expected growth which include the importance of research and scientific studies to strengthen the factors and the driven forces for innovation and for improvement. The overall priorities for strengthening the advancement and innovative technology development should be geared towards scientific research and advancement of medicine.

As leading authorities and outstanding examples to the rest of the world, the priorities of science and technology advancement should be delegate resources and efforts to the everlasting needs of medicinal development and improvement.

Anonymous

1. Make sharing of data and research materials the default

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5. Promote and support training of methodology and reproducibility practices

Anonymous

In response to ""(11) Given recent evidence of the irreproducibility of a surprising number of published scientific findings..."".

It is important that a clear distinction is made between exploratory and confirmatory research and to promote confirmatory research.

Exploratory research is affected by the many degrees of freedom that any researcher has (e.g., sample size, selection of the covariates in the analyses etc.). Because researchers are clearly encouraged to find positive results, these degrees of freedom are too often used strategically and inflates error rates in scientific findings by a huge proportion.

Confirmatory research is done by pre-registering methods and analyses before data collection, using repositories such as http://opensciencframework.org/.

Mandatory pre-registration would increase both the transparency and the reproducibility of research findings. Sharing (anonymized) data and materials should be also encouraged, as it make direct replication studies much easier.

Anonymous

Fund infrastructure for data and results that have been, and importantly, have NOT been published to allow science to progress in knowledge with both positive and null findings.

Anonymous

I think there needs to be a much larger focus on reproducible science. For example:

- Some portion of research funding should be allocated specifically to replications of important findings.

- Support should be given for training people in conduct reproducible science.

- The entire research process should be incentivized to be open, from start to finish. For example, requiring preregistrations or making all research materials and data publicly available in order to publish.

Anonymous

Negative experiments never get published. Making the scientific process more transparent would help greatly by allowing scientists to publish negative results (even if it is anonymously) By doing so, a future researcher in this field would not waste tons of time studying, attaining funding, experimenting on something that someone in the past already figured out failed but did not publish the results of. Instead, given new policies, the new researched would be able to determine WHY the previous scientist failed and perhaps come up with a new solution.

Anonymous

One of the reasons for allowing a more transparent way to manage scientific data is to save numerous scientists time and resources. Currently, scientists have an incentive to publish only their positive results. If their experiment succeeds, they will post it and get money from it. This inherently skews the results. If a scientists does say 100 different experiments about nearly the same thing (they are in fact 100 distinct experiments and not just repeated trials or cases), and only 1 of them succeeds, he will only post that one result. Everyone will take this one result to be truly correct and be fooled into the wrong direction. In simple statistics, if you take a sample of 100 different experiments using 100 different independent variables, then you are likely to have 5 pass (given p value of .05). There could literally be NO CAUSE AND EFFECT relationship at all. But the experiments would still hold true. This is bad. This needs to be fixed.

Anonymous

Reproducibility of scientific projects is of grave concern to the US people. We need to be able to recreate whatever a scientist determines in his lab. This will allow us all to easily determine what advances the scientist made, determine how to improve upon his advances, and eventually lead to a greater breakthrough than originally intended.

Anonymous

Corruption sucks the life out of everything. Right now, many areas of law don't make sense, get in the way of ordinary pursuits, and create odd privileges for already powerful organizations. Similarly, high-profile political disputes can't be separated from an overall innovation strategy.

* Our public schools use a factory analogy, where students are either apprentice workers on an assembly line or, worse, the products of an assembly line. This isn't suitable for any purpose of education in the world we live in, and it doesn't reflect our values. This system greatly limits students' knowledge of available opportunities. It especially makes it hard to teach skills needed for innovation and entrepreneurship. I recommend an explorer analogy, where kids are expected to learn proactively from sources that aren't school-specific.

* Stop setting a goal to grow the pipeline of STEM workers. This is a perpetual scare, and the problem is always that there aren't enough well-paying jobs for the people in the pipeline. A more useful goal would be to increase overall public appreciation for STEM knowledge and skills. In particular, educate against perceptions that technical disciplines are either intangible nonsense or exclusive magic, and teach the workings of scientific institutions in schools.

* Speculative fiction is important as a way to conceptually prototype the future. Not all speculative fiction does this, and not all science fiction is speculative fiction. Create a specific program to fund fiction that prototypes the future.

* Open access to scientific research is necessary. There are many reasons why interested non-scientists might need access to raw science, and these are often the people who are least able to select a specific article or journal to pay money for. In particular, amateur tinkerers and patients with unusual medical conditions would benefit from open access to scientific research. It might be necessary to separate initial publication from curation in order to manage competing concerns of covering costs, allowing any scientist to publish, allowing open access, and managing the reputation of individual studies. A basic version of this is the arXiv; there's plenty of room to invent more sophisticated versions.

* Some distance is needed between university research and corporate research in order to preserve the complementary advantages of the two models. At least in medical research, this separation is too thin, and much of that comes down to where the money comes from. University researchers shouldn't worry about patent secrecy or that the people they're trying to help are poor, and corporations shouldn't be responsible for the early stages of the drug research pipeline.

(11) Require government-funded studies to follow a publishing model in which the journal makes a commitment based on proposed methodology, before the study is conducted. This frontloads risk, helps correct a bias against publishing negative results, and reduces the waiting time between getting results and getting them published.

(15) The first investment is in people. Universities can copy Oregon's plan to charge students a percentage of future income rather than up-front tuition. Beyond that, there's basic income and a more proactive social safety net.

(18) Campaign finance reform. Offshoring wasn't a mere accident.

(17)(19) The FDA uses a fairly centralized, rigid process for approving new drugs. There's room to open this up with staged approval, where earlier-stage experimental drugs are available in limited ways. There could also be a role here for a private certification market, where NGOs can set their own standards and doctors can choose which ones they think are appropriate to match the circumstances. This approach is unusually sensitive to implementation details, but it has a lot of potential benefits. In particular, a hybrid approach could be more resistant to decay from regulatory capture or perverse market incentives than either approach alone, while being more adaptable than the current centralized approach.

(20) Fund infrastructure projects to help make cities more walkable and compact. Also, keep in mind that gasoline taxes indirectly tax urban sprawl.

(21) Patent policy needs to be tailored for the time an innovation is useful. In software, new advances can be obsolete in just a few years. This means that the scope of patentable software inventions needs to be altered so that only inventions profound enough to remain relevant can get patents.

(10)(24) Nutrition research needs dedicated funding, and lots of it. Sound nutrition interventions are much cheaper than other medical interventions, and commercial incentives aren't conducive to adequate, honest investments in this area. Agriculture policy currently works against what we already know about nutrition. It needs to be restructured to support public health.

Anonymous

The public availability of scientific materials and the sharing of data are essential for the health of the scientific process going forward.