NEW MEXICO STATE UNIVERSITY RESPONSE TO OSTP FOR REQUEST FOR INFORMATION FOR NATIONAL BIOECONOMY BLUEPRINT

While the following considerations were developed to address challenges in technology transfer in university settings, they apply generally to broader settings of making the products of basic science marketable and specifically to the life sciences, which share a number of traits with university-developed innovations. In both cases, thoughtful strategies are needed to advance early-stage, high-risk technologies in challenging financial landscapes.

In April 2011, the National Advisory Council on Innovation and Entrepreneurship (NACIE), a subgroup of the U.S. Department of Commerce's Office of Innovation and Entrepreneurship, published a response to a request from then-Secretary of Commerce Gary Locke, who had charged members of NACIE with devising policy recommendations to "facilitate economic growth through entrepreneurial activity, the commercialization of new ideas and technologies into high-growth, innovation-based businesses, and job creation" (www.eda.gov/NACIE). NACIE's initial reply, *Letter to Secretary Locke: Recommendations to Facilitate University-Based Technology Commercialization* was followed by a more comprehensive *Report to Secretary Locke: Improving Access to Capital for High-Growth Companies* (June 2011). The majority of the material in the following sections is derived from these publications.

Moving life science breakthroughs from lab to market:

What are the barriers that keep medical breakthroughs from coming to market in a reasonable amount of time? Can federal agencies alter present practices to ensure treatments come to commercial markets more quickly? Would changes in the Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) programs alleviate some of the recognized barriers? Are there alternatives to the dominant venture funding model? If so, do such alternatives feature a role for government agencies?

U.S. researchers continually produce world-leading innovations in the life sciences. The expertise to develop these innovations, however, is just one component necessary to advance new products to commercial markets. Presently, medical breakthroughs take too long to reach market and the process for commercialization is too variable. Linear models whereby federal funds underwrite purely scientific research resulting in engineered solutions to medical challenges, which must be patented before testing, production, and distribution is not sustainable. In some cases, the original challenges have fundamentally changed before bioengineered solutions can arrive on markets. In others, the cost of RDT&E with flawed intellectual property management discourages firms from investing in the first place. While funding and support for basic research is essential, continued and expanded access to resources for other components of commercialization are equally imperative. The primary barrier to technology transfer is lack of a process that incorporates commercial concerns from the start of research development, as well as a lack of dedicated resources to support and sustain that involvement.

Successful commercialization activities depend upon concerted collaboration by stakeholders from a range of backgrounds: researchers, technology transfer professionals, legal experts, business and marketing specialists, industry representatives, entrepreneurs, investors, government bodies, and economic development organization agents. Creating opportunities for these parties to closely work together throughout the innovation development process and incentivizing technology transfer activities for all involved is essential.

Several strategies have been recommended to universities to facilitate this sort of engagement. Institutions are encouraged to not only promote the importance of technology transfer, but also to encourage participation in related activities by incentivizing researcher involvement in commercialization (which is rarely incorporated in faculty promotion and tenure policies). Universities are also urged to make reporting and compliance obligations as simple as possible, to allow funded researchers to devote their time to other activities. While the reporting requirements for federally-sponsored programs vary by agency, and these requirements pose significant time staff, time, and resource challenges, examining ways to streamline these practices would be worthwhile. Further, institutional policies that create friendly environments for researchers and others engaged in the commercialization activities can help pave the way for new and enhanced streams of revenue.

One of the most powerful drivers of successful commercialization is the establishment of policies and programs that foster productive partnerships between researchers and industry. Many universities are engaged in the development and expansion of initiatives that facilitate industry access to university expertise and resources. One aspect of these efforts is creating spaces and events in which current and potential partners can meet, both informally (e.g., sponsored professional conferences and networking events) and formally (e.g., shared laboratories and facilities, student-faculty-industry research teams working on common goals, and research parks). Another is focused funding of program models that develop and advance technologies based on market pull research and establish early-stage relationships between university and industry partners (e.g., proof of concept programs). Specifically, systems that provide joint access to federally-funded intellectual property can prove extremely successful in merging the interests of researchers and industry partners.

Similarly, the adoption of supportive government policies and agendas can help to address commercialization challenges. Entrepreneurs are the engine of economic growth; those engaged in high-risk potentially high-reward research are the key. Large institutions, both corporate and academic, might not have the flexibility take such chances. Individual faculty members or those in small groups are more likely to succeed. However, efforts by individuals or very small groups are not sustainable . One of the best ways federal agencies may provide support is through the addition or enhancement of collaborative commercialization-supportive components in funding opportunities. For instance, greater inclusion of commercialization plans in proposals and deliverables will both emphasize the importance of these factors in funded research and provide

resources to allow awardees to devote adequate time to plan and execute related activities. Similarly, incorporating market potential evaluation as an early-stage milestone in research benchmarks can help to ensure that researchers keep commercialization considerations in mind and will help to quickly identify those innovations with significant market potential and those which may fall short. Above all, federal assistance in subsidizing early-stage technologies in ways that best mitigate the risks associated with such projects is crucial.

SBIR and STTR programs are among the best examples of this type of funding. While these grants provide researchers strong support as currently structured, modifications to these models could enhance them as drivers to commercial success. One possibility is incorporating into the current SBIR/STTR structure (i.e., Phases I, II, and III) a "Phase 0," which could be used by universities and other institutions to fund commercialization-supportive activities such as developing prototypes, identifying and compensating mentors, and devoting time to assessing market readiness of emerging technologies. Additionally, streamlining the SBIR/STTR approval timeline could be extremely helpful to applicants and awardees. Presently, the average wait time of 6-12 months from application submission to notice of award can be detrimental to researchers and partners attempting to launch start-ups and facing severe financial constraints. Reducing the approval process to, ideally, three months would give awardees a chance to better address gaps in capital that can limit, or even end a project. Additionally, changes to existing phases could be beneficial. For instance, Phase I funding guidelines could incorporate a voucher requiring a dollar-for-dollar match from a private sector partner before it could be cashed in. Grantees could be required to locate in or to contract with a research university. Federal funds could be made available for Phase III grants, ensuring that ventures with strong foundations are not left stranded after significant investment of resources and allowing them to take the final, crucial steps to market.

Public-private partnerships:

What are successful models for public-private partnerships? What would public-private partnerships in the bioeconomy look like, and what goals would they pursue? What opportunities exist for collaboration in the pre-competitive space, and is there a role for government here?

The federal government can play a significant role in shaping favorable environments for public-private partnerships. A number of excellent existing programs serve as models in this arena. For example, the National Institute of Standards and Technology's Advanced Technology Program (ATP) provides public-private partnering opportunities for universities, non-profits, and companies at all stages of development. Its focus on industrial technology needs emphasizes the importance of market-based, demand pull research effectively merges the needs of private industry with the expertise of public institutions. Employing this model in federal initiatives, such as the EDA's plans to focus on regional innovation clusters (RICs) to stimulate economic growth and create jobs, will serve to extract the greatest benefits from all programs. By making

procedures and processes as efficient as possible for partners at all stages of development, the federal government can ensure the strongest collaborative efforts.

NACIE provides recommendations for both early and later stages of high-growth initiatives. The first early-stage recommendation is providing refundable tax credits for individual angel investments, a program with demonstrated success in pilot markets (e.g., British Columbia). Safeguards in such an initiative, such as limiting the program to those investing in accredited Qualified Small Businesses, would offer greater chances of successful ventures. Second, extension of capital gains tax exclusions outlined in the 2010 Small Business Jobs Act could lead to greater investment in early-stage Qualified Small Businesses. Additionally, an extended nine-month rollover period on capital gains could lead to later-stage investments. Third, implementing a100% exclusion on corporate income taxes for Qualified Small Businesses in their first year of profitability and a 50% exclusion on the following two years of profitability could create a safety net in early stages and augment capital for later investment in the venture. This recommendation is noted by NACIE to have significant potential impacts in life sciences research and commercialization, where technologies typically require much longer development times to reach marketability. Fourth, as noted above (see response to "Moving life science breakthroughs from lab to market), shortening average approval times of SBIR/STTR grants would make the awards better-suited to the considerable early-stage capital needs of high-growth projects. Fifth, amending current Small Business Investment Companies (SBIC) program regulations to allow for a reduced approval process and interest rate payment reductions, along with expanding eligibility to certain angel investment groups, micro-VCs and venture development organizations (VDOs) could greatly impact private sector interest in high-growth investments.

NACIE also provides three recommendations for improving later-stage access to capital for high-growth companies, ensuring that the resources invested in launching a venture are well-spent as the project is allowed continued growth. First, the government should commit to sustaining current capital gains tax levels at 15% for funds invested in businesses, rather than following through with increases mandated by Bush Tax Cut expirations and Patient Protection and Affordable Care Act. This could mitigate risks of venture capitalists considering investment in high-growth firms, whose returns on investment would be negatively affected by these tax increases. Second, the U.S. Securities and Exchange Commission (SEC) is encouraged to mediate in the Spitzer Decree, which prohibits use of investment banking revenue to cover costs of market research in start-ups. This type of research is essential to spark investor confidence and is necessary to successfully execute IPOs needed for continued funding. Finally, NACIE recommends mitigation of Sarbanes-Oxley obligations for smaller public firms, allowing these organizations greater freedom in raising later-stage capital through public stock offerings

In planning future initiatives for enhancing public-private partnerships, it is beneficial to consider past successes and build on these models. A prime example in this area is the work of the late Dr. George Kozmetsky, who, in 1977, founded the IC^2 Institute at the University of

Texas at Austin. Through collaboration with partners such as the Austin Technology Incubator, the Bureau of Business Research, and the Global Commercialization Group, the IC^2 Institute continues to affect the convergence of knowledge and technology transfer. Similarly, NASA's Commercial Technology Network supports an array of programs that assist start-ups built around NASA technologies to develop into stable businesses. With Field Centers, Regional, and National Technology Transfer Centers, the program has a searchable TechFinder database for potential collaborators and an impressive record of successful partnerships.