

Building a 21st Century Bioeconomy

Comments by the Advanced Medical Technology Association (AdvaMed)

Overview

AdvaMed is the world's largest medical technology trade association, and represents manufacturers of medical devices and diagnostics. AdvaMed members account for approximately 90 percent of these products consumed in the United States and 50% of those consumed worldwide. The companies in our industry produce virtually everything used in medicine that is not a drug—from products as simple as tongue depressors and surgical gloves to the most complex cardiac implants, imaging machines, and molecular diagnostics.

AdvaMed is enthusiastic about the President's vision for a national bioeconomy blueprint. We believe that our industry, along with other life sciences industries, can be a key driver of future economic growth and job creation. But achieving that potential will depend on a new commitment to comprehensive public policies to maintain America's leadership in this century of the life sciences.

Economic potential of medical technology

The medical technology industry is not only a source of life-enhancing and life-sustaining treatments and cures; it is an important manufacturing industry and a driver of current and future U.S. economic growth. 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.¹ Medical technology jobs are good jobs, with wages exceeding those for the work force as a whole by 40 percent and exceeding average wages in other manufacturing industries by 22 percent.²

While employment in other manufacturing industries has been declining, the medical technology industry has been expanding. Between 2005 and 2007, medical technology employment grew 20.4%, adding 73,000 jobs.³ During the recession, between 2007 and 2008, MedTech employment dropped 1.1%, compared to 4.4% for manufacturing as a whole.⁴

The medical technology industry is also a strong source of exports and is almost alone among manufacturing industries in consistently maintaining a favorable balance of trade. Exports in 2010 totaled \$36 billion, more than double the 1998 level.⁵

Part of the vitality of the medical technology industry comes from its strong base of small and start-up companies, which develop a disproportionate number of the breakthrough products fueling industry growth. A 2007 study by the U.S. International Trade Commission (USITC)

found a total of 7,000 medical technology firms in the U.S.⁶ The U.S. Department of Commerce estimated that 62% of medical technology firms had fewer than 20 employees and only 2% had more than 500.⁷ Even large companies in the medical technology space tend to be smaller than large companies in many other sectors. There are only four pure device and diagnostic companies in the Fortune 500 and none in the Fortune 100.

Another source of industry strength is its strong commitment to research. To fuel innovation, the medical device industry is highly research intensive. U.S. medical technology firms spend over twice the U.S. average on R&D. High technology medical device companies devote upwards of 20% of revenue to R&D.⁸

The medical technology industry is highly price-competitive. A study of medical device prices from 1989 to 2009 found that they increased, on average, only one-quarter as fast as the MCPI and 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.⁹

The future potential for American economic growth driven by the medical technology is great. World-wide markets for medical technology will expand dramatically as populations age in countries around the globe. In the U.S. alone, the elderly population will increase 32 million over the next two decades—a jump of 80%.¹⁰ Worldwide, the elderly population will reach 1.2 billion by 2025—and growth of the elderly in that year will be 3.5 times as fast as the population as a whole.¹¹

World-wide demand for medical technology will also be fueled by the exponential growth in middle-class populations in countries like China, India and Brazil demanding world class medical care. China's middle class alone is projected to exceed the entire U.S. population by 2015, and India's middle class could reach 600 million by 2025.

Growth in medical technology will also be fueled by scientific progress in this century of the life sciences, as fundamental discoveries in the life sciences and continued advances in computing, materials, engineering, and physics create the knowledge base for an explosive growth in the creation of new treatments and cures. To quote Dr. Laurence Summers, president emeritus of Harvard University and former head of the National Economic Council, "The 20th century was an American century in no small part because of American leadership in the application of the physical sciences...If the 20th century was defined by developments in the physical sciences, the 21st century will be defined by developments in the life sciences."

Medical technology and the other life sciences industries also have the potential to fuel economic growth by their role in creating a healthier work force. As a major driver of medical progress and improvements in population health, medical technology is an engine driving productivity and labor force participation, both significant contributors to economic growth and GDP.

Between 1980 and 2000, medical progress added more than three years to life expectancy. The death rate from heart disease was cut in half, the death rate from stroke was cut by one-third, and the death rate from breast cancer was cut 20%.¹² The economic value of the reduction in death and disability from heart disease alone has been equal to one-fifth of our total GDP.¹³

The Milken Institute has compared two alternative futures regarding the growth in chronic disease. Under one path, the current trends in growth in the incidence of chronic disease continue unchecked. Under the other path, the growth is reduced significantly by a combination of better prevention, better management, and continued technological progress in treatment. The difference between the current trend path and the more favorable path was estimated to be \$1.1 trillion in GDP annually by 2023, primarily because of the increased labor force participation and productivity as the result of better health.¹⁴ Similarly, the United BioSource Corporation examined the literature on the economic burden of lost productivity due to eleven chronic and two acute conditions. They concluded that the total drain on the nation's GDP in 2008 from lost productivity and labor force participation due to these conditions was as much as \$1.4 trillion annually in 2008.¹⁵

Need for better policy to sustain American leadership

Today, America is the acknowledged world leader in medical technology, as it is in the other life sciences industries. But that leadership is being challenged. Without new public policies to provide a level playing field between the U.S. and foreign competitors, America's leadership will be lost and with it an important engine of economic growth and manufacturing job creation. At a more profound level, if American leadership in the life sciences industries is lost, America's long-term future as the world's most powerful economy will be jeopardized. Thus, the President's efforts to develop the National Bioeconomy Blueprint are particularly timely.

A recent study by PricewaterhouseCoopers (PwC) found that the U.S. still leads on five key dimensions of medical technology innovation, but our lead is slipping on every dimension. On speed of regulatory approval, we now rank seventh out of nine countries. As they state, "The innovation ecosystem for medical device technology, long centered in the United States, is moving offshore."¹⁶ Indeed, a recent survey of AdvaMed member companies found that while companies projected employment growth over the next five years both in the U.S. and abroad, employment growth was projected to be more rapid abroad—in both percentage and absolute terms.

The slippage of American leadership shows itself in a number of ways. Medical device and diagnostic clinical trials—a crucial step in the development chain—are increasingly conducted outside the United States. In 2004, 86.9% of all medical technology clinical trials listed in ClinicalTrials.gov were carried out in the U.S. By 2009, that proportion had sunk to 45%. The cumulative annual growth rate of U.S. clinical trials 2004-2009 was lower than that of Brazil, China, France, Germany, India, the U.K., Israel, and Japan.¹⁷

First product introduction is also increasingly moving outside the United States, as firms find that they can get products approved much more quickly abroad. The average lag time between introduction of a complex product in Europe and introduction of the same product in the U.S. is now almost four years.¹⁸ Key products that have become available in Europe while languishing in the U.S. approval system include important clinical advances in such areas as heart disease, lung disease, obesity, and arthritis.¹⁹

The movement of clinical trials and first product introductions abroad is not only harmful for American patients, who find their access to the latest treatment and cures significantly delayed; it is also a drag on U.S. competitiveness. In addition to the economic activity generated by the clinical trials themselves, location of trials and early product introduction transfers expertise out of the U.S.

The recent sharp decline in FDA performance is striking and very damaging to industry competitiveness. Since 2007, the average review times for 510(k) products has increased 45 percent. The average time to review PMA products—the most complex and typically the most innovative technologies—has skyrocketed 75 percent.²⁰ Measures of consistency in review—such as the average number of times the FDA sends an application back to a company to ask for additional questions, the number of times reviewers change during the course of a review, and the proportion of times companies withdraw applications before reviews are even completed—have also increased substantially.²¹ It has become more difficult to get a timely and meaningful meeting with the FDA to discuss clinical trial design, and the time it takes to get approval to begin a clinical trial has grown substantially.²²

These failures at the FDA are a key factor driving clinical trials and first product introductions abroad. They add to the costs of American companies and undermine investments in new products. Small companies with promising ideas frequently do not survive because they run out of funds before they can get FDA approval and generate revenue. Improvements at FDA are one of the most important steps that can be taken to sustain American competitiveness and leadership. Fortunately, the current FDA leadership has acknowledged the seriousness of these problems and is making efforts to reverse these trends.

America's commanding lead in venture capital investment in medical technology is also eroding. As noted above, small, venture capital funded firms have been a key factor in creating the breakthrough products that drive industry growth. Comparing 2000 and 2009, venture capital investment in medical technology grew almost 60% in Europe and Israel and less than 40% in the U.S.²³ Overall, the availability of venture capital in other countries is growing dramatically. China now represents the second-largest pool of venture capital, followed by Brazil.²⁴

Not only is venture capital growth in the U.S. slower than abroad, growing regulatory and payment uncertainties in the U.S. are causing VC firms to rethink whether they want to invest in

the medical technology sector. Moreover, as they see longer time—and thus greater cost—in getting products to market as the result of these uncertainties, they are planning to invest the same amount of dollars in fewer companies and shifting investments more to companies that are further along in the development process.²⁵ This exacerbates what is often referred to as the “valley of death” problem, where promising clinical discoveries can receive support for very early stage research, but funding often dries up before the product can reach the stage where it is ready for regulatory review.

The U.S. reimbursement system has historically been relatively open to new technologies, and this has been a significant strength for the U.S. medical technology industry. The role of government programs is especially important. In 2008, Medicare and Medicaid together paid for medical care that accounted for an estimated 48% of total domestic sales of medical technology products.²⁶ Medicare policies are especially critical, because not only do program beneficiaries use a large proportion of medical technologies, Medicare payment and coverage policies are often the model for decisions by private insurers.

While the U.S. system overall has enabled rapid adoption of new technologies, current policies should be improved. For example, gaining a code for a new product—which is often a prerequisite for Medicare or private insurer payment—can take up to two years or more after a product gains FDA approval.²⁷

An additional important problem affecting medical technology innovation is the antiquated and inconsistent system Medicare uses for deciding what to pay for new laboratory tests under the Clinical Lab Fee Schedule. The new generation of molecular diagnostic tests is, in many respects, key to the future of medicine. They are the basis of the emerging field of personalized medicine. They can provide extraordinary precision and speed in diagnosis. They can be used for drug development and drug targeting. But the Medicare payment system does not recognize the value of diagnostic tests, and the payment any new test will be assigned is arbitrary and unpredictable. Such uncertainty creates a significant disincentive for companies to make the sizable investments necessary to develop these new tests.²⁸

Major changes in U.S. payment methods currently in progress pose a significant challenge to medical progress and need to be carefully implemented to avoid exerting a chilling effect on medical technology. The new payment modalities being created for Medicare by the health reform bill as well as payment innovations in the private sector are designed to encourage efficiency, quality, better coordination of care, and better management of chronic diseases. While these new payment paradigms offer the promise of a more efficient and effective health care system, the new systems also create some potential pitfalls that could negatively affect innovation and medical progress if the new systems are not carefully designed to encourage innovation.

The widespread adoption of an improved treatment or cure generally follows a typical path. The treatment is developed by a company or a physician. Following FDA approval (in the case of a drug or device) the new treatment is adopted by cutting-edge physicians and is recognized by insurance companies and other payers. If the treatment proves successful in practice, it gradually diffuses until it becomes the standard of care.

Without special protections for innovation, the new changes in health care delivery models and the application of quality standards to reimbursement risks freezing medical practice in place. New delivery models must ensure patient access to appropriate devices, diagnostics, and other medical technologies and must not penalize early adopters of new technology. The current quality standards are generally “process” standards—for example, for a given specific disease state, a certain course of action should be followed.²⁹ For example, patients presenting with a heart attack are supposed to be treated with percutaneous coronary intervention (PCI) within 90 minutes.³⁰ The new payment modalities embed these quality standards in the level of payment physicians and other providers will receive. Without special provisions in the reporting and payment system, providers who are early adopters of a new, alternative treatment—a new drug or procedure to replace PCI—will be penalized.

The same concern applies to adoption of new treatments that appear to be more expensive than the existing standard of care. Not only does the early adopter face a potential penalty on the quality side, but they also could be treated as inefficient because they are generating higher costs—even if the new treatment represents a significant clinical advance.

Providers could be penalized even if the new treatment actually lowers costs, if the savings appear outside the measurement window. For example, under bundled payments—where all providers treating a patient during an episode of care receive a single, lump sum payment—costs are measured across the episode of care. A drug-eluting stent that reduces costs over the long-term by reducing the need for repeat procedures would appear more expensive than a bare metal stent. So would a heart valve or a knee replacement that lasts for 20 years instead of ten years or other treatments that have better outcomes over a more extended period than the immediate episode of care.³¹

The final rule for Accountable Care Organizations, the first of the new payment modalities to be fully implemented has just been released. Despite the President’s recent Executive Order directing agencies to “seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation,” the proposed rule does not address these issues.

Trade policies of other countries—particularly in the developing world—are increasingly designed to foster home-grown medical technology industries at the expense of U.S.-based companies or to require U.S. companies to locate research and development or production facilities locally as the price of market access. For example, China has developed an “Indigenous Innovation” policy in its government procurement—which could well include the vast public

hospital sector—that is intended to require purchases of products with “domestic” intellectual property and to force the transfer of technology to domestic companies.³² Brazil’s has a stated policy to expand its use of domestic medical technology, including by providing 25% price preferences for government procurement (about half of its health care expenditures) and to use its product approval regulatory agency to favor domestic medical technology firms.³³ In addition, other countries are pursuing bilateral and regional trade agreements that will put U.S. manufacturers at a competitive disadvantage.³⁴

Competitor countries are also aggressively implementing tax and other policies that effectively lower the cost of research, development, and manufacturing of high technology, high value products such as medical technology. America’s failure to match these incentives creates an unlevel playing field for products developed and manufactured in the United States. The U.S. has one of the highest effective corporate tax rates in the world. For a typical small or medium sized business, the effective tax rate in the U.S. is 25.9%, higher than 31 out of 34 Organization for Economic Cooperation and Development countries and 58% higher than the non-U.S. OECD average of 16.4%.³⁵ The U.S. was the first country to establish an R&D tax credit, but 23 countries now offer a more generous credit than we do. Our reliance on temporary extensions of the credit means that it does little to stimulate investment, since it cannot be relied on for planning purposes. The credit does not cover building R&D facilities or purchase of equipment for those facilities, even though the decision to locate an R&D facility in a particular country certainly stimulates further R&D investment to make use of the facility.

Small, start-up companies have no access to the R&D tax credit until they actually have profits. This imbalance exacerbates the cash flow issues that often kill promising ideas and promising companies before they can attain critical mass and defeats the purpose of the credit—to stimulate research and development.

Other countries are experimenting with so-called “innovation box” or similar ideas that provide a reduced corporate income tax for profits flowing out of manufacturing or other activities based on research and development. It makes no sense for American scientists and engineers to develop breakthrough treatments here in the U.S.—and then ship the good manufacturing jobs needed to make those products abroad, because taxes here are so much higher.

An additional tax policy that harms American competitiveness is that the U.S. is one of the few countries among our competitors that maintain a territorial tax system. Other countries do not tax the profits that their companies earn abroad. In the U.S., however domestic taxes are only deferred until U.S. companies bring the profits home. The result: U.S. multinationals are penalized if they invest profits earned abroad in America instead of using them to build research and manufacturing facilities overseas.

In addition to general tax incentives, other countries provide targeted incentives for projects that offer jobs and economic growth, especially projects in high value-added industries. These

incentives include waiving or reducing taxes on the project, providing direct subsidies in the form of below interest loans or grants, or making land and infrastructure available as needed.

Developing countries have been particularly aggressive in working out special deals to attract job-creating projects. India, for example, is building a series of industrial parks expressly designed to attract medical technology investment and the jobs that foreign companies will bring.

The net effect of these strategic policies by other countries, combined with lack of effective American policies to level the playing field, have had the effect of dramatically shrinking America's favorable balance of trade for medical technology products. While the U.S. has maintained a favorable balance of trade, the surplus of exports over imports has been narrowing both in absolute terms and relative to the size of the export-import sector. In 1998, imports and exports together totaled \$24.6 billion and the trade surplus was \$6.6 billion—more than one-quarter of total trade. By 2010, total trade had almost tripled—to \$70 billion, but the trade surplus had shrunk by more than two-thirds—to \$2 billion, and the surplus was only 3% of total trade.³⁶

While America's commercial advantages have been slowly eroding, the fundamental superiority of America's scientific research and development infrastructure and its ability to turn research into commercial projects is increasingly challenged. America's science base, including basic research, the supply of scientists and engineers, and vitality of America's universities as centers of basic and applied research, is critical to the medical device industry, as it is to America's leadership in science and technology more generally. A number of studies have documented the relative decline of America's science base by such measures as R&D investment as a share of GDP, new patents as a share of the global total, global share of scientific researchers, and new doctorates in science and engineering.³⁷

Policy Recommendations

Despite these negative trends, American leadership can be retained and strengthened. A renewed government commitment to strategic policies to maintain medical technology competitiveness by leveling the playing field with foreign companies and governments is needed. The President's National Bioeconomy Blueprint is an unprecedented opportunity to help build America's future prosperity.

AdvaMed has advanced six key policy recommendations to assure America's continued leadership in medical technology. They are:

1. **Innovation in the life sciences must be a government priority.** Since the ability of the life science industries to thrive is affected by a broad range of government policies across many agencies, it is critical that that supporting medical innovation be a priority for the whole government.

- A. An office of medical innovation policy should be created in the White House. This office would have oversight responsibility for major proposed and current government policies to assure that they support medical innovation. The office would serve as a focal point for groups and individuals advocating for medical innovation and could develop an innovation index to track how well the United States measures up to its major competitors in policies to encourage innovation.
 - B. An “innovation impact” statement would be required for major regulations or other actions that affect the health sector. This statement would be analogous to an environmental impact statement. The goal would be to assure that every agency takes into account the effect of its actions on medical innovation and related domestic employment, and economic growth in promulgating government rules.
2. **The FDA review process must be reformed.** The FDA must set a goal of achieving a review and approval process that is as predictable, consistent, and timely as our European competitors, while continuing to assure that products are safe and effective.
- A. FDA must reduce total review times, not just time on the FDA clock, to a level that will significantly speed up review of both 510(k) and PMA products, including reforming the de novo process to make it an efficient and workable system for class II products with no predicate.
 - B. FDA must effectively implement least burdensome processes throughout its operations to eliminate requirements that are not necessary to protect public health.
 - C. FDA must streamline the IDE process to assure timely initiation of clinical trials.
 - D. FDA must develop a full range of guidance documents that identify FDA’s requirements for a specific product submission to ensure a timely and consistent review process.
 - E. FDA must adopt the risk-based review pathway for diagnostic tests.
 - F. The FDA must take steps to ensure that its staff is properly trained, has access to independent scientific and technological information, and to develop a program to monitor the predictability and consistency of the review process.
 - G. FDA must take steps to converge its regulatory practices with the principles established by the Global Harmonization Task Force.
3. **Payment policy must support medical innovation.** Medicare, Medicaid, and private insurers alike must assure that the new payment modalities established by health reform to provide incentives for quality and cost control also support medical progress, innovation and access to appropriate technology. The current Medicare coding and payment processes must be improved to allow more rapid recognition of new technologies.
- A. New payments systems such as accountable care organizations, bundling, and value-based purchasing should include specific provisions to avoid penalizing

- health care organizations or individual providers for offering patients the opportunity to benefit from new treatments that are not yet the standard of care.
- B. New payment systems should be carefully designed to support continued patient access to care appropriate for their individual needs and to recognize the long-term value of treatments.
 - C. CMS should reform the process of coding and determining appropriate payment to avoid delays of up to two years or more before a treatment can be properly recognized for payment purposes.
 - D. CMS should reform payment for new diagnostic tests to encourage the development of high value diagnostics and of personalized medicine.
4. **A vigorous trade policy must support export growth and provide a level playing field for U.S.-based manufacturing.** If trade barriers remain or increase, U.S. efforts to improve domestic competitiveness and expand exports would be undermined. Companies will relocate outside the U.S. to manufacture behind the barriers and foreign companies will thrive at the expense of U.S. competitors. Other countries are pursuing bilateral and regional trade agreements that will put U.S. manufacturers at a competitive disadvantage. Countries in the developing world are increasingly using regulatory policy to promote domestic industries or to force U.S. companies to locate research, development, and manufacturing within their borders. Small and medium size companies need additional assistance to become successful exporters.
- A. The President's National Export Initiative (NEI) should make bilateral and regional free trade agreements (and associated medical technology sectoral agreements) with developed and developing markets alike a priority, including ratification of the Korean-US free trade agreement, negotiation of the TransPacific Partnership free trade agreement and expanding the agreement to include additional Asia-Pacific countries, including Japan.
 - B. The Administration should continue its policy of vigorous opposition to non-tariff barriers to trade, especially use of regulatory policy to set up artificial barriers to imported products and to force local location of research and development and manufacturing by multinational firms. The Administration should support existing and new trade forums that allow government officials and industry representatives to work together to identify and address barriers to trade. FDA should be part of the team working with trade authorities and indicate that assistance to foreign firms seeking to meet U.S. regulatory requirements is conditional on fair treatment of U.S. firms by foreign regulatory authorities.
 - C. The Administration should make regulatory harmonization by developing countries a trade priority, including achieving a commitment next year to regulatory harmonization by 2020 at the Leaders meeting of the Asia Pacific Economic Cooperation forum, based on the principles adopted by the Global Harmonization Task Force.
 - D. Small and medium size enterprises represent the lifeblood of medical technology innovation. Exporting to foreign markets is particularly difficult for companies with little or no foreign trade experience. Under the NEI, US Government agencies – including USTR, SBA, and Commerce – should vigorously pursue

policies to assist small and medium size companies to overcome their lack of experience and specialized knowledge, and other obstacles to competing in export markets.

5. Strategic tax policies to level the playing field must be implemented. *American tax policy must support research and development (R&D) intensive industries at a level sufficient to level the playing field with foreign governments eager to attract American jobs and develop home-grown competitors to American firms. The R&D tax credit must be reformed and made more generous; tax incentives need to be created for keeping R&D based manufacturing in America. The medical device excise tax should be repealed.*

- A. The Research and Development Tax Credit needs to be made permanent; the level of the credit needs to be raised so that it is as good or better than the credits provided by our major competitors; the administration of the credit should be substantially simplified; the credit should support investment in building research infrastructure, including construction of facilities and purchase of equipment; and the tax code should provide additional incentives to invest in small and start-up companies with no profits, which create a disproportionate share of breakthrough treatments.
- B. Manufacturing based on R&D wholly or predominantly conducted in the United States should be eligible for a lower corporate tax rate to reduce the cost advantage that research and development intensive companies locating manufacturing abroad enjoy in the form of lower general corporate taxes, special tax breaks, and direct subsidies.
- C. The medical device excise tax should be repealed, since it absorbs resources that could otherwise be used for research and development or employment expansion and disproportionately burdens and raises the effective corporate tax rate for the medical technology industry to extremely anticompetitive levels.
- D. The United States should move towards a corporate tax system that provides greater parity with our major competitors in tax rates and treatment of foreign earnings.

6. The American research and development infrastructure must be sustained and improved. *American policy must support the maintenance and growth of an R&D infrastructure second to none, with special emphasis on creating the structures necessary to support translational R&D directed at commercialization.*

- A. America must maintain and expand its commitment to basic research and to graduate research and training programs through the NIH and NSF.
- B. Research programs that support moving research farther along the development spectrum toward actual treatments and that support start-up companies developing

breakthrough treatments should be improved and expanded, including increasing funding, eligibility, and maximum grant size for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR programs) and fully funding the Cures Acceleration Network. Additionally, the federal government should provide grant funding to states and localities seeking to establish or expand bioscience research and development clusters.

- C. Programs should be established to more effectively tap the vast intellectual resources of our nation's universities and academic health centers, including creating NIH funded Industry-University Cooperative Research Centers analogous to a long-standing and successful program at the NSF and providing federal technical assistance to establish best practices and improve the effectiveness of university technology transfer programs.

The detailed rationale for these proposals is described in "Backgrounder: The American Medical Technology Industry and American Competitiveness," which can be found on the AdvaMed web site at: http://www.advamed.org/NR/rdonlyres/F015B6D3-B805-4405-8F44-646D49265830/0/CAgenda_Backgrounder.pdf

In addition, some of these proposals are discussed further in answers to specific questions posed by OSTP in its Request for Information.

Responses to Specific Questions in the "Request for Information: Building a 21st Century Bioeconomy."

1. Grand challenges

As described at some length above, the grand challenge the U.S. faces in building a 21st Century Bioeconomy is to create and sustain an innovation ecosystem for the life science industries and to create a level playing field with competitor nations. Each of the six steps described above would contribute to that goal.

2. Constrained Federal Budgets

A number of Federal priorities are critical within a constrained Federal budget. These include:

--Maintain funding for the FDA. An inadequately resourced and managed FDA would be a disastrous choke point for all the life-sciences industries. The U.S. can lead in the life sciences only if the FDA supports innovation through a consistent and timely regulatory review process.

--Assure that pressures for cost containment do not lead to a hostile climate for medical innovation in the federally supported health programs. With regard to the specific issues related to the new payment modalities, suggestions are provided above. Other concerns are excessive cuts in provider reimbursement or inappropriate limitations on coverage of or payment for new technology in the name of cost control.

5. Barriers preventing biological research discoveries from moving to the lab to the commercial markets

It is important to recognize that moving discoveries from the lab to commercialization is a resource-intensive, high-risk business. Several steps would be helpful:

-- Research programs that support moving research farther along the development spectrum toward actual treatments and that support start-up companies developing breakthrough treatments should be improved and expanded, including increasing funding, eligibility, and maximum grant size for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs) and fully funding the Cures Acceleration Network.

--The flow of venture capital and other funding to start-up firms needs to be increased. A variety of tax preferences to encourage investment in these firms should be considered.

--University technology transfer programs vary widely in their effectiveness. Many, if not most, are viewed by device and diagnostic companies as difficult to work with. The Federal government should take the lead in helping technology transfer programs adopt best practices.

--The most important single step that could be taken right now for the device industry, as discussed above, is to improve the predictability and efficiency of FDA review.

6. Specific Changes to the SBIR and STTR programs

Current limitations that bar start-up firms with majority venture capital funding from eligibility for grants are too limiting, given the need for start-up companies to receive significant amounts of venture capital funding to bring products to market. These limitations should be eliminated.

In addition, in view of the rising costs of product development, the limits on the amount of SBIR grants should be raised and overall funding for the program should be expanded.

8. Challenges associated with existing private-sector models for financing

See the data described above on the drying up of venture capital funding for investment in medical device and diagnostic companies, especially for early-stage start-ups.

A variety of tax changes should be considered to encourage venture and angel investment in these companies.

The most important change to restart the flow of capital into early stage companies, as noted above, is improvements to the efficiency and predictability of FDA review.

13. What specific regulations are unnecessarily slowing or preventing bioinnovation.

AdvaMed submitted a letter (attached) to the Secretary of HHS listing some regulations or subregulatory guidances that should be dropped or modified regarding FDA regulation of devices.

With regard to payment regulations, the impact of the new payment modalities included in health reform is still hypothetical. However, the potential for unintended consequences that would have a chilling effect on innovation is significant and can be avoided without undercutting the goal of the new modalities to improve efficiency and quality. The problem is described above. AdvaMed's specific recommendations were described in detail in its comments on the ACO proposed rule.

In brief, AdvaMed recommends that:

--Benchmark spending targets and shared savings pools under ACOS, bundling or other new payment modalities should keep pace with advances in medical treatments and technologies by including adjustments for a reasonable period of time during which a new innovation is diffused and becomes the new standard of care. CMS would determine which advances would qualify. Adjustments would be modeled after those used in the Medicare program today for inpatient and outpatient hospital care but would be broader in application.

--Similarly, quality care measures should keep pace with advances in medical treatments and technologies. In calculating bonuses or penalties, certain cases should be excluded for a reasonable period of time when existing quality measures do not reflect the new treatments available to patients.

In addition, quality under the new modalities needs to be carefully monitored to assure that incentives to reduce costs do not lead to patients not being offered the most appropriate treatment for their condition.

As noted in recommendation #3d in the AdvaMed innovation agenda above, it is critical that the antiquated Medicare payment system for clinical laboratory tests be modernized to reflect the value of new molecular diagnostic and other innovative, high impact laboratory tests.

At a more general level, the whole regulatory process of government needs to be more attuned to the need to foster innovation and competitiveness in the life sciences—particularly for agencies, such as CMS, that do not see innovation as part of their mission but nonetheless have a major impact on the life science industries. Accordingly, as noted in item #1 of the innovation agenda, all agencies issuing major regulations or taking major subregulatory actions that have the potential to impact health care or health research should be required to include an “innovation impact” statement, analogous to the environmental impact statement currently required of many rules. In addition, an office of medical innovation should be created within the White House that could provide oversight of disparate government agencies to assure that their actions support medical innovation and offer a focal point for discussion with groups and individuals concerned with medical innovation.

15. Specific improvements in the regulatory processes for drugs, diagnostics, medical devices and agriculture biotechnology.

The specific improvements needed in the regulatory process for devices are described in item #1 of the AdvaMed competitiveness agenda above. FDA needs better performance metrics focusing on total review time, not FDA time. It needs to streamline the IDE process. It needs to take the “least burdensome” requirements of existing law seriously. It needs to train reviewers and supervise them appropriately. It needs more device specific guidances and other mechanisms, such as regular and substantive meetings with applicants, to assure companies understand what is expected of them and that decisions are consistent. It needs to assure access to the best available advice and scientific information for review decisions.

AdvaMed wishes to thank OSTP for providing this opportunity to comment on this important issue and wishes, once again, to commend the President for identifying the importance of creating a National Bioeconomy Blueprint to secure America’s economic future.

-
- ¹ The Lewin Group, “State Economic Impact of the Medical Technology Industry,” June 7, 2010 and February, 2007.
- ² *Ibid.*
- ³ *Ibid.*
- ⁴ *Ibid.*
- ⁵ ITC data web; The Manufacturing Institute, “The Facts about Modern Manufacturing,” 2009, p. 18.
- ⁶ United States International Trade Commission, “Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets,” March, 2007.
- ⁷ U.S. Department of Commerce, unpublished data, 2002.
- ⁸ USITC, “Medical Devices and Equipment: Competitive Conditions Affecting U.S. Trade in Japan and Other Principal Foreign Markets,” March, 2007.
- ⁹ Donahoe, Gerald and King, Guy. “Estimates of Medical Device Spending in the U.S.” Available at AdvaMed web site.
- ¹⁰ U.S. Administration on Aging, Department of Health and Human Services.
<http://www.un.org/esa/population/publications/worldageing19502050/>
- ¹¹ Population Division, Department of Economic and Social Affairs, “World Population Aging,” 2002,
http://www.aoa.gov/aoaroot/aging_statistics/future_growth/future_growth.aspx
- ¹² MEDTAP International, Inc.. *The Value of Investment in Health Care: Better care, better lives*, 2004, Bethesda, MD: MEDTAP.
- ¹³ Kevin Murphy and Robert Topol, “The Economic Value of Medical Research,” in Kevin Murphy and Robert Topol, eds. *Measuring the Gains from Medical Research: An Economic Approach*, 2003.
- ¹⁴ Ross DeVol and Armen Bedroussian, with Anita Charuworn, Anusuya Chatterjee, In Kyu Kim, Soojung Kim and Kevin Klowden. *An Unhealthy America: The Economic Burden of Chronic Disease*, the Milken Institute, October, 2007.
- ¹⁵ United BioSource Corporation, *The Economic Burden of Chronic and Acute Conditions in the U.S.*, 2009. Available at http://www.advamed.org/NR/rdonlyres/92EABCBA-4A06-4712-BFF0-1EE90C119876/0/A28690BurdenofDiseaseReport_Final_81409_CLEAN_Rev1.pdf
- ¹⁶ PricewaterhouseCoopers, “Medical Technology Innovation Scorecard: The Race for Global Leadership,” January, 2011.
- ¹⁷ Clinicaltrials.gov. PwC analysis.
- ¹⁸ The Boston Consulting Group, “Competitiveness and Regulation: The FDA and the Future of America’s Biomedical Industry,” report prepared for the California Health care Institute, February, 2011.
- ¹⁹ Josh Makower, M.D. et al., *FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies*, November, 2010.
- ²⁰ The Boston Consulting Group, “Competitiveness and Regulation,” op. cit.
- ²¹ FDA, Center for Devices and Radiological Health, “510(k) Working Group Preliminary Report and Recommendations,” August. 2010; Josh Makower, op. cit.
- ²² FDA data.
- ²³ Unpublished data from Ernst and Young.
- ²⁴ Pricewaterhouse Coopers, op. cit.
- ²⁵ Ernst and Young, *Pulse of the Industry: Medical Technology Report 2009*; Batelle Technology Partnership Practice, “*Gone Tomorrow? A Call to Promote Medical Innovation, Create Jobs, and Find Cures in America*,” report prepared for the Council for American Medical Innovation, June 10, 2010.
- ²⁶ Estimate prepared for AdvaMed.
- ²⁷ The Lewin Group, “The Value of Diagnostics: Innovation, Adoption and Diffusion into Health Care,” p. 129.
- ²⁸ *Ibid.*, pp. 5-6; The Institute of Medicine, “Medicare Laboratory Payment Policy: Now and in the Future,” Wolman DM, Kalfoglou AL, LeRoy L (eds) 2000.
- ²⁹ See ACO Proposed Rule, 76 Fed. Reg. 19528, 19571 – 91, April 7, 2011.

³⁰ National Quality Forum (NQF) # 0163; NQF- Endorsed Voluntary Consensus Standard for Hospital Care: Primary PCI within 90 Minutes of Hospital Arrival. *See also* Hospital Inpatient Value-Based Purchasing Program Final Rule 76 Fed. Reg. 26490, 26498, 26501, 26510, 26512, and 26515, May 6, 2011.

³¹ None of the payment schemes address economic benefits from effective treatment that arise outside the health system, from reduced disability, expanded productivity, and reduced dependency.

³² Council of the People's Republic of China. *Medium and Long Term National Plan for Science and Technology Development (2006-2020)*, 2006.

³³ Brazil's Government Procurement Law 495, 2010.

³⁴ World Trade Organization, *Regional Trade Agreements*, http://www.wto.org/English/tratop_e/region_e/region_e.htm.

³⁵ World Bank Group and PwC, "Paying Taxes 2011: the Global Picture," November 18, 2010. <http://doingbusiness.org/data/exploretopics/paying-taxes>.

³⁶ U.S. International Trade Commission Dataweb.

³⁷ Robert D. Atkinson, "Role the U.S. Government can Play in Restoring U.S. Innovation Leadership," testimony before the Committee on Science and Technology, Subcommittee on Technology and Innovation, U.S. House of Representatives, March 24, 2010.