Background: The American Medical Technology Industry and International Competitiveness

The American medical technology industry is the acknowledged world leader and an engine of economic growth and job creation for the American economy. Today that leadership is increasingly challenged. Without strategic government policies to support the medical technology industry's efforts to compete in world markets, American economic leadership will be lost. While the policies advocated by AdvaMed are tailored to the specific issues facing the device industry, the need for strategic government policies is generic to all the high technology, high value sectors in which America must compete effectively if it is to assure robust economic growth and a high standard of living for the American people.

The medical technology industry and its contribution to the American economy

The medical technology industry is comprised of companies developing and manufacturing medical devices and diagnostics. These products are diverse, running the gamut from tongue depressors to the most complicated molecular diagnostic tests and cardiac implants. They are an essential part of modern medical practice, and development of new medical technology has been one of the main engines of medical progress.

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] 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.

These small firms, often venture capital funded, 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 very 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 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.[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 2006 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 18-year period despite a flood of new products that profoundly changed medical practice.[5]

The U.S. medical technology industry is a very dynamic part of the U.S. economy and a source of economic growth and good jobs. The future opportunities for growth are immense.

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 even than the average for manufacturing wages.[7]

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.[8] During the recession, between 2007 and 2008, MedTech employment dropped 1.1%, compared to 4.4% for manufacturing as a whole.[9]

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.[10]

The contribution of medical technology to our economy goes beyond conventional measures of employment, wages, and exports. 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%.[11] The economic value of the reduction in death and disability from heart disease alone has been equal to one-fifth of our total GDP.[12]

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.[13] 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.[14]

The future opportunities for industry growth are great. Worldwide 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%.[15] 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.[16]

The exponential growth in middle-class populations in countries like China, India and Brazil demanding world class medical care is another extraordinary opportunity. 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.

Finally, in this century of the life sciences, technological advances fueled 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. The potential for economic gains is as great as those attributable to the advances in the physical sciences in the previous century that fueled the development of the airplane, the computer, and the cell phone.[17]

Increasing challenges to American leadership

While these trends suggest a bright future for the medical technology industry overall, America's leadership is increasingly challenged by a number of trends. Only a strong public policy focus can assure that American companies and American workers will reap the benefits of future industry progress.

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."[18]

Clinical trials, first product introduction, and regulatory system performance. 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.[19]

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, while it was about a year as recently as 2004.[20] 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.[21]

The movement of clinical trials and first product introductions abroad is not only harmful for American patients, who's access to the latest treatment and cures is 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. As one observer noted, "Many European clinicians are sought after for clinical studies because they have so much experience with early stage technology. That puts them on the map in terms of clinical studies and becoming thought leaders in technology adoption."[22] Since medical devices have such a rapid development cycle, introduction of the product first abroad means that subsequent versions of the technology may also be based on experience gained abroad from foreign physicians and investigators.

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%. The average time to review PMA products—the most complex and typically the most innovative technologies—has skyrocketed 75 %.[23] 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.[24]

The difficulties companies experience with FDA begin even before an application is submitted. Before a company can even begin the clinical trials that are generally a prerequisite for consideration of a PMA, FDA must approve an investigational device exemption (IDE), which is required for any research involving human subjects. Simply to approve an IDE now takes an average of 14 months and sometimes much longer.[25] Companies can wait six months or more just to get a meeting to discuss their IDE before they submit it.

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.

As the USITC reported, even before the recent decline in FDA performance, "…an efficient regulatory approval system is an important factor favoring the medical device industry in the EU."[26] This observation applies not just to medical technology designed to be used in the EU but increasingly to third countries as well. For example, China now requires approval in the country of origin. So, to the extent the EU process is more efficient, medical technology approved in Europe has an edge over the U.S. in China. Likewise, many other countries in Asia and Latin America use approval in the EU or U.S. as the basis for market access to their market, favoring the more efficient EU system. Australia is another case in point, as its regulatory system is based on the European system, thereby expediting approvals.

Venture capital investment. 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.[27] 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.[28]

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.[29] 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.

Payment system: current policies. 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.[30] 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.[31]

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.[32]

Payment system: reform policies. 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, there are also 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.[33] For example, patients presenting with a heart attack are supposed to be treated with percutaneous coronary intervention (PCI) within 90 minutes.[34] 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.[35]

The draft 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. 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.[36] 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 heath care expenditures) and to use its product approval regulatory agency to favor domestic medical technology firms.[37] In addition, other countries are pursuing bilateral and regional trade agreements that will put U.S. manufacturers at a competitive disadvantage.[38]

Tax and other incentives. 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%.[39] 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 "patent 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: foreign-domiciled companies are granted a competitive advantage by their governments. Even worse, 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.

For example, France dedicates funding equal to 2.2% of its GDP to programs designed to foster innovation and R&D—such as research tax credits, incentives for start-ups, federal subsidies, as well as an additional $50 billion grant program about 10% of which is specifically dedicated to health and biotech research. Germany has committed about $1.5 billion to life science research, as well as special cash payments—some covering as much as 50 % of costs—and grants to attract investment. The UK offers a variety of R&D tax credits, special schemes to support job-creating capital investment, and a new Office of Life Sciences specifically designed to involve the highest levels of government in cutting red tape, attracting clinical research and expediting the use of innovative medical technology. Ireland's multiple incentives have attracted over 90 separate medical device companies (including 15 of the world's top medical device firms), according to the USITC. Moreover, the European Commission offers its member states additional incentives to help attract job-creating industries as part of its "Framework Programmes," in which health care related industries are specifically identified.

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.

Shrinking trade surplus. 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. [40]

Diminishing infrastructure advantage. 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.[41]

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 six policy pillars of continued American leadership: Discussion and Rationale

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.

Rationale and discussion:

Competiveness cannot be achieved by a set of isolated policies. It requires a coordinated, government-wide strategy involving all the agencies that affect industry. This is especially true for the medical technology industry—as well as the other life sciences industries—since the industry's products are heavily regulated by the FDA and the competitiveness of the industry is so affected by the policies of government payment programs, research policy, trade policy, and tax policy.

To assure that competitiveness issues are considered as the government acts in each of these areas, an office of medical innovation policy in the White House would be an important first step. It would provide stakeholders a focal point for bringing concerns about the competiveness impact of decisions and policies in agencies across the government, many of whom do not regard considering competitiveness as part of their mission. It would provide an important center of advocacy to assure that the government as a whole makes competitiveness of the life sciences and support for the country's medical research infrastructure a priority.

With regard to regulatory action, the President's recent Executive Order on Improving Regulation and Regulatory Review is designed to assure that agencies consider the economic impact of regulation and try to assure that the least burdensome approach to achieving regulatory objectives is chosen. It also directs that "each agency shall also seek to identify, as appropriate, means to achieve regulatory goals that are designed to promote innovation." This Executive Order is a good first step, but an explicit requirement for an innovation impact statement would be even better. Such a requirement would assure that agency's actually actively consider the impact of their actions on innovation without compromising regulatory objectives. Despite the Executive Order, the new draft rule on Accountable care organizations includes no discussion or consideration of the potential impact of the rule on innovation, despite the fact that, as discussed above, it could have a profoundly negative impact on innovation without proper provisions. Agencies that do not currently view promoting innovation as part of their mission must be given strong direction to actually take the impact of their decisions on innovation into account.

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*

product, 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.*

Rationale and discussion:

As described above, the recent deterioration in FDA's performance has had a devastating impact on the competitiveness of the American medical device industry, as well as on patients. Part of the problem is that FDA manages to the wrong metrics. Under the user fee agreement, FDA's performance is measured by how long it takes them to review devices—but review time is measured by time on the FDA clock. Whenever FDA asks the manufacturer questions about its submission or requests more data, the clock stops. But what matters to industry and to patients is not time on the FDA clock, it is the total time from the time the product is submitted to FDA for review to the time it is cleared for market. Accordingly, FDA must set a goal of reducing total review times.

The de novo pathway is a way to review products that do not have an appropriate predicate device to qualify for 510(k) review but also do not have a significantly great risk profile to warrant PMA review. The current de novo pathway is extremely cumbersome and time consuming—averaging more than two years from submission to approval.[42] FDA has announced its intention to streamline the de novo process as part of its 510(k) reform implementation plan. Improvements in this process would be a significant advance for this group of products.

When FDA insists companies submit greater data than is needed to meet the statutory requirement of a reasonable assurance of safety and effectiveness, the cost and time necessary to develop new treatments and diagnostics soars. The "Food and Drug Administration Modernization Act of 1997" required that FDA use the least burdensome data necessary to demonstrate that the product should be approved. Recently, however, FDA has generally failed to consider this requirement in setting data requirements for approval.

As described above, delays in IDE approval—averaging two years before a clinical trial can even be started—are a major drag on U.S. competiveness and one of the most important factors leading manufacturers to move clinical trials and first product introductions abroad. Improvements to the IDE approval process, especially making it easier for sponsors to get early, productive meetings with FDA on their trial design, would be a major contribution to U.S. competitiveness.

As great a problem as delays in FDA approvals of product submissions and IDE applications is inconsistency in review. When sponsors do not know what FDA requires for approval or clearance or when requirements change depending on which reviewer has responsibility for the review, the loss in time and money is incalculable. As noted earlier, uncertainty about the FDA review process is a major factor driving venture capital investment away from early-stage projects. Specific product guidances laying out the evidence requirements for specific product types are extremely helpful to the manufacturer and restrict the likelihood of inconsistent and arbitrary judgments by reviewers. As part of its 510(k) reform implementation plan, FDA has committed to creating more product-specific guidances and updating current guidances. It has also indicated that it will make more systematic attempts to assure consistency among reviewers, in part by increasing reviewer training. Successful implementation of these proposals is both critical and urgent.

Just as payment reform is important to stimulate the growth of molecular diagnostic tests, so is regulatory reform. AdvaMed has proposed, and FDA is considering, a more risk-based approach to approval and clearance of diagnostic tests, so that FDA can focus its resources on tests that are more novel or more risky. This would speed up approval and clearance of all tests.

Finally, global harmonization is a work in process. To the extent FDA can harmonize its standards, consistent with U.S. law, with international standards, the more efficiently manufacturers can produce medical technology for the global market and the more competitive U.S. based manufacturers will be.

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.*

Rationale and discussion:

As noted above, Medicare and Medicaid beneficiaries represent a large proportion of the U.S. medical device market and Medicare policies, in particular, are often adopted by private insurers. And, as also noted above, it is very important to the future competitiveness of the U.S. industry that the new payment modalities established by health reform be carefully designed to support rather than hinder medical innovation. AdvaMed has developed a number of proposals to achieve this objective—proposals that would not undermine the goals of cost control and improved quality—but would assure that medical progress will not be chilled and that patients would have access to the care most appropriate to their needs.

These policies would build in explicit design features to avoid penalizing early adopters of new technology. We suggest improving the existing new technology add-on payment that is part of the current system by which hospitals are reimbursed for treatment of each Medicare patient and applying a revised version to the new payment modalities. Under the new technology add-on payment provision, hospital reimbursement for patients treated with a new technology that offers the promise of a significant improvement in care and is more costly than current treatments is increased to partially reflect the increased cost of the new treatment. The increase is time-limited, and gives CMS time to gather data on the actual cost of the new technology.

Under the new payment modalities, this kind of a grace period would avoid penalizing early adopters and give new treatments a chance to demonstrate that they should represent a new standard of care. We would also allow a grace period during which providers who adopt new treatments that are alternatives to existing quality standards are not penalized on their quality scores, when those scores are based on providing a specific treatment.

There are undoubtedly other solutions that would achieve these objectives. As noted above, it is disappointing that the new draft rule for Accountable care organizations did not address this issue.

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-U.S. 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, U.S. Government agencies—including USTR, SBA, and Commerce—should vigorously pursue policies to assist small and medium size companies to overcome their lack of experience, specialized knowledge, and other obstacles to competing in export markets.*

Rationale and discussion:

Critical to the future growth of the U.S. industry is access to foreign markets, which offer the greatest opportunity for expansion. As we have seen, the U.S. favorable balance of trade is shrinking, and many foreign governments have created tariff and non-tariff barriers designed to help domestic industries compete with U.S. companies and to force U.S. companies that want access to local markets to locate

manufacturing plants or research and development facilities abroad. To continue to compete, the U.S. industry needs a level playing field in foreign markets—and only vigorous action by the U.S. government can create it. In addition, government assistance can provide an important boost to the encouraging small and medium sized companies to become successful exporters.

5. **Strategic tax policies to level the playing field must be implemented.**
American tax policy must support research and development 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 created for keeping R&D based manufacturing in America; and the medical device excise tax should be repealed.

A. *The R&D 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 incentives equivalent to the credit for companies with no profits, so that small and start-up companies, which create a disproportionate share of breakthrough treatments, can receive benefits at the time of greatest need.*
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 American firms vis-à-vis foreign competitors.*
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.*

Rationale and discussion:

As described in detail above, the American tax structure is a dishonor roll of severe handicaps for American companies as they compete with foreign firms and seek to grow jobs in America. The lack of tax parity is especially damaging in competing for jobs with emerging economies that also use a variety of non-tax tools to attract foreign and boost domestic investment.

To provide a level playing field for American companies and to stimulate job growth in America, the R&D tax credit—a key policy component for stimulating all

research-based high-tech industries—needs to be at least as good as that offered by our major competitors and made permanent. This implies that the level should be raised to a minimum of 20% from the current 14%.[43] It has been estimated that raising the R&D tax credit to 20% would increase GDP by $66 billion annually and the number of patents filed by an estimated 3,800. Moreover, the increased credit would actually pay for itself in increased tax revenues over the course of 15 years.[44]

The U.S. tax credit also fails to cover the cost of constructing research facilities—yet the decision to establish a research facility is critical in determining the location of future research and development.

Beyond the actual level of the tax, the lack of clarity in allowable expenses and the inconsistency of administration by the IRS have a significant dampening effect on the value of the credit as a stimulant to investment. [45]

Finally, as discussed above, one of the key engines of innovation and research and development in the medical technology industry is small, start-up companies that are often venture capital funded. These companies are the most research-intensive in the industry and those that need the credit the most, but they are unable to access it until they obtain profitability. Establishing a mechanism, such as refundability, to give those firms the benefits of the credit when they need it most would be a significant stimulus to investment in the development of new, breakthrough products.

One of the most destructive ironies of the current tax regime is that the R&D tax credit encourages American companies to invest in creation of new products, but comparable incentives to manufacture created in America innovations in America do not exist. A number of other countries, including China, have introduced tax incentives that provide more favorable tax treatment of manufacturing or other activities based on research and development.[46] Since research and development based, high value-added manufacturing is the only kind of manufacturing in which America can hope to be competitive, we need to offer comparable incentives to keep these jobs in America.

The health reform bill imposed a 2.3% excise tax on medical device company domestic sales. While the ultimate incidence of the tax will be determined by market forces, the dollar cost of the tax is quite high as percent of industry profits and research and development investment. Indeed, if the tax is fully absorbed by the companies, it would raise the effective corporate tax rate for medical technology companies by nearly 50% to one of the highest in the world. While AdvaMed supported and continues to support many of the central goals of health reform, this tax has no policy justification, is highly anticompetitive, and should be repealed.

Finally, America needs to move toward a general corporate tax regime that is at least as favorable as our major competitors, including lower general corporate tax rates and a territorial tax system under which foreign earnings of American companies are not taxed at American rates if they are repatriated.

General corporate tax reform needs to be approached thoughtfully, however. Such reform needs to be strategic and assure adequate incentives for firms that compete in the globalized world. Prescriptions for a general lowering of statutory corporate tax rates fully paid for by getting rid of targeted tax incentives could be counterproductive. It would actually raise effective tax rates for manufacturing, while still leaving the overall rate substantially higher than competitor countries. It would hit manufacturing industries that benefit—however inadequately—from the R&D tax credit especially hard. And for multinational manufacturing firms like those prevalent in the medical technology industry, effective tax rates could increase as much as 17%.[47]

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.*
D. *Institutional Review Board activities should be streamlined to reduce barriers to initiating collection of clinical data on new products, particularly for multicenter trials, without sacrificing protection of human subjects.*

Rationale and discussion:

America's life-sciences industries can only be as strong as the research and development infrastructure that supports them. Support for basic and applied research at the NIH and the NSF are critical—not just for the actual research they fund—but for their role in supporting America's great research universities and academic health centers and stimulating the development of trained scientific and engineering personnel.[48] Despite a

surge in funding as the result of the President's commitment to support for basic research and additional funding contained in the stimulus package, support for NIH has actually declined almost 10% in real terms in the last ten years.[49] Federal support for research in the physical sciences has been cut almost in half as a percent of GDP in the last quarter century.[50] In view of the need to reduce government spending overall, a priority for investment in NIH, NSF and other Federal programs that support basic and applied research is especially critical. Because of the economic downturn and the resultant shortfalls in state revenues, the pressure on state-funded research universities is especially great.

As noted above, small often venture-capital funded companies are a key source of innovative products. These companies are having increasing difficulty in sustaining adequate investment to carry new technologies through the arduous process of development to the point where they are ready to be commercialized. Expanding the size of SBIR and STTR grants, allowing companies receiving grants to be more fully funded by venture capital firms, supporting research farther along in the development process, and fully funding the Cures Acceleration Program, which authorizes up to $5 billion in grants to small companies for developing innovative treatments, would help address this issue. In addition, bioscience research and development clusters have been a fruitful source of technological progress, since they help create a critical mass of entrepreneurs, engineers, and scientists.

While America's great universities and academic health centers are tremendous intellectual resources for innovation, the leveraging of these resources to help create new products and treatments is spotty at best. Expanding the very successful NSF Industry-University Cooperative Research Centers to the NIH would be a low-cost but effective means of strengthening the relationship between universities and business. University technology-transfer programs differ widely in their effectiveness, with most not being very successful in engaging industry to commercialize ideas originally created by faculty or students. A program to develop and disseminate best practices so that all research universities emulate the significant successes of the few would be an important step forward. Finally, multicenter clinical trials could be facilitated if university institutional review boards could be encouraged to institute more standardization of their forms and requirements, without sacrificing needed oversight.

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