A Healthy Medical Technology Industry and a Healthy America

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Thank you, Chairwoman Klobuchar, for the opportunity to testify on this important topic. My name is Steve Ubl, and I am the President and CEO of the Advanced Medical Technology Association (AdvaMed). AdvaMed is the world's leading trade association representing manufacturers of medical devices and diagnostics. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

We are very appreciative of this Subcommittee's interest in the issue of the competitiveness of the life sciences industries. While today the U.S. is the recognized world leader in medical technology and the other life sciences industries, its continued leadership is by no means assured. A number of factors, including policies of foreign governments designed to support medical technology, threaten to undermine U.S. leadership and competitiveness. If America fails to lead in medical technology in this century of the life sciences, America's long-term future as the world's most powerful economy will be jeopardized.

Several characteristics of our industry are especially relevant as policies are considered to support the continued preeminence of the American medical technology industry. It is important to recognize that small firms are a key part of our 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 these 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.

Small, venture capital funded firms are particularly critical to the future of U.S. scientific and technology leadership, because they are the source of most of the breakthrough technologies that drive medical practice and industry growth. The National Venture Capital Association has developed an impressive list of breakthrough medical devices and diagnostics that were initially developed by venture capital funded start-ups, ranging from Doppler ultrasound to implantable defibrillators to pulse oximeters.[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.

High levels of research and development (R&D) expenditures are necessary to continue this virtuous cycle of innovation and maintain US competitiveness. As reported by the USITC, research and development is one of the main reasons for the US's competitive advantage. U.S. medical technology firms spent over twice the US average on R&D. The USITC found that high technology medical device companies devote upwards of 20 percent of revenue on R&D.[4] The European Commission reported that US medical technology firms' R&D expenditures as a percentage of sales were, on average,

roughly twice as high as such expenditures in the EU and Japan as of 2005.[5] There are indications, however, that this differential is eroding.

The device industry is highly competitive, and this helps moderate US healthcare costs. 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 eighteen year period despite a flood of new products that profoundly changed medical practice.[6]

A key feature distinguishing medical technology from many other manufacturing sectors is the extraordinary impact of Federal policies. All medical technology products sold domestically are regulated by the Food and Drug Administration (FDA). Most must receive clearance or approval before they can be marketed and all are subject to quality systems and good manufacturing practices regulations. Further, products are monitored for adverse events once marketed to the public and are subject to recall authority. Accordingly, FDA policies are critical to the health and growth of the industry.

Beneficiaries of government programs are important consumers of medical technology. In 2008, Medicare and Medicaid together paid for medical care that accounted for 48 percent of total domestic sales of medical technology products. Patients in the VA and DoD care systems are also major users of medical technology. Meeting the coverage rules of these programs is critical for medical technology companies, given the size of this market, and their reimbursement policies ultimately affect a major share of company revenues. In addition, Medicare coverage decisions and payment methodologies often spillover to the private insurance market, expanding the impact of government decisions significantly beyond the boundaries of the government programs.

The manufacture of medical technology is an American success story. Our industry employs more than 400,000 workers, and, if indirect employment is included, the employment impact is substantially higher.[7] Industry pay levels are 38 percent higher than average pay for all U.S. employment and 22 percent higher than other manufacturing employment.[8] While the number of manufacturing jobs was plummeting across the larger economy, even before the current recession, employment in our industry was expanding. Between 2005 and 2007, medical technology employment grew 20.4%, adding 73,000 jobs.[9] During the recession, between 2007 and 2008, MedTech employment dropped 1.1 percent, compared to 4.4% for manufacturing as a whole.[10]

With $33 billion in total exports in 2008, medical technology ranks eleventh among all manufacturing industries in gross exports.[11] Notably, unlike virtually every other sector of U.S. manufacturing, medical technology has consistently enjoyed a favorable balance of trade. With the aging of both U.S. and foreign populations, the projected explosive growth of large middle class populations demanding modern health care in developing countries like China and India, and the accelerating pace of biomedical discovery, the potential for growth of our industry is great.

The contribution of the life sciences to our economy goes beyond conventional measures of employment, wages, and exports. By improving the health of the population, progress in the life sciences 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 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.[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]

While the medical technology industry is a genuine American success story, our world leadership is not guaranteed to continue. Without sound public policy, it is increasingly likely that the U.S. will fall behind not only in medical devices and diagnostics but in other industries based on the life sciences.

To quote Dr. Laurence Summers, Chairman 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. While the foundational ideas of relativity and quantum mechanics were developed in Europe, the practical application of these ideas occurred in the US. If the 20th century was defined by developments in the physical sciences, the 21st century will be defined by developments in the life sciences. It is natural to ask whether the US will lead in the life sciences in this century as it did in the physical sciences in the last. It is a profoundly important economic question, but one whose implications go far beyond to embrace issues of national security and moral leadership."[15]

There are a number of indicators that show that the gap between America and foreign competitors in the medical technology industry is narrowing. 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 2009, total trade had almost tripled—to $63.5 billion, but the trade surplus had shrunk by more than half—to $3 billion, and the surplus was only 4.7% of total trade.

A troubling trend is the rapid movement of clinical research abroad. In 2004, 78.7% of all clinical trials listed in ClinicalTrials.gov were carried out in the U.S. By

2009, that proportion had sunk to 45%. U.S. clinical trials that were specifically for medical technology products started even higher and finished even lower, dropping from 86.9% of the worldwide total to 44.8% during this period. The cumulative annual growth rate of U.S. clinical trials 2004-2009 was lower that of Brazil, China, France, Germany, India, the U.K., Israel, and Japan.[16]

Given the importance of startup firms in creating breakthrough technologies and fueling the growth of the industry, America's strong network of venture capital firms with an interest in investing in the life science has been a key strength. Here, too, although the U.S. maintains a strong lead in absolute terms, the lead is shrinking relatively. 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.[17]

Not only is venture capital growth in the U.S. slower than abroad, we are increasingly hearing that growing regulatory and payment uncertainties in the U.S. are causing VC firms to rethink whether they want to invest in the 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.[18] If these trends prove durable, they would be very troubling for the future of medical innovation and for the industry. Moreover, there are far more start-ups seeking VC funds than there are funds available, suggesting that significant innovation opportunities are being lost.

Another troubling trend is that many AdvaMed members are increasingly looking to Europe to launch their products, given the longer regulatory process in the US. As the USITC reported "…an efficient regulatory approval system is an important factor favoring the medical device industry in the EU."[19] 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 US in China. Likewise, many other countries in Asia and Latin America use approval in the EU or US 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.

The fact that products are launched first abroad has several negative consequences. From a human point of view, it means that American patients may be denied timely access to the newest and best treatments. From a commercial point of view, as more and more products are launched first abroad, there is a real danger that R and D establishments will follow, so that product development will be close to the first users of the product.

Foreign countries are working to undercut America's leadership in a number of ways that transcend the regulatory system. Many European countries offer a wide range of incentives to attract job-creating industries. For example, France dedicates funding

equal to 2.2 percent 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 percent 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 percent 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 healthcare related industries are specifically identified.

Of course, Europe is not our only competitor, and other governments are eyeing the medical technology industry to bring jobs to their people. They are adopting policies to achieve this. For example, China has implemented 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. Brazil's health minister has publicly proclaimed that he will use Brazil's product approval regulatory agency to favor domestic medical technology firms. India is building a series of industrial parks expressing to attract medical technology investment and the jobs that foreign companies will bring.

In the face of the negative trends noted above and the aggressive policies undertaken by foreign governments to build domestic industries and attract investment from multinationals, what should be the American response? In my view, we need a proactive program to assure that the U.S. retains its commanding lead in medical technology and all the life sciences. We need a program that will allow America to take full advantage of the enormous growth opportunities for medical technology in the 21st century. We need a program that will maximize the industry's contribution to the President's goal of doubling exports within five years.

The comprehensive approach I believe is necessary will include regulatory policy, reimbursement policy, trade policy, tax policy, and policies to support research and development. AdvaMed will continue to develop policy recommendations for the Committee. Today, I can share with the committee a few ideas for your consideration. I hope we can work together over the coming months to positively shape the direction of U.S. policy and assure America's continued leadership.

Regulatory policy

The predictability and speed of FDA decision-making, as well as reasonable, risk-based standards of evidence to show the safety and effectiveness of medical technology

products is essential to maintain innovation and the long-term success of the medical device industry. The FDA clears products for marketing by one of two routes—the 510(k) process or the Pre-market Approval (PMA) process. The 510(k) process clears products based on their similarity to products that are already on the market and is not available to the highest risk products. To be cleared under the 510(k) process, a product must be "substantially equivalent" to a product already on the market, and manufacturers must demonstrate that the product is as safe and effective as the marketed product. If it has different technological characteristics or a different intended use than the product already on the market, the device manufacturer must present data to show that the product does not "raise new questions of safety and effectiveness." The FDA has broad discretion to require any data that it thinks necessary to assure the safety and effectiveness of the device, including clinical data.

The 510(k) process is critical to a vibrant and successful device industry and to the process of medical innovation that provides better products for patients to address unmet clinical needs. In a typical year, 3,600 new products will be cleared for marketing through the 510(k) process. This compares to 30-40 products annually approved through the PMA process.

The FDA is currently conducting a thorough review of the 510(k) process with a view to instituting internal reforms by early September. The IOM has also been asked to review the process and will be making recommendations next year as to any changes it thinks are necessary. The device industry welcomes this review, because we believe the process can be improved and that public confidence in it can be increased. In this regard, we have contributed a number of ideas to the FDA and are pleased that they are being given careful consideration by the Agency leadership.

We also believe, however, that the 510(k) process has an excellent record of protecting the public against unsafe or ineffective products while providing a relatively speedy path to development and approval of innovative products. It is very important to the future of the industry and to continued medical progress that the 510(k) not be altered radically in a way that would unnecessarily increase the time and cost of developing new products.

The PMA process is reserved for products that are most innovative and of highest risk. PMA products are typically required to provide clinical data and often required to conduct a controlled trial of a new product. Development and testing of a PMA product is inherently costly, but the time it takes FDA to complete the review of a product is troubling. According to FDA data, in 2007—the most recent data available--the average time between a product's submission and a final decision by the FDA was 446 days. The device industry entered into a user fee agreement with FDA in 2002 in part to reduce the long time it took to complete a PMA review. Between that time and 2007, however, the average time in review actually increased by two months.

The figures cited above reflect total time between submission of a product to FDA and an FDA final decision. This is the most important metric for industry. As part of the

user fee agreement, however, FDA has committed to achieving review time goals based on time on the FDA clock—that is time in which the FDA is actively reviewing a product. This time clock stops whenever the FDA asks the company for more data or clarifying information and restarts when it is supplied by the company. We have relatively current data for time on the FDA clock, and it shows that the FDA is not meeting its own review goals. We are pleased that the FDA leadership has made correcting this problem a priority and hope that the newest data will show an improvement.

Finally, the FDA recently put out draft recommendations to increase transparency of its operations. Transparency is clearly a laudable objective. FDA's recommendations are well-intentioned and, in some cases, meritorious. We are very concerned, however, that some of the recommendations dealing with release of information on products that are in the review process and cannot be legally marketed will undermine intellectual property and discourage investment in breakthrough products while providing no significant public health benefits. We hope that the final recommendations will address these concerns.

As I noted earlier, it is not a good omen for the future of the U.S. device industry—or for American patients—that an increasing proportion of complex products appear to be undergoing clinical trials and entering the market abroad before they are introduced in the U.S. The FDA leadership understands that promoting medical innovation is part of its mission to protect and improve the public health, and I am hopeful that FDA will find ways to speed up PMA reviews, maintain an effective 510(k) process and increase the predictability and consistency of reviews while maintaining its exemplary record of protecting patients against unsafe or ineffective products.

Payment Policy/Health Reform

A reliable expectation of adequate payment for products offering clinical benefit is a prerequisite for a healthy medical technology industry and for stimulating investment in technological innovation. The new health reform bill makes a number of changes in the way health care is paid for under Medicare that will, over time, create a profound shift in incentives throughout the health system. These changes are generally positive. Most policy analysts agree that the key to reducing growth in health costs and improving quality is to shift incentives in the health care system toward rewarding value and away from simply paying on the basis of volume and cost.

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. For example, patients presenting with a heart attack are supposed to be treated with percutaneous coronary intervention (PCI) within 90 minutes. 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.[20]

These problems can be addressed without undercutting the central goals of payment reform. Possible solutions could include:

- Develop explicit design features to ensure Medicare health care delivery demonstrations and pilots protect patient access to appropriate devices, diagnostics, and other medical technologies and must not penalize early adopters of new technology.
- 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.

- Allowing a grace period during which new treatments that are alternatives to existing quality standards are pulled out of both the numerator and denominator in judging providers' performance.
- Applying a modified version of the outlier policy in the current hospital payment system to the new payment modalities, so that providers are not penalized for providing appropriate care to patients who need more expensive treatments than the norm. Under the outlier policy, hospitals receive an increase in payment for treatment of patients whose care is substantially more costly than the average patient with that diagnosis.

Building innovation into government policy

The discussion of the importance of considering the impact of payment and regulatory policy on innovation suggests another approach to stimulating the competitiveness of the life sciences sector. As agencies carry out their individual missions, most do not consider the impact of policies on medical innovation as part of their mission. As discussed earlier, the new payment paradigms created by health reform could have a profound and negative impact on medical innovation. These negative impacts can be avoided without doing violence to the goals of health reform. But to make sure the changes support rather than inhibit innovation, someone has to be thinking about the issue and build appropriate measures into implementation.

One option for assuring that innovation is considered as policies are implemented across the government would be to create a dedicated, adequately staffed office within the White House with the specific mission of making sure that government policies are sensitive to medical innovation and support the President's goals of assuring that America leads the world in science and technology. The office's activities would be complementary to the current work of OSTP and PCAST. This office would act as an advocate for innovation, provide review and input into policies of individual agencies, and serve as a point of contact for industries, institutions and individuals with an interest in medical, scientific and technological innovation. Such an office could be located within PCAST, OSTP or the National Economic Council, or could be a stand-alone office. This proposal has recently been endorsed by the Council for American Medical Innovation, a coalition of leaders and organizations from research, medicine, academia, industry, and labor.

A related policy that could be considered is to require that each major policy decision or regulation include an analysis of the impact of the policy on medical, scientific and technological innovation. This would be analogous to an environmental impact statement. Requiring that a statement of this kind be included would assure that the issue of innovation is at least considered as policies are developed.

Trade policy

The opportunities for export growth by our industry and corresponding job creation in the United States are very great. Rapid economic growth in emerging markets is 2-3 times faster than in the US, EU and Japan. China's middle class is projected to exceed the entire US population by 2015, and India's middle class could reach 600 million by 2025. These are just two of the largest expanding markets, with smaller but also rapidly growing economies in Southeast Asia, Latin America, and the Middle East. In each of these countries, the emerging middle class is demanding first class medical care and creating a very large potential market for advanced medical technology. Even in Europe, the market for many advanced technologies is historically under-penetrated.

The question is whether the US medical technology industry will retain its leadership position to take advantage of this growth overseas and expand exports and create jobs for Americans. The future seems far less secure in view of the increasing competition by foreign companies and, perhaps more significantly, by foreign governments. Overseas, we see government policies that are designed to encourage domestic growth in, and attract foreign investment to, the medical technology industry. In the US, we need a comparable response.

As I have mentioned**,** there are significant efforts by a number of foreign governments to support a home-grown medical technology industry or to encourage location of research or manufacturing facilities or purchase of locally manufactured components by multinationals. Some of these efforts are legitimate, but others represent abuse of government power. Opening markets and ensuring a level playing field are essential to the future growth of the U.S. medical technology industry. Protection of American intellectual property is particularly vital. We are pleased with the support our industry has received from US agencies involved in trade – the USTR, Commerce and State. The officials in these agencies have worked hard to use the tools they currently have to attack discriminatory practices in other countries.

But they need more firepower to match the efforts of other countries. US trade barriers are very low – virtually non-existent for medical technology. Other countries, especially the fast growing emerging markets, have much higher access hurdles. Unless the US becomes engaged in actively negotiating and implementing free trade agreements (FTAs) that lower those barriers, US exports will suffer. The EU has many more FTAs around the world than the US. China is pursuing FTAs with its Asian neighbors. The barriers that US-made medical technology must overcome drives up the cost of our products in foreign markets compared to domestically made products and even medical technology from their FTA partners.

The proposed Trans-Pacific Partnership (TPP) should be viewed as one important component of the Administration's export promotion for the medical device industry. Implementing the US-Korea FTA should be another, followed by launching many more FTA negotiations**.** In addition to the direct benefits from the specific provisions of the

agreements, each FTA provides a valuable forum for governments to discuss and resolve trade issues. In a highly competitive global market, the United States cannot afford to disengage, as other nations conclude preferential agreements that benefit their industries. U.S. leadership in international trade is always necessary to maintain open markets; at no time has this leadership been more critical than in today's challenging economic environment.

In pursuing free trade agreements, it is important that the U.S. demonstrate a commitment to the strongest possible FTA provisions. In addition to advancing public health and patient access, these agreements should: (1) address non-tariff barriers (NTBs) affecting our industry, especially non-transparent or discriminatory regulatory procedures; (2) include provisions that foster access of foreign consumers to innovative products; (3) encourage harmonization among the signatories of regulations that are necessary for determination of safety and efficacy, consistent with international norms; (4) ensure the strong protection of intellectual property (IP) rights; (5) secure the most expeditious elimination of tariffs possible; (6) grant efficient regulatory approvals, while ensuring product safety; and (7) provide expeditious customs clearance. In addition, new FTAs, like the TPP, should include specific provisions for sectors, like the medical technology industry, to address our unique concerns regarding regulatory approvals and government reimbursement.

We recognize that negotiating new free trade agreements is a long-term process and can only focus on a limited set of countries. In the meantime, the United States is facing ever-greater challenges to its economic position in the world, and U.S. industry is experiencing fiercer competition in the global market place. Companies can deal with the challenges that come from the private sector and that are unaided by foreign government support. However, as I have noted, foreign governments are increasingly assisting their industries, sometimes directly but more often indirectly – for example by championing certain industries and adopting standards and regulations that favor domestic firms -- and that are not consistent with international norms. Such actions that are used to protect the domestic market can have a damaging effect on U.S. exports to those markets, diminishing the U.S. manufacturing base. Therefore, we encourage the U.S. trade agencies to address the goals described above through all means at their disposal.

In that regard, we have two additional suggestions. First, in negotiations with foreign governments to preserve and expand export opportunities for U.S. manufacturers, USTR must have sufficient authority to lead negotiations involving these issues. U.S. agencies with regulatory authority should not have the option of opting out or adopting a posture of only protecting their authority within the U.S. There should be creative ways to maintain and strengthen regulations that protect the health and safety of Americans while improving the U.S. economy.

Second, we believe that one of the goals of regulatory agencies should be to improve U.S. international competitiveness. For example, the primary role of FDA is, and should certainly remain, to protect the health and safety of the American people. At the same time, consistent with that role, FDA should also assist U.S. international

commerce. As it now stands, FDA's international mission is almost exclusively focused on assisting other countries to meet U.S. regulatory requirements – including by establishing offices in many of those countries. This legitimate outreach has the effect of facilitating access to the U.S. market in competition with U.S.-based firms. To maintain balance and help assure reciprocity, those same FDA offices should be staffed and have a mandate to work, in cooperation with the U.S. embassy, with foreign governments to assist entry of safe and effective American products into foreign markets.

Tax policy

As is well recognized by authorities in the field, a number of aspects of American tax policy are not conducive to maintaining America's lead in science and technology or in encouraging medical technology and other industries to locate manufacturing and research and development in the United States. Issues that have been identified include the relatively high American corporate tax rate; the failure to make the R& D tax credit permanent and its lack of generosity relative to competitor nations; and tax policy that makes it expensive to bring profits earned abroad home for investment in America. All of these policies deserve reconsideration.

The R & D tax credit deserves special mention. The U.S. was the first country to establish such a credit, but today it ranks 17th out of 21 OECD companies in its generosity. It has been estimated that raising the credit from 14 percent to 20% would increase economic output by $90 billion and increase federal tax revenues by $90 billion, more than offsetting the $6 billion of additional Federal costs.[21] The failure to make the credit permanent undermines its ability to stimulate research and development, as opposed to subsidizing research and development that would occur anyway. For the start-up companies creating the breakthrough products of tomorrow, the R & D tax credit has limited utility, as described below, and could be much more effective in encouraging innovation.

The newly enacted $20 billion excise tax on medical technology products will inhibit investment and put U.S. domiciled companies and especially small companies at an additional disadvantage relative to foreign competitors. Of course, we want to express our deep appreciation of your successful efforts, Senator Klobuchar, to reduce the level of that tax.

Encouragement of small and start-up companies

As discussed earlier, small and start-up companies are critical engines of innovation for the medical technology industry. These companies are extremely dependent on venture capital and angel investors and sufficient venture capital is often not available to fund many promising ideas, to provide support in the earliest stages of product development, and to sustain development of innovative products over an extended time frame. There are several ideas that could be considered to address this

problem that could potentially have a significant effect in driving scientific and technological innovation:

- For companies with no profits, allow the R & D tax credit to be taken against payroll taxes or received as a refundable tax credit rather than held and used against future profits. This could help provide critical capital during the time when the company most needs a positive flow of funds, and could have a major impact in encouraging private investment and bringing more innovative therapies to fruition.

- Expand the Small Business Innovation Research program at the NIH and liberalize eligibility requirements. This program is potentially extremely valuable in funding early-stage research and development by start-up companies, but the maximum award size and the requirement that applicants can not have majority venture capital ownership are limiting. Since the program precluded awards to majority venture capital owned firms, applications for SBIR grants at the NIH have declined by almost 50%.[22]

- Expand support for regional or local innovation clusters and incubators. Such clusters have been shown to spur development of new technologies and products and additional support for local efforts to establish them could be helpful.

Invest in America's science base

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 and 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.[23] The Administration's proposals, as outlined in the President's address to the National Academy of Sciences on April 27, 2009, will go a long way to rebuilding America's scientific and technical strength and these policies should be maintained.

Conclusion

Thank you again for your interest in this important issue. If I could leave you with one message it is this: to maintain America's world leadership in the life sciences generally and medical technology specifically, we need good policy to support our strengths in this increasingly competitive world.

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