Appendix: Detailed Description of AdvaMed Proposals

What follows are legislative proposals we believe will significantly improve the innovation ecosystem and improve patient access to the best in medical progress.

The breakthrough pathway

The breakthrough pathway proposal would create an accelerated, seamless pathway for FDA approval or clearance and Medicare and Medicaid coverage and payment for products that represent an opportunity to achieve significant improvements in treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. By providing an accelerated route to FDA approval and Medicare and Medicaid coverage and payment, the breakthrough proposal would stimulate development of important new diagnostics and treatments and assure prompt availability of those treatments to patients.

To qualify for FDA designation as a breakthrough product, a product must provide more effective treatment or diagnosis of life-threatening of irreversibly debilitating diseases or conditions. If it meets this threshold, it must also meet one of the following conditions: represent a breakthrough technology, have no approved alternatives, offer significant advantages over existing approved alternatives, or its availability must be in the best interest of patients.

FDA-designated products would then be eligible for a variety of mechanisms to speed development and review, including oversight by top managers; review by a specially trained team of subject matter experts; early agreement on a data development plan, shorter or smaller clinical trials, coupled with adjusted balance between pre- and post-market data; and reliance on surrogate endpoints among others. Not all mechanisms would be applicable to all products.

If a product receives the FDA designation and is approved or cleared by FDA, it would receive automatic transitional coverage by Medicare, using an accelerated coding process, as well as a guaranteed level of reimbursement. Medicaid coverage would also be required. During the five-year transitional period, Medicare would determine what additional data, if any, it needs to make a final decision of whether the product is reasonable and necessary for permanent coverage, and based on that data would make a final decision at the end of the five-year transitional coverage period. During the transitional period, adjustments would be made to benchmarks for the shared savings, bundling, and other risk-sharing programs to assure that adopters of the breakthrough products are not penalized.

The theory behind the proposal is that most treatments that meet the definition of a breakthrough, as determined by the clinical experts at FDA, and are determined by FDA to be safe and effective, would ultimately receive Medicare coverage in any event. But the availability of the accelerated pathway would make these treatments available more quickly to patients. Equally or more important, removing delays and uncertainties from the coverage process and reimbursement for products that truly represent significant clinical advances will be an important stimulus to investment in and development of these breakthrough diagnostics and treatments. Because the coverage is transitional, CMS will be able to insist on gathering of any appropriate additional data and can deny continued coverage after the transition period if a treatment does not live up to its promise.

Proposals to improve FDA's regulatory processes

- Meet and exceed the groundbreaking 2012 user fee agreement goals for such key objectives as reductions in total review times and more frequent and substantive interactions between FDA and product sponsors. The 2012 user fee agreement set new goals for FDA and companies designed to promote more rapid, efficient and interactive product reviews. Key goals included reductions in total review times and more frequent and substantive interactions between FDA and product sponsors. FDA also agreed to supply, on a quarterly and annual basis, data that would assist in measuring its performance and provide a basis for improvement. While the numeric goals of the agreement are being met, continued progress needs to be made to achieve the ultimate objective of providing new technologies first in the world to American patients.

- Revitalize the "least burdensome standard" for regulatory review through enhanced reviewer training and encouraging the use of valid scientific evidence from such sources as registries, experience in foreign markets, and peer-reviewed journal articles where appropriate to support safety or effectiveness determinations. Since 1997, the FDA statute has required reviewers to use the "least burdensome" means to assure that the statutory standard of safety and effectiveness is met. This common sense requirement is designed to minimize the cost and time involved in bringing new treatments to patients, while maintaining FDA's high standards for safety and efficacy. Application of this common sense standard in the actual review process has been spotty, however. A group of proposals in the innovation agenda is designed to assure that the standard is followed so that FDA review will be more efficient and the time and cost of bringing medical technology from the bench to the bedside will be

reduced. Among other requirements, FDA would be required to conduct training on the concept and develop an updated guidance document. In addition, since the definition of what is valid scientific evidence to support an application is critical to application of the least burdensome criteria, the proposal would clarify in statute that well-documented registry data, data from studies conducted outside the United States, and data from peer-reviewed journal articles can be considered valid scientific evidence. This is consistent with current FDA policy, but is often disregarded by reviewers; putting the standard in statute would encourage its consistent use throughout the agency.

- Encourage FDA to accept international consensus standards. FDA, medical device companies, and regulators from all over the world participate in many standard setting organizations. The consensus standards developed by these organizations help increase efficiency for medical device innovators and for the global regulators who evaluate their products. However, FDA's recognition of consensus standards has been uneven and unpredictable. This provision requires FDA, when requested, to recognize international or national consensus standards applicable to medical devices. Should FDA choose not to recognize a standard, they are required to make public its basis for refusal.

- Improve the CLIA-waiver process to accelerate the availability of point-of-care, rapid diagnostic information to physicians and patients. Diagnostic tests are at the forefront of medical innovation, providing vital insights into patient health and transforming care. With the progress of medical science an increasing number of tests can be administered and interpreted outside the traditional lab setting at the point of care ("CLIA waived" tests). Point-of-care tests can provide rapid, actionable information for clinicians and can improve the quality of care while often reducing the cost. These tests may not be used outside the lab setting, however, unless FDA determines that the CLIA requirements can be safely waived. Current FDA guidance on CLIA waivers has resulted in significant regulatory challenges and few new critical tests available to health care professionals in settings ranging from the doctor's office to the clinic to the emergency room. Despite their valuable role in health care delivery and increasing clinician need for simple, portable rapid tests in infectious disease, antibiotic resistance, and other uses, FDA guidance imposes rigid criteria difficult to achieve in practice and limitations that often do not reflect clinical requirements.

  To assure appropriate access to point-of-care tests and continued development of these important diagnostic tools, AdvaMed's proposal would require FDA to revise its

2008 revised guidance, which has slowed approval of needed waivers. Within 12 months of the effective date of the legislation, FDA must issue revised draft guidance on review expectations for CLIA waiver study designs. The new CLIA waiver guidance or regulation would be expected to clearly set forth specific, delineated criteria for review, including comparable performance by untrained users and trained technicians in a laboratory setting.

- Allow the use of central IRBs to facilitate the conduct of multicenter clinical trials. Obtaining local IRB (Institutional Review Board) approval at each participating trial site to conduct a multicenter clinical trial can be a major element in extending the time and cost of a clinical trial. Increasingly, in multicenter research trials that do not involve devices, sponsors and trial sites rely on a single IRB of record to assure that patients are protected, avoiding the need for each trial site to go through a separate certification process. The FDA statute, however, mandates local IRB approval for device trials (520(g)(3)(A). This proposal would eliminate the prohibition on using a single IRB of record for device trials, conforming the statute to the requirements for drug trials and the practice for other types of multicenter trials, and would require FDA to develop guidance on the use of such single IRBs in device trials.

- Reduce the review burden on FDA and companies by allowing companies to make changes to devices without prior FDA approval if their quality system has been certified as capable of evaluating such changes. This proposal would create a voluntary program where companies would have their quality system (with a focus on the company's system for assessing changes to existing products) certified by an FDA-authorized third party. Quality systems are the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. The certification would be valid for two years and would allow companies to self-certify low-risk changes to 510(k) devices that do not involve major technology changes or changes in the product's intended use. Manufacturers would not be required to submit certain supplements for manufacturing changes to PMA products. Taking these items off of FDA's plate, while still ensuring that companies are accountable, would be a significant reduction in FDA's workload, allowing it to focus on higher-priority activities, and would represent a significant cost and time saving for companies.

- Allow FDA to remove products from the Class I reserved list. In general, Class I devices (low-risk devices) are not required to receive pre-market review. Instead, manufacturers are required to meet good manufacturing practice standards. Some

Class I products, however, are placed on the Class I reserved list, meaning that, although the devices are low-risk, FDA believes there are public health reasons for pre-market review. In 1997, Congress required FDA to review its reserve list and remove from the list products where premarket review was no longer necessary. Due to a glitch in the way the law was worded, however, there is no mechanism for FDA to remove additional products from the reserve list if it thinks premarket review is no longer necessary. This provision would correct that problem by giving FDA authority to remove additional products if appropriate.

- Improve the Advisory Committee process to reduce unnecessary delays and promote sound decision-making and reduce unnecessary delays. The time spent in convening advisory committees is adding significantly to delays in decision-making on product applications. In addition, advisory committees sometimes suffer from a lack of committee members with appropriate expertise, inconsistencies in procedures, and an inability for sponsors to participate appropriately to correct misinformation. This proposal would increase the transparency of the panel member selection process and include the opportunity for the sponsor to be part of the nominating process. It would also:
    - Establish clear and consistent timing goals for panel scheduling and availability of the panel materials to the sponsor;
    - Establish clear and consistent procedures for PMA panel reviews to ensure that each panel meeting is consistent;
    - Establish criteria for clinical involvement on panels; and
    - Include an improved structure and process for sponsors to participate during panel meeting discussions.

- Humanitarian Device Exemption (HDE) flexibility and application to in vitro diagnostics for rare diseases and pediatric conditions. A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the U.S. per year. Such devices can receive an HDE, allowing them to be marketed if they show that they are safe and that the probable benefit to health outweighs the risk of injury or illness – a standard that can be met with less data than a standard device approval. This encourages development of devices for patients with rare diseases where the market is limited.

  The current hard cap at 4,000 individuals is excessively restrictive and is a significant disincentive blocking the development of devices for rare diseases and conditions,

especially diseases affecting children. The 4,000 limit is also a special obstacle for the development of diagnostic devices, since FDA interprets the limitation to apply to the number of patients that would receive the diagnostic test, rather than the number of individuals affected or manifesting the rare disease. Obviously, some people who would qualify to be tested based on their symptoms or other characteristics will turn out not to have the disease. If a diagnostic test were developed to diagnose patients with a condition that manifests in 4,000 people or less per year, it is quite likely that physicians would prescribe the test more than 4,000 times a year to diagnose those with the rare disease. AdvaMed proposes to raise the cap to allow treatments for more diseases to qualify for this special incentive.

Proposals to improve Medicare's coverage and payment processes

- Establish automatic Medicare coverage of FDA-approved clinical trials. Medicare currently covers FDA-approved and other device clinical trials under two methods. For a trial of a device that would be used with a currently covered service (Category B), e.g., a new type of heart valve, Medicare will pay the normal cost of a heart valve replacement for patients participating in the trial. For a device that would be used with an entirely new service (Category A), Medicare pays the routine costs associated with the trial that it would ordinarily cover, e.g., hospital room and board, but not the cost of the technology itself. Currently, even if FDA has approved the trial as scientifically sound and appropriately protective of patients, Medicare requires a separate coverage determination. Until recently, this determination was made by local carriers; a new centralized process was just put in place beginning Jan. 1.

  Medicare currently approves virtually all requests for coverage, but the duplicative approval process adds unnecessary time and cost to the conduct of clinical trials. Small start-up companies, in particular, generally find the bureaucratic hurdles too great and often do not even apply for Medicare coverage, making it more difficult for them to acquire patients for their trials and denying the opportunity to participate to senior citizens. Drug trials approved by the FDA are automatically covered by Medicare. Removing this bureaucratic barrier would lower the cost and time associated with conducting clinical trials and help to achieve the goals of the Medicare program: to provide Medicare patients the opportunity to participate in clinical trials and to advance the public interest in supporting medical research.

The proposal would conform the treatment of drug and medical technology trials by eliminating the requirement for separate Medicare approval of medical technology trials that FDA has approved.

- Expand coverage of telehealth services, including remote monitoring. Inappropriate coverage and reimbursement restrictions under Medicare limit access to, and use of, telehealth and remote monitoring technologies. Even though Medicare's fee-for-service program includes a benefit category called telehealth services, coverage is restricted by the site of service where beneficiaries may receive care and the geographic area where they reside, the type of technology used, and services provided by select health care professionals. With their emphasis on care coordination and improvements in the efficiency and quality of care, Accountable Care Organization (ACO) and bundled payment programs are natural candidates for maximizing the benefits of telehealth technologies. However, Medicare's restrictive coverage and payment policies limit their ability to do so and compromise their ability to reduce costs in the Medicare program. With the explosion of e-health and remote applications enabling higher quality care in non-conventional settings, the current limitations are antiquated and deny beneficiaries access to some of the most efficient and effective methods of managing and treating disease.

  Under the AdvaMed proposal, expanded telehealth and remote monitoring services would be covered in delivery reform models implemented by CMS's Center for Medicare & Medicaid Innovation. In the ACO and bundled payment programs, the Innovation Center would be required to test the extent to which expanded services result in Parts A and B savings and improve or maintain quality of care. The Center would also be authorized to use other appropriate payment models for testing this concept.

  Expanded services would be limited to those that (1) assist providers in coordinating care, enhance collaboration among providers, reduce hospital admissions/readmissions, or reduce or replace other covered services; and (2) are targeted at major chronic conditions (e.g., hypertension, chronic kidney disease and cancer) or are conditions used in the Hospital Readmissions Reduction Program (e.g., chronic obstructive pulmonary disease, total hip and knee replacement procedures).

  The test would last for five years. After three years of expanded coverage and data collection, the Innovation Center would be required to begin evaluation of the program. If the Secretary found that specific telehealth/remote monitoring services

resulted in Parts A and B savings and improved or maintained quality, these services would continue to be covered and paid for in delivery reform models beyond the five-year period of testing and evaluation. The Secretary would also be required to cover and pay for services under Medicare's fee-for-service program that were found in delivery reform models to have resulted in savings and improved or maintained quality of care.

- Expand coverage of disposable, prevention and treatment technologies used in the home. The primary method Medicare uses for covering treatments used in the home setting is under the durable medical equipment (DME) benefit. However, Medicare's current interpretation of the scope of the benefit is counterproductive. Medical technologies that are "disposable" cannot be covered for use in the home because they are not "durable," even if they are less expensive or more effective than a durable product currently covered under Medicare's DME benefit. Moreover, CMS has determined that some medical technologies appropriate for use in the home and meeting the durability test cannot be covered because they *prevent* rather than *treat* a condition or illness.

  The AdvaMed proposal would address these problems by requiring coverage of disposable medical technologies that substitute for durable medical equipment, and other technologies that are appropriate for use in the home and *prevent* a medical condition.

- Streamline Medicare's process for granting temporary outpatient and physician payment codes to new technologies and prohibit Medicare contractors from arbitrarily denying payment for these technologies. It can take 14 to 24 months to assign a Current Procedural Terminology (CPT) code to a new service under the American Medical Association's current processes. CMS has a procedure for providing temporary codes to bridge this gap (Category III CPT and HCPCS codes), but this process is also unduly slow. Moreover, Medicare contractors often treat these Category III temporary codes as automatically non-covered services, even though the product is FDA-approved as safe and effective. The result of these barriers is to unnecessarily delay the availability of FDA-approved therapies and diagnostics to patients and discourage investment in development of new treatments.

  AdvaMed proposes that CMS be required to create a mechanism to immediately obtain a Category III CPT/HCPCS Level I code once a device receives FDA approval. CMS contractors would be required to cover Category III codes unless they provide a

formal explanation and rationale for non-coverage. Our proposal would also prevent automatic non-coverage of a Category I code that is based on a previously non-covered Category III code.

- Require state Medicaid programs to take patient views into account in making coverage decisions. State Medicaid programs have considerable discretion over what treatments to cover for their beneficiaries and are under considerable cost pressure. Medicaid beneficiaries are uniformly low income, and many are elderly or disabled. They are not always organized to advocate effectively to protect their interests. This proposal would require state Medicaid programs to include an effective mechanism for taking patient views into account in making coverage decisions.

- Increase the transparency and fairness of the local coverage determination process. As a result of contractor reforms that have taken place over the past several years, local Medicare Administrative Contractors, or MACs, are now responsible for much larger jurisdictions, and there are fewer opportunities for stakeholders to interact with the contractor medical directors who make local medical policies. Moreover, CMS is allowing contractors to coordinate their decisions, effectively transforming local coverage determinations (LCDs) into national ones. But basic procedural fairness for patients, providers, manufacturers and other stakeholders is often lacking in local coverage decisions.

  AdvaMed proposes creating basic procedural fairness for the LCD process by requiring Medicare contractors to establish a timely and open process for developing LCDs that includes such requirements as open public meetings, meetings with stakeholders, the solicitation of comments on draft policies, the posting of responses to comments received and providing public responses to these comments.

- Improve the new technology add-on payment program to capture a larger share of important new technologies and set payments more appropriately. Uncertainties in reimbursement for new medical technologies create disincentives for companies, regardless of size, to invest in research and development that lead to medical technology innovation and improvements in the quality and efficiency of health care. The New Technology Add-on Payment (NTAP) program was created to address this issue by providing a temporary increase in DRG payments for use of new technologies within an existing DRG if the new technology offers substantial clinical improvement, would significantly raise the cost of a service within the DRG, and meets other criteria. This temporary increase in payment would, in theory, avoid penalizing providers who

choose to adopt the new technology. Problems with CMS's implementation of NTAP, however, have minimized the impact this payment has on incentivizing innovation. CMS's definition of "newness" excludes many technologies that receive a payment code long after FDA approval. Additionally, CMS's stringent interpretation of "substantial clinical benefit" generally requires randomized controlled trials while discounting other important evidence. To qualify for the add-on, a technology must raise the cost of a procedure by at least 50 percent. Further, CMS chooses to reimburse the add-on at only 50 percent of the additional costs of new technology. This leaves significant costs uncovered, which is a disincentive for hospitals to add the new service and limits the number of patients that can access the technology. A recent study published in the February 2015 issue of *Health Affairs* highlighted that CMS has allowed only 19 products to qualify for NTAP innovation incentives, that spending on the program has amounted to only 35 percent of CMS's estimates of spending, and that other countries with similar programs have qualified a substantially larger number of new technologies for special treatment.[1]

AdvaMed proposes to address these issues by modifying the definition of "newness" so that it starts from assignment of a reimbursement code or FDA approval, whichever is later; prohibiting CMS from arbitrarily refusing to consider evidence other than randomized controlled trials for documenting "substantial clinical improvement" and providing more specificity to the definition; reducing the level of increased cost that is used to determine eligibility for the designation; and increasing the add-on payment from 50 percent of the cost of the new technology to 100 percent.

- <u>Establish payment levels more promptly for new technologies used in the inpatient setting, using the best available data</u>. Under the current process to update Medicare's inpatient prospective payment system, new technology procedures not qualifying for the new technology add-on payment very often are assigned to an inappropriate MS-DRG grouping, resulting in inadequate payment for the new procedure. CMS typically will not consider reassigning a new technology procedure to a more appropriately paying MS-DRG or a new MS-DRG until it has two years of MedPAR data that demonstrate the cost of the procedure. This lengthy period of inadequate payment is a serious barrier to hospital adoption of and patient access to innovative new therapies.

  AdvaMed proposes to require that CMS use the best available cost data to make an initial MS-DRG assignment for a new technology procedure, instead of waiting two years for MedPAR data to be available before considering an MS-DRG reassignment.

Best available data could include, for example, provider surveys, commercial price data, and manufacturer invoices. The initial MS-DRG assignment would be provisional and subject to review after MedPAR data become available for review.

- Improve the methodology for updating payments to ambulatory surgical centers (ASCs). The ASC rates are currently adjusted for inflation using CPI-U instead of the hospital market basket despite the fact that ASC rates are based on hospital outpatient rates for the same services. The variation in the annual inflation factor is causing ASC payment rates – that are paid using the same Ambulatory Payment Classification (APC) system as outpatient hospital services – to inappropriately decline each year when compared to comparable outpatient hospital surgeries.

  AdvaMed recommends that the update factor for ASC payment should be the same as the update factor for hospital outpatient department payments.

- Improve the methodology for establishing payments used in the outpatient setting. What were formerly inpatient procedures are increasingly migrating to the outpatient setting. However, there are significant flaws in the way technology is valued in that setting. CMS is creating larger payment bundles as more and more complex services are able to be performed on an outpatient basis. With growing complexity and larger bundles, ensuring that these bundles accurately reflect the cost of multiple services has become a problem. High-cost technologies and procedures, in particular, have sometimes been bundled with substantially lower cost technologies and procedures, penalizing hospitals when they use higher cost procedures appropriately to meet patient needs. In addition, annual changes to the valuation of codes are not given adequate consideration when determining Ambulatory Payment Classification (APC) creation and code placement. Therefore, when a CPT code is revised to account for changes in the resources used, increased/decreased complexity, and new innovations, there is no corresponding change to ensure that the overall outpatient APC payment is correct.

  AdvaMed proposes that CMS should be required to factor in the cost of devices and the number of high-cost devices associated with a procedure when determining appropriate APC placement. In addition, CMS should be required to evaluate code value changes on an annual basis as it determines appropriate APC placement for procedures. CMS should also be required to publish in the proposed rule each calendar year which codes have been revised, what their prior APC placement was, and whether that APC placement will change for the upcoming calendar year. This

would provide transparency and a fair opportunity for stakeholders to comment on proposed changes before they are implemented.

- Implement ICD-10 this fiscal year. The ICD-9 code set does not provide a mechanism to code for many advanced procedures that are performed in the inpatient hospital setting. Delays in implementing ICD-10 create a deficit in codes that are available to bill for certain procedures, especially those utilizing new technologies. CMS has implemented a freeze on new codes until one year after implementation of ICD-10 and further delays will exacerbate coding problems for new technologies.

  AdvaMed proposes that ICD-10 implementation this fiscal year should be mandatory.

Proposals to reform the U.S. tax system to make if more competitive and supportive of innovation

- Repeal the medical device excise tax. As discussed, the medical device tax poses a heavy additional burden on medical technology companies attempting to compete in world markets, raising the total U.S. taxes paid by medical technology companies by 29 percent and the average effective federal tax rate for medical technology research and development and manufacturing conducted in the U.S. to 40 percent – surely one of the highest in the world for any industry. An AdvaMed survey has found that the tax has already cost the U.S. 18,500 jobs and projects another 20,500 jobs will be lost or not created over the next five years, for a total of 39,000 jobs lost or foregone.[2] More than half of the respondents said that they had reduced R&D as the result of the tax, and a similar proportion said that if the tax continued they would be forced to make further or first-time reductions in R&D, with obvious implications for long-term competitiveness.[3]

- In the context of comprehensive tax reform, create a level competitive playing field for made-in-America medical technology.

    - Enact new tax incentives to invest in start-up companies creating new treatments and diagnostics. A key difficulty facing all medical technology start-up companies is sustaining an adequate capital flow to complete all the development and regulatory steps necessary to get to market, generate revenue, and finally to achieve profitability. The sharp decline in venture capital investment noted above has made the problem of raising capital even more acute. The developmental steps necessary to complete

FDA approval alone typically take ten years and an investment of almost $100 million.[4]

AdvaMed's recommended reforms to FDA and CMS will help make investment in start-up companies more attractive, but tax changes are also needed to support investment in these companies, which are so critical to development of a high proportion of the truly breakthrough treatments and to the medical technology ecosystem as a whole. Other countries provide special tax incentives for such firms, and they also, in many cases, have a high level of government direct investment, an approach that is not generally regarded as optimal in the U.S. The tax incentive that would have the most substantial impact on investment in medical technology start-up companies would be to allow individual investors to receive some interim tax benefits during the long period before the start-up attains profitability. This could be achieved by relaxing the passive activity loss (PAL) limitations for R&D-focused pass-thru entities. Under this proposal, small companies would be able to enter into a joint venture with their investors. The losses generated by the joint venture, which can't be used directly by the technology company because it has no taxable income, would then flow through to the investors, who would be able to use the tax assets to offset other income. Investors would have the opportunity to enjoy a more immediate return on their investment – providing a significant incentive to invest in the early stage when capital is most difficult to raise. Other tax provisions that would be especially helpful to small medical technology companies include making the section 179 deduction for capital equipment permanent at the $500,000 level and extending bonus depreciation, which benefits all companies making capital investments, but is especially meaningful for small companies facing cash flow problems.

Other tax proposals that might be helpful include allowing Net Operating Losses (NOLs) generated by R&D to be carried forward through ownership changes. Typically, there are disqualifying ownership changes for medical technology start-up companies as there are new rounds of investment. Allowing NOLs to be carried forward would increase profits as companies grow and make them more attractive acquisition targets, stimulating early stage investment.

- Lower the overall corporate tax rate to levels comparable or lower than competitor nations. General corporate tax rates are high and uncompetitive. The statutory corporate tax rate in the U.S. is the highest of any OECD nation and is 58 percent higher than the OECD average.[5] As noted in the body of this report, activities of the medical technology industry located and taxed in the U.S. face an average effective federal tax rate (not including the device tax) of 31 percent, compared to 14 percent for activities located and taxed abroad. These tax rates place activities located in the U.S. at a significant competitive disadvantage and contribute to the erosion of America's leadership in medical technology.

- Provide incentives comparable to other countries for development and manufacturing of technology. Beyond lower general corporate tax rates, other nations provide special incentives to knowledge-based, high value added industries like medical technology. These include more generous and more stable tax credits for research and development and targeted incentives such as "patent boxes" or "innovation boxes," that provide a special low rate to encourage the growth of these industries or attract them from abroad. Moreover, some countries provide special incentives tailored to specific projects.

  If the U.S. is to continue to benefit from a successful, growing economy, it must retain its competitive edge in these industries, since we will never be competitive on the basis of low wages, nor would we want to be. Tax incentives comparable to other industries are essential to achieving this goal. AdvaMed recommends that the R&D credit be made permanent and research and development incentives comparable to or better than competitor nations. The U.S. should institute an "innovation box" regime that provides substantially reduced corporate tax rates for profits derived from intellectual property developed in the U.S. or used in manufacturing products in the U.S. Because a number of medical technology products are based on non-patent intellectual property, the definition of intellectual property should not be solely based on patents.

  Incentives similar to the innovation box are especially important since a lower general tax rate alone will not make our tax system comparable to competitor nations for medical technology and similar industries when other countries offer special incentives below the general rate. Moreover,

even a reduction in our general corporate tax rate to 25 percent would still leave us with the seventh highest rate among OECD nations.[6] Finally, the section 199 manufacturing tax deduction, or some similar mechanism, is important in moving to a more level playing field.

- Conform the treatment of international earnings to that of competitor nations. The U.S. stands alone among the members of the G7 in taxing world-wide earnings and almost alone among OECD nations. The effect of our system is to put American-domiciled companies at a competitive disadvantage and to discourage companies from investing profits earned abroad in the U.S. AdvaMed recommends that the U.S. adopt a territorial tax system.

Improving access to international markets

- Work with the U.S. government to encourage foreign governments to establish regulatory and payment systems for medical technology that are fair, transparent, nondiscriminatory and based on international best practices. The medical technology industry faces several barriers to robust competition in foreign markets that need to be overcome. Just as in the U.S., a sound and efficient regulatory system is essential to provide patients prompt access to needed treatments and diagnostics. Particularly but not exclusively in developing countries, expertise in constructing or administering an efficient system may not exist. Given world-wide interest in cost-containment, payment systems may not always fairly evaluate the benefits of medical technology or provide methods for encouraging adoption of innovative treatments. Finally, some countries, especially in the developing world, have used discriminatory regulatory, payment or contracting procedures to give an unfair advantage to domestic industries or to try to incentivize international companies to place R&D or manufacturing locally. Industry needs the full support of the U.S. government in working with foreign governments to overcome these barriers.

- Enact Trade Promotion Authority to negotiate the Trans-Pacific Partnership and the Transatlantic Trade and Investment Partnership, and assure that those agreements include provisions that improve market access for medical technology. Free trade agreements benefit the medical technology industry and other industries in which the U.S. has a comparative advantage. But genuine free trade agreements require that trade also be fair and exclusion of non-tariff barriers of the kind referenced in the preceding

bullet. In addition, free trade agreements must provide adequate protection for intellectual property.

- Enforce provisions of existing trade agreements such as the U.S.-Korea Free Trade Association to assure fair access for U.S. technology products. While the overwhelming amount of trade between FTA partners flows without facing problems, robust dispute settlement systems are essential to enforce FTA provisions and enhance credibility of the agreement. Vigorous utilization of dispute settlement mechanisms by USTR, if other avenues to resolving the issue are blocked, is necessary.

Proposals to support the maintenance and growth of America's R&D infrastructure

- Provide steady growth in funding for the National Institutes of Health and the National Science Foundation. NIH is the jewel in the crown of the national biomedical research effort, and NSF provides critical support for research in physics, materials science and engineering of special importance to the medical technology industry. Funding from both sources is central not only to specific research products but supporting training of the next generation of researchers and the maintenance of research infrastructure at our nation's great universities and academic health centers. AdvaMed does not recommend a specific level for funding but we believe Congress should prioritize (1) restoring the cuts in real terms that have occurred over the last ten years and (2) then increasing funding at a steady rate that exceeds inflation in research costs.

- Improve the SBIR and STTR programs by raising the amount of funding (in the context of rising NIH and NSF funding) and allowing larger individual grants to better recognize the costs actually incurred by start-up companies. Funding in these two programs is generally limited to $150,000 for phase I awards and $1 million for phase II awards. While SBIR has been an important source of funding for some early phase device companies, capital requirements for development of a medical technology product – even in these early stages – generally substantially exceeds the grant limits. These programs would be more valuable if the limits on individual grants for NIH applications were raised in the context of general increases in funding for the programs that would assure that the number of grant opportunities would also be expanded.

- More effectively tap the vast intellectual resources of our nation's universities and academic health centers by providing federal technical assistance to establish and diffuse technology transfer best practices. Some universities and academic health centers have very effective technology transfer programs that have been a rich source

of new treatments and diagnostics. Unfortunately, many technology transfer programs lack the sophistication and understanding to develop fruitful collaborations with medical technology companies, depriving the country of many promising opportunities for medical progress. A federal technical assistance program could help successful programs share their expertise with other institutions and expand the pool of good ideas that could be developed into actual treatments and cures.

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[1] John Hernandez, et al., "U.S. Hospital Innovation Payments Lag those of France, Germany & Japan," *Health Affairs*, February 2015.
[2] "Impact of the Medical Device Tax: A Status Report from AdvaMed," January, 2015.
[3] Ibid.
[4] Josh Makower, et al., "FDA Impact on U.S. Medical Technology Innovation," November, 2010.
[5] PricewaterhouseCoopers (PWC), "Opportunities and Challenges Ahead: 2015 Tax Policy Outlook." January, 2015, p. 18.
[6] Ibid.