



Edwards

**Testimony of Michael A. Mussallem  
Chairman and CEO, Edwards Lifesciences  
before the U.S. Senate Committee on Health, Education, Labor and Pensions**

**Hearing on  
“Continuing America’s Leadership: Advancing Research and Development for Patients”  
March 24, 2015**

Introduction

Chairman Alexander, Ranking Member Murray and Members of the Committee:

I am Mike Mussallem, chairman and CEO of Edwards Lifesciences, based in Irvine, California, and I am testifying today on behalf of AdvaMed, the Advanced Medical Technology Association. I am truly honored to join my fellow panelists today to discuss a path to revitalizing medical device innovation in the United States.

I am here because I am passionate about helping patients. That’s why I and hundreds of thousands of U.S. medical device industry employees like me come to work each day. We love what we do because it can have such an amazing, direct impact on the lives of patients.

Based on Edwards’ experience in developing and delivering new therapies to American patients over the last several decades, I am very concerned that we are seeing an alarming decline in U.S. medical innovation<sup>1</sup>. The balanced ecosystem that has supported innovation in the U.S. has been eroded by an increasingly costly and cumbersome regulatory process, and risk-averse payment culture.

The U.S. has been the world leader in medical technology for more than a generation, but our leadership is eroding. Venture capital investment, especially investment in the early stage ideas that are the future of innovative therapies, has plummeted—a decline of almost three-quarters between 1997 and 2013.<sup>2</sup> While the current FDA leadership has begun to make

dramatic improvements, the regulatory process remains time-consuming, inefficient, and unpredictable. The payment environment is far less hospitable to new technology today than ever before, meaning investment in new treatments is discouraged and patients are deprived timely access to important new therapies. Additionally, uncompetitive tax policies disincentivize the location of R&D and manufacturing in the United States.

Over the 35 years I have spent working in medical devices, I have had the opportunity to be involved with the development of dozens of innovative therapies. Today, I am privileged to lead the more than 9,000 employees of Edwards Lifesciences, who dedicate their lives in a very personal way to helping critically ill patients and those suffering from heart valve disease around the world. We have been the leaders in heart valve innovation for more than 50 years, starting when an engineer, Miles Lowell Edwards of California, partnered with a cardiac surgeon, Dr. Albert Starr of Oregon, to develop the first commercially available artificial heart valve. I also had the honor of representing our industry in a number of leadership roles, noteworthy among them my term as chairman of our trade association, AdvaMed.

It is my experience that successful medical device innovators keep an unwavering focus on patients. We count it a privilege to serve these patients, creating and supplying devices and therapies that save, enhance and prolong lives. We are the toolmakers for clinicians, working closely with them to develop technologies to address unmet patient needs. Each new innovation is also a stepping stone that lays the path to something even better. Innovation is a powerful and iterative force, and those who are involved in it are never satisfied with the status quo. It is our passion and mission to keep finding better solutions to improve human health.

Edwards' innovation story is similar to many companies that have made medical technology a uniquely American success story. The medical technology industry is central to the development of devices and diagnostics that will provide the life-saving and life-enhancing treatments of the future. Patient access to advanced medical technology generates efficiencies

and cost savings for the health care system and improves the quality of patient care. Over the last three decades (between 1980 and 2010), advanced medical technology helped cut the number of days people spent in hospitals by more than half and added five years to U.S. life expectancy while reducing fatalities from heart disease and stroke by more than half.

The industry is also an engine of economic growth for the U.S, generating high wage manufacturing jobs and a favorable balance of trade. Medical technology is responsible for more than two million U.S. jobs, including both direct and indirect employment.<sup>3</sup> Clusters of innovation in states like California, Texas, Minnesota, Massachusetts, New York and North Carolina, are responsible for addressing the world's most serious health challenges, while, at the same time, serving as a robust economic engine, providing attractive U.S. jobs and economic growth far into the future.

As innovators, we have the unique opportunity to live and breathe the current regulatory process on a daily basis. Our experience with transcatheter aortic heart valve replacement (TAVR), a revolutionary approach to replacing a patient's aortic heart valve without open-heart surgery, has provided us a unique perspective on the current regulatory process. As we have navigated the regulatory channels to bring this therapy to U.S. patients over the last decade, we have taken note of not only the challenges, but also the forward-looking vision of the leaders of FDA and CMS to develop opportunities for better collaboration with the agencies. FDA has learned from the last several years, and we are already seeing much-needed improvements being made.

We believe opportunities remain to reduce barriers in regulatory approval and reimbursement that will help promote America's continued worldwide leadership in the area of medical device development and support innovation. AdvaMed has proposed a new Innovation Agenda (attached). Enactment of this agenda can unleash the potential of medical technology to extend and improve lives, reduce the cost and burden of disease, and maintain and enhance

U.S. scientific and economic leadership. I know the Committee shares these same goals and I applaud you for your focus on these important issues. Today I will focus on three primary areas:

1. FDA's vision to improve the regulatory process must be accelerated.
2. We should strengthen the R&D infrastructure so that it is second to none.
3. To encourage innovation, we need to address issues throughout the entire ecosystem.

### Edwards' Unique Perspective

Edwards Lifesciences has been at the forefront of an ambitious effort to impact the lives of patients suffering from a deadly heart valve disease called aortic stenosis. The Edwards SAPIEN transcatheter aortic heart valves deliver a collapsible prosthetic valve into the body via a catheter-based delivery system. The valve is designed to replace a patient's diseased native aortic valve while the heart continues to beat – avoiding the need to saw open the patient's chest, connect them to a heart-lung machine, and stop the heart. Those of you who have a friend or relative who has had open-heart surgery knows first-hand how difficult this procedure and its arduous recovery can be. In fact, it is so invasive that some patients simply cannot have surgery because the risk of death is too high. Our new heart valve procedure allows patients to avoid that pain and suffering.

Some patients who receive the SAPIEN transcatheter valves can leave the hospital and return home the next day. It's extremely gratifying to hear physicians and patients describe the immediate improvement in patients' health after TAVR. They can breathe and speak more easily, their skin transforms from gray to pink as their vital organs once again receive the oxygen-rich blood they need, and their vibrancy returns within hours.

Patients receiving the Edwards SAPIEN valve return home with potential years of good health added on to their lifespan. Extensive study of this valve – including an unprecedented

record of four *New England Journal of Medicine* papers – has demonstrated the “triple win:” a substantial and sustainable clinical benefit, extraordinary quality-of-life improvement, and cost effectiveness in inoperable patients. In fact, the SAPIEN valves are the most studied heart valve in history. There are more than 3,000 peer-reviewed publications on transcatheter aortic valve replacement (TAVR). There are also more than 60 cost effectiveness studies and at least 30 publications on quality of life related to TAVR.

While our experience with SAPIEN and TAVR, transcatheter aortic valve replacement, has ultimately been successful, it is important to reflect on its unique and challenging regulatory pathway, including some key milestones:

- In 1999, Edwards began an internal program exploring transcatheter valve replacement.
- In 2002, Professor Alain Cribier performed the first-in-human procedure of a transcatheter aortic valve replacement in France.
- In 2007, the Edwards SAPIEN valve, our first commercial transcatheter heart valve, received CE Mark for European commercial sale. The next-generation SAPIEN XT valve received CE Mark three years later.
- Before SAPIEN was approved by FDA, CMS took the unusual step of initiating a National Coverage Determination (NCD) in October 2011.
- Four years after obtaining CE Mark in Europe, and after one of the largest, randomized controlled trials in the history of medical devices, the SAPIEN valve was approved by FDA in November 2011 for the treatment of inoperable patients, making the U.S. the 42<sup>nd</sup> country in the world to approve the device.
- We received regulatory approval for our second-generation device in 2014 and are working on getting the third-generation approved in the U.S. in the near future.

We are encouraged to see that FDA leadership has taken the initial device lag experience with TAVR as a catalyst to improve. In fact, the Agency has made significant progress in

bringing newer generations of TAVR products to patients faster. They have been very actively engaged with many constituencies in the healthcare system, working to better understand and improve predictability and shorten the approval timeline for future generations of transcatheter heart valve devices. In doing so, the device lag for TAVR has narrowed significantly.

One way FDA has worked to improve the process is to use registry data to expand patient access. Under the TAVR NCD, CMS requires that every U.S. patient be enrolled in a qualified prospective registry that tracks appropriate outcomes data to the patient level. In a remarkable effort of collaboration between the medical societies, regulators and other interested stakeholders, the American College of Cardiology (ACC) and the Society of Thoracic Surgeons (STS) helped build what has become one of the most robust clinical evidence and quality measurement tools ever created: the STS/ACC TVT Registry. In an unprecedented step, data from the STS/ACC TVT Registry for transcatheter aortic valve replacement procedures were used by FDA in 2013 to help expand the indications for use of our SAPIEN technology, allowing access to a broader patient population.

At the same time, through close collaboration between FDA and CMS, when new patient populations are approved, they were immediately covered by Medicare. This collaboration took vision and commitment by both FDA and CMS, and they should be commended for their work. We think that these novel approaches reflect agency views that take promotion of public health as seriously as they take patient protection, which as consumers of the system we should all welcome.

We realize that TAVR is a unique example of a breakthrough technology that perhaps warrants this kind of attention from FDA and CMS. If these techniques can be applied to other technologies more broadly, that would go a long way toward revitalizing innovation in the U.S.

## FDA's Vision to Improve the Regulatory Process Must Be Accelerated

As noted through the Edwards transcatheter heart valve experience, improvements in the FDA device review process can reduce the time and cost associated with the development and approval of devices and diagnostics. They can also ensure that the CDRH's stated vision – that American patients will be the first in the world to have access to new devices – is achieved, while maintaining the highest standards of safety and efficacy.

One important area where FDA is heading in the right direction is through its efforts to better involve patients in the regulatory process. Specifically, its guidance document and work through the Medical Device Innovation Consortium, to create a framework and catalog of patient preference measurement tools, will help regulators and device sponsors better incorporate patients' perspectives into the approval process. It is frustrating to Americans to hear that Europeans have access to innovations not available in the US. Many patients have asked me and petitioned our company directly: "It is my life; why can't I make the decision?" The steps that FDA is already taking to listen to the patient perspective can help adjust the regulatory requirements to meet patient demands so that American patients don't feel compelled to seek alternatives.

FDA is taking a number of other initiatives to improve the regulatory processes to help patients access innovative therapies. Thanks to the Food and Drug Administration Safety and Innovation Act (FDASIA), FDA has agreed to improved review and approval performance metrics tied to dramatic increases in manufacturer user fees, and we are just beginning to see positive trends in performance. Beyond that, during the last few years, Dr. Shuren and his team at FDA have outlined strategic priorities to strengthen the clinical trial enterprise, striking the right balance between premarket and postmarket data collection and improving customer service.

Over the past year, a number of guidance documents have been drafted to provide manufacturers and FDA reviewers more clarity, including:

- Priority review for premarket submissions
- IDE and IRB approvals
- IDEs for Early Feasibility clinical studies
- Balancing premarket and postmarket data collection
- Expedited access for certain premarket approval devices

In addition, FDA's expanded efforts to improve device quality and safety by shifting the focus from the old regulatory compliance approach to an upfront quality assurance effort through its "Case for Quality" initiative is promising. Finally, FDA's efforts to improve its regulatory management processes and structure through the recommendations coming from its Program Alignment Group are an important step in the right direction. It would be worthwhile for Congress to spend time assessing how we can move this process forward.

It is important to note the distinction of our industry as compared with others in the healthcare space. Whether created by large or small firms, medical technologies are characterized by a 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 research intensive. U.S. medical technology firms spend over twice the U.S. average on research and development.

Research in our industry means that to support regulatory decisions for approval and reimbursement of new medical technologies in the U.S., manufacturers are required to gather a great deal of clinical and economic evidence. Evidence development can be an extremely costly endeavor at each stage of the process. Focus should be put on reducing the delay and expense that data collection adds at every step in the process.



FDA has recently proposed a number of improvements to the premarket clinical trial process that hold promise, many of which have already been discussed by the House of Representatives through their 21<sup>st</sup> Century Cures hearings. Some of these improvements that we support include:

- Streamlining the investigational device exemption (IDE) approval process to reduce IDE approval timeframes.
- Reducing the legal complexity and inconsistency between each hospital Institutional Review Board (IRB) through the creation of a centralized or standardized review process.
- Addressing potentially duplicative clinical evidence through the consideration of surrogate endpoints and greater use of data developed outside of the U.S.

In addition to these actions that FDA has already taken, AdvaMed has several proposals that would improve FDA's regulatory processes and support innovation:

- The creation of a "Breakthrough Technology" designation, which would clearly identify which specific and innovative attributes qualify to receive preferential treatment in both the approval and reimbursement process.
- Revitalize the "least burdensome standard" for regulatory review to allow for enhanced reviewer training and the ability for device manufacturers to use valid evidence from alternative sources.
- Encourage FDA to accept international consensus standards.
- Reduce the review burden on FDA and companies by allowing companies to self-certify certain changes to devices if their quality system has been certified as capable of evaluating such changes.
- Streamline the CLIA waiver process to accelerate the availability of point-of-care, rapid diagnostic information to physicians and patients.

- Improve the advisory committee process to reduce delays in product approvals and enhance the fairness and transparency of the process.
- Encourage the development of technologies for rare diseases and pediatric populations.
- Work with FDA to assure that post-market surveillance is effective and efficient; provides timely, reliable, and actionable data; minimizes unnecessary burdens on providers and industry; and is facilitated by smooth implementation of the Unique Device Identifier program.

We look forward to working with the Committee and the FDA on these proposals.

#### We Should Strengthen the R&D Infrastructure So That it is Second to None

A robust research and development infrastructure is a critical component of the innovation ecosystem. This Committee appreciates the important role that the National Institutes of Health (NIH) plays in advancing science. To continue this work, we support steady growth in funding for the NIH and the National Science Foundation.

Additionally, the Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) programs can be improved by raising the amount of funding, allowing larger individual grants to better recognize the costs actually incurred by start-up companies.

Lastly, we can 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.

#### To Encourage Innovation, We Need to Address Issues Throughout the Entire Ecosystem

It is important to acknowledge that while we take steps to improve the FDA device review process or strengthen the R&D infrastructure, we must also look at the innovation ecosystem as a whole to retain our innovation leadership. There are a few essential elements

to fostering an ecosystem that incentivizes curiosity and rewards innovators who develop new therapies for patients:

- Patient/physician need
- Ready access to capital and supportive economic climate
- Functional/timely/predictable regulatory processes
- Reimbursement system that welcomes novel therapies as they undergo a continuous improvement process
- Strong intellectual property protection

Unfortunately, however, for the nation's medical technology industry, every part of the innovation ecosystem is under stress. The danger signs include:

- Reduced investment. Venture capital flowing to the medical device sector is both an essential generator of future progress and an index of the attractiveness of investing in the development of new treatments and cures. Venture investment in medical technology declined by 42 percent between 2007 and 2013. First-time funding for medical technology start-ups dropped by almost three-quarters over the same period.<sup>4</sup>
- Movement of clinical trials and first product introduction out of the United States. For more complex products, the new normal is to conduct the first clinical trials and product introductions outside of the U.S. Often, patients in other nations get the second or even third version of a novel treatment or diagnostic while patients in the U.S. are still waiting to get the first version.<sup>5</sup> Among other factors, the decisions to introduce abroad first are driven by the higher cost and time involved in conducting clinical trials in the U.S.; delays and inconsistencies in FDA review; and, increasingly, uncertainties about coverage and payment. We believe this trend is bad for patients and for American jobs. Where research goes, so goes the high-paying research, engineering and manufacturing

jobs. We are encouraged that FDA has made some recent progress in this area through FDA's Early Feasibility Program, which supports the early-stage clinical research.

Edwards Lifesciences has been among the fortunate first few companies to benefit from this program through a U.S.-based early feasibility study of a minimally invasive mitral valve replacement technology. We are hopeful the program can be expanded to benefit many other technologies in the future.

- Increasing difficulty in achieving coverage by public and private insurers for new medical devices and diagnostics. Start-up companies are now reporting that one of the first questions investors now often ask is about the prospects for coverage and payment, while the previous focus was almost exclusively on the FDA. Public and private insurers have been raising the evidentiary threshold for coverage over the last decade. A new study found that in the ten years between 2002 and 2012, technologies being considered for national coverage in Medicare were **20 times** less likely to be successful.<sup>6</sup> When coverage was granted, it was more limited than the FDA approved indications in 40 percent of the cases.<sup>7</sup>
- Declining U.S. competitiveness. The U.S. medical technology industry has been the unchallenged world leader for many years. We still lead, but our continued leadership is threatened as other countries are anxious to wrest leadership from the U.S. Other countries not only have lower general tax rates but many provide specific tax incentives, such as "patent" or "innovation boxes" designed to further reduce rates for domestic development of intellectual property and manufacturing based on that property, in order to attract high-wage, high value-added knowledge-based manufacturing industries.

- Shrinking public research infrastructure. The U.S. has historically led the world in cutting-edge biomedical research. Public funding of NIH and our great universities and academic health centers has been central to the basic and clinical research that has proved to be the foundation of new treatments and cures. But total U.S. medical research effort, as a share of global medical research, declined by more than one-fifth in between 2002 and 2012.<sup>8</sup>

I realize that this Committee's jurisdiction does not extend to Medicare, but a true innovation agenda must address both FDA and Medicare and I urge this committee and the Senate Finance Committee to consult with each other as you move forward to find ways to promote innovation. One of the most important of our innovation agenda proposals—the breakthrough pathway—spans the jurisdiction of both committees and can only effectively be enacted cooperatively.

### The Patient Experience

No discussion about medical technology is complete without understanding the true impact medical advancements have on patients – and we meet a lot of patients.

Earlier this month, we had the pleasure of hosting 50 patients who participated in our first ever Edwards Patient Day held at our Irvine, California headquarters. We brought them there to connect with one another, and to meet the dedicated team of employees who hand-sew every heart valve, stitch by careful stitch. Needless to say, it was a very emotional day for the patients as well as the teams who created their lifesaving valve.

During Patient Day, we met a woman from Colorado who survived Hodgkins lymphoma, but found out she needed a heart valve replacement due to severe aortic stenosis. Since her doctors were not about to crack open her chest made frail by radiation, she was a candidate to

receive a transcatheter valve replacement. She told us how her new valve has kept her healthy and allowed her to get back to her life as a middle school teacher.

We also met a Marine Corps veteran who received TAVR treatment at the VA in Ann Arbor, and was discharged only 48 hours after his procedure. His valve was replaced in January, completely recovered, making the trip from Michigan to Irvine a few weeks ago to share his story with other veterans and Patient Day participants.

It is patients like these – a Salt Lake City father of 10 and grandfather to 25 who received a valve replacement as part of a clinical trial studying the next-generation treatment, and a New York marathoner who, after heart valve replacement, was able to return to running— that remind us of the importance of our daily work, and the chance to bring our ideas out of the lab, into the clinic and to the patients and physicians that need them most.

These and the tens of thousands of other patients we have had an opportunity to help remind us daily that our work is personal, and it impacts people individually. Each heart valve represents a patient and their family, who otherwise would miss out on both the extraordinary and precious ordinary experiences of their daily lives.

Our mission is focused and our way forward is clear. I thank Chairman Alexander, Ranking Member Murray and Members of the Committee for the opportunity to testify today, and to share Edwards' experience in delivering an important new therapy to U.S. patients in need. We look forward to continuing to work with you to support the U.S. innovation ecosystem.

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<sup>1</sup> National Venture Capital Association. (2014). NVCA 2014 Yearbook. Arlington, Virginia: Thomson Reuters.

<sup>2</sup> PWC and National Venture Capital Association, "Venture Capital Investments Q1. 2014—Money Tree Results," April, 18, 2014. There was an increase in 2014 from the low of 2013, but much of the increase was concentrated in digital health, informatics and self-pay technologies, leaving potential technological breakthroughs to diagnose and treat major diseases still starved for resources.

<sup>3</sup> The Lewin Group, "State Economic Impact of the Medical Technology Industry," June 7, 2010 and February, 2007.

<sup>4</sup> PWC and National Venture Capital Association, "Venture Capital Investments Q1. 2014—Money Tree Results," April, 18, 2014.

<sup>5</sup> California Healthcare Institute and Boston Consulting Group, "Taking the Pulse of Medical Device Regulation and Innovation," 2014.

<sup>6</sup> James D. Chambers, et al., "Medicare is Scrutinizing Evidence More Tightly for National Coverage Determinations," Health Affairs, February 2015.

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<sup>7</sup> James D. Chambers, et al., "Factors Predicting Medicare National Coverage: an Empirical Analysis," *Medical Care*, March 2012.

<sup>8</sup> Hamilton Moses, III, MD, et al., "The Anatomy of Medical Research: U.S. and International Comparisons," *JAMA*, 2015;313(2): 174-189.

# Innovation Agenda

*The Medical Innovation Ecosystem – February 2015*

## *Innovation Agenda Background*

The medical technology industry is central to the development of medical devices and diagnostics that will provide the life-saving and life-enhancing treatments of the future. Patient access to advanced medical technology generates efficiencies and cost savings for the health care system, and improves the quality of patient care. Between 1980 and 2010, advanced medical technology helped cut the number of days people spent in hospitals by more than half and add five years to U.S. life expectancy while reducing fatalities from heart disease and stroke by more than half. The industry is also an engine of economic growth for the U.S., generating high wage manufacturing jobs and a favorable balance of payments.

But the innovation ecosystem that supports medical technology is severely stressed. The U.S. has historically been the world leader in medical technology, but our leadership is eroding. Venture capital investment, especially investment in the start-up firms that are the seed corn of the industry, has plummeted. While there have been recent improvements at the FDA, the regulatory process remains too

time-consuming, too inefficient, and too inconsistent. The payment environment is far less hospitable to new technology today than ever before, with the result that investment in new treatments is discouraged and patient access to new treatments that are developed is slower and more difficult. The U.S. tax system is uncompetitive and discourages location of research and development and manufacturing in the United States, a situation that has dramatically worsened as the result of the medical device excise tax. The basic and applied public infrastructure that is critical to long-term advances in the life sciences is eroding.

To respond to these challenges and rebuild the innovation ecosystem, AdvaMed proposes a new Innovation Agenda. Enactment of this agenda will unleash the potential of medical technology to extend and improve lives, reduce the cost and burden of disease, and maintain and enhance U.S. scientific and economic leadership. Failure to act will mean lost lives, unnecessary suffering, reduced job formation, and diminished economic growth.



## The Five Pillars of the Innovation Agenda

1

### Improving FDA's regulatory processes

so that the cost and time of development and approval of devices and diagnostics is reduced and the CDRH mission statement that American patients will be the first in the world to have access to new devices is achieved, while maintaining the highest standards of safety and efficacy.

2

### Restructuring CMS's coverage and payment processes

to support development of new technologies that improve treatment, diagnosis or prevention, and provide prompt patient access to these technologies.

3

### Reform the U.S. tax system to create a level playing field,

starting with repeal of the medical device excise tax—a tax that is draining resources from American manufacturing jobs and research.

4

### Improving access to international markets

by insisting on free and fair trade in medical technology and working with foreign governments to achieve innovation-friendly regulatory and payment policies.

5

### Supporting the maintenance and growth of an R&D infrastructure

second to none.

## Proposals to Implement the Innovation Agenda

### Establish access to breakthrough products:

- Establish a streamlined, seamless path for FDA approval and CMS coverage and payment under the Medicare and Medicaid programs for breakthrough products that make significant improvements in treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

### Improve the FDA's regulatory processes:

**Responding to patient challenges and to rebuild the innovation ecosystem, AdvaMed proposes a new Innovation Agenda.**

- 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.
- 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.
- Encourage FDA to accept international consensus standards.
- Streamline the CLIA waiver process to accelerate the availability of point-of-care, rapid diagnostic information to physicians and patients.
- Allow the use of central Institutional Review Boards to facilitate the conduct of multicenter clinical trials.

## Proposals Continued...

- Reduce the review burden on FDA and companies by allowing companies to self-certify minor changes to devices if their quality system has been certified as capable of evaluating such changes.
- Improve the advisory committee process to reduce delays in product approvals and enhance the fairness and transparency of the process.
- Encourage the development of technologies for rare diseases and pediatric populations.
- Work with FDA to assure that post-market surveillance is effective and efficient; provides timely, reliable, and actionable data; minimizes unnecessary burdens on providers and industry; and is facilitated by smooth implementation of the Unique Device Identifier program.

## Restructure CMS's coverage and payment processes:

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**Enactment of AdvaMed's Innovation Agenda will unleash the potential of medical technology to improve lives, reduce the cost and burden of disease, and enhance U.S. scientific and economic leadership.**

- Establish automatic Medicare coverage of FDA-approved clinical trials rather than requiring a duplicative and potentially time-consuming separate Medicare approval process.
- Expand coverage of telehealth services, including remote monitoring, and of disposable, prevention and treatment technologies used in the home.
- 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.
- Require state Medicaid programs to take patient views into account in making coverage decisions.
- Increase the transparency and fairness of the local coverage determination process.
- Improve the new technology add-on payment program to capture a larger share of important new technologies and set payments more appropriately.
- Establish payment levels more promptly for new technologies used in the inpatient setting, using the best available data.
- Improve the methodology for establishing payment for technologies used in the outpatient setting and for updating payments to ambulatory surgical centers.
- Implement ICD-10 this fiscal year.

## Reform the U.S. tax system:

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- Repeal the medical device excise tax.
- 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;
  - Lower the overall corporate tax rate;
  - Provide incentives comparable to those of other countries for development and manufacturing of technology; and
  - Conform the treatment of international earnings to that of competitor nations.

## Improve access to international markets:

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- 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.
- Enact Trade Promotion Authority to negotiate the Trans-Pacific Partnership and the Trans-Atlantic Trade and Investment Partnership, and assure that those agreements include provisions that improve market access for medical technology.
- Enforce provisions of existing trade agreements such as the U.S.-Korea Free Trade Agreement to assure fair access for U.S. technology products.

## Support the maintenance and growth of an R&D infrastructure second to none:

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The medical technology industry is central to the development of medical devices and diagnostics that provide life-saving and life-enhancing treatments of the future.

- Provide steady growth in funding for the National Institutes of Health and the National Science Foundation.
- Improve the Small Business Innovation Research and Small Business Technology Transfer programs by raising the amount of funding (in the context of rising NIH and NSF funding), allowing larger individual grants to better recognize the costs actually incurred by start-up companies.
- 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.
- Streamline Institutional Review Board activities to reduce barriers to initiating collection of clinical data on new treatments, particularly for multicenter trials, without sacrificing protection of human subjects.