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Thank you Chairman Harkin, Ranking member Enzi, and members of the Committee for the opportunity to testify today.

My name is David Nexon, and I am Senior Executive Vice President of the Advanced Medical Technology Association (AdvaMed). My testimony today on the MDUFA agreement is submitted on behalf of three of the medical technology industry associations who participated in the MDUFA negotiations—AdvaMed, MDMA, and MITA.

I want to thank you for convening today's hearing, and for your interest in improving medical device regulation for patients and industry. Over the course of the last year, members of this committee have demonstrated their focus on improving the efficiency and effectiveness of FDA regulation, and your outreach to the agency and the policy proposals that have been introduced show your commitment to this important issue.

The U.S. Medical Technology Industry

The medical technology industry is an American success story. Our industry directly employs more than 400,000 workers nationwide. Typically, for every worker our industry directly employs, another four workers are employed by businesses supplying components and services to our industry and our employees, so that the total numbers generated by our industry exceeds two million.

The jobs our industry provides are good jobs—the kinds of jobs that allow employees to live the American dream. Industry pay levels are 38 percent higher than average pay for all U.S. employment and 22 percent higher than other manufacturing employment. While the number of manufacturing jobs was plummeting across the larger economy, even before the recent economic downturn, employment in our industry was expanding. Between 2005 and 2007, medical technology employment grew 20.4%, adding 73,000 jobs. During the recession, between 2007 and 2008, MedTech employment dropped 1.1 percent, compared to 4.4% for manufacturing as a whole.

Our industry is heavily skewed toward small companies—the kind of companies that begin with a doctor, and engineer, and an idea to improve patient care. Almost two-thirds of the 7,000 medical technology firms in the U.S. have fewer than 20 employees. A high proportion of the breakthrough products in our industry come from these small, often venture-capital funded companies.

And whether the firm is large or small, success in our industry comes only from innovation—the creation of diagnostics, treatments and cures that extend and enhance lives. Our industry's

investment in research and development is more than twice the national average. Our product life-cycle is only 18-24 months.

Our industry is so competitive that price increases have averaged only one-quarter the rate of other medical goods and services and just one-half the general CPI for almost 20 years.

With $33 billion in total exports in 2008, medical technology ranks eleventh among all manufacturing industries in gross exports. 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.

While we are very proud of our contributions to the U.S. economy, we are even more proud of our contributions to improving patient care. For patients, medical progress has been remarkable. 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%.

FDA Regulation of Medical Devices – MDUFA III

While we are making progress in improving patient care and see immense future opportunities to provide jobs and contribute to long-term economic growth, we are also worried. Today, America is the world leader in medical technology. But there are warning signs. As a recent PriceWaterhouse Coopers report showed, our lead is slipping on a number of dimensions of competitiveness. And a key factor in our loss of competitiveness has been the decline in FDA's performance in ensuring timely patient access to safe and effective medical devices

Put simply, FDA is a critical partner in our companies' efforts to bring safe and effective medical devices to patients. Without a strong, effective, and efficient FDA, we cannot have a strong and competitive industry. The predictability, consistency and efficiency of FDA decision-making, as well as reasonable, risk-based standards of evidence to assure the safety and effectiveness of medical technology products, is essential to drive new innovations for patients and for the long-term success of the medical device industry. While the FDA has consistently maintained a strong record of assuring the safety and effectiveness of the products it reviews, delays in product approval, inconsistency in the review process, and the resulting downstream effects on investment and innovation have undermined the competitiveness of our industry and harmed patient access to new treatments, diagnostics, and cures.

I am pleased to be able to report that after extensive negotiations, the user fee agreement between FDA and industry has been reached and is now awaiting your action. We believe this agreement

has the potential to help achieve meaningful change in FDA performance through groundbreaking accountability and transparency measures and enhanced FDA resources.

The FDA leadership and Dr. Shuren have recognized the need to vigorously address the issues affecting the device center and are already taking a number of steps that we believe have the potential to bring significant improvements. The user fee agreement our industry representatives just concluded with the agency has the potential to be an additional step in the right direction. It is good for industry. It is good for FDA. And most of all, it is good for patients. We urge this Committee and the Congress as a whole to act promptly to reauthorize the user fee program and enact this agreement into law. Failure to act would not only jeopardize the critical improvements made by the new agreement but would have a devastating impact on our industry's ability to bring improved treatments and cures to patients.

The user fee agreement builds the conditions for success in a number major ways:

Total Time Goal

For the first time ever, this user fee agreement establishes average total time goals for FDA product review. All previous agreements have set goals in terms of time on the FDA clock. When the FDA asks sponsors for additional information or data, the FDA clock stops. The result was that while FDA may have been meeting the goals for 510(k) submissions, the total time from submission to final decision increased 43% between the average for 2003-2007 and 2010. Of course, what matters to companies and patients is not an artificial construct like time on the FDA clock, but the time it actually takes to get a decision from FDA.

FDA, of course, often has legitimate questions about an application and it cannot control the amount of time it takes for a sponsor to respond to questions about any individual application. But all sponsors want to submit applications that meet FDA standards, and total time is the best indicator of whether FDA is consistent and efficient in its review and is providing sponsors with adequate information in advance of what data is needed for different types of products. We refer to this new standard as a shared performance goal, because industry also has an obligation to submit good applications. Additionally, FDA will have new authority to decline to begin review of an application that is obviously deficient when it is submitted.

By setting in place this new goal, efforts will be focused on the metric that is truly most important to all concerned.

Improved FDA Day Goals

Second, the agreement also establishes significantly improved goals for time on the FDA clock. For example, for PMAs receiving panel reviews—which tend to be the most innovative products. By the end of this new agreement, 90% of PMA products will be receive a decision within 320

days. The improved FDA day goals and the total time goals work together to encourage FDA to focus on a thorough but efficient review of all product submissions.

Process Improvements

Third, the agreement includes process standards that we anticipate will improve the consistency and timeliness of the review process independent of the specific time goals.

The agreement provides for meaningful presubmission interactions between FDA and companies where agreements reached will not change, so that companies know what FDA expects and FDA is bound by its commitments, unless, of course, new information arises that requires a change to protect public health.

Additionally, there will be a substantive interaction between FDA and the company midway through the review process. This will assure that both companies and FDA identify any deficiencies in the application early, so that they can be corrected promptly.

A new procedure that we call “no submission left behind” will be instituted, so that if the FDA time target is missed, the company and the FDA will meet to work out a schedule for resolving remaining issues, so that the submission doesn’t go to the bottom of the pile.

Greater Accountability

Fourth, the agreement provides for greater accountability. Greater accountability means that FDA’s success under this agreement will be transparent to FDA management, to industry, to patients, and to Congress and the Administration, so that any problems that arise can be corrected promptly. Under the agreement, there will be quarterly and annual reporting on key metrics, providing reliable and consistent tracking of new performance indicators that both FDA and industry have agreed are important.

In addition, the agreement requires an analysis of FDA’s management of the review process by an independent consulting organization, coupled with an FDA corrective action plan to address opportunities for improvement.

Appropriate Resources

Finally, to give FDA additional tools to meet the new goals, the agreement provides $595 million in user fees for 2013-2017. Additional reviewers, lower manager-to-reviewer ratios, enhanced training, and other resources provided by the agreement will give FDA what it needs to improve performance. Overall, the agreement will allow FDA to hire approximately 200 additional FTEs, the vast majority of which will be put it into place where needed most – additional reviewers. This, coupled with additional supervisors who are being hired this year, should lead to move consistency in the review process.

Each of the provisions of this agreement has the potential to make a difference in improving FDA performance. But the whole is truly greater than the sum of its parts. Each of the elements of the agreement reinforces the others. For example, as I noted above, the combination of total time goals and faster FDA time goals should result in greater improvements than either one would achieve separately.

And, of course, no agreement, no matter how good on paper, is self-executing. Making it work as intended will require the full efforts of FDA's dedicated staff and managers. Our industry is committed to work with FDA in any way we can to make it a success. Continued oversight and interest from the Congress will also be important. Patients are depending on all of us.

Conclusion

Finally, I should note that a number of legislative proposals have been introduced with the goal of improving the FDA's operations. We are appreciative of efforts by all Members who seek to give the FDA the tools and structure it needs to succeed. Legislative reforms that do not alter the substance of the negotiated agreement between FDA and industry and seek to improve consistency and predictability in the FDA device review process hold the potential to create a legislative reauthorization package that maximizes the opportunity for success at the agency, which should be the shared goal of all involved.

For example, legislation has been proposed to streamline the de novo process by eliminating the statutory requirement that a sponsor receive a finding of "not substantially equivalent" before even beginning the de novo process. FDA itself has recognized that the current process is cumbersome, and FDA is looking at using its regulatory discretion to improve that process. However, statutory change may be the most effective way to address the problem, which will help FDA, industry, and ultimately patients.

At the same time, I want to emphasize that we are strongly committed to the user fee agreement as negotiated and do not support any proposals that would change the terms of the agreement or undermine its goals.

I thank the Committee for the opportunity to testify and urge you to act promptly to reauthorize this program which is so critical to patients, to the FDA and to our industry.