

Testimony of Scott Whitaker, AdvaMed
HELP Committee Hearing
“FDA User Fee Agreements: Improving Medical Product Regulation and Innovation for
Patients, Part II”
4.4.17

Thank you Chairman Alexander and Senator Murray and members of the Committee for the opportunity to testify today.

My name is Scott Whitaker, and I am the President and CEO AdvaMed, the Advanced Medical Technology Association.

I thank you for convening today’s hearing, and for your interest in improving medical device regulation for patients and industry.

The U.S. Medical Technology Industry

AdvaMed’s member companies produce the medical devices, diagnostic products, and digital health technologies that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies. Collectively, we are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies.

I am very optimistic about what this industry can do for patients if the right policies are in place. Fundamental advances in knowledge of human biology down to the molecular level and continued progress in a range of disciplines – computing, communications, materials science, physics and engineering – are fueling innovation, and the potential to save and improve patients’ lives is almost limitless.

Patient access to advanced medical technology improves outcomes, enhances care quality, and generates efficiencies and cost savings for the health care system. For example, 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.

I’ve been encouraged by progress at FDA’s device center in recent years, but the innovation ecosystem that supports our industry remains stressed. One key barometer of the health of our ecosystem is the level of investment in start-up companies. Unfortunately, we have seen a sharp decline in the number of new medical technology start-up companies each year, going from around 1,500 annually 30 years ago to around 600. Since the early 1990s venture capital (VC) investment in the industry has gone from about 13 percent of total VC dollars to about 4 percent

in recent years. The time horizon for getting a new innovation from the bench to the bedside remains too long, and as a result investors are looking elsewhere.

FDA Regulation of Medical Devices – MDUFA IV

We believe we are on the right track at FDA's device center, and that recent progress combined with the device-related provisions in 21st Century Cures, plus provisions of this new user fee agreement promise to keep things heading in the right direction to strengthen the medtech innovation ecosystem.

The ground-breaking process improvements that were built into the MDUFA III agreement, and the oversight done by this Committee, have led to improvements in FDA's regulation of medical devices. FDA has brought down the total time it takes to receive a decision from FDA on a product submission, while still maintaining the strongest standards for evaluating safety and effectiveness. Opportunities for engagement between applicants and FDA throughout the device review process have increased, leading to fewer misunderstandings and false starts, and a better understanding of FDA data needs. As a result, the consistency and predictability of the FDA review process has shown improvement.

Additionally, the MDUFA IV agreement follows in the same spirit of the recently-enacted 21st Century Cures law, and I thank this Committee for its hard work on that bill. Cures included a number of provisions that will improve the predictability and consistency of FDA's device review process, and these are improvements that ultimately lead to greater patient access to safe and innovative products. The MDUFA IV agreement picks up on this theme and includes complementary process improvements that will also lead to timelier patient access to safe and effective devices.

Of course, there are many areas where FDA could further enhance the predictability and efficiency of its review process, and the new MDUFA IV agreement lays the groundwork for further FDA performance improvements through more ambitious goals, important process changes, and increased accountability, supported by additional resources.

This agreement 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 innovative diagnostics, treatments and cures to patients.

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

Significant Improvements for Total Review Time Goals

Measuring the total time from submission to an FDA decision to either make that technology available to patients or deny approval is the most meaningful measure of the process. Total time goals were first included in MDUFA five years ago, and have been a meaningful measure for both industry and FDA. Building on the total time goal, this MDUFA IV agreement will continue to drive towards reducing the total time that is spent reviewing a submission.

The MDUFA IV goals for total time reviewing a product represent substantial improvements over current performance. For 510(k) products, which are moderate risk medical devices, the total time goal is currently 124 days. The MDUFA IV agreement lowers that goal to 108 days by the fifth year. This represents a 13% decrease, which returns the total time to historical norms.

For PMA products, which are the most innovative and highest risk products, the total time to decision goal is currently 385 days. The MDUFA IV agreement lowers that goal to 290 days by the fifth year. This represents a 25% decrease.

And for the first time, the MDUFA IV agreement includes goals for de novo products, which are generally moderate risk products but brand new innovations, which FDA has never evaluated before.

Patient Input and Involvement in the Regulatory Process

As we all know, patients have a critical voice in product development and evaluation. This MDUFA IV agreement will have increased resources dedicated to supporting patient involvement in the medical device regulatory process. FDA's device center has taken several steps to incorporate the patient perspective into the device review process, through efforts such as voluntary patient preference information and voluntary patient reported outcomes, and this agreement will continue to support that work.

Process Improvements

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

One such example is that the agreement provides for meaningful presubmission interactions between FDA and companies. Interactions between the sponsor of a medical device application and the FDA, prior to the formal submission of a product application, can provide helpful guidance that aids the sponsor in ensuring their application contains all necessary information. This presubmission process was first put into place five years ago, in MDUFA III, and has benefitted both industry and the FDA. This MDUFA IV agreement builds upon this success by adding in a specific time commitment tied to pre-submission meetings. Under the MDUFA IV agreement, FDA will be required to provide meaningful, written feedback to companies at least five days prior to a presubmission meeting, ensuring that the meeting will be a productive one.

Additionally, the agreement supports FDA's efforts to establish a National Evaluation System for Health Technologies, or the NEST. MDUFA funding will be used for a pilot to assess whether real-world evidence can be used to support premarket activities. This NEST pilot will determine the usability of real-world evidence for expanded indications for use, new clearances and approvals, and improved adverse event reporting.

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. New reporting tools and two independent management reports will provide key data to track FDA performance, highlight any failures to meet key goals, and provide the basis for corrective actions.

One of these critical accountability measures involves process reforms for deficiency letters, or letters that applicants receive when their submission is found by FDA to be lacking needed information. Under this MDUFA IV agreement, all deficiency letters will include a statement of what information was provided in a submission and why it is not sufficient, including specific reference to the basis for the deficiency determination. Additionally, all deficiencies will undergo supervisory review by management prior to being issued. These provisions ensure that deficiency letters focus on real data needs and that FDA is clear on what data they require.

In addition, the agreement provides for two analyses of FDA's management of the device review process. This review, or independent assessment, was a critical part of the MDUFA III agreement that helped lead to improvements in FDA performance. The MDUFA IV agreement continues this success by including funds for two additional independent reviews, one at the beginning of MDUFA IV and one at the end.

Enhanced Resources

Finally, to give FDA additional tools to meet the new goals, the agreement provides \$999.5 million (FY15 dollars) in user fees for 2018-2022. This is built off of a baseline of approximately \$679 million from MDUFA III, along with an additional \$228 million in new resources to improve the device review process. In addition, there are \$92.5 million in onetime costs for items such as IT and infrastructure improvements. Collectively, the resources will give FDA what it needs to continue to improve performance.

Each of the provisions of this agreement has the potential to make a difference in continuing to improve FDA performance. But the whole is truly greater than the sum of its parts. Each of the elements of the agreement reinforces the others.

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 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 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 improve the consistency and transparency of FDA inspections of medical device facilities and to move to a risk-based system for device inspections. These common-sense proposals will ensure that FDA's inspections resources are best targeted to public health needs and that companies and FDA are working together.

I appreciate the committee's work in considering these and other appropriate measures that enhance and compliment the underlying user fee agreement, and its focus on enactment of this legislative package as soon as possible.

To reiterate, the MDUFA IV agreement is good for industry. It is good for FDA. And most of all, it is good for patients. We strongly support the vital improvements made by the new agreement and believe that a failure to act would have a destructive impact on our industry's ability to bring new, innovative treatments and cures to patients.

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