Prepared Testimony of Janet Trunzo
Senior Executive Vice President, Technology & Regulatory Affairs
Advanced Medical Technology Association (AdvaMed)
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On Medical Device User Fee Amendments (MDUFA) Reauthorization
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Introduction

Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Eshoo, Ranking Member Guthrie and members of the Committee, thank you for inviting the Advanced Medical Technology Association, or AdvaMed, to testify on the reauthorization of the Medical Device User Fee Amendments program. This legislation is critical to patients continuing to have access to innovative, safe and effective medical technologies, and we are grateful for the opportunity to offer our insights on the program going forward.

AdvaMed is the world's leading trade organization representing medical technology and device companies. AdvaMed represents more than 400 medical device manufacturers, from the smallest companies, including 300 small companies, to the largest medical technology innovators. Our members operate all over the United States and the world. Our members' products span every type of device and diagnostic, with submissions to every device-related review division of the Food and Drug Administration.

I had the pleasure of representing AdvaMed during the discussions of the first device user fee program, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), and each of the reauthorizations since then. The ongoing public health emergency created uncertainties that presented a significant challenge to our discussions for MDUFA V, yet AdvaMed believes the

collective efforts of the industry groups and FDA have produced an agreement that will further strengthen the medical device premarket review program by ensuring the agency has the resources it needs, enhancing review predictability, consistency and performance, and by continuing to ensure patients have timely access to safe and effective devices.

Background

I have been involved in each MDUFA cycle since the very beginning of the program, and it may be useful to share some of the historical context. From the very first user fee program in 2002, the underlying principle is that user fees supplement existing appropriations so that FDA has the resources necessary to support the more timely review of devices and other products. User fees pay for overall timeliness and predictability, but they neither guarantee a particular result nor guarantee the timing of any particular application review. Those remain completely under FDA's authority. Over time, the user fee program has evolved as technologies have advanced and FDA's needs have changed. Industry and FDA have also taken the opportunity during each reauthorization to refine the nature of the goals and other program performance measures. For example, the first MDUFA contained goals that turned out to be too complex, and those were adjusted in MDUFA II. MDUFA III introduced the concept of the shared outcome goal of total time to decision, in addition to review day goals, because patient access to a device is based on total time elapsed. In MDUFA IV, the focus was on the pre-submission process, in recognition that the quality and timing of an application and review depend in part on the ability to obtain feedback prior to the application. Each MDUFA cycle included significant increases in investments, made by the device industry in the device review program, including increasing the number of new FTEs to support the program.

For the purposes of MDUFA V, AdvaMed and the other industry representatives began discussions with FDA in early 2021, after the initial public meeting. We approached this reauthorization with the same two overarching principles we have had in the past: Patients must continue to benefit from access to safe and effective devices; and the user fee program and its associated goals should be refined and improved. We also recognized that the COVID-19 public health emergency had required a significant effort by FDA, and in particular by the Device Center, given the hundreds of EUAs submitted and issued for diagnostic tests, ventilators, and personal protective equipment, and other devices that were critical to the nation's response to COVID-19.

The impact of the COVID-19 response effort and associated workload on the review process for other devices that were not directly related to the public health emergency was unavoidable, as was the overall effect on FDA staff. Therefore, we felt the Device Center needed to have the resources necessary to rebuild its performance to the same levels prior to the public health emergency. We refer to this focus on the fundamentals of the device review program as "back to basics." We also recognized that as the program had grown significantly, there were opportunities for additional transparency in its operation. Finally, it was imperative to us that the premarket review program continue to support the development of innovative devices designed to meet unmet clinical needs.

The MDUFA V Agreement

We recognize that it took longer than expected for FDA and industry to reach an agreement on recommendations to share with Congress on the MDUFA reauthorization package. However, we believe this package is well crafted to provide significant resources and capacity for FDA,

greater predictability for the industry, and is in the best interests of patients. It has the following key components:

First, the general goal structure for submissions is unchanged. The goals are achievable in light of the current public health emergency. Over the course of MDUFA V, we expect to see improvements in review times compared to MDUFA IV goals or compared to current performance, depending on the particular submission type. For the first time, however, we have developed a structure that would allow for enhanced goals, and funding to support those goals, based on FDA's performance during the five-year cycle. If specific submission review times and pre-submission feedback goals meet certain benchmarks in the early years of MDUFA V, FDA would then manage the program to more aggressive review goals, and there would be additional resources provided to support those improved goals through additional FTE hires and funding for general operating costs. These additional resources are truly additive, as the base resources are not affected. This structure provides a mechanism to account for the added uncertainty of the device review program as it transitions out of significant EUA-related work to a more traditional workload.

Second, the package provides significant additional resources to ensure that FDA can provide timely feedback to companies seeking pre-submission guidance from the agency. This process is very important to industry and FDA because it enhances the likelihood that an application will provide the data and information FDA needs to undertake an efficient review of the product and potentially reduces the total time from application to decision. The other source of pre-submission feedback will come through a program FDA will pilot, which the agency refers to as the Total Product Lifecycle Advisory Program, or TAP. This pilot program is designed specifically to provide early feedback primarily to breakthrough devices—those that have been

designated as serving an unmet need of substantially improving treatment or diagnosis compared to available alternatives.

Third, this package will fund targeted initiatives to support the premarket review program. For example, there is enhanced funding for patient science and engagement to enhance incorporation of the patient experience into the medical device evaluation process. There is also funding for initiatives relating to digital health and the use of real world evidence in the review process.

Fourth, this package contains specific performance measures for and evaluation of the program as a whole by funding a quality management program and two independent assessments of aspects of the program and targets for hiring using MDUFA funds.

Finally, this agreement provides enhanced public transparency of MDUFA financing, including clarity on the use of carryover balances and incentives to ensure MDUFA funding is used in a timely manner.

Overall, this recommended package will support, in addition to continuing to fund the base MDUFA funding, an estimated minimum of 273 new FTEs to support the process for device review, with the potential of up to 387 FTEs based on meeting the enhanced goal targets. This structure provides ample support to the agency to deliver on the commitments in the MDUFA V commitment letter and to continue to ensure that patients in the United States have access to the most cutting edge, safe and effective medical devices.

Other Legislative Proposals

AdvaMed would also like to recognize several related legislative initiatives currently under consideration by Congress. As in previous cycles, we recognize that Congress is also considering

targeted reforms to the regulation of medical devices for potential inclusion with the reauthorization legislation. We support a number of these initiatives, which we believe are important to public health and would represent critical reforms to the Food, Drug, and Cosmetic Act. We look forward to working with Congress on these initiatives.

Conclusion

On behalf of AdvaMed, we look forward to working with Congress, FDA, and stakeholders.

We are grateful for the opportunity to share our proposal and perspective with Congress, which has provided valuable oversight and a critical contribution to public health in reauthorizing the MDUFA programs over the years. AdvaMed has valued the opportunity to provide our input to you during each reauthorization cycle, and we stand by to answer questions and provide information as Congress undertakes this critically important legislative task.

Thank you.