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Statement of Janet Trunzo
FDA Public Meeting on Medical Device User Fee Act Reauthorization
August 4, 2025

Thank you for the introduction and thanks to FDA for the opportunity to present here today. I am Janet Trunzo, and I represent AdvaMed, the Medtech Association.

I want to express our appreciation for Commissioner Makary's keen interest in ensuring FDA is well-equipped to review medical technology for safety and effectiveness in a predictable and timely manner and his understanding of the role of user fees in that process.

By way of introduction, AdvaMed is a global trade association, the largest of its kind, representing the breadth of the medical and digital health technology industries. Our more than 650 member companies range from the smallest startups to multinational corporations that are household names. Approximately 80 percent of our member companies are small businesses and startups.

AdvaMed marks its 50th anniversary this year, and our structure reflects the full nature of medtech innovation. You will hear from the leader of our diagnostics division, representing the companies that make the in vitro diagnostic tests critical to health care decision-making. You also will hear from the head of our medical imaging division, covering the makers of complex MRI, CT, and ultrasound systems, increasingly enabled by AI, to diagnose everything from broken bones to cancerous tumors.

Speaking of AI, AdvaMed added a digital health technology division in recent years to reflect the emergence of health solutions such as wearable smart watches to monitor vital signs and digital tools to treat various health conditions, all increasingly AI-empowered. As AdvaMed has evolved to reflect our growing industry, we appreciate FDA's evolution as well to respond to the needs of emerging innovators and their novel products. For example, the agency's recognition of AI-enabled medtech and sensor-based digital health technology is welcome. It demonstrates the agility needed to support and encourage next-generation innovation to serve patients.

In keeping with that agile approach, FDA, Congress, and the medtech field have worked to refine and evolve each MDUFA agreement to better serve patients with timely patient access to safe, effective medical technology.

AdvaMed looks forward to working with FDA and Congress to plan the next Medical Device User Fee agreement—MDUFA VI.

From the very first device user fee program in 2002, our shared goal of timely patient access to safe and effective medical technology has not changed and remains our North Star. Whether we are discussing review timelines or regulatory pathways, we must never lose sight of the patients waiting for the next breakthrough or life-saving device.

The device industry and FDA are united in this mission. We may have different roles in the process, but we share the same ultimate objective.

While user fees support timeliness and predictability by providing FDA with additional resources, user fees are not a guarantee of approval. They never have been, and they never should be.

User fees provide additional resources to the agency to conduct thorough, consistent and predictable reviews. This benefits everyone—patients get timely access to needed technologies, companies can plan their development timelines more effectively, and FDA can maintain the world's gold standard for device regulation.

For each MDUFA reauthorization following the initial user fee agreement in 2002, we have sought to make improvements. The first MDUFA contained goals that turned out to be too complex, and those were adjusted in MDUFA II. In MDUFA III, we introduced the concept of "total time to decision" goals in addition to FDA review day goals, to reflect that patient access to a device is based on total elapsed time. In MDUFA IV, we focused, among other things, 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 submission of the application.

And for MDUFA V we expanded the international regulatory program to support FDA's global regulatory harmonization activities. We also added specific hiring targets and opportunities to add investments for improved decision goals. Each MDUFA cycle included significant increases in investments, including increasing the number of new FTEs to support the program, in the device review program.

Now that we have approached nearly 25 years of user fee programs for medical devices, we are now in a position of merely fine tuning the current program that has worked well to achieve our common goal of timely patient access to safe and effective medical technology.

As we negotiate the next MDUFA agreement, AdvaMed remains committed to supporting FDA with the resources it needs to conduct premarket reviews and to fulfill the commitments outlined in the agreement. We believe the investment in regulatory infrastructure ultimately serves patients by ensuring that patients have continued access to safe and effective medical devices.

Next, I'll turn to my AdvaMed colleagues, Zach Rothstein and Patrick Hope, to describe their respective divisions, diagnostics and medical imaging, and how the MDUFA agreements enable their member companies' ability to serve patients around the clock in our health care system.