Statement of Zach Rothstein, AdvaMed
FDA Medical Device User Fee Amendments (MDUFA VI) Public Meeting
Wednesday, August 5, 2026

Good morning, and thank you to the FDA for the opportunity to speak today.

My name is Zach Rothstein and I am the Executive Vice President of Digital and Diagnostics Technologies at AdvaMed, the Medtech Association. On behalf of the medtech industry, I am pleased to express our strong support for the proposed MDUFA VI Commitment Letter.

I had the privilege of serving as one of industry's lead negotiators for MDUFA VI and as a result, I saw firsthand the amount of work that went into this agreement and the seriousness with which both FDA and industry approached the process.

The negotiations took place over many months and covered a wide range of complex issues. We discussed review performance, staffing, financial resources, communication during the review process, regulatory consistency, emerging technologies, and how FDA can continue preparing for the products it will be asked to review in the years ahead.

FDA and industry approached the negotiation in a highly collaborative manner. Both sides were willing to listen, explain their concerns, work through the data, and look for practical solutions that would strengthen the medical device review program. FDA also periodically shared feedback from its separate consultations with patient and consumer groups, health care professionals, and academic experts. That input informed our discussions and helped keep the focus on patients and providers.

Throughout the negotiations, we continued to come back to the same basic goal: ensuring that patients have timely access to safe and effective medical technology.

I want to thank Dr. Tarver, the FDA negotiating team, the many CDRH staff who supported the negotiations, and our colleagues at MDMA for getting us to this point. I also want to acknowledge CDRH's performance under the current MDUFA program.

Throughout MDUFA V, CDRH has managed a large and increasingly complex workload. The center has met, or remains on track to meet, nearly all of its MDUFA V goals. It has maintained strong review performance while also responding to rapid changes in medical technology, and that is a significant accomplishment. It reflects the dedicated work of FDA reviewers, scientists, engineers, clinicians, managers, and support staff across the center.

MDUFA VI builds on that foundation. It strengthens proven programs and targets practical issues affecting review consistency and total time to decision. It maintains strong performance goals for core premarket programs; improves early engagement through a new focused follow-up pre-submission pathway; promotes greater communication throughout the de novo review process; and adds transparency around staffing, capacity, spending, and performance. It also advances patient science, consensus standards, real-world evidence, international harmonization, and digital health.

The agreement also recognizes that timely patient access can require effective coordination across government. Through programs such as TAP, earlier engagement with CMS have the potential to clarify evidence needs and allow companies to plan their regulatory and coverage strategies earlier, while preserving the distinct roles of the two agencies.

While these are technical provisions, their benefits are concrete. Better early communication can prevent unnecessary bottlenecks and avoid extended review cycles. Clearer deficiency letters allow companies to focus on the scientific questions that matter. And more transparent performance reporting helps FDA and industry identify trends and address challenges before they affect the broader program.

The agreement also prepares FDA for the technologies that will increasingly define the future of medtech. Commitments to expand digital-health expertise, engage on emerging technologies such as generative and agentic AI, and provide greater clarity about which evidence is needed before authorization and which questions can appropriately be addressed through postmarket data will help FDA's framework evolve with the science while continuing to protect patients. Getting that balance right is particularly important for these rapidly evolving technologies, where real-world evidence can answer important questions after a product is in use.

For patients, that can mean earlier access to a diagnostic that detects disease when it is most treatable, a device that makes a procedure safer or less invasive, or a digital tool that helps a clinician identify an issue sooner. For providers, it means confidence in the technologies they use and a stronger pipeline of tools that can improve decision-making, workflow, and outcomes.

The agreement is also fiscally disciplined. It maintains stable fee levels, strengthens financial transparency, and provides fee relief for qualifying U.S. small businesses. Rather than creating major new initiatives, it focuses on strengthening programs that are already working and making the best possible use of the resources supporting them. A strong and efficient FDA review helps keep the United States the best place to develop, invest in, and launch the next generation of medical technology.

Reaching an agreement is an important milestone, but implementation will determine its success. Industry will do its part, and we appreciate CDRH's corresponding commitment to sustain its scientific workforce, meet the agreement's goals, communicate clearly, and use data to improve the program over time.

On behalf of AdvaMed and the medtech industry, we strongly support the proposed MDUFA VI commitment letter. It builds on what is working, makes practical improvements where they are

needed, and prepares the program for the technologies FDA will regulate in the years ahead while ensuring the United States remains the world's leading destination for medical technology innovation. And most importantly, it will support timely patient access to safe and effective medical technology and continue to give providers confidence in the tools they use every day. We urge the timely transmittal of the commitment letter to Congress and look forward to working with Congress and the administration to reauthorize the program. Thank you.