Stakeholder Meetings on MDUFA VI Reauthorization
October 27, 2025, 10:00 AM – 12:00 PM ET
Hybrid:
Virtual via Microsoft Teams and in-person at FDA White Oak Campus, Silver Spring, MD

Purpose

To begin the process of FDA periodic consultation with representatives of stakeholder groups (including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts), to discuss topics identified in prior public feedback, and to continue discussing stakeholder views on the reauthorization and their suggestions for changes to the medical device user fee program performance goals.

Welcome and Background

FDA welcomed the stakeholders and laid out the purpose of these meetings as part of the reauthorization process. FDA reinforced its mission to protect and promote public health. CDRH operates as a person-focused organization with patients at the heart of all activities, emphasizing that every review, meeting, and innovation is anchored on improving lives across America. CDRH is grounded on two mutually reinforcing pillars - safety and innovation - recognizing that true innovation cannot be realized without safeguarding patients, and safety cannot be sustained without fostering better ways to care for people. To do this, FDA uses a comprehensive Total Product Life Cycle (TPLC) approach. The following related topics were covered:

- strengthening patient-centered infrastructure and partnerships with patient groups to integrate patient experiences, perspectives, and preferences into the medical device TPLC in myriad ways
- ongoing efforts with all partners to assure that the U.S. is among the first to detect and address safety signals, including public communication about high-risk recalls
- continued utilization of real-world evidence (RWE) in supporting the TPLC by providing insights into how devices perform in everyday clinical settings, allowing for iterative improvements and greater confidence in device performance for patients and providers
- dynamic partnerships to address medical device supply chain vulnerabilities, support manufacturers in making necessary design or manufacturing changes, and sustain patient access to essential technologies without compromising safety or effectiveness
- international engagements which reduce redundancy for global manufacturers, maintain robust safety standards, and ultimately accelerate access to safe and innovative medical technologies worldwide
- concerted efforts including through the Total Product Lifecycle Advisory Program (TAP) to help innovators overcome barriers that impact people's access to important medical devices, increasing predictability, helping save development time and cost, and better

incorporating insights from a diverse partner network including patients, providers, payers, and more

The MDUFA Program is vital to ensure America remains a global leader in MedTech, and that the American public continues to have timely access to high quality, safe and effective medical devices. Stakeholder input is vital to the reauthorization process and allows FDA to bring together diverse insights that drive meaningful TPLC safety and innovation and improve patient access.

MDUFA VI Reauthorization

FDA outlined the strategic framework for MDUFA reauthorization, emphasizing the user fee program's core premise of improving agency performance through additional resources that enable more efficient reviews, while maintaining rigorous scientific standards. FDA begins negotiations with industry on October 29, 2025, with a goal to complete negotiations in early 2026. The theme for MDUFA VI is "Advancing Regulatory Excellence," focusing on strengthening review fundamentals, elevating the quality of the regulatory journey, and optimizing transparency and accountability. This requires maintaining performance goals and further integrating strategic programs like TAP, RWE, Digital Health, and Patient Science to enhance both innovation and regulatory predictability across the TPLC.

Summary of Stakeholder Feedback to Date and Discussion

FDA welcomed stakeholder input for how to enhance device regulatory programs through the MDUFA reauthorization process or otherwise.

FDA presented a summary of the feedback received during the public meeting held on August 4, 2025, and in the public docket, with a focus on reflecting perspectives offered by stakeholders participating in these venues, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts. To facilitate further dialogue on these topics, FDA utilized breakout sessions for stakeholders to provide input on areas where they believe the device program is working well and where they would like to see the program improve. Stakeholder feedback on the meeting topics is summarized below.

<u>Strengthening TPLC Through RWE</u>: Stakeholders expressed:

- Need to improve RWE collection mechanisms and infrastructure
- Need for enhanced unique device identification (UDI) utilization/implementation consistency to address current gaps where some devices lack proper identification, making adverse event tracking difficult
- Support for FDA efforts to utilize RWE to address challenges faced in the pediatric MedTech innovation ecosystem, to streamline evidence generation and facilitate market adoption

- Concerns about RWE replacing randomized controlled trials (RCTs) for premarket approval, with emphasis that RCTs remain the gold standard for safety and effectiveness evaluation
- Support for RWE as supplementary evidence, particularly valuable for providing a more complete understanding of device performance

Patient-Centered Development: Stakeholders expressed:

- Need for patients to be included early in and throughout the TPLC (including through remote data collection of patient-generated health information)
- Need for patients to have formalized roles in device development
- Critical need for FDA to expand internal patient science expertise and systematically integrate patient perspectives (including pediatric patients)
- Challenges in connecting clinical trial data with real-world data and patient perspectives
- Need to address clinical trial design and data collection challenges through patient-centered outcomes, remote data collection, and use of real-world data
- Building capacity for patients and patient organizations to effectively engage, and interest in developing standards for what constitutes quality patient engagement
- Need to balance innovation with patient safety in rapidly evolving device landscape to maintain trust and transparency

Digital Health: Stakeholders expressed:

- Need to address patient safety through appropriate risk-based TPLC oversight
- Concerns about data quality and data infrastructure
    - Need to strengthen collaboration between FDA and CMS for data extraction and sharing
    - Develop standards for handling missing data in digital health studies
    - Ensure data continuity when clinical trials end and participants transition to regular care
- Need for more AI transparency
    - Concerns about AI models constantly evolving and learning after initial review
    - Suggestion to draft clear summaries about the safety and effectiveness of AI tools
- Need for increased specialty expertise within FDA, especially for AI in devices

Consensus Standards and Conformity Assessment: Stakeholders expressed:

- Need for educational resources (infographics, one-pagers) to help organizations understand how they can participate in standards and conformity assessments
- Need for clearer standards regarding devices with frequent software updates
- Interest in opportunities to participate in international standards development, particularly for patient continuity of care

Closing

FDA thanked stakeholders for attending and sharing their perspectives. The next meeting is scheduled for November 18, 2025.

Attendees

Stakeholders

- Matt Mariani-Seltz, American Academy of Pediatrics (AAP)
- Namrata Pujara, American Academy of Pediatrics (AAP)
- Diane Clynes, American Association of Kidney Patients (AAKP)
- Catherine Jeakle Hill, American Association of Neurological Surgeons/ Congress of Neurological Surgeons (AANS/CONS)
- Lauren Foe, American Association of Neurological Surgeons/ Congress of Neurological Surgeons (AANS/CONS)
- Isabella Xu, Center for Science in the Public Interest (CSPI)
- Natalie Torentinos, Children's Hospital Association
- Juan Marcos Gonzalez, Duke University
- Semra Ozdemir, Duke University
- Dylan Simon, EveryLife Foundation for Rare Diseases
- Alexander Naum, Generation Patient
- June Cha, FasterCures
- Raymond Puerini, FasterCures
- Paul Melmeyer, Muscular Dystrophy Association
- Diana Zuckerman, National Center for Health Research (NCHR)
- Tess Robertson-Neel, NCHR
- Shion Chang, National Health Council (NHC)
- Pamela Gavin, National Organization for Rare Disorders (NORD)
- Madris Kinard, Patient Safety Action Network (PSAN)
- Cynthia A. Bens, Personalized Medicine Coalition (PMC)
- Michael T. Abrams, Public Citizen

FDA

- Eli Tomar, *CDRH, Lead Negotiator*
- Michelle Tarver, *CDRH*
- Owen Faris, *CDRH*
- Kathryn Capanna, *CDRH*
- Barbara Zimmerman, *CDRH*
- Malcolm Bertoni, *Consultant*
- Cherie Ward-Peralta, *CBER*
- Heba Degheidy, *CBER*
- Jonathan Sauer, *CDRH*
- Jaycie Gibney, *OCC*
- Virginia Knapp-Dorell, *OCC*
- Thomas Szivos, *CDRH*
- Ankurita Datta, *CDRH*
- Mimi Nguyen, *CDRH*

- Aftin Ross, *CDRH*
- Lakshmi Kannan, *CDRH*
- Staci Stoller, *CDRH*
- Sydney Baucum, *CDRH*
- Jacqueline Burgette, *CDRH*
- Anindita Saha, *CDRH*
- Astin Ross, *CDRH*
- Cynthia Grossman, *CDRH*
- Scott Colburn, *CDRH*
- Stacey Sullivan, *CDRH*
- Tracy Gray, *CDRH*
- Lexie Perreras, *CDRH*
- Bridgette Hager, *CDRH*
- Christina Webber, *CDRH*
- Rebecca Torguson, *CDRH*
- Daniel Canos, *CDRH*
- Corina Ploscaru, *Consultant*
- Stephen Sobieski, *Consultant*