Stakeholder Consultation Meetings on MDUFA VI Reauthorization
February 25, 2026, 10:00 AM – 12:00 PM ET
Virtual via Teams

Purpose

To continue 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 prioritized by participants, to continue discussing their perspectives on the reauthorization, and their suggestions for changes to the medical device user fee program.

CDRH 2025 Annual Report

FDA provided a walkthrough of the CDRH 2025 Annual Report, highlighting major accomplishments from 2025 and providing updates on CDRH programs of interest previously discussed by stakeholders: early alert communications, premarket performance, real-world evidence (RWE), international affairs, patient engagement, TPLC Advisory Program (TAP), and the quality management system regulation (QMSR).

Stakeholders expressed:

- Interest in CDRH reporting on clinical trial representativeness and connecting the quality of the data submitted (e.g., RWE) directly to performance benchmarks for premarket review goals
- Wanting to see more coverage of postmarket activities in future annual reports
- Questions about whether FDA has sufficient resources to evaluate complex AI utilized by devices (e.g. psychotherapy chatbots)
- Questions about how FDA uses artificial intelligence in its reviews
- Continuing support for TAP and emphasized how the program has fostered trust with patients/patient advocacy organizations during the medical device development process
- Interest in better understanding the impact of QMSR for American patients and consumers

Update on Industry Negotiations

FDA provided an update on the status of industry negotiations, including a summary of the topics discussed at the February 2026 negotiation meetings. FDA described the outstanding items and expressed optimism that the parties are close to reaching agreement.

Stakeholders expressed:

- Interest in understanding if the MDUFA VI agreement will result in incremental or transformational changes for CDRH

- Concerns about industry's influence on FDA budgets and resources
- Interest in better understanding the potential Federal Advisory Committee Act (FACA) question discussed with industry regarding the revised consensus standards proposal
- Continuing concerns about ensuring postmarket surveillance activities are sufficiently resourced

Attendees

Stakeholders

- Matthew Mariani-Seltz, American Academy of Pediatrics (AAP)
- Namrata Pujara, American Academy of Pediatrics (AAP)
- Diane Clynes, American Association of Kidney Patients (AAKP)
- Hayley Dempsey, Arthritis Foundation
- Isabella Xu, Center for Science in the Public Interest (CSPI)
- Natalie Torentinos, Children's Hospital Association
- Juan Marcos Gonzalez, Duke University
- Alexander Naum, Generation Patient
- Raymond Puerini, FasterCures
- Paul Melmeyer, Muscular Dystrophy Association
- Tess Robertson-Neel, National Center for Health Research (NCHR)
- Erin O'Quinn, Parkinsons Foundation
- Lisa McGiffert, Patient Safety Action Network (PSAN)
- Cynthia A. Bens, Personalized Medicine Coalition (PMC)
- Michael T. Abrams, Public Citizen

FDA

- Eli Tomar, *CDRH, Lead Negotiator*
- Kathryn Capanna*, CDRH*
- Malcolm Bertoni*, Consultant*
- Alexandra Hauke, *CDRH*
- Thomas Szivos, *CDRH*
- Jonathan Sauer, *OO*
- Heba Degheidy, *CBER*
- Jaycie Gibney, *OCC*
- Virginia Knapp-Dorell, *OCC*
- Mimi Nguyen*, CDRH*
- Aftin Ross, *CDRH*
- CDR Iman Martin, *CDRH*
- Staci Stoller, *CDRH*
- Sydney Baucum, *CDRH*
- Jacqueline Burgette, *CDRH*
- Nicole Ellis, *CDRH*
- Joshua Nipper, *CDRH*
- Katelyn Bittleman, *CDRH*
- Rebecca Torguson, *CDRH*
- Corina Ploscaru, *Consultant*