Stakeholder Consultation Meetings on MDUFA VI Reauthorization
January 27, 2026, 10:00 AM – 11:30 AM 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, and to continue discussing their perspectives on the reauthorization and their suggestions for changes to the medical device user fee program.

Update on Industry Negotiations

FDA provided an update on the status of negotiations with Industry, including a summary of the topics discussed at the December 2025 and January 2026 negotiation meetings.

Stakeholder Feedback

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

Stakeholders provided input on areas where they believe the device program is working well and where they would like to see improvements. Stakeholder feedback on the meeting topics is summarized below.

Stakeholders expressed:

- Support for the TPLC Advisory Program (TAP) pilot, especially for work in patient engagement, where TAP has facilitated industry interactions with patients and caregivers
- Reiterated support for FDA's leadership in patient science and the importance of patient engagement
- Concerns about limited postmarket surveillance resources through congressional funding and the need for a TPLC approach
- Need to ensure that clinical trials and postmarket data are representative of all patient populations (e.g., include various age demographics such as pediatrics, young adults, and older adults)
- Reiterated the need for FDA to have adequate staffing and resources
- Reinforced the need for FDA to balance authorization speed with review rigor to ensure device safety and effectiveness
- Reiterated concerns about the level of transparency provided to stakeholders during negotiations with industry

Attendees

Stakeholders

- Namrata Pujara, American Academy of Pediatrics (AAP)
- Diane Clynes, American Association of Kidney Patients (AAKP)
- Paul Conway, American Association of Kidney Patients (AAKP)
- 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
- Dylan Simon, EveryLife Foundation for Rare Diseases
- Sneha Dave, Generation Patient
- Peyton Miles, Generation Patient
- 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)
- Erin O'Quinn, Parkinsons Foundation
- Madris Kinard, Patient Safety Action Network (PSAN)
- Cynthia A. Bens, Personalized Medicine Coalition (PMC)

FDA

- Eli Tomar, *CDRH, Lead Negotiator*
- Kathryn Capanna*, CDRH*
- Barbara Zimmerman*, CDRH*
- Alexandra Hauke, *CDRH*
- Thomas Szivos, *CDRH*
- Malcolm Bertoni*, Consultant*
- Jonathan Sauer, *CDRH*
- Heba Degheidy, *CBER*
- Jaycie Gibney, *OCC*
- Virginia Knapp-Dorell, *OCC*
- Mimi Nguyen*, CDRH*
- Aftin Ross, *CDRH*
- CDR Iman Martin, *CDRH*
- Jacqueline Burgette, *CDRH*
- Staci Stoller, *CDRH*
- Sydney Baucum, *CDRH*
- Corina Ploscaru, *Consultant*