

Stakeholder Consultation Meetings on MDUFA VI Reauthorization
December 4, 2025, 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 a summary of the topics discussed at the November 20, 2025 and December 2, 2025 negotiation meetings with Industry.

Stakeholder Feedback

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

FDA presented an update on MDUFA V premarket performance and an overview of proposed premarket goals for MDUFA VI.

Stakeholders expressed:

- Support for maintaining randomized controlled trial requirements for PMA and de novo device classifications to ensure safety and effectiveness
- Concerns about conflict of interest for third-party reviewers
- Need to improve data collection for young adults and special populations across all medical devices
- Concerns about third-party reviewers' experience with a diverse range of device areas
- Adoption challenges for Humanitarian Device Exemptions due to limited eligibility
- Support for increased cross-Center collaboration within FDA's rare disease innovation hub
- Recognition of FDA's leadership in advancing patient science and real-world evidence
- Acknowledgement of FDA workforce and capacity challenges and shared concerns about FDA's ability to handle future increases in medical device innovations
- Emphasis on effectiveness as a key element of FDA's regulatory standard along with safety

- Concerns about FDA resources for handling high volume recalls in product areas not subject to premarket review fees
- Differing views on the appropriate levels of transparency FDA is providing to stakeholders during negotiations with industry

Closing

FDA thanked stakeholders for attending and sharing their perspectives. The next meeting is scheduled for January 27, 2026.

Attendees

Stakeholders

- Matthew Mariani-Seltz, American Academy of Pediatrics (AAP)
- Paul Conway, American Association of Kidney Patients (AAKP)
- Catherine Jeakle Hill, 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
- Katie Wagman, EveryLife Foundation for Rare Diseases
- Sneha Dave, Generation Patient
- Alexander Naum, Generation Patient
- Raymond Puerini, FasterCures
- Diana Zuckerman, National Center for Health Research (NCHR)
- Tess Robertson-Neel, NCHR
- Erin O'Quinn, Parkinsons Foundation
- Madris Kinard, Patient Safety Action Network (PSAN)
- Cynthia A. Bens, Personalized Medicine Coalition (PMC)
- Michael T. Abrams, Public Citizen

FDA

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|---|--------------------------------------|
| • Eli Tomar, <i>CDRH, Lead Negotiator</i> | • Malcolm Bertoni, <i>Consultant</i> |
| • Owen Faris, <i>CDRH</i> | • Heba Degheidy, <i>CBER</i> |
| • Kathryn Capanna, <i>CDRH</i> | • Cherie Ward-Peralta, <i>CBER</i> |
| • Barbara Marsden, <i>CDRH</i> | • Jaycie Gibney, <i>OCC</i> |
| • Alexandra Hauke, <i>CDRH</i> | • Mimi Nguyen, <i>CDRH</i> |
| • Thomas Szivos, <i>CDRH</i> | • Aftin Ross, <i>CDRH</i> |
| • Jonathan Sauer, <i>CDRH</i> | • CDR Iman Martin, <i>CDRH</i> |

- Lakshmi Kannan, *CDRH*
- Staci Stoller, *CDRH*

- Jacqueline Burgette, *CDRH*
- Corina Ploscaru, *Consultant*