

Stakeholder Consultation Meetings on MDUFA VI Reauthorization

November 18, 2025, 1:00 PM – 3:00 PM ET

Hybrid:

Virtual via Teams and in-person at

FDA White Oak Campus, Silver Spring, MD

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 MDUFA program topics, 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 October 29, 2025 and November 4, 2025 Industry negotiation meetings.

Stakeholder Feedback

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

FDA presented overviews of the Total Product Lifecycle Advisory Program (TAP) and International Affairs (including Global Supply Chain Resilience). FDA presented a summary of the feedback received on the two topics during the public meeting held on August 4, 2025, and in the public docket. The summary focused on perspectives offered by stakeholders, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts.

To facilitate further dialogue on these topics, FDA held 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 improvements. Stakeholder feedback on the meeting topics is summarized below.

International Affairs (including Global Supply Chain Resilience): Stakeholders expressed:

- Support for FDA's continued leadership as a global regulatory leader
- Encouragement of continued sharing of regulatory expertise and best practices with international counterparts
- Support for harmonization efforts that could speed device access while maintaining safety standards, particularly for rare diseases requiring global data collection
- Interest in FDA pursuing international collaborations throughout the medical device total product lifecycle

- Incorporating international patient perspectives, especially for specialized devices, and devices that serve the needs of rare disease and pediatric populations as this may provide valuable clinical evidence to support benefit-risk assessments and trial design
- Consideration for leveraging existing international relationships for identifying mitigations for supply chain issues
- Support for increased unique device identifier (UDI) utilization
 - Stakeholders expressed interest in advancing UDI implementation, especially in electronic health records
 - Stakeholders supported U.S. leadership in ensuring UDI systems are implemented consistently worldwide to avoid divergent approaches that burden manufacturers and complicate issue identification
- Interest in continued focus on protecting the most vulnerable patients, especially the pediatric and rare disease populations who are often affected first by supply chain disruptions
 - Request for consideration of more proactive communication for supply disruption to strengthen patient preparedness
- Request for additional communications on FDA's role in global harmonization and how this impacts stakeholders

Total Product Lifecycle Advisory Program (TAP): Stakeholders expressed:

- Recognition of the benefits and impacts for small companies who may lack expertise in navigating the regulatory process
- Recognition of the limited resources of some patient organizations to participate in TAP
- Recommendation to expand TAP beyond current limited device areas, especially in technology areas with unclear coverage and reimbursement pathways
- Support for consideration of the development of a pre-competitive collaborative platform for companies to access high-quality shared resources to navigate the development of medical devices
- Need for additional training and education for participating companies about regulatory process, reimbursement, and coverage decisions

Attendees

Stakeholders

- Namrata Pujara, American Academy of Pediatrics (AAP)
- Isabella Xu, Center for Science in the Public Interest (CSPI)
- Natalie Torentinos, Children's Hospital Association
- Juan Marcos Gonzalez, Duke University

- Dylan Simon, 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
- Shion Chang, National Health Council (NHC)
- Pamela Gavin, National Organization for Rare Disorders (NORD)
- Erin O'Quinn, Parkinsons Foundation
- Lisa McGiffert, Patient Safety Action Network (PSAN)
- Cynthia A. Bens, Personalized Medicine Coalition (PMC)

FDA

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| • Eli Tomar, <i>CDRH, Lead Negotiator</i> | • Aftin Ross, <i>CDRH</i> |
| • Michelle Tarver, <i>CDRH</i> | • CDR Iman Martin, <i>CDRH</i> |
| • Owen Faris, <i>CDRH</i> | • Lakshmi Kannan, <i>CDRH</i> |
| • Kathryn Capanna, <i>CDRH</i> | • Staci Stoller, <i>CDRH</i> |
| • Barbara Marsden, <i>CDRH</i> | • Sydney Baucum, <i>CDRH</i> |
| • Alexandra Hauke, <i>CDRH</i> | • Jacqueline Burgette, <i>CDRH</i> |
| • Malcolm Bertoni, <i>Consultant</i> | • Erin Cutts, <i>CDRH</i> |
| • Heba Degheidy, <i>CBER</i> | • Tammy Beckham, <i>CDRH</i> |
| • Jaycie Gibney, <i>OCC</i> | • Carl Newman, <i>CDRH</i> |
| • Virginia Knapp-Dorell, <i>OCC</i> | • April Marrone, <i>CDRH</i> |
| • Thomas Szivos, <i>CDRH</i> | • Kai Kadoich, <i>CDRH</i> |
| • Ankurita Datta, <i>CDRH</i> | • Corina Ploscaru, <i>Consultant</i> |
| • Mimi Nguyen, <i>CDRH</i> | • Stephen Sobieski, <i>Consultant</i> |