

## **Stakeholder Consultation Meetings on MDUFA VI Reauthorization**

**March 24, 2026, 10:00 AM – 11:30 AM ET**

**Hybrid:**

**Virtual via Microsoft Teams and in-person at FDA White Oak Campus, Silver Spring, MD**

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### **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.

### **Stakeholder Engagement Mechanisms**

FDA provided an overview of ways to engage with CDRH beyond MDUFA stakeholder consultation meetings. The programs covered included: [Patient and Caregiver Connection](#), [Network of Experts](#), [TPLC Advisory Program \(TAP\) Partner Network](#), [Collaborative Communities](#), [Digital Health Center of Excellence](#), and [Home as a Health Care Hub](#).

### **Update on Industry Negotiations**

FDA provided an update on the status of industry negotiations, including a summary of the topics discussed at the March 2026 negotiation meetings. FDA shared that the parties had reached agreements in principle on the discussed proposals and will continue to memorialize such agreement in a draft commitment letter. In addition to recapping recent negotiation meetings, FDA walked through the key elements of the agreement and framework for MDUFA VI.

Stakeholders expressed:

- Interest in additional details on the agreements in principle for IT tools, TAP, digital health, continuous process improvements for premarket review, international fees, and trigger reform
- Questions about real-world evidence (RWE) safeguards and transparency of RWE use in premarket
- The importance of resources for Digital Health Center of Excellence
- Interest in additional context on the MDUFA reauthorization steps of external review (by HHS and OMB) and if there would be additional touchpoints with industry

### **Stakeholder Feedback**

FDA welcomed stakeholder input on the upcoming MDUFA VI Public Meeting. Stakeholders provided input on aspects they believed worked well in the opening MDUFA public meeting and where they would like to see changes. Stakeholder feedback on the meeting topics is summarized below.

Stakeholders expressed:

- Appreciation for the Q&A panel format of the August 2025 MDUFA public meeting
- Interest in seeing a comparison of MDUFA V and MDUFA VI commitments
- Request for update about MDUFA IV Voluntary Malfunction Summary Reporting
- Interest in learning about topics that were considered but not a part of the final MDUFA VI commitments
- Interest in MDUFA VI public meeting presenters disclosing medical device manufacturer funding
- FDA should continue to prioritize and advance postmarket activities to promote patient safety
- Interest in how stakeholder input was incorporated into the MDUFA VI reauthorization process
- Positive feedback on accessibility of virtual participation in the MDUFA VI stakeholder consultation meetings
- Request to include stakeholders in joint negotiations with industry for future MDUFA reauthorizations

## **Attendees**

### Stakeholders

- Matthew Mariani-Seltz, American Academy of Pediatrics (AAP)
- Namrata Pujara, American Academy of Pediatrics (AAP)
- Hayley Dempsey, Arthritis Foundation
- Natalie Torentinos, Children's Hospital Association
- Dylan Simon, EveryLife Foundation for Rare Diseases
- Luis Gil Abinader, Generation Patient
- Sneha Dave, Generation Patient
- Paul Melmeyer, Muscular Dystrophy Association
- Tess Robertson-Neel, National Center for Health Research (NCHR)
- Shion Chang, National Health Council (NHC)
- Cara Tenenbaum, National Organization for Rare Disorders (NORD)
- 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

- Eli Tomar, *CDRH, Lead Negotiator*
- Michelle Tarver, *CDRH*
- Owen Faris, *CDRH*
- Kathryn Capanna, *CDRH*
- Barbara Marsden, *CDRH*
- Alexandra Hauke, *CDRH*
- Malcolm Bertoni, *Consultant*
- 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*
- Corina Ploscaru, *Consultant*