Stakeholder Consultation Meeting on MDUFA V Reauthorization
June 9, 2021, 1:00-3:00 PM
Virtual via Zoom

Purpose

To continue the process of FDA periodic consultation with representatives of stakeholder groups on their perspectives on the reauthorization and their suggestions for changes to the medical device user fee program. The June 9th meeting focused on presentations from stakeholders.

Update on Industry Negotiations

FDA provided an update on the negotiation meeting with Industry on May 19, 2021.

Stakeholders Presentations

Nine stakeholders presented on their topics of interest for MDUFA V. Stakeholders commented on the following key areas.

Postmarket Surveillance

Stakeholders expressed that postmarket surveillance should be given the highest priority in the user fee negotiations. Stakeholders reiterated their concern with the evidentiary standards for clearance and approval of devices and expressed that postmarket surveillance and inspections are even more important when minimal data are available premarket.

Stakeholders' recommendations included:

- Consider safety metrics for cleared devices including predicate tracking. Adverse events for predicates should be considered as part of the premarket review, and devices cleared based on predicates that have been recalled or are no longer marketed should receive additional monitoring.
- Improve transparency on counts of devices that are sold, used (e.g., deployed, implanted), or withdrawn from the market.
- Increase efforts to analyze adverse event reports and address postmarket signals.
- Improve transparency and capabilities of the Manufacturer and User Facility Device Experience (MAUDE) database to support public analyses.
- Improve the integration of real-world evidence (RWE) into postmarket surveillance.
- Improve information in the Unique Device Identifier (UDI) and GUDID database and support UDI integration into electronic health records (EHRs), claims, recalls and adverse event reports, especially for implanted devices.

FDA Communications to the Public

Stakeholders' recommendations included:

- Simplify alert communications about recalls, safety warnings and devices withdrawn from the market.
- Increase awareness among patients, consumers, and healthcare providers about reporting adverse events directly to the FDA.

- Communicate all implant materials to providers and patients through labeling and in GUDID database.
- Collaborate with patients to create materials such as patient booklets and informed consent checklists that are short, understandable, and user-friendly.

Patient Engagement

Stakeholders expressed that CDRH has long been a leader in patient engagement efforts and the commitments made during MDUFA IV built upon that legacy. Stakeholders pointed to the robust patient engagement through the Patient Engagement Advisory Committee and the Patient and Caregiver Connection Programs. In addition, the advancement in the conduct and use of patient preference information is directly attributable to the Center's commitment to meaningful incorporation of patient experiences in the regulatory process.

Stakeholders' recommendations included:
- Include patients and consumers at the negotiation table.
- Engage healthcare providers and patients across TPLC, including in trial development, surveillance, digital technology, and patient science.
- Educate patients to more effectively serve on panels and in studies.
- Engage with pediatric and rare disease communities on the expansion of patient preference studies for novel device development.
- Expand the use of artificial intelligence and machine learning to help shorten the time to diagnosis.
- Encourage collaboration with other regulatory bodies and overseas counterparts to expand applied science of patient input and RWE.

Device Innovation for Rare Disease and Pediatrics

Stakeholders expressed that, as compared to drugs and biologic products, devices for rare diseases receive significantly less focus. Stakeholders urged FDA to consider Humanitarian Use Device (HUD) reforms during the MDUFA negotiations and explore ways to continue to grow the impact of the HUD program so that more companies are incentivized to develop products for rare disease indications.

Stakeholders mentioned that the currently available pathways such as the HUD Program and the Investigational Device Exemption do not adequately address the challenges of studies in pediatric populations, including special ethical considerations, unique device design concerns, and clinical trial design and sample size considerations. As a result, pediatric device development is often not viewed as commercially viable by industry, and adult device approvals are considerably greater than pediatric device approvals.

Stakeholders proposed to exempt prospective research on off-label pediatric devices, create new pathways for pediatric device approvals, leverage existing academic registries and consortia, increase the speed and quality of data acquisition at a lower cost, and provide real world data to support regulatory processes and lead to iterative improvements in devices and their use.

Attendees:

Stakeholders:

- Ryne Carney, *Alliance for Aging Research*
- Brandy Keys, *American Academy of Orthopedic Surgeons*
- Noelle Larson, *Pediatric Orthopaedic Society of North America and Scoliosis Research Society Pediatric Device Task Force, & the American Academy of Orthopaedic Surgeons*
- Paul Conway, *American Association of Kidney Patients*
- Catherine Hill, *American Association of Neurological Surgeons / Congress of Neurological Surgeons*
- Marcia Howard, *Consumer Healthcare Products Association*
- Dylan Simon, *EveryLife Foundation for Rare Diseases*
- Amy Ohmer*, International Children's Advisory Network*
- Bennie Johnson, *Juvenile Diabetes Research Foundation International*
- Paul Melmeyer, *Muscular Dystrophy Association*
- Andrew Sperling, *National Alliance on Mental Illness*
- Diana Zuckerman, *National Center for Health Research*
- Jennifer Dexter, *National Health Council*
- Madris Kinard, *Patient Safety Action Network*
- David Davenport, *Personalized Medicine Coalition*
- Michael Abrams, *Public Citizen*
- Lisa McGiffert, *Patient Safety Action Network*
- Linda Radach, *USA Patient Network, Patient Safety Action Network*

FDA Attendees:

- Lauren Roth*, OC OP, Lead Negotiator*
- Kathryn Capanna*, CDRH*
- Josh Chetta*, CDRH*
- Misti Malone*, CDRH*
- Don St. Pierre*, CDRH*
- Michelle Tarver*, CDRH*
- Malcolm Bertoni*, Consultant*
- Cherie Ward-Peralta*, CBER*
- Louise Howe*, OCC*
- Darian Tarver*, OC OO*
- Suzanne Schwartz, CDRH
- Nia Benjamin*, CDRH*
- Marta Gozzi*, CDRH*
- Sharon Davis, *CDRH*
- Brittany Caldwell, *CDRH*
- Allen Chen, *CDRH*
- Anindita Saha, *CDRH*
- Christina Webber, *CDRH*
- Mimi Nguyen, *CDRH*
- Jessica Weinberg, *CDRH*
- Tracy Gray, *CDRH*
- Hanah Pham, *CDRH*
- Aron Yustein*, CDRH*
- Olele Chinyelum*, CDRH*
- Ellen Olson, CDRH
- Cherron Blakely, CDRH
- Jennifer Tomasello, *CDRH*
- Diane Goyette, *ORA*
- Vasum Peiris, *CDRH*
- Fraser Bocell, *CDRH*