Stakeholder Consultation Meeting on MDUFA V Reauthorization
May 12, 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 May 12th meeting focused on Digital Health, Patient Science & Engagement, and Real-World Evidence.

Update on Industry Negotiations

FDA provided an update on the latest negotiation meeting with Industry.

Digital Health

FDA highlighted that the goal for digital health efforts is to foster responsible digital health innovation that enhances patients' access to high-quality digital health products, enables manufacturers to rapidly improve software products, and ensures a least burdensome approach to maintaining a reasonable assurance of safety and effectiveness. FDA cited the recently created Digital Health Center of Excellence (DHCoE), which coordinates digital health work across the FDA and aims to empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation. FDA indicated that in response to the COVID-19 pandemic, digital health technology adoption is expected to increase beyond current projections and expressed the need for FDA to continue to evolve and adapt in expertise, policies, and oversight.

Stakeholders' feedback included the following:

- Digital health is a relatively new area for most stakeholders, but it is growing and has vast potential, including applications for remote patient monitoring and care, collecting patients' perspectives, and reporting adverse events.
- Stakeholders expressed support for digitalized implant cards to facilitate device tracking and more efficient management of recalls.
- Digital health tools should incorporate patients' perspectives, especially those of pediatric patients.
- FDA should consider the impact on different patient populations. While the use of digital health technologies may have a positive impact on certain patient populations, it may have a different impact on those patients who have limited access or comfort with technology. It will be important to keep those patients in mind, so health disparities are not further exacerbated.
- Interoperable and safe digital health devices with respect to cybersecurity are important features.
- FDA should collaborate with federal partners to ensure alignment and harmonization.

Patient Science & Engagement

FDA described the Patient Science and Engagement Program's mission to engage with patients, understand their perspectives, and proactively integrate patients' perspectives into the total product life cycle (TPLC) of medical devices to help protect and promote public health. The

Patient Science and Engagement Program aims to apply consistent and transparent policy, build capacity, optimize the research roadmap, foster a culture of patient science and engagement, and expand patient impact on device review. FDA emphasized the importance of patients' empowerment and ways in which patients can contribute to medical device development and evaluation.

Stakeholders commended CDRH's efforts on Patient Science and Engagement and provided other feedback:

- FDA should explore techniques to more proactively interact with and empower patients.
- FDA should increase the use of existing patient-reported outcome instruments and develop new tools to support regulatory and healthcare decision-making.
- Linking data across various systems (e.g., internal and external adverse event databases) would be beneficial.
- FDA should consider perspectives from various patient populations, including patients with rare diseases, pediatric patients, and patients who have experienced medical device harm.

Real-World Evidence (RWE)
FDA presented on its efforts to support and promote the use of RWE in regulatory decision making, including the recently published 90 illustrative examples highlighting a breadth of real-world data (RWD) sources used for regulatory purposes and the guidance document issued in 2017 describing considerations for how FDA evaluates RWD. FDA cited the Medical Device Safety Action Plan and emphasized that achieving the goals outlined in that plan will entail timely access to and timely analysis of high-quality data.

Stakeholders commended CDRH's advancement of RWD and RWE and provided the following feedback:

- Stakeholders expressed continued interest in potential applications for RWE, including postmarket surveillance, hypothesis generation, and possible use of RWE to evaluate previous FDA decisions.
- RWE should not replace traditional clinical trials.
- Stakeholders advocated for data transparency and access and better communication of device safety concerns to the Public.
- UDI adoption and UDI transparency are important.

Attendees:

Stakeholders
- Michael Ward, *Alliance for Aging Research*
- Ryne Carney, *Alliance for Aging Research*
- Brandy Keys, *American Academy of Orthopedic Surgeons*
- Edward Hickey, *American Association of Kidney Patients*
- Maria Gmitro, *Breast Implant Safety Alliance*
- Marcia Howard, *Consumer Healthcare Products Association*
- Dylan Simon, *EveryLife Foundation for Rare Diseases*

- Leanne West*, International Children's Advisory Network*
- Amy Ohmer*, International Children's Advisory Network*
- Bennie Johnson, *Juvenile Diabetes Research Foundation International*
- Andrea Baer, *Mended Hearts and Mended Little Hearts*
- Paul Melmeyer, *Muscular Dystrophy Association*
- Andrew Sperling, *National Alliance on Mental Illness*
- Diana Zuckerman, *National Center for Health Research*
- Meg Seymour, *National Center for Health Research*
- Jennifer Dexter, *National Health Council*
- Lisa McGiffert, *Patient Safety Action Network*
- Madris Kinard, *Patient Safety Action Network*
- Cynthia Bens, *Personalized Medicine Coalition*
- Michael Abrams, *Public Citizen*
- Linda Radach, *USA Patient Network, Patient Safety Action Network*

FDA

- Lauren Roth*, OC OP, Lead Negotiator*
- Kathryn Capanna*, CDRH*
- Josh Chetta*, CDRH*
- Sonja Fulmer, *CDRH*
- Misti Malone*, CDRH*
- Elizabeth McNamara, *CDRH*
- Don St. Pierre*, CDRH*
- Michelle Tarver*, CDRH*
- Malcolm Bertoni*, Consultant*
- Cherie Ward-Peralta*, CBER*
- Jan Welch*, ORA*
- Claire Davies*, OCC*
- 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*
- Srikanth Vasudevan, *CDRH*
- Olufemi Babalola, *CDRH*
- Mimi Nguyen, *CDRH*
- Jessica Weinberg, *CDRH*
- Tracy Gray, *CDRH*
- Anita Bajaj, *CDRH*
- Hanah Pham, *CDRH*
- Bakul Patel, *CDRH*
- Felipe Aguel, *CDRH*
- Jacqueline Puigbo, *CDRH*
- Vasum Peiris, *CDRH*
- Fraser Bocell, *CDRH*
- Astin Ross, *CDRH*