Stakeholder Consultation Meeting on MDUFA V Reauthorization
July 14, 2021, 1:00 – 3:00 PM
Virtual via Zoom

Purpose

To continue the process of FDA periodic consultation with representatives of stakeholder groups, 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.

In response to interest expressed by stakeholders during the initial consultation meeting in March 2021, FDA focused discussion during the July 2021 meeting on the topic of medical device innovation. The meeting format included overviews of innovations in medical devices and process improvements from the Center for Devices and Radiological Health (CDRH).

FDA's Innovation Efforts

FDA presented an overview of its innovation efforts to improve FDA operations and to evaluate innovative technologies. This work included reorganizing CDRH with a Total Product Life Cycle approach and building an agile infrastructure that can adapt to future organizational, regulatory, and scientific needs like responding to COVID-19. The reorganization enabled better information-sharing across the organization and empowered FDA staff to leverage their expertise in pre- and post-market information for optimized decision making.

CDRH presented on its role in the COVID-19 response, which included facilitating availability of and access to medical devices, engaging with a variety of external stakeholders and manufacturers, developing flexible policies, and mitigating supply chain shortages.

FDA described the Agency's investments in Digital Transformation to modernized IT infrastructure as a key effort to support innovation and improved capabilities.

FDA summarized innovative regulatory programs for addressing patient needs by expediting development and prioritizing review of certain devices. These programs include the Breakthrough Devices and Safer Technologies (STeP) programs, which are intended to help patients have more timely access to innovative, safe and effective technologies. These programs leverage existing and new policies to expedite development and review of innovative devices, while preserving statutory standards for market authorization.

Stakeholder Feedback

Stakeholders expressed interest in Breakthrough and STeP programs and asked about examples of devices that have been approved or cleared as part of these programs. They also expressed interest in more information on how the STeP program is being evaluated for effectiveness and resourcing, the cost to the healthcare system, and the value to the people who get these devices. Stakeholders inquired about the possibility of translating these innovative programs to support the needs of pediatric patients and patients with rare diseases.

Stakeholders expressed support for FDA's work in Digital Transformation to improve communication and called for efforts to improve transparency and availability of interactions with all stakeholders. Stakeholders asked about enhancements to the MDR system, including plans for improving the public-facing MAUDE interface and the tracking of adverse event reporting.

Update on Industry Negotiations

FDA provided a summary of topics discussed at the June 16 and June 30, 2021 Industry negotiation meetings.

Attendees:

Stakeholders

- Ryne Carney, *Alliance for Aging Research*
- Brandy Keys, *American Academy of Orthopedic Surgeons*
- Will Shaffer, AAOS
- Catherine Hill, *American Association of Neurological Surgeons / Congress of Neurological Surgeons*
- Maria Gmitro, *Breast Implant Safety Alliance*
- Marcia Howard, *Consumer Healthcare Products Association*
- Dylan Simon, *EveryLife Foundation for Rare Diseases*
- 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*
- Lisa McGiffert, *Patient Safety Action Network*
- David Davenport, *Personalized Medicine Coalition*
- Cynthia Bens, *Personalized Medicine Coalition*
- Michael Abrams, *Public Citizen*

FDA

- Lauren Roth*, OC OP, Lead Negotiator*
- Cherron Blakely*, CDRH*
- Kathryn Capanna*, CDRH*
- Josh Chetta*, CDRH*
- Elizabeth Hillebrenner, *CDRH*
- Misti Malone*, CDRH*
- Elizabeth McNamara, *CDRH*
- Jonathan Sauer, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver*, CDRH*
- Darian Tarver, *OC OO*
- Malcolm Bertoni*, Consultant*
- Cherie Ward-Peralta*, CBER*
- Claire Davies*, OCC*
- Louise Howe*, OCC*
- Jennifer Tomasello, *CDRH*
- Nia Benjamin*, CDRH*
- Ellen Olson*, CDRH*
- Sharon Davis, *CDRH*
- Allen Chen, *CDRH*
- Anindita Saha, *CDRH*
- Christina Webber, *CDRH*

- Mimi Nguyen, *CDRH*
- Tracy Gray, *CDRH*
- Jessica Weinberg, *CDRH*
- Astin Ross, *CDRH*
- Daniel Montgomery, *CDRH*
- Jerry Logue, *CDRH*
- Maureen Dreher, *CDRH*
- Steve Luxenberg, *CDRH*
- Jake Kyprianou, *CDRH*