Patient and Consumer Stakeholder Meeting on MDUFA V Reauthorization
March 10, 2021, 1:00-3:00 PM
Virtual via Zoom

Purpose

To begin the process of FDA periodic consultation with representatives of stakeholder groups, to discuss topics identified in prior public feedback, and to continue discussing stakeholder views on the reauthorization and their suggestions for changes to the medical device user fee program performance goals.

Welcome and Background on MDUFA process

FDA welcomed the stakeholders and laid out the purpose of these meetings as part of the reauthorization process.

FDA described its mission to protect and promote public health, and CDRH's vision for patients in the United States (U.S.) to have access to high-quality, safe, and effective medical devices of public health importance first in the world. FDA described how the Agency advances these goals through premarket submission review and approval or clearance of safe, effective, and high-quality devices; helping ensure that consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and can use this information to make health care decisions; quickly identifying poorly performing devices; and accurately characterizing real-world performance of medical devices, among other important functions.

FDA described how the MDUFA program supports the goal of providing timely access to high-quality, safe and effective medical devices. The central concept for all the medical product user fee programs at FDA is the following: user fees support improvements to program performance by providing resources so FDA can complete work more efficiently, while maintaining the same regulatory standards. Under the user fee agreements, FDA commits to meeting specific performance goals regarding the timeliness of our reviews and other measures of performance.

The reauthorization process involves consultation with representatives of patient and consumer advocacy groups, healthcare professionals, scientific and academic experts, regulated industry, and Congressional authorizing committees. FDA provided an overview of the reauthorization timeline, which includes holding a public meeting, gathering public input and hosting periodic consultations during negotiations. FDA also seeks public feedback on recommendations for the MDUFA program prior to submitting revised recommendations to Congress in January 2022.

Overview of MDUFA IV Performance

FDA provided an overview of the Agency's performance under the current MDUFA IV agreement as of the end of FY 2020. The Agency noted that performance during MDUFA IV remains strong—for instance, for submissions received in FYs 2018 and 2019, as of the end of FY 2020, FDA had met all of the review performance goals for which there was sufficient information to calculate performance. FDA also noted, however, signs of strain in the Agency's

ability to continue meeting some performance goals due to the current focus on addressing the COVID-19 pandemic. FDA noted that, during the pandemic to-date, FDA's response has included: reviewing approximately 6,000 Emergency Use Authorizations (EUAs) and pre-EUAs; monitoring for potential shortages by conducting outreach to over 1,000 manufacturing sites across 12 countries and collaborating with industry, U.S. government partners, and impacted stakeholders to minimize disruptions; and continuing to engage extensively with industry, healthcare provider communities, and other stakeholders including through posting of over 25 guidance documents and over 300 FAQs, holding over 60 webinars and town halls, and responding to more than 380,000 inquiries.

FDA's vision for MDUFA V

Overall, FDA expressed that MDUFA IV continues to build programs that deliver and improve consistency, predictability, and transparency in service of timely patient access to high-quality, safe, and effective medical devices. However, the Agency recognizes that the medical device ecosystem continues to evolve, and FDA must continue to stay ahead of the curve. In addition, as part of the MDUFA negotiations, FDA is exploring how to leverage lessons learned during the COVID-19 pandemic response in order to support enduring change. In sum, FDA has identified three overarching goals for MDUFA V reauthorization: (1) enhance operational success, reduce development times, and further accelerate patient access to high-quality, innovative, safe and effective devices; (2) optimize FDA infrastructure, staffing, and resources to keep pace with scientific development; and (3) improve device safety across the total product lifecycle.

Summary of stakeholder feedback to date

FDA welcomes stakeholder input for how to enhance device regulatory programs through the MDUFA reauthorization process or otherwise. FDA presented a summary of the feedback received during the public meeting on October 27, 2020 and in the docket, with a focus on reflecting perspectives offered by stakeholders participating in these meetings, including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts.

FDA's activities and performance related to topics identified in stakeholder feedback

FDA presented a high-level overview of ongoing device program activities that are related to the topics that patient, physician, and consumer stakeholders had identified during the public meeting and docket as being of interest. These included activities related to patient engagement, the Medical Device Safety Action Plan, real-world evidence (RWE), innovation (i.e., Breakthrough Program and Safer Technologies Program), digital health, and cybersecurity.

Discussion of stakeholder perspectives

To facilitate dialogue, FDA utilized breakout sessions of smaller groups of the stakeholder participants to identify topics important to each organization and key areas of interest for discussion at future stakeholder meetings. Participants provided input on areas where they believe the device program is working well and where they would like to see the program improve. The topics of interest and points raised by stakeholders during the breakout discussions are summarized below.

Staffing

- Stakeholders expressed support for increased staffing resources to balance workload strain due to increased efforts to support the COVID-19 response.

Patient-engagement: Stakeholders expressed:

- Appreciation for FDA's focused effort to enhance patient engagement;
- Interest in exploring opportunities to integrate insights from patient involvement and use of tools that capture aggregate patient perspectives into areas where FDA and CMS already collaborate to exchange information about certain technologies (e.g., artificial intelligence (AI) technologies, home use devices, and technologies that enable home treatment options such as telehealth or telemonitoring);
- Interest in exploring patient preference for diagnostic testing;
- Interest in the development of clearer and more accessible patient labeling.

Diversity and Inclusion: Stakeholders expressed:

- Interest in improving diversity in clinical trials, RWE, and the patient engagement program to represent the diverse U.S. population, including expanding and strengthening the Health of Women program;
- Concern about the potential for AI/Machine Learning (ML) technology to incorporate biases related to gender and other groups which may exacerbate inequities in healthcare.

Innovation: Stakeholders expressed:

- Interest in advancing innovation for underserved populations, reducing burdens for pediatric innovation and addressing unique human factors needs for these populations;
- Interest in exploring ways to foster innovation for rare diseases and unmet needs, and to incorporate patient experiences with and input on rare diseases in the review process for humanitarian device exemptions (HDEs);
- Interest in developing best practices for personalized medicine for products with high unmet needs.

Digital Health

- Stakeholders expressed support for the Digital Health Center of Excellence, including digital health technologies as a source of patient experience information, and work to advance responsible use of AI tools.

Real-World Evidence: Stakeholders expressed:

- Interest in seeing FDA continue to build and resource the RWE program to inform regulatory decision-making;
- Interest in enhancements to the RWE program to facilitate using existing knowledge from real-world care, such as NESTcc and collaborative multi-stakeholder efforts to expand use of registries as a "middle ground" to bridge the needs of manufacturers, patients, clinicians and payors;
- A desire for increased public transparency on data from studies done using RWE sources.

Device Safety: Stakeholders expressed:

- The perspective that there is an imbalance in the level of staffing resources allocated for postmarket surveillance and other device safety work as compared to MDUFA premarket review work;
- That FDA should consider a MDUFA performance goal related to postmarket safety to complement review timeliness goals;
- That FDA should consider opportunities for retrospective learning from devices that have actions taken to address a safety issue;
- That FDA should explore additional opportunities to educate and empower patients on adverse event reporting, to consider unstructured patient adverse event reports as real world data safety signals and to evaluate other ways to tap into patient data to identify potential safety signals;
- That FDA should continue to explore ways to enhance the clarity and utility of risk communications to patients and providers;
- Concern about the safety and effectiveness of certain types of devices reviewed under the 510(k) pathway;
- Concern about cybersecurity of devices, including for patients in rural areas who may be underserved.

Concluding Remarks

FDA conducted a brief survey based on themes identified at the public meeting and in the docket to identify priority topics for upcoming stakeholder meetings. FDA thanked the stakeholders for their participation and feedback.

Attendees

Stakeholders

- Michael Ward, *Alliance for Aging Research*
- Ryne Carney, *Alliance for Aging Research*
- Brandy Keys, *American Academy of Orthopedic Surgeons (AAOS)*
- Paul Conway, *American Association of Kidney Patients*
- Richard Knight, *American Association of Kidney Patients*
- Edward Hickey, *American Association of Kidney Patients*
- Catherine Hill, *American Association of Neurological Surgeons (AANS) / Congress of Neurological Surgeons*
- Adam Amdur, *American Sleep Apnea Association*
- Anna Hyde, *Arthritis Foundation*
- Marcia Howard, *Consumer Healthcare Products Association*
- Dylan Simon, *EveryLife Foundation for Rare Diseases*
- Leanne West*, International Children's Advisory Network (iCAN)*
- Amy Ohmer*, International Children's Advisory Network (iCAN)*
- Marjana Marinac, *JDRF 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 (PMC)*
- Cynthia Bens, *Personalized Medicine Coalition (PMC)*
- Michael Abrams, *Public Citizen*
- Renee Ridgeley, *Less Than Two Breasts*
- Melissa Laitner, *Society for Women's Health Research*
- Cara Tenenbaum, *Postpartum Pelvic Health Advocates*
- Maria Gmitro, *Breast Implant Safety Alliance*
- Kristina Kaiser, *USA Patient Network*
- Linda Radach, *USA Patient Network, Patient Safety Action Network*

FDA Attendees

- Lauren Roth*, OC OP, Lead Negotiator*
- Cherron Blakely*, CDRH*
- Kathryn Capanna*, CDRH*
- Josh Chetta*, CDRH*
- Rhonda Corbin*, CDRH*
- Sonja Fulmer, *CDRH*
- Elizabeth Hillebrenner, *CDRH*
- Misti Malone*, CDRH*
- Edward Margerrison*, CDRH*
- Elizabeth McNamara, *CDRH*
- Elizabeth Miller, *CDRH*
- Don St. Pierre*, CDRH*
- Michelle Tarver*, CDRH*
- Barbara Zimmerman*, CDRH*
- Malcolm Bertoni*, Consultant*
- Cherie Ward-Peralta*, CBER*
- Jan Welch*, ORA*
- Claire Davies*, OCC*
- Louise Howe*, OCC*
- Darian Tarver*, OC OO*
- Eli Tomar, *CDRH*
- Jennifer Tomasello, *CDRH*
- Emily Galloway*, OC Econ*
- Nia Benjamin*, CDRH*
- Marta Gozzi*, CDRH*
- Jessica Nguyen*, CDRH*
- Ellen Olson*, 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*