Stakeholder Consultation Meeting on MDUFA V Reauthorization
April 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 April 2021 meeting on the topic of medical device and patient safety. The meeting format included overviews of device safety subjects by experts from the Center for Devices and Radiological Health (CDRH) and facilitated breakout sessions with stakeholders to solicit their reactions and other feedback.

Update on Industry Negotiations

After welcoming stakeholders, FDA provided a summary of topics discussed at the March 17 and April 7, 2021 Industry negotiation meetings.

FDA Device Safety Efforts

FDA presented an overview of its efforts to protect patients and promote patient safety. This work includes understanding device performance in real-world settings, detecting and refining safety signals, formulating mitigation strategies, informing stakeholders, and taking action to prevent harm when possible, including through a focus on quality improvement and safety-focused innovation. FDA explained that the Agency's investments in a modernized approach to device and patient safety have focused on two key principles: (1) timing is everything, and (2) information is key. FDA summarized multi-pronged safety initiatives to get better information through data access and analytics, to facilitate more timely and efficient action through integration of pre- and postmarket functions and better internal coordination, to spur innovation toward safer devices, and to engage patients, caregivers, and the clinical and public health communities on safety issues.

In addition, FDA presented more detailed information related to four topics:

1. FDA's Toolbox to Address Safety Issues

FDA presented an overview of tools it uses to address safety signals. This includes a range of communications to alert users of a safety issue and provide recommendations for mitigations. FDA may bring safety issues to public meetings and workshops to solicit stakeholder feedback. FDA also issues public safety communications, letters to health care professionals, Medscape videos, and webinars, and safety signals may prompt labeling changes. FDA may also undertake compliance activities (*e.g.*, inspections and Warning Letters) or other regulatory actions (such as requiring 522 Postmarket Surveillance Studies, requesting modification to IDE and PAS protocols, and restricting devices). Finally, FDA may pursue other activities such as guidance documents and standards development/recognition. For any given signal, the Center may decide that one, more than one, or even no action is warranted at the time.

2. Case Example: Health of Women

FDA presented a snapshot of the Health of Women program. The Women's Health Technologies Coordinated Registry Network (WHT-CRN) Initiative is a case example of multi-stakeholder collaboration to leverage real-world data (RWD) and real-world evidence (RWE) to understand clinical questions on technologies uniquely affecting women. The WHT-CRN integrates RWD from over 550,000 records across clinical registries, administrative claims data, EHRs, and patient-generated data. Initially focused on treatment of uterine fibroids, pelvic organ prolapse, stress urinary incontinence, female sterilization and long-acting reversible contraception, the tools, methodologies and collaborative infrastructure enable efficient expansion to other clinical conditions critical to the health of women. FDA also summarized the Health of Women program efforts in priority areas such as sex/gender-specific analysis, addressing emerging issues in an integrated fashion, and research to promote diversity clinical trials and registries.

3. Cybersecurity

FDA presented on its efforts to address cybersecurity as a patient safety issue. Healthcare relies highly on connectivity and ubiquitous computing platforms, software, sensors and other medical devices. These advances have significant benefits, but also expose patients, caregivers, and healthcare systems to risk of cybersecurity threats. FDA described two recent cases to illustrate how vulnerabilities could allow unauthorized users to access, control, and command compromised devices, potentially leading to patient harm. FDA is developing a medical device cybersecurity program that leverages expertise from across the sector to ensure that devices are appropriately assessed for cybersecurity controls and design prior to market authorization, and that cybersecurity issues that arise in postmarket situations are quickly and effectively managed. FDA conducts cybersecurity reviews for a range of products, including devices that are software-enabled, are software as a medical device (SaMD), and/or contain external communication capabilities. FDA also collaborates across government, the health sector and with international regulators to evaluate and coordinate responses to cybersecurity threats and incidents, and to develop and implement standards and best practices, including use of tools to improve consistent cybersecurity evaluation. Increasing number of vulnerabilities, and volume and complexity of FDA cybersecurity reviews are a growing challenge for FDA and the medical device sector more broadly.

4. STeP: Spurring Innovation Toward Safer Devices

FDA presented an overview of the Safer Technologies Program (STeP), which is intended to spur innovation toward safer devices. The program is designed to expedite development and review for certain devices reasonably expected to significantly improve the safety of currently available treatments or diagnostics. The program was launched in March 2021 and was modeled after the Breakthrough Devices Program, including features to expedite development and review such as highly interactive engagement, efficient and flexible clinical study design, expedited review of manufacturing and quality systems compliance when applicable, and timely postmarket data collection (when appropriate).

Stakeholder Feedback

Stakeholders provided their input on areas of interest related to medical device and patient safety. Stakeholder perspectives are summarized below.

1. FDA's Initiatives on Device Safety

Stakeholders expressed general support for cybersecurity efforts, STeP, and a focus on innovative clinical study designs with diverse patient population (*e.g.*, age, gender, sex, socioeconomic status) in order to continue advancing medical devices and ensuring the safety and effectiveness of the devices.

2. Stakeholder's Interactions with FDA and Industry on Device Safety Issues

Regarding interactions with FDA and Industry, stakeholder perspectives included that:

- Interactions with FDA generally work well due to CDRH's willingness to engage with stakeholders and FDA's patient-oriented efforts.
- Initiatives on safety communications and patient engagement should be further enhanced.
- All stakeholders (*e.g.*, FDA, patients, sponsors, clinicians) should connect early in the total product lifecycle (TPLC) to best utilize all stakeholder resources.
- Areas for improvement include helping patients understand safety information from manufacturers and clarifying FDA points of contact when a safety issue is identified by patients or patient organizations.
- Patient organizations can act as "middleman" between FDA and patients to more effectively communicate safety issues.

3. General Device and Patient Safety Efforts

More generally, stakeholder perspectives included that:

- FDA safety communications could be improved by helping patients and stakeholders better understand various FDA actions regarding safety issues, using targeted safety messages resonating with patients and consumers, using plain language, and focusing on providing adequate information for decision making.
- Some stakeholders placed particular emphasis on proactive communication around implantable devices to be provided to patients in advance of procedures, including materials that may cause allergies or other biocompatibility responses.
- Patient education related to adverse event reporting could be improved. Stakeholders explained how completion of adverse event reporting forms can be challenging for patients, and they expressed interest in improvements to the Manufacturer and User Facility Device Experience (MAUDE) database, which houses medical device reports (MDRs) submitted to FDA, such as features for searching free text and custom analysis.
- Stakeholders expressed a variety of perspectives related to the use of RWE to inform regulatory decision-making. This included transparency of studies using RWE sources, using RWE as a complementary data source, and continuing multi-stakeholder collaboration around coordinated registries.
- The FDA website could provide more safety signal information and FDA safety-related data analyses.
- Stakeholders expressed the view that there is an imbalance in the level of resources for premarket review work compared to postmarket safety work, and recommended MDUFA V include a performance goal related to postmarket safety.

Attendees:

Stakeholders

- Michael Ward, *Alliance for Aging Research*
- Ryne Carney, *Alliance for Aging Research*
- Scott Haber, *American Academy of Ophthalmology*
- Brandy Keys, *American Academy of Orthopedic Surgeons*
- Paul Conway, *American Association of Kidney Patients*
- Richard Knight, *American Association of Kidney Patients*
- Edward Hickey, *American Association of Kidney Patients*
- Diana Clynes, *American Association of Kidney Patients*
- 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*
- Leanne West*, International Children's Advisory Network (iCAN)*
- Amy Ohmer*, International Children's Advisory Network (iCAN)*
- Bennie Johnson, *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*
- Richard White*, National Organization for Rare Disorders*
- Madris Kinard, *Patient Safety Action Network*
- Lisa McGiffert, *Patient Safety Action Network*
- David Davenport, *Personalized Medicine Coalition*
- Cynthia Bens, *Personalized Medicine Coalition*
- Cara Tenenbaum, *Postpartum Pelvic Health Advocates*
- Michael Abrams, *Public Citizen*
- Melissa Laitner, *Society for Women's Health Research*
- Linda Radach, *USA Patient Network, Patient Safety Action Network*

FDA

- Lauren Roth*, OC OP, Lead Negotiator*
- Cherron Blakely*, CDRH*
- Kathryn Capanna*, CDRH*
- Josh Chetta*, CDRH*
- Misti Malone*, CDRH*
- Elizabeth McNamara, *CDRH*
- Michelle Tarver*, CDRH*
- Barbara Zimmerman*, CDRH*
- Malcolm Bertoni*, Consultant*
- Cherie Ward-Peralta*, CBER*
- Jan Welch*, ORA*
- Claire Davies*, OCC*
- Louise Howe*, OCC*
- Jennifer Tomasello, *CDRH*
- Emily Galloway*, OC Econ*
- Suzanne Schwartz, CDRH
- Jonathan Sauer, CDRH
- Nia Benjamin*, CDRH*
- Marta Gozzi*, CDRH*
- Ellen Olson*, CDRH*
- Sharon Davis, *CDRH*
- Allen Chen, CDRH
- Anindita Saha, *CDRH*
- Christina Webber, *CDRH*

- Srikanth Vasudevan, *CDRH*
- Olufemi Babalola, *CDRH*
- Mimi Nguyen, *CDRH*
- Tracy Gray, *CDRH*
- Anita Bajaj, *CDRH*
- Hanah Pham, *CDRH*
- Bakul Patel, *CDRH*
- Ron Yustein, *CDRH*
- Terri Cornelison, *CDRH*
- Jessica Wilkerson, *CDRH*
- Ouided Rouabhi, *CDRH*