Stakeholder Consultation Meeting on MDUFA V Reauthorization
September 30, 2021, 1:00-3:00 PM
Virtual via Zoom

Purpose

To continue the process of FDA periodic consultation with representatives of stakeholder groups, the ongoing dialogue on topics prioritized by participants, and the discussion of 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 the September 2021 meeting on presentations from stakeholders on the topic of diversity, inclusion, and health equity.

Update on Industry Meetings

FDA welcomed stakeholders and provided a summary of three meetings that were held with Industry since the last stakeholder consultation meeting in August 2021: the September 9, 2021 working group meeting focused on the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program and the September 22, 2021 FDA-Industry negotiation meeting, which was followed by a working group meeting on Real World Evidence (RWE).

Stakeholders asked about the negotiation timeline and FDA's proposals related to patient safety and patient science and engagement. Stakeholders reiterated the importance of postmarket surveillance, and recommended that support for postmarket surveillance be included in MDUFA V.

Stakeholders also reiterated concerns related to regulatory capture, regulatory standards for safety and effectiveness for premarket evidence, and the lack of transparency in the number of devices that are sold, used, or withdrawn from the market. Stakeholders expressed support for including public health indicators as part of annual MDUFA performance measures.

Stakeholders' Presentations on Diversity, Inclusion, and Health Equity

FDA shared its approach for promoting diversity and inclusion in its proposals for MDUFA V, and representatives from six stakeholder organizations presented on the topic. Stakeholders provided examples of health and healthcare disparities based on a variety of characteristics, such as race, ethnicity, sex, gender, and age. Stakeholders expressed that the lack of diversity in clinical research (in clinical trial enrollment and subgroup analyses) conducted or reported can have serious ramifications, including missing differences in important treatment outcomes. Stakeholders' recommendations included:

Engage Patients Early and Across the TPLC. Stakeholders indicated that increased diversity in patient engagement is needed throughout the medical product development process. Diverse groups of patients and consumers based on demographic characteristics (e.g., sex, gender, race, ethnicity, age, location of residency) and non-demographic characteristics (e.g., patients with disabilities, rare diseases, or who experienced medical device harm) should be included from the

beginning to the end of device development. FDA pointed out that its proposal for a TPLC Advisory Program (TAP) Pilot includes features, such as the option for early engagement with patients, that could contribute to addressing this need.

Enhance Tools to Capture Patient Experience. Stakeholders expressed continued support for the incorporation of patient perspectives into medical product development and regulatory decision making. Stakeholders encouraged FDA to increase utilization of existing tools and to develop new ones to capture patients' full experiences, to help assure the full set of impacts are collected during device design, evaluation, and review.

Improve Accessibility of Information. Stakeholders expressed that information must be provided in accessible formats to improve the informed consent process for all clinical trial participants and cautioned that if information is not presented in an accessible format from the start, some groups of patients and consumers could be excluded. This includes using plain language, translation, and use of digital and other delivery formats. Stakeholders also encouraged FDA to collaborate with patients to create materials that are concise, understandable, and include information about which groups of individuals were studied and how results varied.

Increase Diversity in Clinical Trials. Stakeholders expressed a critical need to increase diversity in clinical trial participation. They cautioned FDA that when trials are not inclusive, the FDA may be making approval and clearance decisions about devices for groups who have not been represented in studies. They encouraged enrollment of participants with a wide range of characteristics to create a study population that more accurately reflects the patients likely to use the marketed device and allows assessment of the impact of those characteristics on device safety and effectiveness. They noted that community engagement is key to clinical trial recruitment and diversity, and that building relationships and having information and education delivered by trusted voices can help create a path forward.

Conduct Subgroup Analyses. Stakeholders encouraged FDA to work with sponsors to require subgroup analyses and include subgroup results in labels. They stated that the approved indications should reflect the types of patients studied, not "all adults of all ages" and expressed that differences in outcomes based on demographics and diversity should be published publicly and disclosed to patients. They indicated that postmarket studies should ensure diversity and subgroup analyses as well, and that adverse event reporting should also be used to help analyze information on those who may not have been included in studies. They encouraged FDA to make it easier for patients, consumers, and healthcare providers to report adverse events directly to the FDA.

Support Post-Market Surveillance. Stakeholders emphasized that postmarket surveillance should be prioritized in user fee negotiations and expressed support for more comprehensive postmarket databases and surveillance that highlight information from subgroup analyses and include postmarket evidence from harmed patients. They encouraged FDA to consider postmarket safety information and demographic data for predicates as part of device submission review.

Concluding Remarks

FDA reinforced its commitment to promote diversity, inclusion, and health equity in the medical device arena, as shown by key elements of its proposals for MDUFA V, and thanked the stakeholders for the dialogue and the continued engagement.

Attendees

Stakeholders

Ryne Carney, *Alliance for Aging Research*
Brandy Keys, *American Academy of Orthopedic Surgeons*
Catherine Hill, *American Association of Neurological Surgeons / Congress of Neurological Surgeons*
Peter Konrad, *American Association of Neurological Surgeons / Congress of Neurological Surgeons*
Maria Gmitro, *Breast Implant Safety Alliance*
Marcia Howard, *Consumer Healthcare Products Association*
Jack Meloro, *EveryLife Foundation for Rare Diseases*
Amy Ohmer, *International Children's Advisory Network*
Bennie Johnson, *Juvenile Diabetes Research Foundation International*
Paul Melmeyer, *Muscular Dystrophy Association*
Diana Zuckerman, *National Center for Health Research*
Thomas Eagen, *National Center for Health Research*
Jennifer Dexter, *National Health Council*
Elisabeth Oehrlein, *National Health Council*
Madris Kinard, *Patient Safety Action Network*
Cynthia Bens, *Personalized Medicine Coalition*
David Davenport, *Personalized Medicine Coalition*
Cara Tenenbaum, *Postpartum Pelvic Health Advocates*
Michael Abrams, *Public Citizen*

FDA Attendees

Lauren Roth, *OC OP, Lead Negotiator*
Cherron Blakely, *CDRH*
Kathryn Capanna, *CDRH*
Josh Chetta, *CDRH*
Misti Malone, *CDRH*
Don St. Pierre, *CDRH*
Cherie Ward-Peralta, *CBER*
Claire Davies, *OCC*
Jennifer Tomasello, *CDRH*
Suzanne Schwartz, *CDRH*
Michelle Tarver, *CDRH*
Nia Benjamin, *CDRH*
Marta Gozzi, *CDRH*
Ellen Olson, *CDRH*
Sharon Davis, *CDRH*
Brittany Caldwell, *CDRH*
Allen Chen, *CDRH*
Anindita Saha, *CDRH*
Mimi Nguyen, *CDRH*