FDA – Industry MDUFA V Reauthorization Meeting
February 24, 2021, 1:00 pm – 4:00 pm EST
Virtual Via Zoom

Purpose
To discuss MDUFA V reauthorization.

Attendees

FDA

- Lauren Roth, *OC OP*
- Sara Aguel, *CDRH*
- Cherron Blakely, *CDRH*
- Kathryn Capanna, *CDRH*
- Josh Chetta, *CDRH*
- Rhonda Corbin, *CDRH*
- Owen Faris, *CDRH*
- Elizabeth Hillebrenner, *CDRH*
- Misti Malone, *CDRH*
- Edward Margerrison, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Barbara Zimmerman, *CDRH*
- Malcolm Bertoni, *Consultant*
- Cherie Ward-Peralta, *CBER*
- Diane Goyette, *ORA*
- Jan Welch, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Darian Tarver, *OC OO*
- Emily Galloway, *OC Econ*
- Nia Benjamin, *CDRH*
- Marta Gozzi, *CDRH*
- Jessica Nguyen, *CDRH*
- Ellen Olson, *CDRH*
- Sharon Davis, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- Phil Desjardins, *Johnson & Johnson*
- Michael Pfleger, *Alcon*
- Danelle Miller, *Roche*
- Nicole Taylor Smith, *Medtronic*

MITA Team

- Peter Weems, *MITA*
- Diane Wurzburger, *GE Healthcare*
- Elisabeth George, *Philips*
- Nicole Zuk, *Siemens Healthineers*

MDMA Team

- Mark Leahey, *MDMA*
- John Manthei, *Latham & Watkins*
- Mark Gordon, *Alcon*
- Melanie Raska, *Boston Scientific*
- Elizabeth Sharp, *Cook Group*

ACLA Team

- Thomas Sparkman, *ACLA*
- Don Horton, *Labcorp*
- Shannon Bennett, *Mayo Clinic Laboratories*

Meeting Start Time: 1:00 pm EST

Introduction, Ground Rules for Negotiations and Virtual Environment

FDA opened the meeting by presenting the statutory requirements for MDUFA reauthorization. The ground rules governing MDUFA V Reauthorization negotiations were discussed and agreed upon by both parties. FDA presented expectations regarding conducting negotiations in a virtual environment, and there were no additional comments or questions. FDA presented a target timeline to complete the draft recommendations, and the parties agreed.

FDA Perspective on Reauthorization

FDA expressed its commitment to promoting timely patient access to high-quality, safe, and effective medical devices. FDA stated its belief that MDUFA IV has been a success overall and pointed to similar public comments from Industry.

FDA discussed the overall experience to-date in MDUFA IV, emphasizing the agency's performance in meeting its review performance goals and its performance enhancement commitments. Specifically, for FY2018, FDA noted that the agency met all review performance goals. For FY2019 and FY2020, the agency has met all review performance goals for cohorts that are sufficiently complete to determine the outcome.

FDA and Industry met the shared outcome goals of total time to decision (TTD) for PMAs and 510(k)s in FY2018. FDA noted that, since FY2013, the agency and industry have met the progressively shorter TTD goals for PMAs. FDA noted concern, however, that performance for the 510(k) TTD has plateaued between FY2013 and FY2018, despite implementation of efficiencies under MDUFA IV. Accordingly, FDA observed that the parties may want to explore changes to review processes and policies that could reduce the number of review cycles, such as actions to improve submission quality.

Regarding the performance enhancement commitments for FY2018-2020, FDA noted the breadth and number of commitments that the agency has successfully met, including commitments related to quality management, guidances, real-world evidence, patient engagement, time-reporting, and the total product life cycle (TPLC) reorganization.

FDA cited the outcome of the MDUFA IV Phase I Independent Assessment, which stated that the improvements made as part of previous commitments have been successful in standardizing CDRH operations, increasing staff knowledge to perform submission reviews, increasing regulatory process clarity, and improving decision-making consistency. The assessment also identifies opportunities for additional improvements, which FDA observed should be explored as part of the MDUFA V reauthorization process.

FDA also shared additional programmatic successes that have gone beyond MDUFA commitments, including work to continue advancing patient engagement and the science of patient input, use of real-world evidence in regulatory decisions, a record number of Breakthrough Device designations in 2020, record numbers of novel medical device authorizations (in 2018 and 2020), and multi-faceted efforts to enhance medical device safety,

including providing additional, non-user fee funding to the NEST for it to build out active surveillance capabilities.

FDA also summarized the agency's expansive efforts to address medical device needs in response to the COVID-19 pandemic. FDA noted its sense that the TPLC reorganization within CDRH has been critical to supporting the Center's COVID-19 response efforts. The agency also emphasized that an important "lesson learned" from the pandemic response has been the value of frequent, robust engagement with sponsors in helping to facilitate emergency use authorizations and to identify and address other issues, such as potential supply disruptions or shortages, in record times.

FDA summarized that its perspective for the MDUFA reauthorization is based on three foundational observations: 1) Overall, the MDUFA program has been a success. With the additional resources and commitments under MDUFA IV, FDA has continued to build a program that delivers—and continues to improve—consistency, predictability, and transparency in service of timely patient access to high-quality, safe and effective medical devices. 2) Despite success, FDA is seeing signs of strain. Given the extraordinary effort needed to address COVID-19, FDA expects MDUFA performance to be impacted in FY21 and potentially for years to come. 3) Our work is not "done." MDUFA must continue to advance additional, strategic change. FDA noted that the MedTech ecosystem continues to evolve, and that opportunities for critical, strategic growth in the MDUFA program have been surfaced through the Independent Assessment findings, implementation of MDUFA IV, FDA's other policy and programmatic efforts, and lessons learned during COVID-19 pandemic response.

FDA articulated three overarching goals for MDUFA reauthorization: 1) To enhance operational success, reduce device development times, and further accelerate patient access to high-quality, innovative, safe and effective devices; 2) To optimize FDA infrastructure, staffing, and resources to keep pace with scientific development; and 3) To improve device safety across the total product lifecycle.

Industry Perspective on Reauthorization

ACLA noted that its participation is not intended to constitute, and shall not be construed as, a waiver or release of any potential argument or legal relief to which ACLA and/or its members may be entitled with respect to the potential regulatory oversight of Laboratory Developed Tests (LDTs) or clinical laboratories by FDA. ACLA further noted that participation of ACLA and its members in these negotiations is intended to allow labs to address MDUFA issues that would arise if LDTs are regulated as medical devices and if labs are required to register as device establishments. ACLA noted that uncertainties related to the regulation of LDTs may affect the medical device user fee negotiations.

Industry expressed appreciation of FDA efforts during the pandemic and continued collaborations. The four trade associations reaffirmed their support for MDUFA and stated that innovators and regulators have a mutual goal under the medical device user fee program to ensure timely patient access to safe and effective medical technologies. Industry took the position that congressional appropriations should remain the primary source of funding and user

fees are additive to the CDRH and CBER budget. They further stated that MDUFA funds should be used solely for the premarket review process. Through funding provided in MDUFA I, II, III and IV, industry noted significant and material investments in the device review program.

Industry articulated two goals for the MDUFA reauthorization: 1) focus on fundamentals, and 2) establishment of an accurate baseline. Regarding the "focus on fundamentals", industry expressed concerns with a number of key performance expectations under MDUFA IV that industry asserted were not being met or were unlikely to be met, and recognized the unique challenges in evaluating the performance of the program during the COVID-19 public health emergency. Specifically, industry referred to the average total time to decision for 510(k)s, the number of AI letters that continue to lack specific justifications for the cited deficiencies, potential performance in meeting the FY 2021 pre-submission performance goal, and not meeting certain digital health commitments. Furthermore, industry noted that FDA had 36 MDUFA IV FTEs that are currently funded by industry and vacant. Industry also presented data showing that the number of "FTEs related to the device review process" decreased by 19 FTEs from FY18 to FY19, despite significant increases in user fees during this time.

Industry also stated that they would like to better understand the dynamics around hiring and the breakdown of MDUFA program full time equivalents (FTEs) that are funded by non-user fee appropriations and user fee funds. Industry also expressed an interest in seeing FDA fill vacancies for all funded positions. Industry expressed a hope that, given the current trajectory of pandemic response, FDA will be in a position to clear any backlog of submissions that have been caused by the unprecedented workload of the pandemic by October 2022. Industry noted that there may be shared interest in targeted improvements and incorporating lessons learned from COVID-19.

Regarding establishing an accurate baseline, Industry expressed interest in obtaining a more detailed understanding of how FDA calculates MDUFA costs per FTE. Industry also noted the current amount of the MDUFA carryover balance was $122M in FY19 and collections in FY20 were $70M more than anticipated. Industry requested more information about how the carryover balance will be used to support the premarket review process. Finally, Industry noted that the one-time costs that were incorporated into MDUFA IV should not be included as part of the "baseline" for MDUFA V. Industry noted that it shares FDA's vision of bringing safe and effective devices to patients, and Industry looks forward to these discussions.

Discussion

After each party's presentation, FDA and Industry had an opportunity to discuss follow-up questions. Specifically, industry cited data provided by FDA that the average base salary, benefits and bonus for employees encumbering new MDUFA IV positions at the end of FY 2020 was approximately $162,000. However, FDA also provided data that estimates the average fully-loaded cost per FTE FDA-wide was over $303,000. Industry asked whether FDA calculated the total cost per FTE by simply taking the total FDA budget and dividing by the FTEs. FDA first noted that salary figure cited by industry does not reflect broader average pay costs for MDUFA FTEs; FDA also stated that subject matter experts would need to provide greater detail on these questions. Industry said this was a critical discussion to have during the next negotiation

meeting. Industry also stated it needed a better understanding of the current carryover balance and details on how many MDUFA I-III funded FTE positions are currently vacant. Industry also inquired both about FDA's use of congressionally appropriated funds to address the COVID-19 pandemic and about FDA time-reporting data. FDA stated that they would consider these requests for information.

Industry expressed an interest in further discussing the findings of the Independent Assessment, and FDA agreed that this was an area of mutual interest.

FDA requested that industry clarify its basis for asserting that the pre-submission goal for FY2021 was "not being met or unlikely to be met" and industry acknowledged that it was too early to project whether FDA would miss the goal. FDA also requested that industry clarify its assertion that additional digital health goals had been missed.

Next Meeting

The next meeting is scheduled on March 17, 2021.

Meeting End Time: 3:41 pm EST