FDA – Industry MDUFA V Reauthorization Meeting
April 7, 2021, 12:30 pm – 4:30 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*
- Owen Faris, *CDRH*
- Douglas Kelly, *CDRH*
- Misti Malone, *CDRH*
- Edward Margerrison, *CDRH*
- Jonathan Sauers, *CDRH*
- Suzanne Schwartz, *CDRH*
- Don St. Pierre, *CDRH*
- Michelle Tarver, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Jan Welch, *ORA*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Darian Tarver, *OC OO*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Sharon Davis, *CDRH*
- Sonja Fulmer, *CDRH*
- Ellen Olson, *CDRH*
- Hanah Pham, *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*
- Shannon Bennett, *Mayo Clinic Laboratories*

Meeting Start Time: 12:30 pm EST

Executive Summary

During the April 7, 2021 user fee negotiation meeting, FDA presented its initial proposal for a TPLC Advisory Program (TAP). Industry presented the concepts of getting back to basics, accountability, and establishing the baseline for MDUFA V.

Administrative

FDA and Industry agreed to form a working group to discuss topics related to MDUFA finances, in particular as related to resources and hiring, the Agency's methodology regarding calculation of cost per FTE, and the carryover balance, and to report out on those discussions at a future negotiation meeting.

FDA Presentation on Proposal for a TPLC Advisory Program

FDA opened the meeting by expressing that, since its inception, the MDUFA program has led to a more timely, transparent, predictable, and reliable FDA, yet there are existential challenges facing today's MedTech ecosystem that the current program has not adequately addressed. Citing declining investment and startup activity in the MedTech sector, FDA took the position that it and Industry must do more to ensure that U.S. patients have greater access to safe, effective, high-quality, innovative medical devices first in the world.

Building on the foundation laid by prior MDUFA agreements, applying lessons learned from the COVID-19 pandemic response, and filling key gaps in the current MDUFA program, FDA believes that patient access can be accelerated efficiently and broadly while maintaining high standards of safety, effectiveness, and quality. From the Agency's perspective, the current MDUFA program has been optimizing a limited portion of the Total Product Lifecycle (TPLC). By investing in earlier and more strategic coordination of stakeholder input, as well as more frequent FDA interactions and faster FDA responses, FDA believes the MDUFA program can continue to help nurture the MedTech ecosystem and help ensure that U.S. patients have access to high-quality, safe, effective, and innovative medical devices first in the world for years to come.

Industry's interest in interactive review before a filing has led to a significant increase in Pre-submissions. In addition, Breakthrough interactions have exceeded expectations. These highly-utilized programs are not resourced to provide rapid-response capacity or optimally engage FDA reviewers and other stakeholder experts across the full spectrum of device types. MDUFA IV funded Pre-submissions to a specific number of submissions, and FDA has received more than double that. Breakthrough designations and interactions have increased, and without dedicated funding, it will be difficult for the program to reach its full potential. FDA has also allocated resources in reviewers, guidance, templates, and other efforts to increase interaction and communication.

FDA proposed an integrated proposal that addresses these challenges—the TPLC Advisory Program (TAP), which is intended to enable earlier, more frequent, and more strategic communication between FDA and sponsors, as well as to facilitate sponsors' early engagement and coordination with external stakeholders that impact patient access to medical technologies, such as payors and physician professional societies. The program would be designed to leverage, scale, and enhance existing FDA programs and to support convening external stakeholders to provide early strategic input to sponsors. FDA indicated that its proposed initial targets for TAP are devices eligible for the Breakthrough Devices Program and Safer Technologies Program (STeP) and other devices with features of public health importance, such as devices targeted to underserved populations (e.g., pediatrics).

The FDA shared three case examples representing a range of industry experiences, submission types, and level of interaction that could be facilitated by TAP. FDA explained how the TAP proposal builds on lessons learned from the COVID-19 pandemic response, including how early, frequent, and strategic communications between FDA and sponsors could yield more rapid patient access to safe, effective, and innovative medical devices. In addition, FDA described its view of how the TAP proposal, while an evolutionary step in the MDUFA program, would be designed to yield transformative results for sponsors, patients, and the MedTech ecosystem more broadly.

Industry Presentation

Industry presented its guiding principles for user fee reauthorization: timely patient access to safe and effective products; that Congressional appropriations remain the primary source of FDA's funding and that user fees are additive; that use of fees should be solely for the premarket review process, but that industry is willing to partner with stakeholders on additional appropriations for post-market activities; that industry has made significant and material investments under MDUFA I-IV; and that user fees should support mutual premarket goals and process improvements to achieve timely patient access.

Industry described the amount of user fee collections, and the full time equivalents (FTEs) that support the device review process, between FY 2003-FY 2020. Specifically, industry noted that annual user fee collections have increased from $21M in in FY03 to $289M in FY20. In addition, Industry stated that, despite significant increases each year, including an increase from $197M in FY18 to $212M in FY19, the FTEs that support the device review process actually decreased from 1711 in FY18 to 1692 in FY19.

Industry articulated its focus on getting "back to basics," including focusing on meeting MDUFA IV commitments; maintaining the current goal structure; seeking targeted improvements to the premarket review process; eliminating the backlog of submission and Pre-submission requests; building accountability into resource and staffing targets; and reinvesting the carryover balance that is available for use into areas of mutual agreement to enhance the premarket review program.

Specifically, related to staffing targets, industry proposed: a full accounting and quarterly reporting for all MDUFA (I to V) hires and vacancies, annual specific hiring targets for MDUFA V hires; annual specific vacancy percentage targets for all MDUFA (I to V) hires; and that unused hiring funds be used to offset fees in the fifth year of MDUFA V.

Related to financial accountability, Industry proposed: an independent third-party financial audit on use of MDUFA funds; to reinstate the fifth year offset in fees from overcollections; to reevaluate inclusion of "one-time" MDUFA IV costs; to establish a baseline using a revised cost per FTE; and to apply prior MDUFA carryover balances available for use within MDUFA V.

Finally, Industry noted that it had sent to FDA a summary of activities that have been undertaken to support the MDUFA IV total time to decision goals.

Discussion

Regarding the TAP Proposal, Industry reiterated its perspective that MDUFA V should reflect a "back to basics" approach and questioned the need for a new program, rather than continued targeted improvements to the premarket review process (e.g., like the eSTAR pilot). Industry expressed concern about the willingness of external stakeholders (e.g., private payors) to participate in providing early strategic advice. TAP would go beyond the scope of FDA's traditional premarket review role. In addition, Industry provided the perspective that they are not focused solely on the expediency of FDA review, but also the "quality of the journey" in terms of transparency, consistency, and predictability, which Industry was concerned could be at risk by introducing a new program. Industry questioned the interaction between the TAP Advisors and the review teams, and FDA responded. Industry expressed a perspective that the current FDA programs, with all MDUFA-funded FTEs hired, can provide the necessary early interaction and efficient review. FDA explained its perspective that feedback received on the existing Pre-submission program, as well as lessons learned from early engagement with sponsors through the pre-EUA process in response to the COVID-19 pandemic, suggest otherwise. Industry questioned whether the types of devices that FDA would initially target for the TAP program would justify the creation of a new program. FDA explained their view that TAP is expected to yield fundamental benefits across the spectrum of device companies. FDA described how, from the Agency's perspective, the strategic, interactive model envisioned by TAP would be designed to reinforce those fundamental goals of transparency, consistency, and predictability, while also building on lessons learned from COVID-19 pandemic response about outcomes from early communication and engagement and evaluating how to facilitate even more timely patient access to medical devices. FDA confirmed that the agency was not proposing any changes to existing review goals based on implementation of the TAP program.

FDA requested clarification regarding Industry proposals, such as related to hiring and reinstating the fifth-year offset. As part of a discussion about hiring and the number of process FTE hours during MDUFA IV, FDA noted that, prior to the start of the COVID-19 pandemic, the Agency was on-track to meet or exceed almost all of the review and performance goals of the commitment letter. Regarding Industry's interest in reverting to past practice for overcollections to offset fees in the fifth year and adding a new proposal that would provide for fee offsets for unused hiring funds, FDA expressed the view that eliminating the fifth year offset was a smart move to stabilize MDUFA program finances, especially since the program does not include a workload adjuster. Regarding Industry's request for visibility on tracking of positions funded from MDUFA I through III, FDA explained that it did not have a system for tracking and reporting new MDUFA positions prior to MDUFA IV. Industry also reiterated its interest in better understanding the increased size of the carryover balance and applying the balance to areas of mutual agreement. FDA noted that factors contributing to the size of the carryover balance included the Agency's use of non-user fee appropriations substantially above the statutorily required spending trigger and the spike in registration fees in FY2020 related to the COVID-19 pandemic.

Next Meeting

The next meeting is scheduled on April 28, 2021.

Meeting End Time: 4:00 pm EST