

FDA – Industry MDUFA V Reauthorization Meeting
April 28, 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*
- Misti Malone, *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*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Sharon Davis, *CDRH*
- Ellen Olson, *CDRH*
- Marta Gozzi, *CDRH*
- Hanah Pham, *CDRH*
- Douglas Kelly, *CDRH*
- Aron Yustein, *CDRH*
- Daniel Canos, *CDRH*
- Felipe Aguel, *CDRH*
- Mimi Nguyen, *CDRH*

Industry

AdvaMed Team

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

MITA Team

- Peter Weems, *MITA*
- Diane Wurzbarger, *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: 12:30 pm EST

Executive Summary

During the April 28, 2021 user fee negotiation meeting, Industry presented its overall proposal for the MDUFA V package. FDA provided an update on how CDRH is addressing the impact of COVID-19 workload on “conventional” premarket submission review. FDA also presented a proposal for enhancing post-market medical device safety, and it presented additional data to support its proposal for the TPLC Advisory Program. Finally, FDA also reiterated its goals for MDUFA reauthorization and presented a roadmap of key topics to address those goals.

Industry’s Presentation

Industry presented its overall proposal for the MDUFA V package. Industry began by confirming its principles for the User Fee Program: 1) Supporting timely patient access to safe and effective medical devices and to maintain the U.S. review process as the gold standard in the world for patient safety; 2) That Congressional appropriations remain the primary source of CDRH’s funding such that user fees are additive; 3) That user fees are solely for the premarket review process, while Industry is actively supportive of additional general appropriations for patient safety and patient engagement initiatives; 4) Recognition that Industry has made significant and material investments in building up the program through MDUFA I through IV, such that there has been a sizable growth in resources and the program is now on very stable footing; and 5) That user fees should support mutually shared goals and process improvements to help achieve timely patient access to safe and effective devices.

Industry introduced the key elements of its proposal for reauthorization of MDUFA, which reflects Industry’s recommended focus on program fundamentals:

- Establish an accurate baseline using revised lower per-FTE costs.
- Address certain MDUFA IV one-time costs, maintaining some, not renewing others that were completed, and potentially identify other one-time costs for funding. In particular, Industry proposed continuing to fund initiatives for patient engagement, recruitment, retention, and the independent assessment, with the details and costs for each to be discussed. Two one-time costs—the investment to stand up time reporting, and the IT investment to support digital health—seemed no longer applicable and Industry proposed not to extend them. Industry indicated the following one-time costs would require further discussion to determine if there was a mutual interest in extending them: IT enhancements for premarket review work; real world evidence; standards conformity assessment; and third party review. Finally, Industry proposed one new one-time cost, for an independent audit of MDUFA financials.
- Maintain the MDUFA IV commitments and quantitative goals under MDUFA V. Industry noted that many of the MDUFA IV goals themselves were continuations of MDUFA III goals, and some of the current goals are not particularly aggressive based on past results. However, maintaining the current goals and goal structure will ensure stability and continuity at a time when it will be difficult to evaluate current performance against goals, given that the Agency will be working to adjust to the ongoing effects of the COVID-19 public health emergency. This approach will also allow additional time for any MDUFA IV commitments that have not been fully met to be achieved, and to ensure those that have been met continue to be met based on ongoing performance.

- Set annual specific numerical hiring targets for MDUFA V. Although Industry and FDA discussed hiring targets in MDUFA IV, Industry recommends more formality to the establishment of hiring targets in MDUFA V to ensure there is transparency as well as prioritization within the agency to meet those targets. The appropriate targets will need to be discussed.
- Set vacancy percentage targets for MDUFA I-V hires and apply unused staffing funds above vacancy target to offset fees in the fifth year. Because vacancies result in time periods during which the intended reviewer support for the review process is unavailable and cannot be recaptured, and given the unexpectedly large accumulation of the carryover balance, Industry believes it is more appropriate to offset amounts unspent due to vacancies above an appropriate target. Industry recognizes that some level of vacancy is to be expected, and appropriate vacancy thresholds will need to be discussed.
- Reinstate 5th year offset in fees from over-collections, similar to MDUFA I-III. The carryover balance has grown to a much more significant level than had been contemplated when Industry initially agreed to rescind the 5th year offset.
- Apply appropriate annual inflation adjustments, to be negotiated.
- Invest carryover balance “available for use” based on mutual agreement (currently ~\$209mm), either by agreeing on initiatives to fund and/or crediting the amount generally to the MDUFA V baseline

Industry subsequently provided additional feedback on the TAP proposal FDA outlined during the negotiation meeting on April 7th.

- Industry sought feedback from its respective members on the proposal by FDA at the last meeting. Each of the Industry groups’ membership does not support the proposal as described during the April 7th meeting and Industry has a fundamentally different view of the MDUFA program and its purposes. Industry believes that some aspects of the TAP proposal, for instance related to convening stakeholders such as private payors, would extend beyond the scope of MDUFA and beyond FDA’s purview overall and would require statutory changes to implement. Moreover, Industry is concerned that it would drive up program costs and put the fundamentals of the device review program at risk. Breakthrough devices already receive heightened engagement in the review process, and there are multiple initiatives extending beyond FDA seeking to address coding and coverage for innovative devices. Industry also expressed concern that this proposal would add significant complexity to the premarket review process. At a time when the premarket review program is readjusting after a significant response to the COVID-19 public health emergency, and companies are experiencing delays to device submissions as a result while others are waiting to submit applications, Industry believes the focus should be on assuring a reliable premarket review program. Industry expressed concern that TAP risked distracting the program from the core mission of premarket review. Finally, Industry noted that MDUFA’s existing scope is reflected in goals for review performance in terms of time and predictability of the process, and recommended remaining within that scope.

Industry concluded its presentation by identifying suggested next steps and key themes. Industry highlighted its focus on meeting the MDUFA IV commitments and making sure the gains are sustainable. Industry noted the importance of subsequent discussion of the cost-per-FTE.

Industry also requested FDA's confirmation that there will be discussion and consensus reached about how the agency will spend the carryover balance, and noted remaining lack of clarity about how the amount had grown to the current amount. Next, Industry stated its desire for additional visibility into MDUFA I-III hiring and vacancies, as well as how the supplemental appropriations from Congress are being applied to the device review program.

FDA's Update on Addressing the Impact of COVID-19 Workload

FDA acknowledged Industry's interest in how the Agency is addressing the impact of COVID-19 workload (pre-EUA and EUA submissions) on "conventional" premarket submission types (510(k)s, De Novos, Premarket Applications, and Q-submissions). FDA noted that, during 2020, CDRH received over 5,500 pre-EUA and EUA submissions and also experienced an increase in "conventional" premarket submission types to over 17,000 files, resulting in an overall increase in premarket submissions of 38%. FDA noted that this increase in workload impacted FDA's ability to meet review timelines for certain MDUFA submissions, most notably in the IVD product space. For non-IVD product areas, however, FDA noted that premarket submission reviews and Pre-submissions are generally continuing under typical timelines. In divisions reviewing files for personal protective equipment (e.g., respirators, facemasks), FDA is experiencing longer timelines for Pre-submissions, and a small number of other submissions may experience delays on a case-by-case basis. Otherwise, although the COVID-19 pandemic resulted in an unprecedented increase in workload, and COVID-19 work remains a priority, the backlog of MDUFA submissions is occurring primarily in non-COVID-19 IVD submissions. FDA noted that COVID-19 has exposed that the Center could be better resourced to better absorb systemic shocks in the future.

FDA's Proposal Related to Device Safety

FDA presented a proposal to strengthen its post-market surveillance capabilities by enhancing its ability to more accurately and precisely identify the scope of potential concerns, to more efficiently resolve device performance and patient safety issues, and to provide timely and clear communications with patients and healthcare providers. FDA highlighted the benefits of improving FDA's capacity to evaluate emerging performance issues more rapidly to determine whether they are truly signals. Moreover, FDA discussed how public confidence in the safety and effectiveness of marketed medical products relies on a robust post-market safety net, one that allows for development and distribution of information that accurately reflects the benefit-risk profile of a device.

FDA described how the current system for signal management is limited by limited access to available real-world data and largely relies on passive surveillance and mandated post-market studies, which can lead to delays in identifying appropriate mitigations and providing definitive actionable information to impacted parties. To address these limitations, FDA proposes to improve its access to data that would facilitate more timely signal evaluation; to strengthen its internal capabilities to conduct such analyses more efficiently, comprehensively, and quickly; and, if warranted, to identify and implement more timely, precise, and effective signal resolution strategies. To further improve FDA's communication about safety signals and mitigations, FDA also proposes to increase direct engagement with stakeholders through product safety focused

workshops, and to develop and maintain a centralized, well-organized, publicly accessible repository for up-to-date device labeling and patient-centric device information.

Industry responded to FDA's proposal by explaining that Industry would be willing to work with stakeholders to secure additional congressional appropriations for appropriate postmarket activities.

FDA's TPLC Advisory Program Proposal

FDA presented additional details on the TPLC Advisory Program (TAP). By providing a new model for frequent and rapid FDA interaction with sponsors, earlier in the device development cycle, TAP would build upon lessons learned from FDA's engagement with sponsors during the COVID-19 pandemic response, as well as successes and challenges with the current programs such as the Breakthrough and Pre-submission programs. It would also respond to industry feedback that FDA has received through its interactions with companies, requesting more frequent, high-quality, rapid-response interaction.

Using data from FDA's current Breakthrough and Pre-submission programs, FDA explained how the TAP proposal would benefit the broad range of companies that use those programs. For example, data show that, in FY 2018-2020, 485 different companies of all sizes submitted Breakthrough Designation Requests to FDA; in FY 2019, 1,750 different companies, also reflecting a broad range of sizes, submitted Pre-submissions to FDA.

FDA described the need to build capacity and expertise to support this new engagement model. In particular, the proposal reflects the addition of review staff, increasing clinical and technical expertise, additional training and professional development, expanding capabilities of existing stakeholder programs, and strengthening the infrastructure that supports program outcomes. To support the need for additional capacity, FDA provided preliminary data showing the number of FDA resources it took to review Pre-submissions in a recent six-month period.

Industry sought clarification on which technologies TAP intends to target. FDA explained that it envisions the program would begin with devices in the Breakthrough and the Safer Technologies Program (STeP) programs, as well as devices with other features of public health importance, such as devices for underserved populations (e.g., pediatrics).

In response to Industry's opposition to the TAP proposal, FDA explained that it has received positive feedback regarding its engagement with some sponsors during the pre-EUA process as part of the COVID-19 pandemic response; the broad-based popularity of existing programs that facilitate current engagement (namely, the Breakthrough and Pre-submission programs); and the common request that FDA hears from members of regulated industry for an opportunity to engage with FDA more frequently and with more rapid feedback timelines. In addition, FDA emphasized how, by developing and sustaining this new model for engagement, TAP would address Industry's goal of focusing on the fundamentals of the MDUFA program—for instance, that more iterative engagement earlier in the device development process could help ultimately to facilitate higher quality premarket submissions and, accordingly, fewer review cycles. Moreover, rather than adding complexity to the premarket review process, TAP Advisors would help streamline sponsors' engagement with the Agency and support CDRH's strategic goal of

simplicity, as reflected in CDRH's Strategic Priorities for 2018-2020. Finally, by supporting the operational success of key FDA programs, the TAP program would help achieve both FDA and Industry's goal of facilitating timely patient access to safe and effective devices. FDA expressed that it looks forward to continuing to address Industry's questions about the proposal, so that FDA can explain how features of the TAP proposal meet both Industry and FDA's objectives for MDUFA reauthorization.

Upon the conclusion of FDA's second presentation regarding TAP, industry reiterated its opposition for the reasons previously stated.

FDA's MDUFA V Goals and Proposed Roadmap

FDA reiterated its three goals for MDUFA V and provided an overall roadmap of the topics and proposals that the Agency sees as supportive of those goals. Specifically, FDA's goals are to: 1) enhance operational success, reduce device development times, and further accelerate patient access to high-quality, innovative, safe and effective devices; 2) improve device safety across the total product lifecycle; and 3) optimize FDA infrastructure, staffing, and resources to keep pace with scientific development.

FDA Feedback on Industry Proposals

FDA noted that they would take back and consider the proposals that Industry described, as well as consider Industry's categorization of what one-time costs from MDUFA IV should be continued in MDUFA V. As an initial matter, however, FDA noted significant concerns with some of Industry's proposals related to MDUFA finances and, in particular, expectations of a negative response from Agency leadership to the proposal to reinstate or expand the 5th year offset in fees, given the negative effects that had caused FDA to seek and Industry to support discontinuing the offset provision as part of MDUFA IV. Industry stated that its expectation in ending the 5th year offset was that fees above the baseline would be reinvested into the program on areas of mutual interest to FDA and industry. To help facilitate this discussion, FDA suggested that industry provide details of how it proposes that carryover funds could be allocated.

Next Meeting

The next meeting is scheduled on May 19, 2021.

Meeting End Time: 4:13 pm EST