FDA – Industry MDUFA V Reauthorization Meeting
May 19, 2021, 12:30 pm – 4:25 pm EST
Virtual Via Zoom

Purpose
To discuss MDUFA V reauthorization.

Attendees

FDA
- Lauren Roth*, OC OP*
- 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*
- Diane Goyette*, ORA*
- 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*
- Aron Yustein, *CDRH*
- Daniel Canos, *CDRH*
- Felipe Aguel, *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*
- 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: 12:38 pm EST

Executive Summary

During the May 19, 2021 user fee negotiation meeting, Industry presented their principles and proposals for MDUFA V. FDA presented a readout of financial work group meetings held to-date; a proposal for a workload capacity adjuster; and additional details to support its proposal for enhancing postmarket medical device safety.

Industry's Presentation

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 used solely for the premarket review process, while Industry is supportive of additional general appropriations for appropriate postmarket 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 addressed the current resource baseline for the device review program and reiterated its request for an accounting of the allocation of additional appropriations received from Congress. In particular, industry noted that Congress allocated $716 million to support COVID-19 related activities across the FDA, including device review activities. Industry fully supports funding for COVID-related work and the importance of FDA's work in reviewing COVID-related devices. It is important to have transparency as to how those funds have been and are being allocated. The appropriations are not limited solely to EUA work, so they are potentially being used or could be used for other COVID-related premarket device review work. This is relevant in light of the diversion of review resources to COVID-related work during the public health emergency. It is also relevant in light of the unspent available carryover MDUFA balances. Given that COVID-related work will include traditional premarket review work going forward, it is also relevant to know how much of that appropriation has already been spent or remains to be spent in the coming years. Finally, it is also germane to having a realistic expectation for the amount of hiring that can occur over a set period of time. Ultimately, it is difficult to get a full picture of resource needs without understanding how those appropriations are being used.

Industry also expressed a continuing interest in understanding the percentage of vacancies for CDRH overall, and the percentage of vacancies for MDUFA-funded positions. Relatedly, Industry asked whether FDA's funding request for MDUFA V would be based on an assumption of 100% capacity/zero vacancies.

Industry next discussed the issue of the cost per FTE used to calculate MDUFA funding. Industry provided its understanding of the Agency's current model of using an Agency-wide cost per FTE, which is calculated to be $303k. Industry offered its view that taking the actual salary, benefit, and costs for MDUFA IV hires and for CDRH into account, plus reasonable overhead, a more appropriate cost per FTE would be $225k. Industry provided an example of how additional appropriations by Congress can increase the cost per FTE calculation, and noted how costs outside of the MDUFA program could increase the Agency-wide cost per FTE.

With regard to available carryover balances, Industry offered its proposal for how to use those funds. Industry expressed its expectation for a process to be used to reach agreement with FDA about the use of the $209 million in available carryover. Industry noted that the overall incentive should be for MDUFA funds to be used in real time, rather than to go unused. Industry's initial

recommendations for use of those funds are to focus on enhancements for CDRH Offices of Health Technology (OHTs) to support reviews and pre-submissions, funding to support citations of justifications in additional information/major deficiency letters, and to support total time to decision goals.

Industry elaborated on its prior proposal on one-time costs, indicating that there was a need for an evaluation of each of the one-time costs in terms of use of funds, status of commitments relating to such costs, assessment of whether the initiatives were successful, and specific initiatives for MDUFA V.

Finally, Industry offered its initial response to the Agency's proposal on device safety. Industry offered its assessment that FDA is currently the global gold standard for device safety, and that Industry is eager to work with the Agency and stakeholders to support appropriate postmarket initiatives to be funded by Congressional appropriations. In Industry's view, user fees are best used for premarket review activities and it is not advisable to include these initiatives in MDUFA. FDA confirmed that the Agency has not sought Congressional appropriations for this specific postmarket safety initiative.

FDA Feedback on Industry Proposals

FDA began by noting areas of common ground between the Parties' approach to MDUFA negotiations—in particular, that both FDA and Industry share a goal of promoting timely patient access to safe and effective products, and that Industry has made significant and material investments to the MDUFA program since 2003. FDA also identified current areas of disagreement—in particular, Industry's view that user fee funds should not support a greater share of total CDRH expenses and that the scope of the MDUFA program should not be expanded to include additional postmarket activities. FDA questioned the basis for Industry's positions, and noted that, just because things were done a certain way in the past, that does not prevent a new approach going forward; the rationale for prior approaches may no longer apply. Rather, from FDA's perspective, the MDUFA program can and should reflect evolving resource needs and other program needs, including to support postmarket activities that help ensure patient safety.

Regarding Industry's request for information about allocation of COVID supplemental funds, FDA provided its perspective that there is not a direct link between the COVID supplemental funds and MDUFA, since the vast majority of COVID work is not considered MDUFA process work.

FDA addressed Industry's proposals related to hiring and establishing vacancy percentage targets for MDUFA I-V hires. Regarding Industry's request for more information on vacancies, FDA reiterated its prior explanation that CDRH's position tracking mechanism was implemented at the beginning of MDUFA IV, so it includes only new hires from MDUFA IV. In addition, because an individual employee may perform a mixture of MDUFA and non-MDUFA process work, the Agency uses MDUFA Process FTE data, which is based on time-reporting data, to measure and track the number of paid staff years devoted to the MDUFA program. FDA

recognized that this is a topic of interest to Industry, and suggested the Parties continue to discuss how to address Industry's interest in hiring and retention.

In response to Industry's inquiry about the method for establishing the financial baseline for the MDUFA program, FDA explained that the "baseline" refers to the total user fee target revenue during the current user fee cycle, adjusted for inflation. In response to Industry's question about the percentage of MDUFA process expenditures attributable to FTEs, FDA explained that, typically, approximately 60 percent of those expenditures are used for MDUFA payroll expenses and approximately 40 percent are used for non-payroll expenses.

FDA questioned how Industry arrived at a calculation of target cost per FTE. FDA reiterated its explanation of the Agency-wide methodology for calculation of cost per FTE.

FDA's Overview from the Financial Work Group Meetings

FDA provided an overview of information presented during the work group meetings between representatives from FDA and Industry on April 23 and May 12 to discuss questions related to MDUFA administrative and financial topics: (1) status of hiring and process FTE during MDUFA IV to-date; (2) factors contributing to the amount of the carryover balance as of the end of FY 2020; and (3) inputs to FDA's Agency-wide methodology for calculation of cost per FTE.

On the first topic, FDA recapped that the work group had discussed both the challenges that impacted the Agency's ability to hire 100% of new MDUFA IV positions in prior years of MDUFA IV and the talent management accomplishments that contributed to a successful hiring year in FY 2020 and projected continuing hiring success. FDA presented information on MDUFA process FTE through FY 2020, including a breakdown of process FTE funded by budget authority (non user-fee appropriations) and user fees across MDUFA I – IV.

On the second topic, FDA recapped its explanation that there were several contributing factors to the amount of carryover at the end of FY2020, including: (1) an unprecedented amount of excess earned collections in FY 2020 ($69M); (2) MDUFA IV funds that were allocated as one-time enhancement funding, and returned to the carryover to be utilized during the MDUFA IV timeframe; (3) a relatively stable amount that has historically been carried forward, starting in MDUFA II; and (4) funds that accumulated, beginning in FY 2017, as a result of FDA directing additional budget authority funds to the MDUFA program and returning user fee dollars to the carryover. Specifically, FDA noted that it was able to return funds to the carryover through belt-tightening decisions such as stopping annual, routine upgrades to existing, aging IT systems and applying, where appropriate, increased available budget authority and Cures funding to the MDUFA program. To help illustrate this point, FDA noted the significant amounts of total process spending attributable to budget authority between FY 2017-2020.

On the third topic, FDA noted that they had already provided a summary of the Agency-wide fully loaded cost methodology as part of the earlier discussion.

FDA's Proposal Related to Development of a Capacity Adjuster

FDA proposed that MDUFA V include a capacity adjuster to address the risk that unanticipated, sustained increases in MDUFA workload could negatively impact the Agency's ability to meet performance commitments.

FDA explained the rationale: Although FDA and Industry work to accurately predict workload in the next five-year period, that doesn't mean we get it right. For instance, the number of pre-submissions has exceeded MDUFA IV projections and FDA far exceeded the MDUFA IV goal. In addition, there is an increase in submissions that impact the device review program that have no fee. FDA first sought a workload adjuster as part of MDUFA IV negotiations, and FDA continues to see the importance of this type of mechanism to support the long-term financial stability of the MDUFA program.

FDA proposed that next steps should be to evaluate potential options for a pilot capacity adjustment methodology, pressure test a model, and translate workload percentage change to resource needs. FDA disagreed with Industry's perspective that increases in hiring could be supported by funds in the carryover balance, pointing out that, in a given year, the carryover balance might not have sufficient resources available for use.

FDA's Proposal Related to Device Safety

FDA presented additional details for a proposal to support device safety by strengthening FDA internal capabilities in order to refine potential postmarket signals more efficiently, comprehensively, and quickly and, if needed, identify and implement more timely, precise, and effective postmarket signal resolution strategies.

FDA started by noting that, as part of a public workshop held in November 2020 regarding FDA's safety communications about medical devices, Industry broadly acknowledged the complexity of the issue and expressed interest in FDA continuing to improve the content and process for its safety communications, with a focus on ensuring that the information provided to the public is timely, accurate, and actionable. FDA noted that access to additional sources of information is one of the main pillars of the proposal, and FDA provided examples to explain how leveraging these sources of information could help increase the timeliness of issue evaluation and resolution.

In response to a question from Industry about whether FDA had sought new Congressional appropriations to support these enhancements to postmarket safety, FDA responded that it had not.

Next Meeting

The next meeting is scheduled on June 16, 2021.

Meeting End Time: 4:25 pm EST