FDA – Industry MDUFA V Reauthorization Meeting
February 10, 2022, 3:00 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*
- Misti Malone, *CDRH*
- Jessica Pittman, *CDRH*
- Don St. Pierre, *CDRH*
- Eli Tomar, *CDRH*
- Barbara Zimmerman, *CDRH*
- Cherie Ward-Peralta, *CBER*
- Angela Granum, *CBER*
- Claire Davies, *OCC*
- Louise Howe, *OCC*
- Emily Galloway, *OC Econ*
- Malcolm Bertoni, *Consultant*
- Nia Benjamin, *CDRH*
- Ellen Olson, *CDRH*

Industry

AdvaMed Team

- Janet Trunzo, *AdvaMed*
- Zach Rothstein, *AdvaMed*
- Nathan Brown, *Akin Gump*
- Phil Desjardins, *Johnson & Johnson*
- Danelle Miller, *Roche*
- Michael Pfleger, *Alcon*
- 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: 3:00 pm EST

Executive Summary

During the February 10, 2022 user fee negotiation meeting, FDA and Industry discussed draft commitment letter language for the Third Party Review Program. FDA also responded to Industry's questions on Consensus Standards and aspects of FDA's proposed financial package regarding cost per FTE and operating costs.

Third Party Review Program

FDA and industry discussed the draft Commitment Letter language for the Third Party Review (3PR) program. FDA proposed updating the language to reflect the approach whereby FDA would continue the current 3PR program using the unspent one-time resources provided in MDUFA IV. FDA noted that of the $14 million allocated to the 3PR program over the 5 years of MDUFA IV, only approximately $5 million had been spent through FY 2021, hence FDA expected to have sufficient unspent resources to continue operating the 3PR program at the current scope through MDUFA V. Industry asked why FDA's draft did not include the MDUFA IV language stating that the goal was to eliminate routine re-review of 3PR 510(k)s. FDA reiterated its ongoing commitment to that objective for 3PR, and clarified that because the MDUFA IV independent assessment had concluded that FDA had met its commitments related to eliminating routine re-review, resulting in progress toward reducing re-review, FDA thought that the old language was not applicable to MDUFA V. FDA also noted that the remaining unspent resources were not sufficient to expand the scope of the program in MDUFA V. FDA noted that there appears to be a consensus to recommend extending the sunset date for the 3PR program through the end of MDUFA V.

Consensus Standards

Industry asked if the accreditation scheme for conformity assessment (ASCA) would apply to in-vitro diagnostic (IVD) devices in MDUFA V. FDA noted that it did not see any reason why standards relevant to IVDs would be categorically excluded. Industry also mentioned that it would be helpful to see a readout on the results of the ASCA pilot and how it has applied. FDA clarified that the current MDUFA IV Commitment Letter includes a viability report on the ASCA pilot that would address this issue.

Cost per FTE and Operating Costs

Industry asked for clarification regarding why FDA's proposed financial package included separate line items for operating costs when the "fully loaded cost per FTE" model already includes operating cost components. FDA noted that the separate lines for "operating costs" associated with the pre-submissions and back-to-basics/fill MDUFA gaps categories were intended to capture several ways in which the standard Agency-wide methodology was not sufficient to account for MDUFA-specific payroll and operating costs, which resulted in FDA not being able to keep up with rising costs. FDA further addressed this question in several parts.

First, the cost per FTE model is based on a standard Agency-wide methodology that is derived from historical data about actual payroll and operating costs. This can lead to under-estimation of future costs due to several reasons, including:

- When payroll costs are accelerating, the time lag from using a 3-year average of historical payroll costs for the pay component of the inflation adjustment creates a gap between the amount FDA receives through the inflation adjustment and the actual costs experienced in the current year. In recent years, CDRH experienced increases in several categories of payroll costs, including cost of living adjustments and retirement benefits contributions.

- The payroll component of the inflation adjustment is based on year-to-year changes in Agency-wide payroll costs, whereas the actual costs experienced in the MDUFA program are based on the payroll costs in the organizations participating in MDUFA, which is roughly 80% CDRH. CDRH has increased the use of Cures pay authority in the past two years, which has contributed to accelerating payroll costs that aren't captured adequately in the FDA-wide calculations.
- The non-pay component of the inflation adjustment is based on the consumer price index, whereas MDUFA-specific operating costs appear to be increasing at a higher rate.

To ensure that the cost estimates for MDUFA V adequately captured these increased costs, FDA included separate line items to augment the estimated base program costs.

FDA further explained that because the historical cost data did not capture many of these more recently increasing costs, the average cost per FTE model for new FTEs would otherwise under-estimate the cost of MDUFA V program expansion, so the separate line item also corrects for that under-estimate.

Industry expressed concern about the magnitude of what FDA explained were under-estimates of MDUFA IV costs representing approximately $380 million and the desire to identify better ways to calculate return on investment.

Meeting End Time: 4:30 pm EST