FDA – Industry MDUFA IV Reauthorization Meeting
March 4, 2016; 9:00 am – 12:40 pm
FDA White Oak Building 66, Silver Spring, MD
Room 4404

Purpose

To discuss details of FDA's updated proposal package for MDUFA IV reauthorization.

Participants

FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marc Caden	Office of Chief Counsel (OCC)
Joni Foy	Center for Devices and Radiological Health (CDRH)
Sonja Fulmer	CDRH
Louise Howe	OCC
Aaron Josephson	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Toby Lowe	CDRH
Daniel Montgomery	CDRH
Thinh Nguyen	Office of Combination Products (OCP)
Geeta Pamidimukkala	CDRH
Prakash Rath	Office of Legislation (OL)
Eric Rechen	CDRH
Don St. Pierre	CDRH
Darian Tarver	OC
Jacquline Yancy	CDRH
Barb Zimmerman	CDRH

Industry

Hans Beinke	Siemens (representing MITA)
Nathan Brown	Akin Gump (representing AdvaMed)
Phil Desjardins	Johnson & Johnson (representing AdvaMed)
Sergio Gadaleta	Becton Dickinson (representing AdvaMed)
Elisabeth George	Philips (representing MITA)
Allison Giles	Cook (representing MDMA)
Mark Gordon	Abbott (representing MDMA)
Megan Hayes	Medical Imaging & Technology Alliance (MITA)
Donald Horton	Laboratory Corporation of America Holdings (representing ACLA)
Tamima Itani	Boston Scientific (representing MDMA)

Mark Leahey	Medical Device Manufacturers Association (MDMA)
Michael Pfleger	Alcon (representing AdvaMed)
Jim Ruger	Quest Diagnostics (representing ACLA)
Paul Sheives	American Clinical Laboratory Association (ACLA)
Patricia Shrader	Medtronic (representing AdvaMed)
Janet Trunzo	Advanced Medical Technology Association (AdvaMed)
Diane Wurzburger	GE Healthcare (representing MITA)

Meeting Start Time: 9:00 am

Executive Summary

FDA presented an updated proposal package, which focused on proposals for sustaining and enhancing the medical device user fee program. FDA's proposal was intended to support these objectives while attempting to optimize the benefit-cost ratio. FDA also presented areas for continued consideration during the negotiations.

FDA's March 4 Proposal

FDA presented an updated proposal package that supports FDA's objectives for sustaining and enhancing the medical device user fee program under MDUFA IV. In response to feedback from Industry, FDA prepared a proposal package that explored ways to reduce cost and optimize the benefit-cost ratio of the package. FDA proposed a package that would add $329 million to the MDUFA III baseline over 5 years, ramping up staffing to add 201 FTE by the end of MDUFA IV. This package includes components that reflect FDA's highest priorities for sustaining and enhancing the program, organized into two groupings. The first grouping includes core components to sustain and strengthen the program with an investment of $196 million and 144 FTE through the following proposals:

- To provide 20 FTE to establish a quality management (QM) system.
- To provide $4.5 million for the development of the myDevices Portal and eSubmitter, as described in FDA's January 27 proposal and as proposed by AdvaMed, MDMA, and MITA on February 18. This investment would also include the ability to track and report data specific to laboratory-developed tests, as proposed by ACLA.
- To provide 14 FTE and $0.35 million to establish an integrated review process model, as described in FDA's January 27 proposal.
- To provide 20 FTE to increase the capacity of Branch Chiefs to provide greater oversight and ensure consistency of review procedures, as described in FDA's January 27 proposal.

- To provide 43 FTE to support additional review capacity to ensure consistency in process and feedback for each innovative device's entire regulatory lifespan, from Pre-Submission through marketing authorization.

- To provide 6 FTE and $8.5 million to implement effective recruitment and hiring strategies.

- To provide 41 FTE to maintain current performance on submissions without goals, including Pre-Submissions and De Novo requests, given projected workload increases. FDA noted that in addition to this investment, a one-time up-front effort is required to stabilize the program by eliminating the current backlog of Pre-Submissions and De Novo requests.

- To establish a mechanism to address workload uncertainty.

The second grouping of FDA's proposed package includes additional components to enhance the program with an investment of $133 million and 57 FTE through the following proposals:

- To provide 17 FTE and $4.5 million to strengthen the Third Party Premarket Review program.

- To provide 13 FTE and $3.6 million to provide consistent review of software and issues related to Digital Health.

- To provide 12 FTE and $3.5 million to develop staff capacity to more efficiently and effectively review submissions that contain Patient Preference Information (PPI) and to support the development and review of Patient Reported Outcomes (PROs) for pre-market submissions.

- To provide 15 FTE and $50 million to contribute to the implementation of a system that improves the quality of Real World Evidence (RWE) and linkages among data sources to enable premarket reviewers to use RWE for premarket decision-making.

Industry expressed disappointment that FDA's proposal requested $329M in addition to the MDUFA III baseline for many enhancements that did not align with industry's priorities, and without including any improved performance goals for De Novo submissions or Pre-Submissions. FDA explained that the proposal clarifies FDA priorities and shows how cost could be reduced. FDA also explained that the most recent time reporting data revealed trends that indicate a higher level of effort would be required to attain previously proposed performance levels due to increased intensity of interactions and effort involved in reviewing submissions, in particular direct De Novo submissions and submissions associated with the Expedited Access Pathway (EAP) program. Industry asked why FDA's presentation appeared to prioritize other initiatives over De Novos, which have a statutory timeline. FDA explained that even though De

Novos have a statutory target of 120 days, Congress did not provide additional resources to meet the statutory goal. FDA also explained that the proposed initiatives have broad applicability to public health because of their impact on multiple review processes. Industry then stated that it would be in "listen only" mode for other aspects of the presentation, and noted that the gap between FDA's March 4 proposal and the February 18 proposal from AdvaMed, MDMA and MITA was significant.

FDA's Proposed Areas for Continued Consideration

FDA provided a list of additional proposal topics for continued consideration and discussion, which reflect areas where FDA would like to reach agreement with Industry, yet the scope and cost requires some additional discussion, and therefore was not included in the above package. These topics included the proposal to continue the Independent Assessment, to establish performance goals for Pre-Submissions and De Novo requests, and to develop a Standards Accreditation Program. Industry asked why the continuation of the Independent Assessment was excluded from the $329 million package in addition to the MDUFA III baseline. FDA indicated that it was not as high a priority for the agency compared to the other items that FDA did include, but that FDA would like to discuss how to fit it in. FDA also included shorter CLIA Waiver by Application goals on the list of areas for further consideration, but noted that FDA's initial analysis indicates that there could be legal impediments to FDA using MDUFA funds to implement the CLIA proposal. FDA noted its willingness to continue working with Industry on these topics to reach agreement on the level of funding FDA needs to make improvements in these areas. Industry pointed out that FDA had previously signaled that De Novos and Pre-Subs were two areas of common interest, so it was disappointing that FDA had not included enhancements to these areas in its cost proposal. FDA explained that its March 4 proposal package included maintaining current performance for De Novos and Pre-Subs in the face of workload increases as a way to reduce cost.

FDA's Proposed Areas for Exclusion from Further Consideration

On February 18, AdvaMed, MDMA, and MITA proposed to exclude review summaries and 513(g) performance goals from further consideration. At the March 4 meeting, FDA agreed to exclude those proposals and further proposed to exclude from consideration proposals for device-specific guidance development and Submission Issue Meeting (SIM) performance goals. Industry agreed to exclude the guidance and SIM proposals. FDA noted that excluding these four proposals represents a savings of $53 million over 5 years compared to FDA's January 27 proposal. Industry indicated its agreement to drop these four proposals from consideration.

Additional Details on FDA's Updated Proposal

De Novo Program Maintenance

FDA explained that newly obtained workload data from FY15 supports FDA's earlier observations that the de novo program has reached a tipping point and performance is decreasing as compared to previously reported performance for FY14, based upon increased workload driven by the number of direct De Novos. FDA proposed hiring 13 FTE to maintain current de novo performance throughout MDUFA IV.

Pre-Submission Program Maintenance

FDA described a revised Pre-Sub proposal that would maintain FY15 performance without establishing performance goals. FDA explained that recently obtained workload data from FY15 shows 33% of Pre-Submissions have a meeting or receive feedback within 60 days. FDA proposed hiring 28 FTE to maintain Pre-Sub performance at that level throughout MDUFA IV.

Backlog

FDA explained that previous proposal estimates did not include resources needed to eliminate the backlog of Pre-Submissions and De Novo submissions. FDA and Industry discussed the potential impact of the backlog on MDUFA IV performance. Industry asked why available FTEs from MDUFA III have not been used to address these backlogs rather than for other projects, particularly for de novo reviews, which have a statutory timeline. FDA responded that the emergence of the backlog is new information that is still being analyzed, and that the use of MDUFA III funding is one of the options that FDA is investigating. Industry also noted that previous MDUFA negotiations looked at 3-5 year averages to establish workload and trends and that looking at just one year may be misleading. FDA noted that the most recent time reporting data is consistent with the most recent performance data, and the fact that there has been an increase in use of the EAP and direct De Novo programs. FDA also noted that it is still analyzing the newly obtained data and planned to discuss options for addressing the backlog at a future meeting.

Third Party Review Program

FDA provided additional detail on the Third Party Review Program proposal. FDA described a need for competent Third Party reviewers. FDA proposed to accomplish this through adequate training of Third Party reviewers, audits of Third Parties to improve confidence in their decisions, and making more data resources available to Third Parties. FDA further proposed to increase the range of device types that are eligible for Third Party Review and to improve the timeliness and predictability of FDA's review of Third Party review memos. FDA noted that the improved program would support international harmonization efforts, such as the Medical Device Single Review Program (MDSRP).

Digital Health

FDA provided additional details about improvements that could be made to the Digital Health program to support a review paradigm designed for innovative digital health products. FDA explained that the current review infrastructure, staff expertise, and capacity are not able to address many of the challenges presented by digital health products, such as rapid changes during software development, emerging issues on cybersecurity, and an increasing volume of submissions. The risks of not making improvements to the Digital Health program include, among other things, prolonged review cycles and delays in getting devices to patients.

FDA proposed to improve the review of digital health products by focusing on higher risk products, implementing a model that relies heavily on review of a sponsor's quality system, hiring staff with the appropriate technical skills and expertise, and engaging with stakeholders to align review practices with advances in technology, clinical practice, and product delivery.

FDA reiterated that its proposal of 13 FTE includes 11 FTE to review submissions and conduct training and 2 FTE to leverage the Medical Device Single Audit Program (MDSAP) and respond quickly to industry's questions about digital health products. FDA further proposed $3.6 million over 5 years in IT infrastructure improvements. FDA described several benefits of this investment, including the alignment of software development timelines and practices, the alignment of premarket evidence requirements and rapid software changes, the ability to address emerging issues on cybersecurity, the potential for greater use of the single audit model, the reduction of review cycles through early engagement and rapid policy determination, and the reliance on transparent rules for review of digital health products.

Mechanism for Addressing Workload Uncertainty

FDA provided more details on the proposal to establish a mechanism to address workload uncertainty. FDA described steps to monitor a weighted workload, including identifying workload categories and associated weights for each submission type, documenting the planned workload volume, and calculating negotiated assumptions on the planned weighted workload. FDA described three scenarios to determine the allowable variance for the mechanism. In the first scenario, the actual weighted workload may slightly exceed or fall below the planned weighted workload within a pre-specified band of tolerable uncertainty above and below the planned level. In this case, no action would be required. In the second scenario, the actual weighted workload may significantly exceed the planned weighted workload by at least the pre-specified band of tolerable uncertainty. In this scenario, the authorization amount would be increased to meet the increased workload demands. FDA would access already collected resources that exceed the initial authorization amount. If the excess fees are exhausted, fees would be increased to meet the increased workload demands. In the third scenario, the actual weighted workload may significantly fall below the planned weighted workload by at least the pre-specified band of tolerable uncertainty. In this case, FDA would focus the extra work

capacity on a list of prioritized areas for performance enhancements that is agreed upon by FDA and Industry.

FDA noted the need to continue consideration on the size of the band of tolerable uncertainty, and to establish assurances that any increase in amount of resources is matched to the workload and that those resources are allocated to where the workload increased. Additional consideration is also needed to establish rules for how fees would be increased if over-collections are insufficient to handle increased workload.

Cost per FTE and Inflation Adjustment Calculation

In response to Industry's request for additional details on FDA's cost per FTE model, FDA provided a detailed description of the calculation. FDA explained that the MDUFA pay component is a weighted blend of CDRH and CBER pay based on the proportion of effort by those two Centers on MDUFA process work. The blended pay rate is determined by adding 90% of the average CDRH pay to 10% of the average CBER pay. FDA also described the non-pay component, which includes general and administrative costs that cover support functions such as human resources and accounting. The non-pay cost for MDUFA IV reflects less than 5% of the total cost per FTE, in contrast to the previous user fee staffing model, which allocated 10% of the total cost per FTE to general and administrative functions. FDA also provided history on the MDUFA program cost for FY 2009 through FY 2014. FDA noted that the proposed cost per FTE for MDUFA IV is lower than the cost per FTE would be if using a 2% inflation adjustment to the actual cost per FTE in FY 2014. .

FDA also provided additional detail on the inflation adjustment methodology. FDA showed that the year-over-year changes in FDA-wide pay component values are less volatile than those for CDRH, while being similar in overall magnitude. Consequently, FDA has proposed continuing to use the FDA-wide pay data as the basis for the pay component of the inflation adjustment calculation.

Discussion

Upon the conclusion of the presentation, AdvaMed, MDMA, and MITA expressed concern over the lack of performance goals for Pre-Submissions and De Novo requests and the absence of an Independent Assessment in FDA's updated proposal. AdvaMed, MDMA, and MITA noted that their proposal had incorporated some of FDA's key initiatives, such as quality management, while FDA's proposal had moved key industry priorities into an area for further discussion. FDA reiterated its desire to continue discussions on establishing performance goals for these submissions and the attendant resource requirements. FDA clarified that the proposal's intent was to address AdvaMed, MDMA, and MITA's primary concerns of improving the consistency of the review program and minimizing cost without decreasing current performance. AdvaMed, MDMA, and MITA noted that certain of FDA's proposals do not have support among their members because their members do not perceive a meaningful and measurable return on

investment or a broad-based industry benefit, nor do they seem to fall within the scope of the user fee program. They would prefer to consider initiatives with quantitative performance goals or specific metrics for accountability relating to the consistency and quality of the review program. FDA reiterated the difficulty in determining metrics for consistency and expressed its intent to continue to work on identifying metrics that are valuable to Industry; FDA also asked Industry to identify metrics for consistency that would be meaningful to them. AdvaMed, MDMA, and MITA further expressed concern over the small overlap on high priority areas. FDA stated that the areas for continued consideration remain important to the Agency, but that FDA leadership emphasized the need to advance the program in areas that are high priorities for FDA in order to justify the risks and costs of program disruption that are inevitable side-effects of making significant organizational changes intended to enhance the program in the long run. AdvaMed, MDMA and MITA further clarified that they are not aligned with FDA on the same priorities, and are reluctant to fund areas such as Real World Evidence because they believe FDA's proposal to be relevant to a small segment of the industry only, to have not yet been proven as an effective concept, and to not fit within the premarket premise of user fees. Furthermore, AdvaMed, MDMA and MITA expressed their view that FDA did not identify specific efficiencies in the form of enhanced performance. FDA noted it disagrees with these characterizations, as FDA believes its proposals are broadly applicable to industry and fit well within the user fee program. FDA and AdvaMed, MDMA, and MITA acknowledged that there remains a significant gap between the parties regarding what are considered high priority components and the scope of the negotiations going forward, and that the parties need to find a way to close this gap so that the scope of the ongoing MDUFA IV discussions can be further clarified before working through the details that will determine the exact resource levels and features of an agreement. FDA and Industry agreed to organize an interim conference call to clarify the best path forward prior to the next scheduled negotiation meeting.

Next Meeting

The next meetings are scheduled for April 6 and 7, 2016.

Meeting End Time: 12:40 pm