Stakeholder Meeting on MDUFA III Reauthorization
September 15, 2015, 9:00 – 11:00 AM
FDA White Oak Campus, Silver Spring, MD
Building 31, Room 1503

Purpose

To provide a status update of the ongoing MDUFA III negotiations.

Participants

FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marc Caden	Office of Chief Counsel (OCC)
Anna Fine	OC
Jonette Foy	Center for Devices and Radiological Health (CDRH)
Sonja Fulmer	CDRH
Elizabeth Hillebrenner	CDRH
Heather Howell	CDRH
Aaron Josephson	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Thinh Nguyen	Office of Combination Products (OCP)
Kathryn O'Callaghan	CDRH
Geeta Pamidimukkala	CDRH
Prakash Rath	Office of Legislation (OL)
Karen Riley	OC
Anindita Saha	CDRH
Don St. Pierre	CDRH
Darian Tarver	OC
Tammy Wirt	CDRH
Kim Worthington	CDRH
Barb Zimmerman	CDRH

Stakeholders

Cynthia Bens	Alliance for Aging Research
Victoria Burack	Consumers Union
Ryne Carney	Alliance for Aging Research
Diane Dorman	dDConsulting
Beatriz Duque Long	Epilepsy Foundation
Eric Gascho	National Health Council
Marisol Goss	American Academy of Orthopedic Surgeons
Tamar Haro	American Academy of Pediatrics
Maureen Japha	FasterCures
Bennie Johnson	JDRF
Jibran Khan	SEARLE

Andrea Lowe	Society for Women's Health Research
Anqi Lu	Pew Charitable Trusts
Paul Melmeyer	National Organization for Rare Disorders
Jessica Tyson	Avalere Health
Ernest Voyard	The Leukemia & Lymphoma Society

Meeting Start Time: 9:00 am

FDA welcomed stakeholders and discussed the purpose and role of stakeholder input during MDUFA negotiations:
The stakeholder meetings are an opportunity for FDA to receive input from patient and consumer advocacy groups and to understand their issues and concerns relating to the reauthorization of MDUFA. These stakeholder meetings are not a forum for the representation of the interests of the medical device industry, physicians, or other stakeholders. FDA has included registrants who might have particular expertise and insights into how the medical device user fee program affects patients, and we expect that the inclusion of all participants will aid FDA's consideration of the interests of patients and consumers. From FDA's perspective, these stakeholder meetings are important to ensure that patient and consumer perspectives are taken into consideration when FDA meets with regulated industry to develop the draft recommendations for reauthorization. FDA explained that user fee negotiations and related meetings (such as this one) are not intended to be a forum for resolving policy issues outside of the scope of the user fee program, but FDA may channel those topics as they arise to more appropriate avenues.

FDA provided an overview of the history and scope of MDUFA:
The revenue from pre-market submission user fees and registration fees paid by industry are used by FDA to pay for staff and other resources to enhance the medical device review process. Negotiations with industry focus largely on methods to improve consistency, predictability, and efficiency in the review process.

The MDUFA program is about ten years younger than the Prescription Drug User Fee Act (PDUFA), its counterpart in the regulation of drugs. MDUFA I was originally authorized for fiscal years 2003 through 2007, and included only application fees, which led to instability of the fee structure. MDUFA I also had a complicated goal structure that included decision cycle goals. MDUFA II included an increase in user fees and the introduction of facility registration fees. MDUFA II moved to a two-tiered goal structure, which may have contributed to some unintended consequences, such as an increase in total time to decision. Under MDUFA III, industry and FDA reached an agreement to increase user fees in exchange for a restructured and simplified set of performance goals that reflect more ambitious performance targets. FDA and industry also committed to new shared outcome goals to reduce the total time to decisions for 510(k) and pre-market approval (PMA) submissions. Additionally, FDA committed to greater transparency and providing quarterly performance reports, which are publically available on FDA's website. FDA also agreed to an independent assessment conducted to identify areas to improve the premarket review process. Booz Allen Hamilton (BAH) was

selected to conduct the assessment and issued their final recommendations to FDA in June 2014. FDA completed the implementation plan in December 2014. BAH is currently assessing FDA's progress and a final report will be available in February 2016. FDA and industry are encouraged by the results thus far under MDUFA III.

FDA explained how fees supplement Congressional appropriations:
User fees from device companies supplement FDA's budget authority (i.e., federal general revenues that Congress appropriates). Those fees allow FDA to hire more engineers, scientists, and other personnel to conduct reviews. In exchange for the fees, FDA agrees to review submissions in a certain amount of time. FDA's budget authority has remained relatively unchanged from FY 2009 through FY 2014 while user fee revenues have been gradually increasing during MDUFA III according to the agreement that FDA and the device industry reached, and Congress authorized. By the last year of MDUFA III in 2017, FDA will be authorized to collect approximately $130 million plus an estimated $11 million in inflation adjustments (which are determined by a formula in the law).

FDA discussed its vision for the negotiations:
As we begin the negotiations for MDUFA IV, it is important to start off by emphasizing CDRH's vision and the Agency's public health goals, which are noted on the center's website. It is also important to keep the interests of the patients at the forefront of our discussions and at the negotiation table. FDA intends to highlight two key areas during the negotiations that will lead to operational excellence: (1) the importance of shoring up the foundations and gains of the program to ensure the reliability and sustainability of the device review program created in MDFUA III; and (2) the importance of improving the consistency, predictability, and efficiency of the program while also promoting innovative approaches to keep pace with new technologies and public health challenges. There were a lot of points of agreement between FDA and industry during the first negotiation meeting. As we move forward in the negotiations, we will be trying to reach agreement on the right size of the program and where to make targeted investments.

FDA provided a high level summary of FDA's activities and performance in MDUFA III that are important to the stakeholders group:
CDRH is meeting or exceeding all of the MDUFA III decision goals. In addition to decreasing review times, the approval and clearance rates have been increasing, resulting in more beneficial safe and effective products coming to market sooner. In addition to improved performance, FDA has made a number of process improvements, particularly in relation to patient safety and risk tolerance. The agency has implemented a new benefit/risk framework which established a structured decision-making approach to incorporate patient tolerance for risk in the review of PMA and *de novo* submissions and has issued a draft guidance on incorporating benefit/risk in the review of investigational device exemptions (IDEs), which are the mechanisms by which FDA provides oversight on clinical trials for medical device development. FDA is moving towards greater inclusion of patient preference information in premarket reviews via the Medical Device Innovation Consortium (MDIC), which produced a catalog of methods for collecting and assessing patient preference info. FDA has also been working on initiatives not funded

through MDUFA, such as establishing a national medical device surveillance system, implementation of the Expedited Access Program (EAP) to address areas of unmet need and importance to public health, and working with the international medical device forum. FDA has been a good steward of the MDUFA program by meeting our commitments and going beyond our user fee commitments; however, we can achieve more with additional resources. The purpose of these patient and consumer stakeholder meetings includes identifying opportunities for refinements to existing programs and considering other components that have not been included in the user fee programs thus far. While any proposed program refinements or additions would need to be agreed upon by industry before they could be included in any draft recommendations, these discussions are an important forum to allow FDA to hear patient and consumer stakeholders' ideas and interests regarding improvements to MDUFA.

FDA summarized the MDUFA public meeting and the comments received to the docket: FDA held the first MDUFA public meeting for the MDFUA IV negotiations on July 13, 2015. The meeting was attended by the industry groups that are participating in the negotiations as well as representatives and individuals from academia, health care professionals, and patient and consumer advocates. FDA received 9 sets of comments to the docket. FDA identified some key themes discussed at the meeting and in the comments. Many agreed that MDUFA III laid the groundwork for improvements and MDUFA IV should focus on process improvements aimed at improving predictability. Another suggestion focused on strengthening capabilities for the total product life cycle (TPLC) such as unique device identifier (UDI) adoption, improving patient registries and partnerships for post market monitoring. As FDA and stakeholders consider this feedback, it is important to be mindful of the scope of the user fee program.

The stakeholders broke into smaller groups to identify topics and key areas of interest for discussion at future stakeholder meetings. Each group had an FDA facilitator. The identified topics for future discussion are as follows:

- Clarity on the process for the following pre-market programs: humanitarian device exemption (HDE), *de novo*, and pre-submissions.
- Additional discussion on incorporating patient perspectives in FDA reviews: Discuss FDA's and industry's resource constraints that limit the use of patient preference, the implications of getting devices to market using patient preference information, ways in which industry is incorporating and seeking patient. preference information (i.e., the role of this information in the development process) and how FDA uses that information.
- Ways in which FDA can be supported to get the resources needed for expertise in specific patient populations, such as pediatrics and geriatrics.
- The rare disease community has concerns relating to reimbursement issues.
- Identify the ways in which the stakeholders can support the position of the agency to get the needed resources through the next user fees reauthorization to reduce the magnitude of differences in funding levels between PDFUA and MDFUA.
- Increasing the use and utility of patient registries.

FDA closing remarks and summary of the first industry/FDA negotiation meeting:

In response to a question from one of the participants, FDA provided a brief summary of the first MDUFA IV negotiation meeting between FDA and industry on September 9, 2015. Both sides reiterated their shared commitment to the goal of timely access to safe and effective medical devices, and agreed that the first few years under MDUFA III represent an improvement to the program. Industry acknowledged that the restructured goals, and FDA's efforts to implement the program, appear to be yielding improvements in performance. Industry showed appreciation for the challenges FDA faces in achieving the new ambitious goals and the efforts FDA has taken to move the program in the right direction. Industry expressed that the program appears to be "right-sized" and there is no need for further restructuring; rather, some targeted investments may be warranted. FDA agreed that there are areas where consistency and predictability can be improved. FDA also presented the case for investments that are necessary to shore up the foundations to ensure the reliability and sustainability of the program. Moving forward, FDA and industry need to come to agreement on the baseline cost of the program. FDA's second meeting with industry will be in October. The agenda will include discussion of FDA databases and information systems used to manage the program. Limitations in FDA databases and data collection and management systems are creating challenges in providing all the data that industry has requested. FDA intends to give industry greater insight into our processes and limitations with our current systems to help them identify the areas they may want to support or improve.

The quarterly reporting has been helpful in diagnosing issues early and rectifying them quickly. The decrease in the Refuse to Accept rates are a good example of how the quarterly reporting has helped both industry and FDA identify and modify an emerging issue. The implementation of the BAH independent assessment recommendations was also an important element in building trust between FDA and industry. CDRH has been implementing the recommendations and going beyond. Industry appears pleased with the progress being made and is getting separate briefings from BAH on FDA's efforts.

FDA feels there is a constructive atmosphere for negotiations. We need to identify the areas for investment from industry where there are improvements to public health as well as benefits to the companies and other stakeholders.

Meeting End Time: 11:00 am