Patient and Consumer Stakeholder Meeting on MDUFA IV Reauthorization
March 15, 2016, 9:00 – 11:00 AM
FDA White Oak Campus, Silver Spring, MD
Building 31, Great Room Section A

Purpose

To provide a status update on the ongoing MDUFA IV negotiations, plan for future stakeholder meetings and obtain stakeholders views on the focus topic of Inter-center review process for combination products.

Participants

FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marc Caden	Office of Chief Counsel (OCC)
Jonette Foy	Center for Devices and Radiological Health (CDRH)
Sonja Fulmer	CDRH
Elizabeth Hillebrenner	CDRH
Louise Howe	OCC
Heather Howell	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Thinh Nguyen	Office of Combination Products (OCP)
Prakash Rath	Office of Legislation (OL)
Christine Saba	OC
Darian Tarver	OC
Shannon Thor	OC
Jacquline Yancy	CDRH
Barb Zimmerman	CDRH

Stakeholders

Jonathan Bryan	Duke University
Paul Brown	National Center for Health Research
Ryne Carney	Alliance for Aging Research
Beatriz Duque Long	Epilepsy Foundation
Christin Engelhardt	National Coalition for Cancer Survivorship
Eric Gascho	National Health Council
Lisa Goldstein	American College of Cardiology
Catherine Hille	American Academy of Neurosurgery
Maureen Japha	FasterCures
Andrea Lowe	Society for Women's Health Research
Anqi Lu	Pew Charitable Trusts
Paul Melmeyer	National Organization for Rare Disorders

Ben Moscovitch	Pew Charitable Trusts
Mark Williams	FasterCures
Jeffrey Wojton	Research!America
Jessica Tyson	Avalere Health

Meeting Start Time: 9:00 am

FDA welcomed stakeholders and briefly reiterated the role of stakeholder input during MDUFA negotiations.

FDA updated stakeholders on the last four meetings with Industry held on January 20, January 27, February 18, and March 4, 2016.

FDA discussed the current status of proposals

FDA described the status of proposals. Specifically, FDA stated that at the January 20, 2016 meeting, FDA provided an estimate of the costs of Industry's proposal presented at the November 18, 2015 meeting, and explained to Industry the assumptions made to cost out their proposals. FDA's estimate of the cost of the additional enhancements to the program identified by Industry, which included goals for pre-submissions and de novos, was $456 million, in addition to the baseline cost for MDUFA III, plus inflation adjustments.

FDA explained that at the January 27, 2016 meeting, FDA presented an integrated proposal that included elements that FDA thought were of interest to Industry as well as elements that were priorities for FDA. This integrated proposal was based on feedback and discussion with Industry where FDA proposed adjustments on performance levels to reduce the cost. FDA explained that after the adjustments, savings, and additionally proposed elements, the total amount for the integrated proposal was approximately $500 million dollars, in addition to the baseline cost for MDUFA III, plus inflation adjustments. FDA explained that there was considerable discussion regarding elements on the innovation side that FDA felt were important, particularly with respect to real world evidence and patient engagement.

During the February 18, 2016 meeting, Industry presented a counter proposal that included separate tiers. One tier included common elements that FDA and Industry proposed and another tier that Industry was still interested in discussing. FDA explained that Industry was still interested in the patient engagement proposal, specifically Patient Preference Information (PPI), but expressed concerns about Patient Reported Outcomes (PRO). FDA further explained that the counterproposal presented by Industry at the meeting on February 18, 2016 did not include a full estimate of costs. FDA explained that several areas of interest for FDA were not included in either of the tiers for further consideration, such as real world evidence, which FDA interpreted as representing a third tier where industry was expressing a lower level of priority or coalition agreement. The detailed meeting minutes for these meeting are available on the FDA website.

FDA spoke generally about the March 4, 2016 meeting in which FDA presented a proposal that represented FDA's highest priorities, and noted additional areas for further consideration. Industry expressed concern that there appeared to be a large gap between FDA's priorities and those of industry. As a result, FDA and Industry indicated that additional discussions would be needed to close the gap.

For the focus topic, FDA presented on the Inter-center consultation review process for combination products

FDA presented information regarding the process and challenges associated with the current Inter-center consultations process for combination products. FDA described the history of the program, which began 12 years ago. FDA explained that originally, the program was an email-driven process where very few Divisions/Offices were involved. Today, however, the program has expanded not only by the number of combination products needing inter-center review but also by the number of Divisions/Offices involved. Additionally, FDA explained that some of the challenges with the current process are that (1) reviewers from one center have limited access to other centers' document systems, (2) getting and maintaining access is time-limited and burdensome, and (3) coordinating the response and consultation process as the review timelines for each Center are different.

FDA stated that an internal assessment of the inter-center consult process was conducted to better understand the challenges related to combination product review. The study examined the coordination and timeliness of the review process, workload challenges associated with inter-center consultations, as well as FDA and sponsor interactions. FDA explained that there has been an increase in the overall number of inter-center consult requests since 2004, and a closer review of the overall workload found that some Divisions or Offices within each Center receive a much larger proportion of consult requests. The assessment also noted that there are some differences between policies, review practices, review timelines, and the review team structure among the Centers. Additionally, since conducting consulting reviews for another Center competes for time needed to meet the reviewer's own Center's user fee performance goals, there can be challenges setting priorities and meeting consult review timelines when resources are limited.

FDA explained that increased collaboration from the centers, consistency in the combination product review process, and improved access to IT systems are needed to achieve the goals for combination product reviews. Additional recommendations that resulted from the assessment included establishing clear guidance for common types of combination products, especially data expectations, providing expedited and long-standing access to databases for reviewers across Centers, developing a standardized process for requesting consults, and developing and maintaining a current directory of contacts for coordinating the review of combination products throughout the Centers and OCP. FDA explained that the implementation of these recommendations is ongoing and a priority of the agency.

The next patient and consumer stakeholder meeting is scheduled for Monday, April 25, 2016.

Stop 10:10am