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

Purpose

To provide a status update on the ongoing MDUFA IV negotiations, plan for future stakeholder meetings and provide clarification of the current proposals.

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)
Kathryn O'Callaghan	CDRH
Darian Tarver	OC
Shannon Thor	OC
Jacquline Yancy	CDRH
Barb Zimmerman	CDRH

Stakeholders

Cynthia Bens	Alliance for Aging Research
Paul Brown	National Center for Health Research
Ryne Carney	Alliance for Aging Research
Diane Dorman	dDConsulting
Christin Engelhardt	National Coalition for Cancer Survivorship
Mark Fleury	American Cancer Society Cancer Action Network
Eric Gascho	National Health Council
Lisa Goldstein	American College of Cardiology
Marisol Goss	AAOS
Maureen Japha	FasterCures
Bennie Johnson	JDRF
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
Brian Smith	Research!America
Andrew Sperling	National Alliance on Mental Illness
Jessica Tyson	Avalere Health

Meeting Start Time: 9:00 am

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

There were no updates from the industry negotiations as there had not been an industry meeting since the last Patient and Consumer Stakeholder Meeting held on December 18, 2015.

FDA discussed the current status of proposals

FDA described the current status of the proposals. Specifically, FDA identified the places of commonality in proposals posed by the agency and industry such as with *de novos* and Pre-Submissions. FDA pointed out that although the subject area was the same, in some cases, the approach to addressing the underlying issue differed and would need additional discussion to bring the two sides together. For example, adding performance goals and fees around *de novos* and Pre-Submissions were areas in which both FDA and industry presented proposals, yet the two sides proposed different details. As a result FDA and industry agreed to address the differences through more detailed working group discussions to determine the best path forward to bring the sides together.

FDA reiterated the need to further develop the review infrastructure and the need for having a robust quality management system in place. These proposals included introducing performance-based incentive pay for managers and reducing the manager-to-reviewer ratio to help improve consistency through better management oversight of review staff. The quality management infrastructure would be responsible for conducting audits and generating reports to determine if SOPs are being followed and identify areas needing additional development.

FDA stated that both industry and FDA put proposals on the table to improve the Pre-Submission process. Specifically, the improvements related to format of meetings, timeliness of feedback and meeting scheduling. Industry proposed process improvements for the CLIA waiver review process. FDA described the proposal for the IT platform that involves a modern cloud-based interface with industry to allow electronic submission and tracking. FDA emphasized that the capabilities and benefits of the modernized IT platform can be achieved much faster with dedicated user fees. FDA also presented on a more detailed explanation of our innovation proposals regarding the use of clinical experience information and patient input. FDA indicated that this area has been a challenge for industry with regard to requesting user fees to fund this effort. FDA briefly described a proposed mechanism to handle future workload uncertainty to assure that any

significant deviations from workload projections are managed effectively, and adequate resources remain available to achieve performance commitments.

FDA addressed clarifying questions from the stakeholders

FDA addressed questions related to the third party review program for 510(k) submissions. Specifically, FDA described the program and informed the stakeholders of the challenges with those reviews. For example, in some instances there was disagreement between the third party reviewer and the FDA review staff which resulted in FDA reviewing the submission in addition to the third party reviewer memo, but not receiving any user fees for that additional review effort, which also delays the final decision. FDA explained that the Agency proposed an approach to address the issues identified with the third party review program.

FDA addressed concerns from stakeholders regarding the progress of the *de novo* program. FDA explained that although the agency has been able to decrease the time it takes to review these submissions through internal process improvements we are currently not consistently meeting the 120 statutory timeframe. Based on the increasing number of direct *de novo* submissions we are reaching the tipping point in our current performance and without dedicated resources we will continue to get further behind in fulfilling our statutory timeframe of 120 days.

FDA addressed concerns expressed by industry regarding patient reported outcomes and patient preference information as well as national registries. FDA explained that although some members from industry stated their support for the endeavors, they raised questions about whether user fees were the appropriate way to fund the programs. FDA explained that the proposals for these areas are focused on activities that would benefit the pre-market review program, and that could apply to a broad spectrum of device manufacturers.

The next patient and consumer stakeholder meeting is scheduled for Tuesday, February 16, 2016.

End 10:41am