Patient and Consumer Stakeholder Meeting on MDUFA IV Reauthorization
April 25, 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 establishing a National Evaluation System for Medical Devices.

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
Aaron Josephson	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Thinh Nguyen	Office of Combination Products (OCP)
Kathryn O'Callaghan	CDRH
Danica Marinac-Dabic	CDRH
Prakash Rath	Office of Legislation (OL)
Gregory Pappas	CDRH
Darian Tarver	OC
Shannon Thor	OC
Jacquline Yancy	CDRH
Barb Zimmerman	CDRH

Stakeholders

Cynthia Bens	Alliance for Aging Research
Jonathan Bryan	Duke University
Paul Brown	National Center for Health Research
Ryne Carney	Alliance for Aging Research
Christin Engelhardt	National Coalition for Cancer Survivorship
Eric Gascho	National Health Council
Lisa Goldstein	American College of Cardiology
Catherine Hille	American Association of Neurological Surgeons
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
Mark Williams	FasterCures
Jeffrey Wojton	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.

FDA updated stakeholders on the March 4th meeting and stated that the meeting minutes from the April 6th and 7th meeting were being finalized for posting.

FDA discussed the current status of proposals
FDA informed the patient and consumer stakeholders that FDA presented a counter proposal to industry at the March 4, 2016 meeting that clarified the agency's priorities. The proposals presented were those items that the agency had established were the core infrastructure of a quality system that was very important for establishing consistency and long-term stability. The proposals provided some cost estimates to address the key innovation initiatives that are important to patient and consumer groups, such as patient input, Real World Evidence (RWE), and digital health. FDA explained that they communicated to industry that other parts of the package that needed additional dialogue included de novos and presubmissions. The overall cost of the counter proposal FDA presented to industry on March 4 was $329 million above the MDUFA III base; this estimate did not include additional components and enhancements that FDA had identified for further discussion. FDA explained that industry expressed concern that there was too little overlap in priorities between FDA's March 4 package and previous proposal packages presented by both parties.

FDA shared that FDA and industry had continued constructive discussions on April 6 and 7, which would be explained in the minutes from that meeting and could be discussed at a future patient/consumer stakeholder meeting.

For the focus topic, FDA presented on the establishing a National Evaluation System for Medical Devices

In response to a request from various patient and consumer stakeholder groups, FDA presented information regarding the progress with establishing a national evaluation system for medical devices and the relation of the user fee negotiations to that process. FDA described the investments made by the agency between 2011 and 2015 that included the establishment of the Unique Device Identifier (UDI) system and 50 projects that were conducted over that time that have included the creation or improvement of RWE data sources. FDA explained that

approximately $20 million and significant staff time has been invested to lay the foundation for a national evaluation system for medical devices.

FDA explained that the goal is to establish a collaboration that leverages data from routine clinical care that exists in registries, medical claims, electronic health records, and potentially other sources. FDA shared that real world evidence has been leveraged for both premarket and postmarket regulatory decisions in areas such as post-approval studies, continued access studies, labeling extension studies, and postmarket surveillance studies. FDA stated that to help develop the necessary infrastructure for a national evaluation system, FDA has been working with a planning board to help develop the organizational structure and governance model of the national evaluation system's coordinating center, a financial plan for sustainability, and an implementation plan. FDA stated that the selection and operation of a coordinating center for a national evaluation system depends on securing funding, either from Congressional budget authority appropriations, private-sector funds, or a combination of both.

FDA gave a high-level description of the RWE user fee proposal it presented to industry, which includes 15 FTEs that will develop and implement the framework for using RWE for premarket decision-making by supporting the work of the coordinating center as well as reviewing and analyzing the data submitted to support a premarket decision. The proposal also includes $10 million per year, all of which would support the establishment and operation of the coordinating center and projects to improve RWE data sources and increase their use. FDA emphasized that the user fee investment will yield better quality registries so the data can be used in premarket regulatory decision-making and will provide the opportunity to nest clinical trials in registries, which is one way to reduce the cost of evidence generation. FDA shared some of the concerns Industry expressed regarding the use of user fees to pay for the coordinating center and related projects, and whether the benefits of the system would be broadly based and during the MDUFA IV timeframe. FDA explained that the coordinating center could develop a self-sustaining funding model, and that FDA believes the benefits of the system could be available to the entire industry because a broad range of companies can benefit from lower costs to generate evidence and earlier marketing authorization through the premarket/postmarket shift.

The next patient and consumer stakeholder meeting is scheduled for Friday, May 27, 2016.

Stop 10:36 am