Stakeholder Meeting on PDUFA VI Reauthorization
September 28, 2015, 1:30 PM – 3.05 PM
FDA White Oak Campus, Silver Spring, MD

Purpose

To discuss the current status of the human drug and biologic review programs, review stakeholder perspectives shared at the July 15, 2015 public meeting and docket submissions, and plan topics for future stakeholder discussions.

Participants

FDA

Josh Barton	CDER
Steve Berman	CDER
Amanda Edmonds	OC
John Jenkins	CDER
Chris Joneckis	CBER
Andrew Kish	CDER
Theresa Mullin	CDER
Mary Parks	CDER
Grail Sipes	CDER
Graham Thompson	CDER
Terry Toigo	CDER
Brad Wintermute	OIMT

Registered Stakeholders

Jeffrey Anders	Lupus and Allied Diseases Association
Cynthia Bens	Alliance for Aging Research
Marc Boutin	National Health Council
Paul Brown	National Center for Health Research
Allyson Browne	Patient
Ryne Carney	Alliance for Aging Research
Diane Dorman	dD Consulting
Christin Engelhardt	National Coalition for Cancer Survivorship
Stephanie Fischer	EveryLife Foundation for Rare Diseases
Mark Fleury	American Cancer Society Cancer Action Network, Inc.
Kara Gainer	Cure SMA (Spinal Muscular Atrophy)
Eric Gascho	National Health Council
James Gelfand	March of Dimes Foundation
Rob Goldsmith	Cancer Support Network
Lisa Goldstein	American College of Cardiology
Tamar Haro	American Academy of Pediatrics
Anna Hyde	The Arthritis Foundation
Maureen Japha	FasterCures
Bennie Johnson	Juvenile Diabetes Research Foundation

Ethan Jorgensen-Earp	American Academy of Pediatrics
Rasika Kalamegham	American Association for Cancer Research
Madeleine Konig	American Heart Association/American Stroke Association
Ian Kremer	Leaders Engaged on Alzheimer's Disease
Jeffrey Last	Alzheimer's Association
Andrea Lowe	Society for Women's Health Research
Nick Manetto	National Psoriasis Foundation
Paul Melmeyer	National Organization for Rare Disorders (NORD)
Amanda Pezalla	American Academy of Dermatology Association
Thair Phillips	RetireSafe
Tracy Rupp	National Center for Health Research
Andrew Sperling	National Alliance on Mental Illness
Joseph Stewart	Health and Medicine Counsel of Washington
Saira Sultan	Pancreatic Cancer Action Network
Timothy Swope	Bipartisan Policy Center
Laura Thornhill	Alzheimer's Association
Ernest Voyard	The Leukemia & Lymphoma Society, Office of Public Policy
John Wylam	National Multiple Sclerosis Society

Meeting Start Time: 1:30 PM

Welcome and FDA Introductions
FDA began the meeting by welcoming stakeholders and discussing the purpose of these meetings as part of the reauthorization provisions as specified in statute. These monthly meetings are meant to continue the discussions of stakeholder perspectives that began at the July 15, 2015 public meeting. Reauthorization of PDUFA focuses on enhancements to the drug review process, not FDA policy.

Background on PDUFA and Review of Stakeholder Perspectives
FDA provided a brief historical perspective on user fee legislation for prescription drugs and highlighted the commitments and goals incumbent upon FDA as a result of PDUFA V. FDA reviewed its performance related to the metric goals and commitments and commented on the successes achieved. FDA offered perspective on some environmental challenges facing its operations, such as funding uncertainties, unfunded mandates, and the difficulty it faces in hiring and retaining qualified regulatory professionals. A review of perspectives on PDUFA VI by patient advocates, consumer advocates, healthcare professionals and academics, and representatives from regulated industry shared at the July 15, 2015 public meeting and in the docket was presented.

Stakeholder Introductions and Topics

A representative from each stakeholder organization offered an introduction and highlighted their group's primary topics pertaining to the PDUFA VI renegotiation. Key themes echoed by stakeholders centered on continuing to involve patient voice in drug development, ensuring

that the FDA has adequate resources to recruit and retain qualified staff, and improving methods for including biomarkers and advanced clinical trial designs in drug development and regulation.

Wrap-Up and Overview of Future Meetings

Based on the topic summary categories identified by the FDA, stakeholders were asked to indicate their preference for the order in which the subject areas would be addressed in future meetings. Advancing the science of patient engagement was selected as the preferred topic for the next stakeholder meeting. Regulatory science and trial design, enhanced postmarket signal monitoring, and ensuring continued FDA performance were selected, in order, for subsequent meetings.

Meeting End Time: 3:05 PM