Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

October 27th, 2020 | 2:00pm-3:15pm

Virtual Format

PURPOSE

To provide progress updates on each of the subgroups and to agree upon principles that will inform and advance discussions about useful reports on HR and hiring data.

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	Rob Blanks	BIO (Ardelyx)
Amanda Edmonds	OC	Danielle Friend	BIO
Chris Joneckis	CBER	Carl Garner	PhRMA (Eli Lilly)
Andrew Kish	CDER	Brad Glasscock	BIO (BioMarin)
Ted Liazos	OC	Kelly Goldberg	PhRMA
Theresa Mullin	CDER	Mathias Hukkelhoven	PhRMA (BMS)
Carol Rehkopf	CBER	Robert Kowalski	PhRMA (Novartis)
Khushboo Sharma	CDER	Ann Kurowski	BIO (Alkermes)
Mary Ann Slack	CDER	Heidi Marchand	BIO (Gilead and Kite)
Peter Stein	CDER	Mark Taisey	PhRMA (Amgen)
Mary Thanh Hai	CDER	Lucy Vereshchagina	PhRMA
Terry Toigo	CDER		
Patrick Zhou	CDER		

FDA began the meeting by clarifying that the patient preference studies discussion within the Real-World Evidence and Real-World Data topic may need to be moved from the Pre-Market Subgroup to the Regulatory Decision Tools Subgroup. Industry acknowledged having this discussion and indicated they wanted to discuss internally before confirming. Additionally, FDA reviewed the schedule for the remainder of the calendar year, emphasizing the need to advance discussions in order to complete negotiations in a timely manner. There followed a brief, high-level update on progress in the subgroups.

Regulatory Decision Tools High-Level Update

In addition to presenting the remainder of its proposals and answering more questions on previous proposals, FDA explained the openness to explore use of the capacity planning adjuster to provide additional resources for the pilots. At the next meeting in two weeks, both groups hope to begin

identifying areas of potential agreement. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update
FDA and industry continued their conversations on the cell and gene therapy proposals, specifically on incorporating patient perspectives, clarifying evidentiary standards, and leveraging sponsors' own internal prior knowledge on submissions. Both sides hope to move toward developing commitment language in the coming weeks. More information can be found in the corresponding meeting summary for this subgroup.

Digital Health and Informatics High-Level Update
After reviewing all the proposals and clarifying questions and answers, FDA and industry identified areas of common interest with significant overlap in multiple areas. Both sides plan to discuss commitment language in the coming weeks. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
FDA discussed with industry its inflation adjustment proposal and elaborated on the capacity planning adjuster models. FDA clarified questions regarding adjustments and methodology and agreed with industry to discuss performance reporting proposals in the next meeting. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
FDA had further discussion on three topical areas with industry: the CBER Biologics Effectiveness and Safety (BEST) System, Sentinel, and REMS. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update
FDA and industry held discussions regarding the remaining proposals on bioinformatics, real-time review, and new meeting types. Real-World Evidence and Real-World Data will be discussed in the next meeting. After discussing more details and sharing clarifications, both sides expect to prioritize areas where there can be an alignment of interests. More information can be found in the corresponding meeting summary for this subgroup.

CMC and Inspections High-Level Update
Industry asked questions about structure of information requests (IRs), prompting FDA to explain its 4-part harmony approach to IRs. FDA and industry also discussed FDA's process and approach to risk-based inspections. More information can be found in the corresponding meeting summary for this subgroup.

The following topics were discussed after the high-level updates.

FDA and Industry Shared General Principles for Human Resources and Hiring Discussions
To help facilitate the discussion on human resources and hiring, FDA first presented its proposed guiding principles. The principles focused on reporting, including data that would be efficient to collect and post; that captures meaningful metrics to describe the health of the workforce, gaps in staffing, and barriers to realizing needed staffing; that articulates steps to overcome barriers; and ensures accountability and transparency in resource utilization. Industry shared its principles for

hiring and retention focused on essential staffing, recruiting critical expertise, retaining high-performing personnel, improving HR functions, and reporting detailed and useful metrics. Both sides discussed potential ideas to help sustain and advance the current progress toward these goals.

FDA and industry then agreed that the Finance Subgroup will take the next phase of discussion to brainstorm potential reporting metrics and data that align with these principles.

Next Steps
FDA and industry agreed to convene the Steering Committee the week after Election Day. Additionally, both sides agreed to continue sharing progress updates and to share a potential agenda for the next meeting in the coming week.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.