Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

December 2, 2020 | 9:00am-12:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	E. Cartier Esham	BIO
Yanming Chae	CBER	Carl Garner	PhRMA (Eli Lilly)
Angela Granum	CBER	Brad Glasscock	BIO (BioMarin)
Bharat Khanna	CDER	Kelly Goldberg	PhRMA
Ted Liazos	OC	Ann Kurowski	BIO (Alkermes)
Alison Lyndaker	CDER	Kristy Lupejkis	PhRMA
Robert Marcarelli	OO	Mark Taisey	PhRMA (Amgen)
Patrick Zhou	CDER	Lucy Vereshchagina	PhRMA

MEETING SUMMARY

Limitation on Allowable Expenses
Neither FDA's nor Industry's position has changed since the prior meeting. FDA indicated that this topic would be referred to the Steering Committee.

Technical Fixes
Industry indicated that they have no substantive technical issues with four of the technical fixes FDA proposed. Industry had further questions on four other technical fixes. FDA and Industry agreed to discuss these remaining details in a subsequent meeting.

Health of the Workforce Follow-Up
FDA and Industry continued discussing the metrics that could be provided within an annual report describing the Health of the Workforce. The conversation focused on what is an appropriate level of granularity for metrics to ensure that potential issues could be identified and tracked, while not being overly burdensome for FDA to provide. FDA and Industry discussed the cadence of these metrics. This proposal will be discussed in additional detail at a subsequent meeting.

Operating Reserve Adjustment
Industry and FDA agreed at the subgroup level on the details pertaining to the Operating Reserve Adjustment. This includes FDA's proposal to interpret "operating reserve" to not include funds considered unappropriated for the purposes of calculating operating reserves and Industry's proposal to establish a statutory minimum amount of operating reserves to maintain each fiscal year. This statutory minimum would be 8 weeks of operating in fiscal year 2023, 9 weeks of operating in fiscal year 2024, and 10 weeks of operating in fiscal year 2025 and future fiscal years.

3rd Party Assessment
Industry and FDA continued discussions on the Industry proposal for a third-party assessment of PDUFA program financial topics. The group discussed focusing an assessment on new aspects of the program that will continue to mature over PDUFA VII, including resource capacity planning, utilization of time reporting

to help inform resource needs, and related topics. FDA agreed to provide proposed commitment letter language on this topic.

Resource Capacity Planning Follow-Up
FDA and Industry continued discussions regarding Industry and FDA's Resource Capacity Planning proposals. The proposal is focused primarily on the publication of a resource capacity planning implementation plan over the course of PDUFA VII. FDA and Industry discussed edits to draft commitment letter language and agreed to discuss further edits in subsequent meetings.

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