Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Postmarket Subgroup, Meeting #10 Summary

January 13, 2021, 2 – 4pm

Virtual Format (Zoom)

PURPOSE

The purpose of this meeting was to discuss Industry and FDA proposed commitments.

PARTICIPANTS

FDA		Industry	
Bob Ball	CDER	Robert Kowalski	PhRMA (Novartis)
Jason Bunting	CDER	Ann Kurowski	BIO (Alkermes)
Nancy Derr*	CDER	Camelia Thompson	BIO
Mary Ross Southworth	CDER	Lucy Vereshchagina	PhRMA
Terry Toigo	CDER		
Craig Zinderman	CBER		

*Note taker

DISCUSSION SUMMARY

The meeting began with two administrative announcements: The meeting on January 20th was moved to January 21st and will begin at 8 am and the meeting on January 27th will begin at 2:30 rather than 2 pm.

Industry representatives noted that they believed progress is being made on the proposals, but some questions remain.

Pregnancy Safety Proposal

The industry representatives generally agreed with the pregnancy safety demonstration proposal but asked for clarity on some points, for example, about the definitions used in the proposal. FDA agreed to clarify. Industry asked if electronic health records (EHR)/claims data could be used in all demonstration projects listed in the proposal. FDA agreed to explore the use of EHR linked systems for all demonstration projects but would be limited to the extent that Sentinel has the capability to do so. There is interest in using linked systems as part of CBER's BEST project.

Additional discussion focused on FDA providing more information in the commitment language around the timing of the demonstration projects. FDA thought that it would be possible to provide some general timing language. FDA noted that the demonstration projects are complex and will be informed by workshops. FDA also highlighted the need to establish clear goals that

can be achieved. FDA agreed to see if more specific timing language can be provided. FDA agreed it had a sufficient understanding of Industry's last questions to be able to finalize its commitment language.

Sentinel Analytics Enhancements

Industry identified the three analytics projects it is interested in pursuing as part of PDUFA VII work with the Sentinel System: analyses using negative controls, IPCW (inverse probability of censoring weighted), and QBA (qualitive bias analysis). Industry representatives also underscored their desire that projects result in the development of tools. Industry concern remains around the proposed costs of some of the projects. One cost determinant with Sentinel projects is Sentinel's use of a distributed database with multiple partners in multiple platforms. Projects involving EHR data are more complex when working in a distributive environment. Additionally, FDA/Sentinel is just learning how to operate in the EHR environment—it is part of the FDA five-year goal for Sentinel. FDA noted that it was a challenge to provide a cost estimate for this new type of project—adding that projects that do not result in the development of a specific tool are less costly. Industry repeated their interest in work that ultimately results in a tool.

REMS Assessments

Industry representatives expressed general satisfaction with the REMS assessments proposal. Last questions revolved around identifying the expected timing of the FDA-proposed guidance document. Industry expressed interest in the commitment language that describes a process for a systematic look at REMS and eliminating REMS when they are no longer needed, or for making them more efficient. Industry also requested additional background information be included in the introduction of FDA's commitment, ideally to describe more clearly the value of the REMS process to regulatory decision making. FDA agreed to propose some language for the Industry representatives to review and comment on.

Close of the Meeting

Attendees spent some time at the end of the meeting discussing Industry and FDA's perspectives, respectively, around the contributions of the Sentinel System and its constraints. FDA and Industry agreed that more thinking is needed around how to communicate better to the public about Sentinel, how it works, its constraints, and what its contributions are to drug safety and to regulatory decision making,

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