DOCTORS FOR AMERICA

July 14, 2025

Public Comment from Dr. Jan Krommes at the Public Meeting on Prescription Drug User Fee Act (PDUFA)

Commissioner Makary, Director Kish and members of the FDA staff, thank you for the invitation to speak here today. I am the chair of the FDA Task Force, a part of Doctors for America. Doctors for America is a non-partisan organization of 27,000 physicians. We reject industry funding so that we can teach physicians how to truly be the voice in the room for our patients.

We welcome your request to comment on the overall performance of PDUFA VII which includes changes that have evolved over the iterations of PDUFA.

I speak today first and foremost as a clinician. Having started medical practice before the first PDUFA, I have seen two profound changes: the explosion of new groundbreaking medical products that have been no less than miraculous, and the shrinking of evidentiary standards for approval. Our main concern is that the quantity and rapidity of drug approvals is a problem for clinicians and patients when approval studies do not answer two basic questions – is it truly safe enough, is it truly better enough? An example is Xeljanz, as it took 8 years after approval to know its risks, 3 years after full implementation of the Sentinel Initiative.

PDUFA VII improves previous PDUFAs post-marketing risk management with expansion of REMS and the Sentinel Initiative. We are particularly concerned that cuts in federal funding to Harvard University, where the Sentinel program is based, may affect the entire Sentinel network. The Initiative has ongoing work to address current limitations including outcome identification and semantic interoperability, and we would like to see the Initiative ultimately provide efficacy data.

Surveillance measures take time, but clinicians must prescribe (or not as I chose with Xeljanz) before those signals are known. Clinicians must decide based on smaller, shorter, often single-arm studies or surrogate marker results. For this reason, there will be instances where there is still a need for confirmatory clinical studies.

PDUFA VII increased focus on real-world evidence, but inherent biases such as selection bias and others can incorrectly influence conclusions. Clear guidelines and establishment of best practices is evolving, but critical questions such as access to patient-level data must be addressed. More direct, publicly available feedback on the use of Real-world evidence in regulatory decisions is needed.

PDUFA VII increases the interactions between Pharma and the FDA at all stages of the approval process. This is intended to save time and resources but can result in even greater industry influence.at the expense of other stakeholders. We agree with the concept of greater communication with Pharma, but approval decisions should be made with transparency and engagement of outside experts and stakeholders.

In terms of changes to the current fee structure, Doctors for America supports a relative increase of investment in post marketing evaluation and transparent communication at all phases of product development.

Thank you again for the opportunity to bring the views of Doctors for America to this forum.