



Prescription Drug User Fee Act (PDUFA) Reauthorization

Stakeholder Meeting with FDA

November 7, 2025 | 9:00 - 11:00 am

FDA White Oak Campus, Silver Spring, MD and Virtual Format

MEETING PURPOSE

To start the process of FDA periodic consultation with stakeholders that consist of representatives of patient and consumer advocacy groups. The consultation seeks to understand the stakeholders' views on the reauthorization and to collect their suggestions for changes to the PDUFA performance goals and statutory sections in follow up to the initial July 14th PDUFA Reauthorization public kick off meeting discussion. The main goals of this first meeting were to explain the consultation process and scope of discussions, provide background on the PDUFA program, and listen to the groups' topics of interest for prioritization in subsequent meetings.

MEETING SUMMARY

Welcome and Periodic Consultation Series Overview

FDA welcomed the attendees and outlined the role of these meetings in the reauthorization process specified by statute. FDA stated that these monthly meetings will be used to continue the discussions of stakeholder perspectives on PDUFA reauthorization that began at the public meeting held on July 14, 2025. FDA emphasized that reauthorization of PDUFA focuses on enhancements to the drug review process, not FDA policy.

PDUFA Accomplishments and Reauthorization Process

FDA provided an overview of the PDUFA reauthorization framework, including the statutory requirements and the purpose and objectives of the stakeholder consultation meetings. FDA also presented background on PDUFA's history, trends in program workload and performance, and an overview of PDUFA finances and fee structure. To facilitate actionable input from the consultation meetings, FDA clarified that modifications to the PDUFA VII commitment letter and amendments to the PDUFA user fee statutory sections are in scope; however, amendments to other sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act), such as section 505, are out of scope of PDUFA VIII negotiations.

Meeting Structure, Communication and Information Sharing Challenges

After FDA's presentation, FDA provided an opportunity for participants to ask questions about the reauthorization process and the stakeholder consultation meetings.

Participants questioned why FDA conducts negotiations with Industry separate from the monthly consultation meetings with public stakeholders. Some participants noted that no proprietary information is discussed in FDA's negotiations with Industry and advocated for combined meetings to enhance transparency with the public. FDA explained that the current approach follows established statutory requirements and legal interpretations, while acknowledging the feedback for future consideration.

Stakeholders also highlighted that it is challenging to share perspectives relevant to negotiations without understanding FDA and Industry's priorities. To help public stakeholders provide meaningful input, participants asked for greater transparency about FDA and Industry's priorities for PDUFA VIII. FDA acknowledged this challenge and committed to sharing priorities through the public meeting minutes from each negotiation meeting with Industry. FDA explained that there are some details of the negotiations that are not disclosed during their active discussion, due to their evolving nature.

Participants sought greater clarity on topics that are considered in and out of scope for PDUFA negotiations. FDA provided examples of topics that are in scope for PDUFA negotiations and stakeholder input, such as content in the PDUFA VII commitment letter and allocation of PDUFA funding.

Stakeholder Perspectives on Topics for Future Meetings

Following questions about the reauthorization process, participants shared their perspectives on topics of interest for future stakeholder consultation meetings. Topics raised during the discussion - not all of which are in scope for PDUFA VIII negotiations - include the status of PDUFA pilot programs and their outcomes, biomarker qualification processes, clinical trial design flexibility (including real-world data use and surrogate endpoints), diversity action plans for clinical trials, Patient-Focused Drug Development (PFDD) programs, concern about the recent lack of Advisory Committee meetings, and impact of the Commissioner's National Priority Voucher Pilot Program on PDUFA timelines and resources. FDA agreed to distribute a survey to registered meeting attendees to gather additional input on priority topics for future meetings. Based on the survey results and which topics are in scope for PDUFA VIII negotiations, FDA will plan focused discussions for future meetings.

Next Steps

The goal for the next stakeholder consultation meeting on December 5th is to gather perspectives on a specific topic or set of topics that are relevant to PDUFA negotiations and of interest to the registered public stakeholder participants. FDA will identify that topic based on the feedback provided in the November 7th meeting and in the survey distributed following the meeting.

PARTICIPANTS

STAKEHOLDERS

(* = in person attendee, ** = online attendee)

Alexander Naum*	Generation Patient
Alexander Sell	Children's Hospital
Amanda Berhaupt	National Center for Health Research
Annie Kennedy*	EveryLife Foundation for Rare Diseases
Anthony D. So	Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT), Johns Hopkins Bloomberg School of Public Health
Ashleigh Tharp**	National Multiple Sclerosis Society
Brian Koffman**	CLL Society
Brianna Greeno	Breakthrough T1D
Stephen Karpen**	Breakthrough T1D
Brittany Avin McKelvey*	LUNgevity Foundation
Carly Harrington	CLL Society
Chanel Press**	Breakthrough T1D
Courtney Wallin**	LEAD Coalition
Cynthia Bens*	Personalized Medicine Coalition
Diana Zuckerman*	National Center for Health Research
Emily Anderson*	Physicians Committee for Responsible Medicine
Erin O'Quinn	Parkinson's Foundation
Gavin Clingham**	Alliance for Patient Access
George Eastwood	Emily Whitehead Foundation
Hayley Mason	National Organization for Rare Disorders
Ian Kremer*	LEAD Coalition
Irene Ulrich**	Center for Science in the Public Interest
Isabella Xu	Center for Science in the Public Interest
Jamie Sullivan*	EveryLife Foundation for Rare Diseases
Jason L. Schwartz**	Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT), Yale School of Public Health
Jeanne Ireland*	The diaTribe Foundation
Jeff Allen*	Friends of Cancer Research
Joseph S. Ross	Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT), Yale School of Medicine
Kara Berasi**	Haystack Project
Kathryn "Taylor" Livelli*	1Day Sooner
Kaylin Bower**	On a Mission for Multiple Sclerosis LLC
Keith Desserich	The Cure Starts Now Foundation
Keith Fargo	Lewy Body Dementia Association, Inc.
Mark Fleury**	American Cancer Society, Cancer Action Network
Michael Jones**	n/a

Michael T. Abrams	Public Citizen
Michelle Adams*	Leavitt Partners
Natalie Torentinos	Children's Hospital
Nishith Pandya**	American Cancer Society, Cancer Action Network
Pamela Gavin	National Organization for Rare Disorders
Patricia Kelmar*	U.S. PIRG
Patrick Wildman	Lupus Foundation of America
Paul Melmeyer*	Muscular Dystrophy Association
Reshma Ramachandran**	Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT); Yale School of Medicine
Ryan Fischer	Foundation for Angelman Syndrome Therapeutics
Saira Sultan	Haystack Project
Sam Sears	National Consumers League
Shion Chang**	National Health Council
Sneha Dave*	Generation Patient
Sophia Phillips**	Doctors of America
Sudhir Sivakumaran**	Lewy Body Dementia Association, Inc.
Suzanne Robotti	MedShadow Foundation
Tess Robertson-Neel**	National Center for Health Research
Therese Ziaks**	Yale School of Medicine
Victoria Gemme	National Organization for Rare Disorders

FDA

Andrew Kish	CDER
Emily Ewing	CDER
Pamela Acero	CDER
Christine Hunt	OCC
Sara Abdollahi	CDER
Jason Bunting	CDER
Yanming Chae	CBER
Kate Greenwood	OCC
Rebecca Kemp	CBER
KaLonna Maul	CDER
Mary Thanh Hai	CDER
Amy Ramandham	CDER