2025 Current Fiscal Year Report: Drug Safety and Risk Management Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Drug Safety and Risk Management Advisory Committee	847

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/31/2024	05/31/2026	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
2	0	0	0	2

Meetings and Dates

Purpose	Start	End

The Drug Safety and Risk Management Advisory Committee and Psychopharmacologic Drugs Advisory Committee met jointly to discuss the reevaluation of the Clozapine Risk Evaluation and Mitigation Strategy (REMS) and possible changes to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of clozapine.	11/19/2024 - 11/19/2024
The Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee met jointly to discuss the findings of the completed extended-release/long-acting opioid analgesic (ER/LA OA) postmarketing requirements (PMRs) 3033-1 and 3033-2 (https://www.fda.gov/media/95546/download). These PMRs are prospective (3033-1) and retrospective (3033-2) epidemiologic studies that examined the serious risks and predictors of misuse, abuse, addiction, and fatal and non-fatal opioid overdose in patients with long-term use of opioid analgesics for management of chronic pain, including patients prescribed ER/LA OAs.	05/05/2025 - 05/05/2025

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$13,728.00	$24,336.00
18a(2). Personnel Pmts to Federal Members	$2,496.00	$3,744.00
18a(3). Personnel Pmts to Federal Staff	$137,106.00	$50,372.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$24,675.00	$42,113.00
18b(2). Travel and Per Diem to Federal Members	$2,775.00	$4,185.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00

18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$54,076.00	$42,596.00
18e. Total Costs	$234,856.00	$167,346.00
19. Federal Staff Support Years (FTE)	0.85	0.25

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates information on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances.

20b. How does the Committee balance its membership?

Members and the Chair are selected by the Commissioner or designee from among authorities

knowledgeable in the fields of risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

20c. How frequent and relevant are the Committee Meetings?

In FY-25, the Committee held 2 meetings. On November 19, 2024, the Drug Safety and Risk Management Advisory Committee and the Psychologic Drugs Advisory Committee met jointly to discuss the reevaluation of the Clozapine Risk Evaluation and Mitigation Strategy (REMS) and possible changes to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of clozapine. The issues the Committees discussed included whether clozapine healthcare providers have sufficient knowledge and access to resources about the risk of neutropenia and need for absolute neutrophil count (ANC) monitoring, and whether ANC monitoring would be performed without the requirements of the REMS. The Committees were in near unanimous agreement (14 Noes and 1 Yes) that the following REMS requirements are not necessary to ensure safe

use of clozapine: documentation of ANC results by providers and verification of those results by pharmacies, and requirements for education of healthcare providers about the risk of severe neutropenia and need for ANC monitoring. Agency Action: As of February 24, 2025, the Agency no longer expects prescribers, pharmacies, and patients to participate in the REMS program for clozapine or to report results of absolute neutrophil count (ANC) blood tests before pharmacies dispense clozapine. FDA still recommends that prescribers monitor patients' ANC according to the monitoring frequencies described in the prescribing information. On May 5, 2025, the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee met jointly to discuss the findings of the completed extended-release/long-acting opioid analgesic (ER/LA OA) postmarketing requirements (PMRs) 3033-1 and 3033-2 (https://www.fda.gov/media/95546/download). These PMRs are prospective (3033-1) and retrospective (3033-2) epidemiologic studies that examined the serious risks and predictors of misuse, abuse, addiction, and fatal and non-fatal opioid overdose in patients with long-term use of opioid analgesics for management of chronic pain, including patients prescribed ER/LA OAs. The Committees discussed their interpretation of the findings from PMRs 3033-1 and 3033-2 on the incidence and prevalence of misuse, abuse, Opioid Use Disorder (OUD), and fatal and nonfatal overdose in patients using OAs long-term, their thoughts on the most important findings, as well as any novel findings they believed FDA should communicate to healthcare providers, patients, and other members of the public. Agency Action: The Agency is still reviewing the

recommendations made at the meeting. It is expected that the Committee will meet 3-6 times during FY-26.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
Members of the Committee are drawn from academia, research and/or clinical practice. Their advice and input is considered as part of FDA's regulatory decision-making and helps those decisions stand up to intense public scrutiny. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full time basis at a great expense to the government.

20e. Why is it necessary to close and/or partially closed committee meetings?
The committee held no closed meetings during FY-25.

21. Remarks
Although the current charter states that the Committee shall hold meetings approximately 3-6 times a year, this is only an estimation based on data from previous years. As the FDA convenes advisory committees based on the needs of the Agency, it should not be construed as an exact figure. The committee chair is currently vacant on this committee.

Designated Federal Officer
Jessica Seo Acting Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Amirshahi, Maryann	10/31/2024	05/31/2028	Professor of Emergency Medicine, Georgetown University School of Medicine ; Department of Emergency Medicine, MedStar Washington Hospital Center	Special Government Employee (SGE) Member

Ballon, Jacob	11/19/2024	11/19/2024	Associate Professor Co-Division Chief - Division of General Adult Psychiatry and Psychology Co-Director, INSPIRE Clinic Department of Psychiatry Stanford University	Special Government Employee (SGE) Member
Becker, William	05/05/2025	05/05/2025	VA Connecticut Healthcare, Internal Medicine	Regular Government Employee (RGE) Member
Blanco, Carlos	05/05/2025	05/05/2025	National Institutes of Health - Epidemiologist	Regular Government Employee (RGE) Member
Brisbin, Michael	11/19/2024	11/19/2024	Patient Representative	Special Government Employee (SGE) Member
Dejos, Michael	09/20/2023	05/31/2027	System Medication Safety Officer, Methodist Le Bonheur Healthcare, Assistant Professor, University of Tennessee Health Science Center	Special Government Employee (SGE) Member
Dublin, Sascha	06/01/2022	05/31/2026	Senior Scientific Investigator, Kaiser Permanente Washington Health Research Institute	Special Government Employee (SGE) Member
Ehret, Megan	11/19/2024	11/19/2024	Professor, Co-Director Mental Health Program University of Maryland, School of Pharmacy	Special Government Employee (SGE) Member
Floyd, James	06/01/2022	05/31/2026	Co-Director, Cardiovascular Health Research Unit; Professor of Medicine, Adjunct Professor of Epidemiology, University of Washington	Special Government Employee (SGE) Member
Gordon, Adam	05/05/2025	05/05/2025	VA Salt Lake City, UT - Internal Medicine	Regular Government Employee (RGE) Member

Hertig, John	06/01/2021	05/31/2025	Associate Professor, Department of Pharmacy Practice, Butler University College of Pharmacy and Health Sciences	Special Government Employee (SGE) Member
Huybrechts, Krista	06/01/2021	05/31/2025	Associate Professor of Medicine and Epidemiology, Harvard Medical School and Harvard T.H. Chan School of Public Health, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital	Special Government Employee (SGE) Member
Lo Re, Vincent	06/01/2021	05/31/2025	Associate Professor of Epidemiology and Medicine, Center for Clinical Epidemiology and Biostatistics, Center for Pharmacoepidemiology Research and Training, Perelman School of Medicine, University of Pennsylvania	Special Government Employee (SGE) Member
McAdams DeMarco, Mara	06/01/2021	05/31/2025	Associate Professor, Associate Vice Chair for Research, Department of Surgery, New York University	Special Government Employee (SGE) Member
Perkins, Jeremy	11/19/2024	11/19/2024	Deputy Director, Hematopoietic Stem Cell Program, Murtha Cancer Center, Walter Reed National Military Medical Center , Hematology-Medical Oncology Service, Dept of Medicine, Associate Professor of Medicine, Uniformed Services Univ of the Health Sciences	Regular Government Employee (RGE) Member
Rebo, Mary	10/31/2024	05/31/2028	Executive Director, Pharmacy Quality and Medication Safety, National Pharmacy Services, Kaiser Permanente	Special Government Employee (SGE) Member

Rodriguez, Ignacio	06/11/2024	10/31/2027	Vice President, Global Head Medical Safety, Novartis Pharmaceuticals Corporation	Representative Member
Salvas, Brian	11/19/2024	11/19/2024	Vice President, Pharmacy Innovation and Engineering, CVS Health	Special Government Employee (SGE) Member
Stegmann, Jens-Ulrich	11/19/2024	11/19/2024	Senior Vice President, Global Head Clinical Safety and Pharmacovigilance, EU QPPV GlaxoSmithKline (GSK)	Representative Member
Vyas, Gopal	11/19/2024	11/19/2024	Clinical Assistant Professor, Department of Psychiatry, University of Maryland School of Medicine, Maryland Psychiatric Research Center	Special Government Employee (SGE) Member

Number of Committee Members Listed: 20

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Drug Safety and Risk Management Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data on risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility and making appropriate recommendations to the Commissioner of Food and Drugs. The Committee also advises the Commissioner of Food and Drugs regarding the scientific and medical evaluation of all information

gathered by the Department of Health and Human Services and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Services with regard to the marketing, investigation, and control of such drugs or other substances. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	

Cost Savings Other

Cost Savings Comments
The utilization of the Drug Safety and Risk Management Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce external input from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
77

Number of Recommendations Comments
The Committee made 77 recommendations from FY-03 through FY-25.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
84%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, therefore, the Agency has the option of not implementing the advice. This number represents an approximation of the percentage of recommendations that the agency has fully implemented or plans to fully implement.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
10%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to

implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

When appropriate, information is made available to the public. Actions related to guidance documents or other general matters or issues are available publicly when implemented. Please see https://www.fda.gov/.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☑
Issued new regulation	☑
Proposed legislation	☑
Approved grants or other payments	☐
Other	☑

Action Comments

FDA approves or chooses not to approve an investigational new medical product or other regulatory decision-making.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

N/A