2023 Current Fiscal Year Report: Drug Safety and Risk Management Advisory Committee

Report Run Date: 03/28/2024 12:12:52 PM

1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2023

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	05/31/2022	05/31/2024	

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
1	0	0	0	1

Meetings and Dates

Purpose	Start	End

The Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs Advisory Committee met jointly to discuss proposed changes to the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) requirements to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of isotretinoin oral capsules for patients.	03/28/2023	03/29/2023

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$18,848.00	$36,844.00
18a(2). Personnel Pmts to Federal Members	$2,356.00	$2,456.00
18a(3). Personnel Pmts to Federal Staff	$194,627.00	$203,869.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
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. Other(rents,user charges, graphics, printing, mail, etc.)	$58,548.00	$90,928.00
18d. Total	$274,379.00	$334,097.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The Committee advises the Commissioner of Food and Drugs 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 regards to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by the Department of Health and Human Sevices with regard to the maketing, investigation, and control of such drugs or other substances.

20b. How does the Committee balance its membership?

Members are authorities in the fields of risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse. The Committee includes one technically qualified voting member who is identified with consumer interests. The Committee may include one non-voting member identified with industry interests.

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

In FY-23, the Committee met once. On March 28-29, 2023, the Drug Safety and Risk Management Advisory Committee met jointly with the Ophthalmic Drugs Advisory Committee to discuss proposed changes to the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS)

requirements to minimize burden on patients, pharmacies, and prescribers while maintaining safe use of isotretinoin oral capsules for patients. The majority of the members (4 Yeses, 17 Noes, 1 Abstention) voted “No” to the question as to whether the iPLEDGE REMS should retain the 19-day lockout period requirement before patients can take an additional pregnancy test to be eligible to receive isotretinoin. Regarding the vote question as to when should the REMS require prescribers to document counseling for patients who cannot become pregnant in the iPLEDGE system, ten (10) members voted that the REMS should only require prescribers to document counseling patients who cannot become pregnant with the first prescription as part of patient enrollment; one (1) member voted that the requirement should remain the same because there was no data to inform a change, six (6) members voted that the requirement should be switched to every 120 days with two of these members commenting they were comfortable with documentation only at treatment initiation, and five (5) members voted that the requirement should be changed to another frequency. Regarding recommendations on the pregnancy registry requirement and ways in which it could be streamlined to encourage more participation to yield high quality data, members agreed it is not necessary to continue to collect “follow-up data” (i.e., pregnancy and fetal outcome information) and that more effective communication and transparency are needed regarding how patients’ data will be used if they participate in the iPLEDGE Pregnancy Registry. Agency Action: The Agency is still reviewing the recommendations made at the meeting. It is expected that the Committee will meet three to six times in FY-24.

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 lends credibility to regulatory decisions made 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-23.

21. Remarks

There were no reports required for this Committee in FY-23. Although the current charter states that the committee shall hold meetings approximately three to six times a year, this is only an estimation based on data from previous years. As the FDA convenes advisory committees regarding based on the needs of the Agency, it should not be construed as an exact figure.

Designated Federal Officer

Philip A. Bautista Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Berenson, Abbey	03/28/2023	03/29/2023	Director, Population and Preventive Health, University of Texas Medical Branch	Special Government Employee (SGE) Member

Calis, Karim	06/01/2019	05/31/2023	Director of Clinical Research and Compliance, Office of the Scientific Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development	Regular Government Employee (RGE) Member
Chambers, David	03/28/2023	03/29/2023	Deputy Director for Implementation Science, Division of Cancer Control and Population Sciences, National Cancer Institute, NIH	Regular Government Employee (RGE) Member
Cowen, Edward	03/28/2023	03/29/2023	Chief, Dermatology Consultation Service, National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH	Regular Government Employee (RGE) Member
DeLost, Kort	03/28/2023	03/29/2023	Community Pharmacist	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
Floyd, James	06/01/2022	05/31/2026	Associate Professor of Medicine, University of Washington	Special Government Employee (SGE) Member

Hernandez-Diaz, Sonia	03/28/2023	03/29/2023	Professor of Epidemiology, Harvard T.H. Chan School of Public Health	Special Government Employee (SGE) Member
Hertig, John	06/01/2021	05/31/2025	Associate Professor and Vice Chair, Department of Pharmacy Practice, Butler University College of Pharmacy and Health Sciences	Special Government Employee (SGE) Member
Hovinga, Collin	06/01/2020	05/31/2024	Senior Vice President, Institute for Advanced Clinical Trials (I-ACT) for Children	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	Special Government Employee (SGE) Member
Liu, Tao	06/01/2022	05/31/2026	Associate Professor of Biostatistics, Brown University	Special Government Employee (SGE) Member
Lo Re, Vincent	06/01/2021	05/31/2025	Associate Professor of Epidemiology and Medicine, Perelman School of Medicine, University of Pennsylvania	Special Government Employee (SGE) Member
Ludwinski, Donna	03/28/2023	03/29/2023	Director of Research Advocacy, Solving Kids' Cancer	Special Government Employee (SGE) Member
McAdams DeMarco, Mara	06/01/2021	05/31/2025	Associate Professor, New York University	Special Government Employee (SGE) Member

Mehta, Reema	11/01/2019	10/31/2023	Vice President, Head of Risk Management, Pfizer	Representative Member
Nelson, Lewis	06/01/2020	05/31/2024	Professor and Chair of Emergency Medicine, Rutgers New Jersey Medical School	Special Government Employee (SGE) Member
Rasmussen, Sonja	03/28/2023	03/29/2023	Professor, Johns Hopkins University School of Medicine	Special Government Employee (SGE) Member
Robotti, Suzanne	01/19/2017	05/31/2024	CONSUMER REP; President, MedShadow; Executive Director, DES Action USA	Special Government Employee (SGE) Member
Salvas, Brian	03/28/2023	03/29/2023	Executive Director, Pharmacy Operations, CVS Pharmacy	Special Government Employee (SGE) Member
Schrieber, Courtney	03/28/2023	03/29/2023	Stuart and Emily B.H. Mudd Professor of Human Behavior and Reproduction, Perelman School of Medicine, University of Pennsylvania	Special Government Employee (SGE) Member

Number of Committee Members Listed: 21

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 professional services 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?

75

Number of Recommendations Comments

The Committee made 75 recommendations from FY-03 through FY-23.

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.

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