2024 Current Fiscal Year Report: Science Advisory Board to the National Center for Toxicological Research

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2024

3. Committee or Subcommittee	3b. GSA Committee No.
Science Advisory Board to the National Center for Toxicological Research	1023

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	06/02/2022	06/02/2024	

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
0	0	0	0	0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$0.00	$0.00
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.)	$0.00	$0.00
18d. Total	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The National Center for Toxicological Research (NCTR) Science Advisory Board (SAB) advises the Director in establishing, implementing and evaluating the research programs that assist the Commissioner of the Food and Drug Administration (FDA) in fulfilling regulatory responsibilities. This external body of recognized scientific experts is a key component of the review and planning process, and helps to ensure that the research programs at NCTR are scientifically sound and pertinent to the FDA.

20b. How does the Committee balance its membership?

Members are leading authorities in the fields related to toxicological research. Members represent academia, clinical research, and other scientific disciplines.

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

It is likely that the Board will hold one site visit and one meeting of the full Board in FY-2024.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

This function could be performed on an ad hoc basis; however, it would be a much more costly process than what is currently being spent using SGEs. There would be no reduction in allotted Federal staff time, since that time would still be required to support the ad hoc review activity. Moreover, utilizing an ad hoc review approach would not permit the seamless evaluation of the total NCTR research agenda, the inter-relationships of its research components, and the long-range impact on the FDA mission.

20e. Why is it necessary to close and/or partially closed committee meetings?

The Board meets in closed session to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 522b(c)(6)). These portions of the meetings are closed to permit discussion of issues related to personnel progress and promotion.

21. Remarks

During FY23 there was 1 two-day meeting of the full board. On April 4-5, 2023, the Committee met virtually. The NCTR Director provided a

Center-wide update on scientific initiatives and accomplishments during the past year. The Science Advisory Board was presented with an overview of the Division of Bioinformatics and Biostatistics Site Visit Report and a response to this review. There were updates from the NCTR Research Divisions and a public comment section. There was a statement given by the FDA Chief Scientist. The Center for Biologics and Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, and the Center for Tobacco Products. Each Center briefly discussed their center-specific research strategic needs and potential areas of collaboration.

Designated Federal Officer

Donna L. Mendrick Associate Director for Regulatory Activities, Washington Operations, NCTR

Committee Members	Start	End	Occupation	Member Designation
ASCHNER, MICHAEL	08/22/2017	06/30/2024	Professor of Molecular Pharmacology, Albert Einstein College of Medicine	Special Government Employee (SGE) Member
Cosenza, Mary Ellen	08/19/2019	06/30/2026	President MEC Regulatory & Toxicology Consulting, LLC	Special Government Employee (SGE) Member
Ganey, Patricia	08/19/2019	06/30/2026	Professor Department of Pharmacology and Toxicology Michigan State University	Special Government Employee (SGE) Member
Lanza, Gregory	05/31/2016	06/30/2024	Professor of Medicine, Biomedical Engineering and Biology and Biomedical Sciences,Washington University School of Medicine	Special Government Employee (SGE) Member

Ramos, Kenneth	04/20/2018	06/30/2025	Executive Director, Texas A&M Inst. of Biosciences and Technology	Special Government Employee (SGE) Member
Sauer, John-Michael	08/22/2017	06/30/2025	Senior Director, Nonclinical Lead, Peptilogics	Special Government Employee (SGE) Member
Tropsha, Alexander	07/01/2020	06/30/2024	K.H. Lee Distinguished Professor, Associate Dean for Pharmacoinformatics and Data Science, University of North Carolina-Chapel Hill	Special Government Employee (SGE) Member
Walker, Cheryl	02/18/2022	06/30/2026	Alkek Presidential Chair in Environmental Health, Dir, Center for Precision Environmental Health, Prof., Dept. of Molecular & Cell Biology and Medicine, Baylor College of Medicine	Special Government Employee (SGE) Member

Number of Committee Members Listed: 8

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 Science Advisory Board to the National Center for Toxicological Research supports FDA's strategic priorities by establishing, implementing and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling her regulatory responsibilities. The Board provides an extra-agency

review in ensuring that the research programs at NCTR are scientifically sound and pertinent to the mission of the FDA.

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

NA

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 Science Advisory Board to the National Center for Toxicological Research enables 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 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?
37

Number of Recommendations Comments
The committee made 37 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,and 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 issues are available publicly when implemented.

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 new medical products.

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

No

Grant Review Comments

NA

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

NA