2020 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	2020

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	06/02/2020	06/02/2022	

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

Meetings and Dates

Purpose	Start	End
On December 3, 2019, the Science Advisory Board Chair welcomed the participants, and the National Center for Toxicological Research (NCTR) Director provided a Center-wide update on scientific initiatives and accomplishments during the past year. The Science Advisory Board (SAB) was presented with an overview of the Science Advisory Board Subcommittee Site Visit Report and a response to this review. 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, the Center for Tobacco Products and the Office of Regulatory Affairs each briefly discussed their specific research strategic needs and potential areas of collaboration. On December 4, 2019, there were updates from the NCTR Research Divisions and a public comment session. Following an open discussion of all the information presented, the open session of the meeting closed so the SAB members could discuss personnel issues at NCTR at the end of the day.	12/03/2019	12/04/2019

On August 18, 2020, the Science Advisory Board (SAB) Chair welcomed the participants, and the National Center for Toxicological Research (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 Science Advisory Board Subcommittee Site Visit Report and a response to this review. 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, the Center for Tobacco Products and the Office of Regulatory Affairs each briefly discussed their specific research strategic needs and potential areas of collaboration. On August 19, 2020, there were updates from the NCTR Research Divisions and a public comment session. Following an open discussion of all the information presented, the open session of the meeting was closed so the SAB members could discuss personnel issues at NCTR at the end of the day.	08/18/2020 - 08/19/2020

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$21,800.00	$12,100.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$202,003.00	$203,025.00
18a(4). Personnel Pmts to Non-Member Consultants	$7,650.00	$2,200.00
18b(1). Travel and Per Diem to Non-Federal Members	$9,567.00	$5,083.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$1,965.00	$986.00
18b(4). Travel and Per Diem to Non-member Consultants	$2,394.00	$2,406.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$60,518.00	$55,815.00
18d. Total	$305,897.00	$281,615.00
19. Federal Staff Support Years (FTE)	1.00	1.00

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-2021.

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 alotted 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 disucssion where disclosure would constitute a clearly unwarrented 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 FY20 there were 2 two-day meetings of the full board. On December 3-4, 2019, the Committee met in-person. 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 Genetic and Molecular Toxicology Research Program Site Visit Report nd 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. On August 18-19, 2020, the Committee held a virtual-only meeting. On August 18-19, 2020, the Science Advisory Board Chair welcomed the participants, and 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 Subcommittee Review of the Division of Neurotoxicology Research Program Site Visit Report and a response to that review. The Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, the Center for Tobacco Products and the Office of Regulatory Affairs each briefly discussed their specific research strategic needs and potential areas of collaboration. There were also updates from each of the NCTR Research Divisions.

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	06/30/2021	Professor of Molecular Pharmacology, Albert Einstein College of Medicine	Special Government Employee (SGE) Member
Cosenza, Mary Ellen	08/19/2019	06/30/2023	President MEC Regulatory & Toxicology Consulting, LLC	Special Government Employee (SGE) Member
Felter, Susan	09/29/2014	06/30/2020	Principle Toxicologist,Proctor & Gamble	Special Government Employee (SGE) Member
Ganey, Patricia	08/19/2019	06/30/2023	Professor Department of Pharmacology and Toxicology Michigan State University	Special Government Employee (SGE) Member
Kaspar, Charles	07/01/2018	06/30/2022	Professor & Chair, Department of Bacteriology,University of Wisconsin	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	06/30/2022	Professor of Medicine, Texas A&M College of Medicine Associate Vice President for Precision Health Sciences University of Arizona Health Sciences	Special Government Employee (SGE) Member
Sauer, John-Michael	08/22/2017	06/30/2021	CONSUMER REPRESENTATIVE.Program Officer, Biomarker Programs and Executive Director, Predictive Safety Testing Consortium,Critical Path Institute	Special Government Employee (SGE) Member
Stice, Steven	05/31/2016	06/30/2021	Director of the Regenerative Bioscience Center,University of Georgia	Special Government Employee (SGE) Member
Tropsha, Alexander	07/01/2020	06/30/2024	Professor	Special Government Employee (SGE) Member

Number of Committee Members Listed: 10

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?

Number of Recommendations Comments
The committee made 33 recommendations from FY-03 through FY-20.

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