2025 Current Fiscal Year Report: Tobacco Products Scientific Advisory Committee

Report Run Date: 08/02/2025 06:45:22 AM

1. Department or Agency 2. Fiscal Year

Department of Health and Human

Services

2025

3b. GSA
3. Committee or Subcommittee

Committee No.

Tobacco Products Scientific Advisory

Committee

70466

4. Is this New During 5. Current 6. Expected 7. Expected Fiscal Year? Charter Renewal Date Term Date

No 08/12/2009

8a. Was Terminated During 8b. Specific 8c. Actual Termination Term Date

Authority

No

9. Agency 10b.

Recommendation for Next Req to Terminate?

| Continue of the c

Continue Not Applicable Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment

13. 14. 14c. Effective Committee _

Authority Presidential?

Date Type

H.R. 1256 Family Smoking

Prevention and Tobacco

06/22/2009 Continuing No

Control Act; FD&C 21 U.S.C.

387q

15. Description of Committee Scientific Technical Program

Advisory Board

16a. Total Number of

No Reports for this FiscalYear

Reports

17a

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

Meetings and Dates

	Curren FY	t Next FY
18a(1). Personnel Pmts to	\$0.00	0\$0.00
Non-Federal Members	ψ0.00	σφο.σσ
18a(2). Personnel Pmts to	\$0.00	0\$0.00
Federal Members	4 515	, ,
18a(3). Personnel Pmts to	\$0.00	0\$0.00
Federal Staff	·	·
18a(4). Personnel Pmts to	\$0.00	0\$0.00
Non-Member Consultants	·	·
18b(1). Travel and Per Diem to	\$0.00	0\$0.00
Non-Federal Members	·	·
18b(2). Travel and Per Diem to	\$0.00	0\$0.00
Federal Members		
18b(3). Travel and Per Diem to	\$0.00	0\$0.00
Federal Staff		
18b(4). Travel and Per Diem to	\$0.00	\$0.00
Non-member Consultants		
18c. Administrative Costs (FRNs,	1	
contractor support,	\$0.00	\$0.00
In-person/hybrid/virtual		
meetings)		
18d. Other (all other funds not	ድር ርረ	ο Φ Ο ΟΟ
captured by any other cost	\$0.00	0\$0.00
category)	<u></u>	ን ው ለ ለ ለ
18e. Total Costs	Φ0.00	0\$0.00
19. Federal Staff Support Years	0.00	0.00
(FTE)		

20a. How does the Committee accomplish its purpose?

The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides advice, information and recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. One voting member is an officer or employee of a state or local government or of the Federal Government. One voting member is a representative of the general public. In addition to the voting members, the Committee includes 3 non-voting members who are identified with industry interests. These members include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. This final position can be filled on a rotating, sequential basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Committee.

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

This committee convened on June 26, 2024, holding one meeting in FY 24 and anticipates holding between two and four meetings in FY 25.

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. They provide advice and input that FDA considers as part of its regulatory decision-making. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full-time basis at great expense to the government.

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

There were no closed meetings to report in FY 24.

21. Remarks

There was one committee meeting in FY 2024. Time was also devoted to reviewing applications for new nominees, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training.

Designated Federal Officer

Serina Amy Hunter-Thomas Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Bailey, William	02/01/2017	01/31/2029	University of Kentucky Research and Education Center	Representative Member
Delnevo, Cristine	03/04/2021	01/31/2029	Director and Professor, Rutgers Cancer Institute of New Jersey	Special Government Employee (SGE) Member
Guy, Mignonne	07/19/2022	01/31/2026	Associate Professor & Chair	Special Government Employee (SGE) Member
Jordt, Sven	04/23/2023	04/23/2027	Associate Professor of Anesthesiology, Pharmacology and Cancer Biology	Special Government Employee (SGE) Member
Leventhal, Adam	05/19/2020	01/31/2026	Director and Professor, University of Southern California Keck School of Medicine	Special Government Employee (SGE) Member

Popova, Lucy	03/04/2021	01/31/2029	Assistant Professor, School of Public Health at Georgia State University	Special Government Employee (SGE) Member
Rigotti, Nancy	06/17/2023	06/17/2027	Physician and Investigator	Special Government Employee (SGE) Member
Robinson, Risa	07/19/2022	01/31/2026	Professor & Department Head of Mechanical Engineering	Special Government Employee (SGE) Member
Scout, NFN	07/19/2022	01/31/2026	Executive Director	Special Government Employee (SGE) Member
Upson, Dona	07/19/2022	01/31/2026	Physician	Regular Government Employee (RGE) 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 Tobacco Products Scientific Advisory Committee supports FDA's strategic priorities by reviewing and evaluating safety, dependence, and health issues relating to tobacco products and making recommendations to the Commissioner of Food and Drugs.

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 commi	ttee?
Chaokad	if Applica

	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 Tobacco Products Scientific Advisory Committee 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 only on an as needed bases 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 <u>Number</u> of recommendations produced by this committee for the life of the committee?

Number of Recommendations Comments

The committee made 10 recommendations from FY09 through FY23.

What is the approximate <u>Percentage</u> of these recommendations that have been or will be <u>Fully</u> 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.

What is the approximate <u>Percentage</u> of these recommendations that have been or will be <u>Partially</u> 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 ag	gency provide the co	mmittee with feedback	regarding actions	taken to
implement	recommendations or	advice offered?		

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.

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			
The Agency will use the committee's advice in implementing the Family Smoking Prevention and Tobacco Control Act.			
Is the Committee engaged in the review No	w of applications for grants?		
Grant Review Comments			
N/A			
How is access provided to the informa	tion 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			