

## 2024 Current Fiscal Year Report: Tobacco Products Scientific Advisory Committee

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### 1. Department or Agency

Department of Health and Human Services

### 2. Fiscal Year

2024

### 3. Committee or Subcommittee

Tobacco Products Scientific Advisory Committee

### 3b. GSA

### Committee No.

70466

### 4. Is this New During Fiscal Year?

5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
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No

08/12/2009

### 8a. Was Terminated During Fiscal Year?

No

### 8b. Specific Termination Authority

### 8c. Actual Term Date

### 9. Agency Recommendation for Next Fiscal Year

Continue

### 10a. Legislation Req to Terminate?

Not Applicable

### 10b. Legislation Pending?

Not Applicable

### 11. Establishment Authority

Statutory (Congress Created)

### 12. Specific Establishment Authority

H.R. 1256 Family Smoking Prevention and Tobacco Control Act; FD&C 21 U.S.C. 387q

13. Effective Date	14. Committee Type	14c. Presidential?
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06/22/2009 Continuing No

### 15. Description of Committee

Scientific Technical Program Advisory Board

### 16a. Total Number of Reports

No Reports for this Fiscal Year

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
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### Meetings and Dates

No Meetings

	Current FY	Next FY
<b>18a(1). Personnel Pmts to Non-Federal Members</b>	\$0.00	\$0.00
<b>18a(2). Personnel Pmts to Federal Members</b>	\$0.00	\$0.00
<b>18a(3). Personnel Pmts to Federal Staff</b>	\$0.00	\$0.00
<b>18a(4). Personnel Pmts to Non-Member Consultants</b>	\$0.00	\$0.00
<b>18b(1). Travel and Per Diem to Non-Federal Members</b>	\$0.00	\$0.00
<b>18b(2). Travel and Per Diem to Federal Members</b>	\$0.00	\$0.00
<b>18b(3). Travel and Per Diem to Federal Staff</b>	\$0.00	\$0.00
<b>18b(4). Travel and Per Diem to Non-member Consultants</b>	\$0.00	\$0.00
<b>18c. Other(rents,user charges, graphics, printing, mail, etc.)</b>	\$0.00	\$0.00
<b>18d. Total</b>	\$0.00	\$0.00
<b>19. Federal Staff Support Years (FTE)</b>	0.00	0.00

**20a. How does the Committee accomplish its purpose?**

The committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate 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 May 18, 2023 holding one meeting in FY 23 and anticipates holding at least two meetings 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 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 23.

## 21. Remarks

There was one committee meeting in FY 2023. 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	01/31/2025	University of Kentucky Research and Education Center	Representative Member
Delnevo, Cristine	03/04/2021	01/31/2025	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	05/15/2020	01/31/2024	Director and Professor, University of Southern California Keck School of Medicine	Special Government Employee (SGE) Member
Popova, Lucy	03/04/2021	01/31/2025	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	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 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 appropriate 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	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>

Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

### Outcome Comments

NA

### What are the cost savings associated with this committee?

Checked if Applies

None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>
Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

### 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 Number of recommendations produced by this committee for the life of the committee?

10

### Number of Recommendations Comments

The committee made 10 recommendations from FY09 through FY23.

### 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.

**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**

It usually does. Product approval issues are first released to the sponsor. 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	<input checked="" type="checkbox"/>
Reallocated resources	<input type="checkbox"/>
Issued new regulation	<input checked="" type="checkbox"/>
Proposed legislation	<input type="checkbox"/>
Approved grants or other payments	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

**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 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	<input checked="" type="checkbox"/>
Online Agency Web Site	<input checked="" type="checkbox"/>
Online Committee Web Site	<input checked="" type="checkbox"/>
Online GSA FACA Web Site	<input checked="" type="checkbox"/>
Publications	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

**Access Comments**

N/A