

# 2025 Current Fiscal Year Report: Vaccines and Related Biological Products Advisory Committee

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## 1. Department or Agency

Department of Health and Human Services

## 2. Fiscal Year

2025

## 3. Committee or Subcommittee

Vaccines and Related Biological Products  
Advisory Committee

## 3b. GSA

## Committee No.

1041

## 4. Is this New During Fiscal Year?

No

## 5. Current Charter

12/31/2023 12/31/2025

## 6. Expected Renewal Date

## 7. Expected Term Date

## 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

Authorized by Law

## 12. Specific Establishment Authority

21 U.S.C. 394

## 13. Effective Date

12/31/1979

## 14. Committee Type

Continuing

## 14c. Presidential?

No

## 15. Description of Committee

Scientific Technical Program  
Advisory Board

## 16a. Total Number of Reports

No Reports for  
this Fiscal Year

## 17a. Open

0

## 17b. Closed

0

## 17c. Partially Closed

0

## Other Activities

0

## 17d. Total

0

## Meetings and Dates

No Meetings

Current Next  
FY 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. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)</b>	\$0.00 \$0.00
<b>18d. Other (all other funds not captured by any other cost category)</b>	\$0.00 \$0.00
<b>18e. Total Costs</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 Vaccines and Related Biological Products Advisory Committee (VRBPAC) reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines, allergenics, and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and as required, any other products for which the Food and Drug Administration has regulatory responsibility. The

Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner of Food and Drugs.

**20b. How does the Committee balance its membership?**

Members are experts in immunology, allergy and allergenic diseases, molecular biology, rDNA, virology; bacteriology, parasitology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, hypersensitivity reactions to vaccines, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. One member is technically qualified and identified with consumer interests and one non-voting member represents the point of view of industry.

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

The committee held 4 meetings in FY24 and estimate that this committee will hold 6 meetings in FY25. The Committee receives information regarding the scope and mission of the research programs from the Office of Vaccines Research and Review (OVRR). All discussions are related to components of the Strategic Plan and FDA's Critical Path to New Medical Products. 1. October 5, 2023 – The committee met in open session via web conference to discuss the Strain Selection for the Influenza Virus Vaccines for the 2024 Southern Hemisphere Influenza Season. Agency Action: February 14, 2024, FDA approved Fluzone Quadrivalent, southern hemisphere and Fluzone

Quadrivalent High-Dose southern hemisphere for the 2024 southern hemisphere influenza season.

2. March 5, 2024 – The committee met in open session via web conference to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2024-2025 Northern Hemisphere Influenza Season. Agency Action: On July 1, 2024, FDA approved 2024-2025 United States Formulation of Influenza vaccines for the 2024-2025 northern hemisphere influenza season. 3. June 5, 2024

(May 16, 2024), the committee met in open session to discuss and make recommendations on the selection of the 2024-2025 Formula for COVID-19 vaccines. Agency Actions: On August 22, 2024, FDA had four regulatory actions [approval/authorizations] on COVID-19 vaccines. COVID-19 Vaccines (2024-2025 Formula)

Approval of Supplements to Biological License Applications: • Spikevax (COVID-19 Vaccine, mRNA) STN 125752/220 – Strain change to 2024-2025 Formula for use as a single dose in individuals 12 years of age and older • Comirnaty (COVID-19 Vaccine, mRNA) STN 125742/564 – Strain change to 2024-2025 Formula for use as a single dose in individuals 12 years of age and older Authorization of Amendments to the Emergency Use Authorizations: • EUA 27034, Pfizer-BioNTech COVID-19 Vaccine - Use of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) in individuals 6 months through 11 years of age. • EUA 27034, Moderna COVID-19 Vaccine - Use of Moderna COVID-19 Vaccine (2024-2025 Formula) in individuals 6 months through 11 years of age. August 30, 2024 Authorization of Amendments to the Emergency Use Authorizations: • EUA 28237, Novavax COVID-19 Vaccine, Adjuvanted COVID-19 Vaccine - Use of Novavax COVID-19 Vaccine, Adjuvanted

(2024-2025 Formula) in individuals 12 years of age and older. 4. September 20, 2024-Topic I, the committee will meet in open session to discuss considerations related to the use of pertussis controlled human infection models [CHIMs] in clinical development of new pertussis vaccines. Topic II, the committee will meet in open session to hear an overview of the research programs of the Laboratory of Mucosal Pathogens and Cellular Immunology (LMPCI), Division of Bacterial, Parasitic and Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVRR). Agency Action: The Agency is discussing next steps following VRBPAC recommendations.

**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 process. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensation.

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

There was one closed meeting to report for FY2024. The meeting was closed in accordance with 21 CFR section 14.27 (b), implementing 5 USC 552b(c)6), for the review of matters that would constitute a clearly unwarranted invasion of personal privacy if disclosed.

**21. Remarks**

No reports are required for this committee. The September 20, 2024, meeting minutes have not been finalized as of the completion of this report.

We will provide it as soon as its finalized.

## Designated Federal Officer

Sussan Paydar Designated Federal Officer,  
DSAC, Center for Biologics Evaluation and  
Research, FDA

Committee Members	Start	End	Occupation	Member Designation
Berger, Adam	02/01/2022	01/31/2026	National Instituters of Health	Regular Government Employee (RGE) Member Special
Bernstein, Henry	02/01/2022	01/31/2026	Cohen Children's Medical Center	Government Employee (SGE) Member Special
Chatterjee, Archana	06/21/2019	01/31/2027	Chair and Dean, Department of Pediatrics, University of South Dakota	Government Employee (SGE) Member Special
El Sahly, Hana	06/10/2016	01/31/2026	Professor/Baylor College Of Medicine	Government Employee (SGE) Member Special
Gans, Hayley	06/21/2019	01/31/2027	Professor, Department of Pediatrics, Stanford University Medical Center	Government Employee (SGE) Member Special
Janes, Holly	06/10/2016	01/31/2025	Associate Member, Fred Hutchinson Cancer Research Center	Government Employee (SGE) Member Special
Jodar, Luis	02/01/2024	01/31/2028	Chief Medical Officer, Senior Vice President, Pfizer	Representative Member Special
Monto, Arnold	02/01/2022	01/31/2026	Professor/University of Michigan	Government Employee (SGE) Member Special
Offit, Paul	02/01/2018	01/31/2025	Physician - Children's Hospital of Philadelphia	Government Employee (SGE) Member Special
Perlman, Stanley	08/23/2022	01/31/2026	Physician - University of Iowa	Government Employee (SGE) Member Special
Portnoy, Jay	02/01/2022	01/31/2025	Director, Division of Allergy/Asthma/Immunology, The Children's Mercy Hospital	Representative Member

Rubin, Eric	02/01/2022	01/31/2026	Adjunct Professor, Harvard, TH Chan school of Public Health	Special Government Employee (SGE) Member
Shane, Andrea	02/01/2018	01/31/2025	Physician - Emory University School of Medicine	Special Government Employee (SGE) Member

## Number of Committee Members Listed: 13

### 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 Vaccines and Related Biological Products Advisory Committee supports FDA's mission and strategic action plan by reviewing and evaluating available data relating to the safety and effectiveness of vaccines and related biological products, which are intended for, use in the prevention, treatment, or diagnosis of human diseases. The Committee also considers the quality and relevance of FDA's research programs which provides scientific support for the regulation of these products. The Committee supports FDA's mission by using science-based efficient risk management in all of its activities. The Committee recommendations provide the most health promotion and protection at the least cost for the public. This Committee assists the Agency in ensuring timely, high quality, cost-effective processes for review of new technologies/pre-market submissions, effective communication and working relationships with stakeholders to enhance U.S. and global health outcomes, accurately analyzing risks associated with medical products, facilitating the development and availability of medical countermeasures to limit the effects of a terrorist attack on the civilian and military populations, protecting the safety and security

of biologics, especially vaccines, all key components of FDA's strategic plan objectives.

**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 Vaccines and Related Biological Products 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 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?**

143

**Number of Recommendations Comments**

The Committee made approximately 143 recommendations from FY2003 through FY2024.

**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**

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	<input checked="" type="checkbox"/>
Reallocated resources	<input checked="" 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**

FDA approves or chooses not to approve a new medical product or other regulatory decision-making.

**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	<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