

## 2025 Current Fiscal Year Report: Advisory Committee on Blood and Tissue Safety and Availability

Report Run Date: 06/13/2025 03:05:27 AM

### 1. Department or Agency

Department of Health and Human Services

### 2. Fiscal Year

2025

### 3. Committee or Subcommittee

Advisory Committee on Blood and Tissue  
Safety and Availability

### 3b. GSA

Committee  
No.

5147

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

No

### 5. Current Charter

10/09/2024 10/09/2026

### 6. Expected Renewal Date

### 7. Expected Term Date

04/01/2025

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

Yes

### 8b. Specific Termination Authority

2025 Secretary  
Directive

### 8c. Actual Term Date

04/01/2025

### 9. Agency Recommendation for Next Fiscal Year

Terminate

### 10a. Legislation Req to Terminate?

Not Applicable

### 10b. Legislation Pending?

Not Applicable

### 11. Establishment Authority

Authorized by Law

### 12. Specific Establishment Authority

42 USC 217a, Sec 222,  
Public Health Service Act

### 13. Effective Date

10/17/1962 Continuing

### 14. Committee Type

### 14c. Presidential?

No

### 15. Description of Committee

National Policy Issue 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 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 ACBTSA provides recommendations to the Secretary, through the Assistant Secretary for Health, on blood and tissue safety and availability. To accomplish its mission, the Committee collaborates with external and internal stakeholders. Subject to approval of the Secretary or designee, the Committee establishes subcommittees to obtain assistance for carrying out its mission. The established subcommittees provide information on issues for which additional data is needed for the Committee to develop

recommendations that are submitted to the Secretary. The subcommittees discuss and pursue objectives in cooperation with other external and internal stakeholders.

Recommendations developed by the subcommittees are given to the Committee for discussion and consideration for them to be forwarded to the Secretary.

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

The Committee consists of 23 voting members appointed by the Secretary and 6 non-voting ex-officio federal members. In appointing members, the Secretary shall ensure that the Committee includes a diverse group of patient advocates, scientific and health professionals. The Committee is composed of 14 public members, including the Chair, who are selected from State and local organizations, patient advocacy groups, provider organizations, academic researchers, ethicists, physicians, surgeons, scientists, risk communication experts, consumer advocates, legal organizations, and from among communities of persons who are frequent recipients of blood or blood products or have received cells, tissues or organs. While there is no prescribed formula for distribution of membership, every attempt is made to ensure that there is equal and diverse representation. In addition, the membership includes 9 individuals who are designated to serve as official representative members of the blood, blood product, cell, tissue and organ professional organizations or business sectors. These members include representatives from the AABB, American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations(AOPO), one of either the American National Red Cross (ARC) or America's Blood

Centers (ABC) on a rotating basis. The Committee composition can include additional representation from either the plasma protein fraction community or a trade organization; a manufacturer of blood, plasma or other tissue/organ test kits; a manufacturer of blood, plasma, or other tissue/organ equipment; and a major hospital organization or major hospital accreditation organization. Where more than one company produces a specified product or process, representatives from those companies shall rotate on the same schedule as public members. Composition of the Committee membership includes physicians, representatives of the blood and plasma and hospital and medical devices communities, and consumer representatives.

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

The Committee meets, at a minimum, one time a year. The Committee will hold additional meetings during the year, depending on the availability of funds and public health requirements. At the Committee meetings, the members receive information from various outside sources and then formulate policy recommendations to be given to the Secretary.

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

The Advisory Committee on Blood and Tissue Safety and Availability provides advice to the Secretary, through the Assistant Secretary for Health, on a range of policy issues to include: (1) identification of public health issues that affect safety and availability of blood supply and blood products; (2) broad public health, ethical and legal issues related to transfusion and transplantation safety; (3) the implications of various economic

factors affecting product cost and supply on safety and availability; and (4) risk communications related to these products. These public health concerns require actions that are inherently governmental, thus requiring the framework of FACA to gather advice.

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

All meetings of the Committee have been and will continue to be open to the public. Since June 2010, all Committee meetings have been webcast.

#### **21. Remarks**

2025 Secretary Directive-Elimination of Federal Advisory Committees Within the Department of Health and Human Services, Terminated 04.01.2025. EO 14217 Reducing the Scope of the Federal Bureaucracy. Through its collaborative efforts with external and internal stakeholders, the Committee has fulfilled its mandate by conclusively establishing that maintaining an adequate supply of safe blood for transfusion is integral to public health and a national priority; and that instability in the blood centers threatens to exacerbate existing spot blood shortages, reduce resilience in the face of public health emergencies through elimination of surge capacity, and reduce ability to provide the most appropriate routine and specialty products and services. With these objectives now accomplished the Committee has completed its advisory role as initially chartered and termination is recommended.

#### **Designated Federal Officer**

James J. Berger Senior Advisor for Blood and Tissue Policy

Committee Members	Start	End	Occupation	Member Designation
Barnes, Louis	07/06/2023	03/31/2025	Certified Tissue Bank Specialist	Representative Member

Barnhard, Sarah	09/04/2024	03/31/2025	Medical Director of Transfusion Services	Special Government Employee (SGE) Member
Basavaraju, Sridhar	10/01/2022	03/31/2025	Physician Scientist	Ex Officio Member
Brubaker, Scott	10/01/2022	03/31/2025	Tissue Subject Matter Expert	Ex Officio Member
Corning, Diane	10/01/2022	03/31/2025	Policy Subject Matter Expert	Ex Officio Member
Delaney, Meghan	09/04/2024	03/31/2025	Director, Transfusion Medicine Children's National Hospital	Representative Member
Eder, Anne	11/16/2022	10/09/2024	FDA CBER	Ex Officio Member
Galel, Susan	09/04/2024	03/31/2025	Stanford University School of Medicine	Representative Member
Hermelin, Daniela	09/04/2024	03/31/2025	Chief Medical Officer, ImpactLife Blood Center	Special Government Employee (SGE) Member
Josephson, Cassandra	07/06/2023	03/31/2025	Director, Cancer and Blood Disorders Institute Director, Blood Bank/Transfusion Medicine/Apheresis	Special Government Employee (SGE) Member
Kim, Michelle	09/04/2024	03/31/2025	Patient Advocate	Special Government Employee (SGE) Member
Levi, Marilyn	10/01/2022	03/31/2025	Transplantation Subject Matter Expert	Ex Officio Member
Miller, Yvette	09/04/2024	03/31/2025	Executive Medical Officer, American Red Cross	Special Government Employee (SGE) Member
Pandey, Suchitra	01/11/2024	03/31/2025	Chief Medical Officer, Stanford Blood Center	Special Government Employee (SGE) Member
Penrod, Josh	01/11/2024	03/31/2025	Head of Global Plasma, PPTA	Representative Member
Pouch, Stephanie	09/04/2024	03/31/2025	Division of Infectious Diseases, Emory School of Medicine	Representative Member
Sime, Stacy	01/11/2024	03/31/2025	CEO, LifeServe Blood Center	Representative Member
Stroncek, David	10/01/2022	03/31/2025	Senior Clinician	Ex Officio Member

Wilson, Diane	07/06/2023 03/31/2025	Chief Operating Officer of Community Blood Center / Community Tissue Services	Special Government Employee (SGE) Member
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Number of Committee Members Listed: 19

Narrative Description

The Secretary is responsible under Sections 301, 351, and 361 of the Public Health Service Act, as amended (42 U.S. Code 241, 262, 264), and various provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), for carrying out research in health fields including diseases involving blood and blood products, and for issuing and enforcing regulations concerning the collection, preparation, and distribution of blood and blood products, and regulations related to the transmission of communicable diseases. The Advisory Committee on Blood and Tissue Safety and Availability advises, assists, consults with, and makes policy recommendations to the Secretary, through the Assistant Secretary for Health, regarding these broad responsibilities. In FY2024, the committee discussed and voted on recommendations related to surge capacity for blood and blood products. Additionally, the committee discussed recommendations related to tissue biovigilance. No additional recommendations have been made in FY25.

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 checked="" type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>

Implementation of laws or regulatory requirements



Other



### Outcome Comments

N/A

### 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

Improved quality care through increased safety and availability of blood, blood products, plasma clotting factors, tissue products and transplantation safety is difficult to measure. Many recommendations are made which influence policy and the prevention of disease.

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

205

### Number of Recommendations Comments

The Committee worked on and submitted 18 recommendations to the Assistant Secretary for Health in FY24.

### What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

30%

### % of Recommendations Fully Implemented Comments

Recommendations made during previous fiscal years are long-term recommendations



requiring coordination and collaboration within HHS.

**What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?**

20%

**% of Recommendations Partially Implemented Comments**

Many of the recommendations require long-term action which can not be accomplished in a fiscal year.

**Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?**

Yes ☒ No ☐ Not Applicable ☐

**Agency Feedback Comments**

Internally the recommendations are provided to the PHS agencies which support the ACBTSA. These recommendations are discussed, if needed, at the Blood, Organ, and Tissue Senior Executive Council (BOTSEC) as described in the internal charter. Feedback is provided to the ACBTSA through direct communication that the DFO has with the Assistant Secretary for Health. The DFO provides this information initially to the Committee Chair and then to the Committee at the next scheduled public meeting. The DFO provides the Committee information on the progress and outcome.

**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 checked="" type="checkbox"/>
Other	<input checked="" type="checkbox"/>

**Action Comments**

The Committee has worked with HHS operating divisions to realign priorities and provide clarification in some areas for transfusion and transplantation safety.

**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