2025 Current Fiscal Year Report: Patient Engagement Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2025

3. Committee or Subcommittee	3b. GSA Committee No.
Patient Engagement Advisory Committee	2532

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	10/06/2023	10/06/2025	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
Yes	2025 Secretary Directive	04/01/2025

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	10/06/2015	Continuing	No

15. Description of Committee Non Scientific Program Advisory Board

16a. Total Number of Reports	No Reports for this FiscalYear

17a. Open	17b. Closed	17c. Partially Closed	Other Activities	17d. Total
1	0	0	0	1

Meetings and Dates

Purpose	Start	End

On October 30, 2024, the Committee discussed and made recommendations on “Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products.” The individuals who volunteer to participate in clinical research play an integral role in advancing scientific knowledge and supporting the development of potentially life-saving therapies for patients in need. Informed consent is a key element in clinical studies and can be one of a patient’s first interactions with the clinical community. Too often, however, informed consent forms are lengthy and difficult for potential research participants to understand. FDA has worked to improve informed consent over the years, including several recent activities such as developing a draft guidance in identifying key information in informed consent. The Committee provided recommendations on the informed consent process and the areas of focus of the informed consent. The Committee also provided recommendations on factors to consider when communicating informed consent to clinical study participants to increase the likelihood of participants understanding the key elements of research.	10/30/2024 - 10/30/2024	

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$5,239.00	$0.00
18a(2). Personnel Pmts to Federal Members	$660.03	$0.00
18a(3). Personnel Pmts to Federal Staff	$87,702.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$1,650.00	$0.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00

18c. Administrative Costs (FRNs, contractor support, In-person/hybrid/virtual meetings)	$0.00	$0.00
18d. Other (all other funds not captured by any other cost category)	$51,312.00	$0.00
18e. Total Costs	$146,563.03	$0.00
19. Federal Staff Support Years (FTE)	0.40	0.00

20a. How does the Committee accomplish its purpose?

The Committee provides advice to the Commissioner of Food and Drugs on complex scientific issues related to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, post market safety, available alternatives, patient-reported outcomes, and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives to improve communication of benefits, risks and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

20b. How does the Committee balance its membership?

The Patient Engagement Advisory Committee charter specifies that the Committee shall consist of a core of 9 voting members including the Chair.

Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, patient experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, scientific methodologies for patient-reported outcomes and eliciting patient preferences, and strategies for communicating benefits, risks and clinical outcomes to patients and research subjects, as well as other relevant areas. The core of voting members may include 1 technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Committee may also include a nonvoting member selected from a group of individuals nominated by industry.

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

The Patient Engagement Advisory Committee charter specifies that meetings shall be held approximately one to two times a year. During the meetings the Committee will provide advice to the Commissioner of Food and Drugs on complex issues relating to medical devices, the regulation of devices, and their use by patients. The Committee held 1 meeting in FY 2025.

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

The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. The

alternate means of accessing this advice would involve the recruitment of large numbers of specialists on a full-time basis at maximum rates of compensation.

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

Not Applicable

21. Remarks

Per "2025 Secretary Directive" this FACA Committee has been terminated.

Designated Federal Officer

Letise Williams Program Analyst, Center for Devices and Radiological Health, FDA

Committee Members	Start	End	Occupation	Member Designation
Burkhart, Ian	05/01/2023	04/01/2025	Vice President, North American Spinal Cord Injury Consortium, Columbus, OH	Special Government Employee (SGE) Member
Diaz, Teresa	05/27/2022	04/01/2025	Co-Founder, Global Patient Advocacy Coalition, Orlando, FL	Special Government Employee (SGE) Member
Edwards, Necie	05/22/2017	04/01/2025	Health and Wellness Educator, Fibro Patient Education & Support Organization, Vernon Hills, IL	Special Government Employee (SGE) Member
Joniak-Grant, Elizabeth	06/29/2023	04/01/2025	Sociologist, Qualitative Research Consultant and Patient Experience Collaborator Injury Prevention Research Center, Univ. of North Carolina, Chapel Hill, NC	Special Government Employee (SGE) Member

Roy, Rita	07/23/2020	04/01/2025	CEO, National Spine Health Foundation, Reston, VA	Special Government Employee (SGE) Member
Rutherford, Philip	05/01/2022	04/01/2025	Chief Operating Officer, Faces & Voices of Recovery, Washington, DC	Special Government Employee (SGE) Member
Schrandt, Mary	05/22/2017	04/01/2025	Founder, CEO & Chief Patient Advocate, Exppect, LLC, Arlington, VA	Special Government Employee (SGE) Member
White, David	05/01/2024	04/01/2025	Lead Proofreader (Nights), Debevoise Plimpton, New York, NY	Special Government Employee (SGE) Member

Number of Committee Members Listed: 8

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 Patient Engagement Advisory Committee supports FDA's strategic priorities by providing advice to the Commissioner of Food and Drugs on complex, scientific issues relating to medical devices, the regulation of devices, and their use by patients. Topics to be considered by the Committee include Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues. The Committee performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or

barriers, and identifying unintended consequences that could result from FDA policy. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

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 Patient Engagement Advisory Committee enables the Agency to

obtain required services from experts who are knowledgeable in areas such as clinical research, primary care patient experience, and health care needs of patient groups in the United States 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?
8

Number of Recommendations Comments
The Patient Engagement Advisory Committee made 8 recommendations since its establishment in FY 2016 through FY25.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
33%

% of Recommendations Fully Implemented Comments
The function of the 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 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?
67%

% 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

The Agency developed a guidance document to address the committee's recommendation. The guidance document and other general matters issues are available. 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	✓
Reallocated resources	
Issued new regulation	
Proposed legislation	
Approved grants or other payments	
Other	✓

Action Comments

The committee will address patient related issues and take appropriate programmatic steps.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

Not Applicable

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

Not Applicable