2024 Current Fiscal Year Report: Pediatric Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2024

3. Committee or Subcommittee	3b. GSA Committee No.
Pediatric Advisory Committee	21515

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	09/27/2012		

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
Public Law 107-109, Public Law 108-155, FDAAA	01/07/2003	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

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

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

18a(1). Personnel Pmts to Non-Federal Members	$0.00	$0.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$0.00	$0.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$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. Other(rents,user charges, graphics, printing, mail, etc.)	$0.00	$0.00
18d. Total	$0.00	$0.00
19. Federal Staff Support Years (FTE)	0.00	0.00

20a. How does the Committee accomplish its purpose?

The committee makes recommendations to the Commissioner of Food and Drugs in response to specific questions posed by the FDA. Recommendations for regulatory or policy decisions are reviewed by FDA staff and by the Commissioner, who then implements changes or forwards recommendations to the Department of Health and Human Services.

20b. How does the Committee balance its membership?

Members are authorities knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics. Members also include a patient-family representative , one

technically qualified consumer representative, and may include one non-voting industry representative and one non-voting representative from a pediatric health organization.

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

The Committee met 1 time during FY-23.

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

The Pediatric Advisory Committee is mandated by law. In addition, the committee will have advisory functions for many pediatric products regulated by the FDA. The committee will provide expert advice on specific regulatory and policy areas related to pediatric therapeutics, including (1) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501,502, 505, 505A, and 505B, 510K, 515, and 520m of the Federal Food, Drug, and Cosmetic Act; (2) identification of research priorities related to pediatric therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments of specific pediatric diseases or conditions, (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices, (4) pediatric labeling disputes as specified in Public Law 107-109, Public Law 110-85, and Public Law 112-144, (5) pediatric labeling changes as specified in Public Law 107-109, Public Law 110-85, and Public Law 112-144, (6) adverse event reports for drugs studied under Public Law 107-109, 110-85 and labeled, and Public Law 112-144 (7) any safety issues that may occur as specified Public Law 107-109, Public Law 110-85,

and Public Law 112-144, (8) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products, (9) pediatric ethical issues including research involving children as subjects as specified in 21 CFR 50.54, (10) advise and make recommendations to the Secretary on the development of countermeasures for pediatric populations in H.R.307, Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, and (11) any other matter involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary directly or to the Secretary through the Commissioner of Food and Drugs on research involving children as subjects that is conducted or supported by the Department of Health and Human Services as specified in 45 CFR 46.407.

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

There was one partially closed meeting to report in FY23. The purpose of this meeting is for the advisory committee to discuss appropriate development plans for establishing safety and effectiveness of artificial womb technology (AWT) devices, including regulatory and ethical considerations for first in human (FIH) studies. On September 19, 2023, the advisory committee met in an open public session to discuss general development of AWT devices. The session followed a more focused discussion on September 20, 2023, when the advisory committee received confidential, proprietary information from Vitara Biomedical, Inc. on their data for a future IDE submission to the agency. The sponsor is developing the EXTra-uterine Environment for Neonatal Development (EXTEND) System, which is a neonatal life support system that incorporates

a pumpless extracorporeal life-support circuit and an extrauterine environment that is designed to support normal fetal growth and organ maturation after extreme premature delivery. The EXTEND system is designed to mimic key physiologic support of a fetus aged 23 weeks to 24 weeks, six days, where the chance of mortality or life-altering complications are extremely high with the current standard of care. The advisory committee discussed ethical and safety implications for the development of this system, which are key components of the overall risk/benefit analysis.

21. Remarks

There were no reports required for FY23. As provided in section 14(d) of the Best Pharmaceuticals for Children Act as amended by section 507 of the Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. 112-144, notwithstanding section 14 of the Federal Advisory Committee Act, the Pediatric Advisory Committee (PAC) will continue to operate to carry out the advisory committee's responsibilities under sections 505A, 505B, and 520(m) of the Federal Food, Drug, and Cosmetic Act. During FY 2023, the Pediatric Advisory Committee was convened once for a total of 1 meeting over 2 days. On September 19 , 2023, the PAC met to discuss the appropriate development plans for establishing safety and effectiveness of artificial womb technology (AWT) devices, including regulatory and ethical considerations for first in human (FIH) studies. The discussion was limited to the use of AWT as an alternative to current standard-of-care management of extremely premature infants in the Neonatal Intensive Care Unit. On September 20, 2023, the meeting was closed to permit discussion and review of trade secret and/or confidential

commercial information (5 U.S.C. 552b(c)(4)).

Designated Federal Officer

Shivana Srivastava Lead Public Health Specialist/Designated Federal Officer, Office of Pediatric Therapeutics

Committee Members	Start	End	Occupation	Member Designation
Baker, Susan	07/01/2023	06/30/2027	The State University of New York	Special Government Employee (SGE) Member
Czaja, Angela	07/01/2021	06/30/2025	Department of PEdiatric, Criticial Care University of Colorado School of Medicine Children's Hospital Colorado Aurora CO	Special Government Employee (SGE) Member
Diekema, Douglas	07/01/2023	06/30/2027	University of Washington, Department of Pediatrics, Divisions of Bioethics and Emergency Medicine	Special Government Employee (SGE) Member
Dracker, Robert	07/01/2021	06/30/2024	Summerwood Pediatrics 4811 Buckley Rd. Liverpool NY	Special Government Employee (SGE) Member
Fischer, Gwenyth	07/01/2022	06/30/2026	University of Minnesota College of Medicine, Minneapolis, MN	Special Government Employee (SGE) Member
Goldman, Jennifer	07/01/2020	06/30/2024	Children's Mercy Hospital Kansas City, MO	Representative Member
Guillory, Charleta	07/01/2023	06/30/2027	Texas Children's Hospital	Special Government Employee (SGE) Member
Holubkov, Richard	07/01/2020	06/30/2024	University of Utah Department of Pediatrics, Salt Lake City, UT	Special Government Employee (SGE) Member

Jones, Bridgette	07/01/2021	06/30/2025	Children's Mercy Hospital 2401 Gillham Rd. Kansas City MO	Special Government Employee (SGE) Member
Krug, Steven	07/01/2022	06/30/2026	Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL	Special Government Employee (SGE) Member
McMillan, Gianna	11/03/2020	06/30/2024	Patient-Family Rep	Special Government Employee (SGE) Member
Nelson, Robert	08/30/2022	06/30/2026	Johnson and Johnson	Representative Member
Ortiz-Aguayo, Roberto	07/01/2020	06/30/2024	The Children's Hospital of Philadelphia, Philadelphia, PA	Special Government Employee (SGE) Member
Oster, Randi	04/24/2018	06/30/2026	CEO, Help Me Health, Fairfield, CT	Representative Member
White, Michael	07/01/2022	06/30/2025	Ochsner Health System	Special Government Employee (SGE) Member

Number of Committee Members Listed: 15

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 Pediatric Advisory Committee supports FDA's strategic priorities by providing advice and making recommendations to the Commissioner of Food and Drugs on matters relating to pediatric therapeutics, pediatric research, and any other matter involving pediatrics for which the Food and Drug Administration has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary pursuant to

45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services. The recommendations of this committee support the agency by improving patient and consumer safety.

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 Pediatric Advisory Committee (and subcommittees) enabled 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?
569

Number of Recommendations Comments
The committee made 569 recommendations from June of FY03 through FY23.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
90%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations of 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, 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 or issues are available publicly when implemented https://www.fda.gov/advisory-committees

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 has made product labeling changes as a result of committee recommendations.

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	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	

Access Comments

N/A