FOOD AND DRUG ADMINISTRATION
Office of the Commissioner
MINUTES OF THE PEDIATRIC ADVISORY COMMITTEE MEETING
The public meeting was convened virtually on July 9, 2025

PAC Members Present (voting) Gwenyth Fischer, MD *(Chair)* Susan Baker, MD, PhD Douglas Diekema, MD, MPH Charleta Guillory, MD, MPH Richard Holubkov, PhD Roberto Ortiz-Aguayo, MD, MMM **Patient Family Representative (voting)** Gianna McMillan, DBe, MFA **Consumer Representative (voting)** Randi Oster, MBA **Temporary Members (voting)** Premchand Anne, MD, MBA, MPH K. Sarah Hoehn, MD, MBe Liza-Marie Johnson, MD, MPH, MSB	**Designated Federal Officer (DFO)** Shivana Srivastava, RN, MS, PMP **Pediatric Health Organization Representative (non-voting)** Jennifer Goldman, MD, MS **Industry Representative (non-voting)** Robert Nelson, MD, PhD

All PAC members and consultants in attendance have been provided background materials for today's discussion

Office of the Commissioner (OC) Dionna Green, MD, FCP Director Office of Pediatric Therapeutics (OPT)	**Center for Devices and Radiological Health (CDRH)** Scott Colburn, MS, BSN, RN Director Office of Readiness and Response

Center for Drug Evaluation and Research (CDER) Ivone Kim, MD Senior Medical Officer Office of Surveillance and Epidemiology	**Center for Biologics Evaluation and Research (CBER)** Craig Zinderman, MD, MPH Associate Director for Medical Policy Office of Biostatistics and Pharmacovigilance

Call to Order and Introduction of the Committee

Gwenyth Fischer, MD

- Dr. Gwenyth Fischer called to order the Pediatric Advisory Committee (PAC) meeting at 10:00 a.m. EST on July 9, 2025, by welcoming all committee members, FDA staff, and public attendees. The meeting was focused on reviewing pediatric-focused post-market safety data for products regulated by the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), and the Center for Drug Evaluation and Research (CDER). Dr. Fischer noted that the FDA's review of adverse event reports for the products under discussion did not identify any new pediatric safety concerns. Therefore, no product-specific presentations from the FDA or industry were planned, and the committee's role would be to provide input on ongoing safety surveillance measures.

Introduction of FDA Representatives

Shivana Srivastava, RN, MS, PMP Designated Federal Officer

- Shivana Srivastava, Designated Federal Officer (DFO), facilitated the introduction of FDA Representatives present at the meeting.

Conflict of Interest Statement

Shivana Srivastava, RN, MS, PMP Designated Federal Officer

- Shivana Srivastava, the Designated Federal Officer for the PAC, reviewed the conflict-of-interest statement. She confirmed that all voting members of the committee had been screened for potential conflicts and were found in compliance with federal ethics regulations.

FDA Opening Remarks

Dionna Green, MD, FCP

- Dr. Dionna Green, Director of the Office of Pediatric Therapeutics, delivered opening remarks. She emphasized FDA's commitment to ongoing pediatric safety monitoring as mandated by the Best Pharmaceuticals for Children Act (BPCA), the Pediatric Research Equity Act (PREA), and the Pediatric Medical Device Safety and Improvement Act. Dr. Green also provided updates on PREA non-compliance letters issued since the last PAC meeting in September 2024, including one from CBER and fifteen from CDER.

Open Public Hearing

Gwenyth Fischer, MD

- The Open Public Hearing segment began at 10:30 a.m.; there were no Open Public Hearing speakers at this meeting. The floor remained open for any public participation until 10:45 a.m., but no further requests to speak were made.

Center for Devices and Radiological Health

Listing of products and clarifying questions

Scott Colburn MS, BSN, RN

- Scott Colburn presented the list of CDRH devices under review. Committee discussions raised questions about device-related mechanical failures, data reliability, and reporting accuracy. Dr. Charu Gupta and Mr. Colin O'Neill from FDA provided detailed responses, particularly regarding the frequency of tether breakages and how these events are categorized. Concerns were also expressed

about missing patient data, protocol deviations in post-approval studies, and the accuracy of Unique Device Identifier (UDI) reporting. Dr. Dense Clayborne provided expertise on medical device reporting (MDR) and data accuracy. She explained that UDIs are mandatory in manufacturer reports but often missing in voluntary reports, and the FDA prioritizes follow-up on serious cases. She also clarified that a spike in MDRs for Medtronic devices was due to improved reporting processes after an FDA inspection. Finally, she supported adding implant data in future reports for better context.

Committee Discussions and Votes

Voting Question: FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDRH products under discussion. Does the Pediatric Advisory Committee concur?

The results of the vote are displayed in the table below. Following the vote, each PAC member had the opportunity to comment on their vote. Most of the PAC members voted "yes" that they concur with FDA's recommendation to continue routine, ongoing postmarket safety monitoring of each of the CDRH products under discussion. One PAC member voted "No" on certain products, citing issues with missing patient age for Medtronic Activa Neurostimulator reports, high reoperation rate for MID-C System suggesting a surgical learning curve, double counting of adverse events in the REFLECT device data, and insufficient long term follow-up data for Tether-Vertebral Body Tethering device.

CDRH Voting Results

Product / PAC Member	**Anne**	**Baker**	**Diekema**	**Guillory**	**Hoehn**	**Holubkov**	**Johnson**	**McMillan**	**Ortiz-Aguayo**	**Oster**
LIPOSORBER LA-15 System	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Medtronic Activa Neurostimulator	Yes	Recused	Yes	Yes	Yes	Recused	Yes	Yes	Yes	No
MID-C System	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
REFLECT Scoliosis Correction	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Tether-Vertebral Body Tethering	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

Center for Biologics Evaluation and Research

Listing of products and clarifying questions

Craig Zinderman, MD, MPH

- Dr. Zinderman presented the list of CBER-regulated products under review. Questions from the PAC members addressed by Dr. Zinderman included missing age data in adverse event reports, the evaluation of reported neuroinflammatory

conditions in the context of expected background levels, incorporation of data from lawsuits and social media for signal detection, and vaccine co-administration risks to evaluate real-world co-administration scenarios. One PAC member also raised concerns about MedWatch data gaps and the need for expanded literature reviews to include social media and lawsuits to identify underreported adverse events. PAC members discussed the incidence of acute disseminated encephalomyelitis (ADEM) following Gardasil and manufacturing and graft survival issues with Epicel grafts.

Committee Discussions and Votes

Voting Question: FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CBER products under discussion. Does the Pediatric Advisory Committee concur?

The results of the vote are displayed in the table below. Following the vote, each PAC member had the opportunity to comment on their vote. The majority of the PAC members voted "yes", that they concur with FDA's recommendations to continue routine, ongoing postmarket safety monitoring of each of the CBER products under discussion. One PAC member voted "no" on Fluzone Quadrivalent due to the feeling that FDA should do more to evaluate adverse events linked to co-administration of vaccines, and commented that these data did not adequately address these interactions and voted "No" on Gardasil 9 because the PAC member believed that the literature review and MedWatch data were insufficient, calling for inclusion of data from lawsuits and social media to improve safety monitoring.

CBER Voting Results

Product / PAC Member	Anne	Baker	Diekema	Guillory	Hoehn	Holubkov	Johnson	McMillan	Ortiz-Aguayo	Oster
Dengvaxia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Epicel	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fluzone Quadrivalent	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Gardasil 9	Yes	Recused	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

Center for Drug Evaluation and Research

Listing of products and clarifying questions

Ivone Kim, MD,

- Dr. Kim presented the list of CDER-regulated products under review. Questions from the PAC members addressed by Dr. Kim included missing age data in adverse event reports, concerns about data completeness (e.g., exclusion of reports with

missing details), and prenatal exposures, particularly for drugs like Topicort. One PAC member also highlighted the need for better monitoring of drug-drug interactions when multiple therapies are administered.

Committee Discussions and Votes

Voting Question: FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDER products under discussion. Does the Pediatric Advisory Committee concur?

The results of the vote are displayed in the table below. Following the vote, each PAC member had the opportunity to comment on their vote. Most of the PAC members voted "yes", that they concur with FDA's recommendations to continue routine, ongoing postmarket safety monitoring of each of the CDER products under discussion. One PAC member cast "No" votes on several products because of incomplete safety data, including reports excluded due to missing details, concerns about prenatal exposures, and lack of sufficient follow-up data on long-term pediatric outcomes as reasons. The need for more robust evaluation of drug-drug interactions, particularly for combination therapies was also cited. One PAC member abstained from voting on Liletta and Potassium Phosphates and cited that the data were insufficient to make a conclusive recommendation.

CDER Voting Results

Product	Anne	Baker	Diekema	Guillory	Hoehn	Holubkov	Johnson	McMillan	Ortiz-Aguayo	Oster
AUVI-Q Auto-Injector	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Diovan	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Entresto	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Eraxis	Yes	Yes	Yes	Yes	Yes	Recused	Yes	Yes	Yes	Yes
Eucrisa	Yes	Yes	Yes	Yes	Yes	Recused	Yes	Yes	Yes	No
Exjade, Jadenu, Jadenu Sprinkle	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Fiasp	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Jakafi, Opzelura	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

Latuda	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Liletta	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Abstain
Mycamine	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Nityr	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Potassium Phosphates	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Abstain
Repatha	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Rozlytrek	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Stelara	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Sutent	Yes	Yes	Yes	Yes	Yes	Recused	Yes	Yes	Yes	No
Tasigna	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Topicort	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Triumeq, Triumeq PD	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Xyrem	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

ADJOURNMENT **Gwenyth Fischer, MD**
Chairperson, PAC

The summary minutes for the July 9, 2025, meeting of the Pediatric Advisory Committee (PAC) were approved on September 3, 2025.

I certify that I attended the July 9, 2025, meeting of the Pediatric Advisory Committee (PAC) and that these minutes accurately reflect what transpired.

_____**/s/**_____
SHIVANA SRIVASTAVA, RN, MS, PMP
Designated Federal Officer, PAC

_____**/s/**_____
GWENYTH FISCHER, MD

PAC Chairperson