









Office of Pediatric Therapeutics, Office of the Chief Medical Officer, Office of the Commissioner

Pediatric Advisory Committee Meeting

September 16, 2026

10:00 a.m. – 4:00 p.m. ET

Meeting notice and materials are available on the PAC website

2026 Meeting Materials, Pediatric Advisory Committee | FDA

Please direct all technical inquiries to the email listed below

Virtual-WOCC-Support@fda.hhs.gov

Information for Media/Press and Public

- For press inquiries, please contact the FDA Newsroom at www.fda.gov/news-events/fda-newsroom to document your attendance, ask questions, or make interview requests for any FDA speakers

- For Open Public Hearing speakers, industry and the press, please sign in by sending an email to PAC@fda.hhs.gov

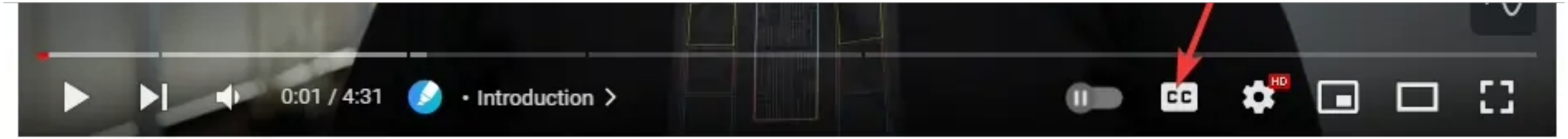
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  - Virtual-WOCC-Support@fda.hhs.gov

Closed Captioning

- Closed captioning can be accessed by clicking on the icon pictured here within YouTube

How to enable closed captions on YouTube:

- On the video player: Click the "CC" (Closed Captioning) icon at the bottom right of the video player.
- If you are signed into your YouTube account, you may access closed captioning through default settings: Navigate to your YouTube account settings, navigate to "Playback and performance," and select "Always show captions"



Call to Order

Dr. Premchand Anne, PAC Chairperson

Introduction of the Committee

Dr. Premchand Anne, PAC Chairperson

Pediatric Advisory Committee Meeting

September 16, 2026

Introduction of FDA Representatives

Shivana Srivastava, RN, MS, DCPM, PMP

Designated Federal Officer, PAC

Conflict of Interest Statement

Shivana Srivastava, RN, MS, DCPM, PMP
Designated Federal Officer, PAC

FDA Opening Remarks

An Massaro, MD
Director, Office of Pediatric Therapeutics
Office of the Chief Medical Officer, Office of the Commissioner, FDA

Opening Remarks

- Personnel updates
- Upcoming pediatric workshops
- Non-compliance letters
- Purpose of the meeting
- Summary of prior meeting discussion
- Agenda
- Voting Procedures

Personnel Updates

- Pediatric Advisory Committee Membership

We thank the following PAC Members for their service:

  - Dr. Gwenyth Fischer (Served as PAC Chair)
  - Dr. Robert Nelson (Served as Industry Representative)
  - Dr. Steven Krug

- Office of Pediatric Therapeutics Recognition

We thank the following staff members for their contributions to the office:

  - Dr. Prabha Viswanathan (Previous Deputy Director, OPT)
  - Dr. Mohamed Mohamoud
  - Margaret Caulk

Welcome to Dr. Shelby Elenburg as Acting Deputy Director, OPT!

Upcoming Pediatric Workshops

Regulatory Science Innovations Catalyzing Medical Device Development

Friday, September 25, 2026

- 8:30 am – 4:30 pm ET
- Register here

RISE to the Challenge: Statistical Considerations for Rare Disease Clinical Investigations

Tuesday, September 29, 2026

- 9:00 am - 4:30 pm ET
- Register here

Navigating the FDA Bayesian Draft Guidance: Design, Analysis, and Review Considerations

Wednesday, October 14, 2026

- 12:00 pm – 1:00 pm ET
- Register here

PREA Non-Compliance Letters

- Center for Biologics Evaluation and Research (CBER, n=7)
  - https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/prea-non-compliance-letters
- Center for Drug Evaluation and Research (CDER, n=202)
  - https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act
- Websites list the sponsor, product, a copy of the non-compliance letter, the sponsor's response (if available), and the status of the PREA requirement (e.g., released, replaced, fulfilled)

PREA Non-Compliance Letters

- CBER: No new letters since the last PAC meeting
- CDER: 15 new letters since the last PAC meeting

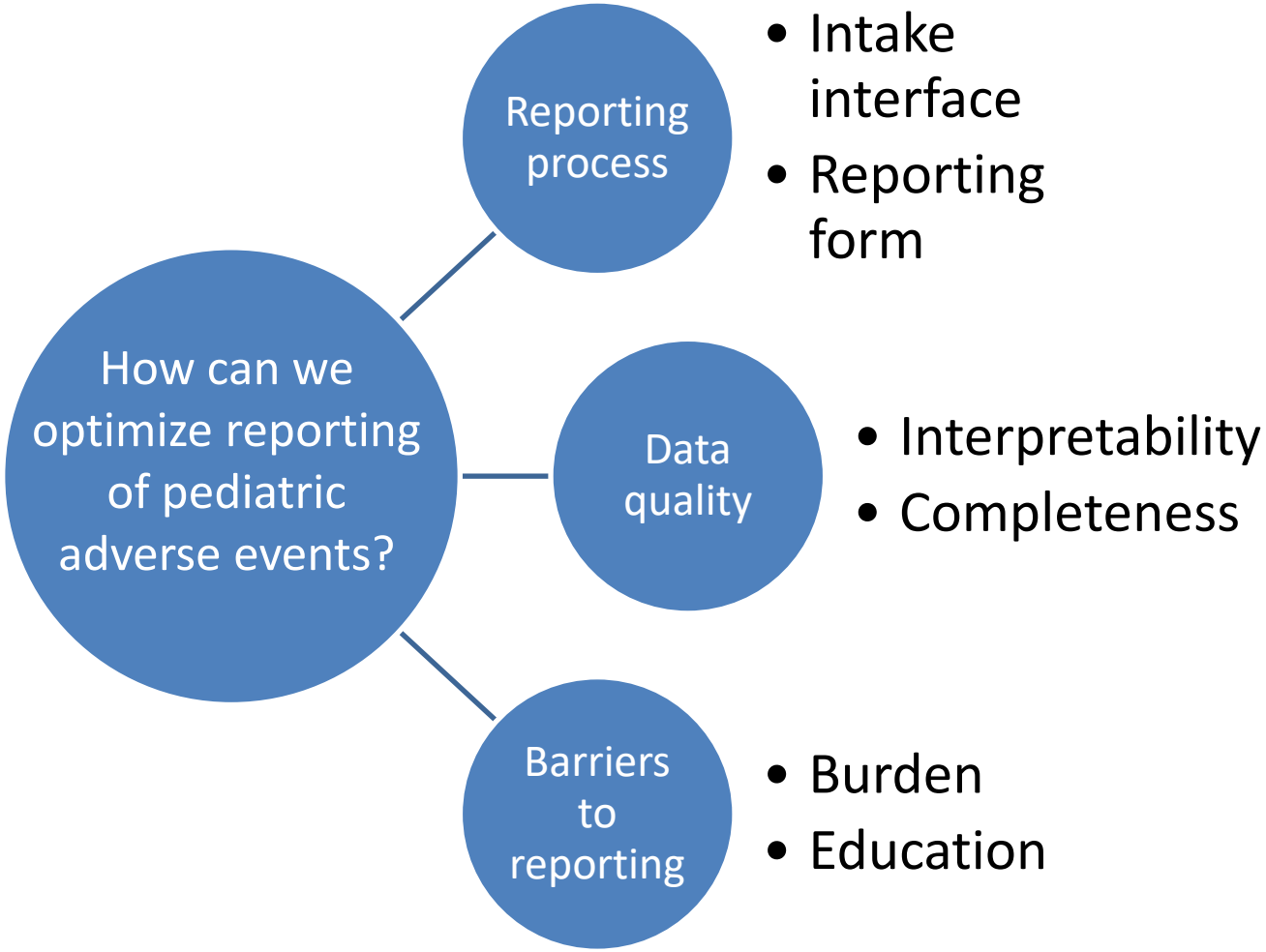
PREA Non-Compliance Letters (CDER)

Sponsor	Product	Date of Letter
Heron Therapeutics, Inc.	Aponvie (aprepitant) injectable emulsion	7/1/2026
Bausch Health Americas, Inc.	Duobrii (halobetasol propionate and tazarotene) lotion	6/12/2026
Phathom Pharmaceuticals, Inc.	Voquezna (vonoprazan) tablet	6/11/2026
Aucta Pharmaceuticals, Inc.	Motpoly XR (lacosamide) capsule	4/28/2026
Cipher Pharmaceuticals, Inc.	Natroba (spinosad) topical suspension	4/23/2026
Evive Biotechnology Singapore PTE. Ltd.	Ryzneuta (efbemalenograstim alfa-vuxw) injection	3/18/2026
Tanvex BioPharma USA, Inc.	Nypozi (filgrastim-txid) injection	2/25/2026
Tris Pharma, Inc.	Onyda XR (clonidine hydrochloride) extended-release oral suspension	2/18/2026
Teva Pharmaceuticals Inc.	Alvaiz (eltrombopag) tablets	2/6/2026
Azurity Pharmaceuticals, Inc.	Eprontia (topiramate) oral solution	2/3/2026
Harrow Eye, LLC	IHEEZO (chloroprocaine hydrochloride) ophthalmic gel	2/3/2026
Cosmo Technologies, Ltd.	AEMCOLO (rifamycin) delayed-release tablets	1/23/2026
Commave Therapeutics SA	Azstarys (serdexmethylphenidate chloride and dexmethylphenidate hydrochloride) capsules	12/1/2025
Acacia Pharma Ltd	Barhemsys (amisulpride) injection	11/24/2025
Azurity Pharmaceuticals, Inc.	Eprontia (topiramate) oral solution	11/21/2025

Purpose of the Meeting

- The Pediatric Advisory Committee (PAC) is meeting to discuss pediatric-focused postmarket safety reviews as mandated by statute:
  - Best Pharmaceuticals for Children Act (Pub. L. 107-109)
  - Pediatric Research Equity Act of 2003 (Pub. L. 108-155)
  - Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 110-85, title III)

November PAC Meeting Recap



FDA Response to November Meeting

- FDA acknowledges the recommendations from committee members regarding opportunities to improve reporting of pediatric safety information
- Several issues (e.g., education/outreach, EHR integration) will require multi-stakeholder collaboration
- FDA will share current processes for AE reporting, including ongoing activities and recent advancements, as part of FDA's commitment to optimize surveillance efforts to monitor post-market safety in children exposed to medical products

Meeting Agenda

- 10:30 a.m. FDA Presentation
  - Overview of Adverse Event Reporting to FDA: A CDER Perspective
  - Q&A
- 11:00 a.m. Open Public Hearing
- 12:00 p.m. Lunch
- 1:00 p.m.* Products evaluated in the pediatric-focused postmarket safety reviews
  - Center for Drug Evaluation and Research (CDER)
  - Center for Devices and Radiological Health (CDRH)
  - Center for Biologics Evaluation and Research (CBER)
- 4:00 p.m.* Closing Remarks and Adjournment

*Times subject to change based on number of speakers

Discussion and Voting Procedures

- Three separate voting sessions (one each for CDER, CDRH, and CBER) following the PAC's discussion
  - Voting will occur via the Zoom platform
  - A separate ballot will be launched for each vote
  - Each ballot will contain a series of voting questions – one for each of the products listed on the ballot
    - *Note*: Some CDER products were grouped into the same pediatric-focused postmarket safety review, and these products will be grouped for voting purposes as well

Voting Procedures

- Meeting participants trying to join the meeting during voting or vote tabulation will be placed in a waiting room until the meeting resumes, which may be ten minutes or more
- The PAC will have a short break while FDA staff tabulate the votes
- Once the meeting resumes, the vote results will be displayed and read into the record
- PAC members will be called upon to read out their individual vote for the record and provide commentary, if desired

Thank you

Overview of Adverse Event Reporting to FDA: A CDER Perspective

Pediatric Advisory Committee Meeting
September 16, 2026

CDER OSE Presenter:

- Quocbao “Bao” Pham, PharmD, MBA

Objectives

Provide an overview of how Adverse Events are reported to the FDA

- Overview of current submission pathways and intake mechanisms

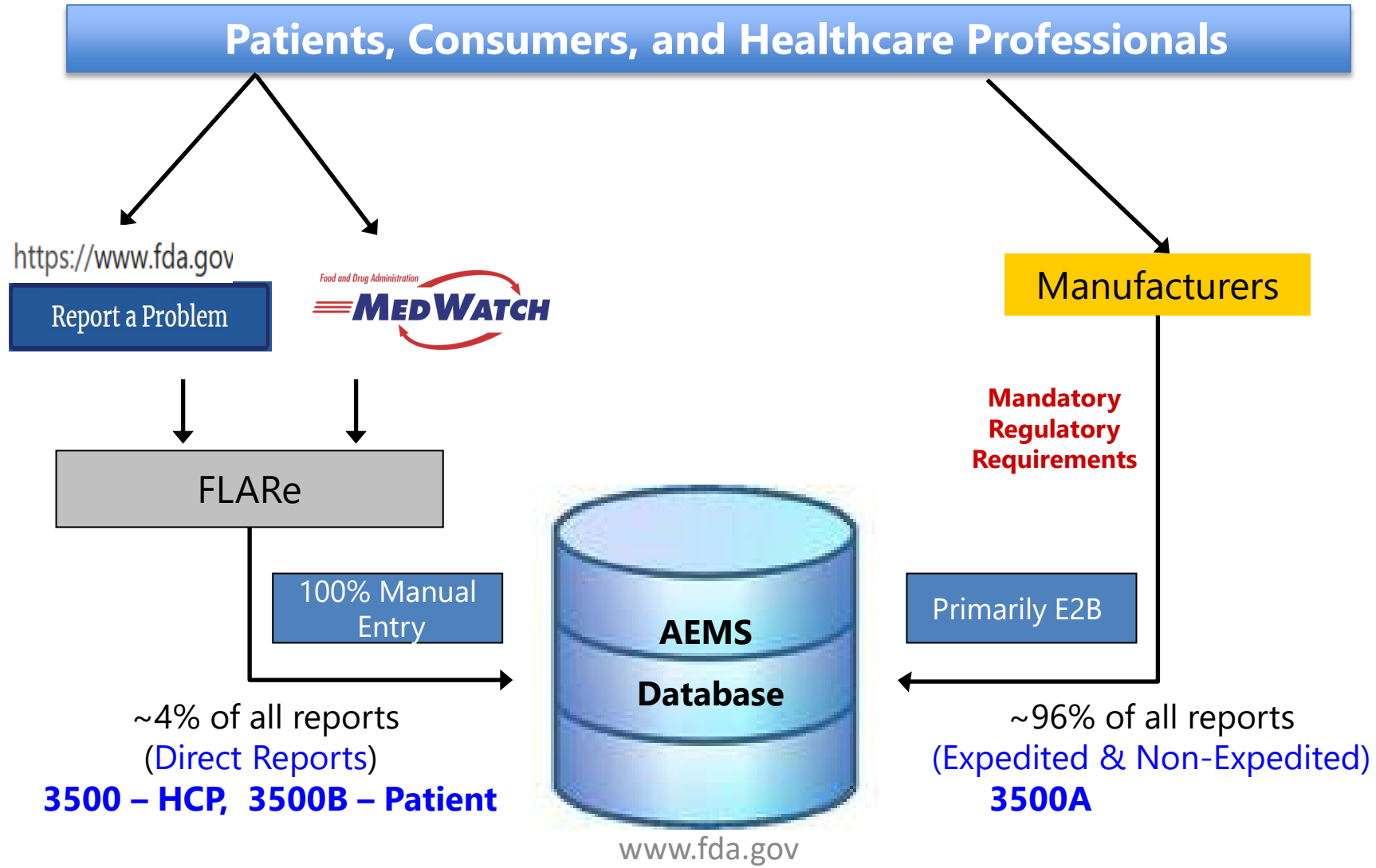
Identify the types of issues that are reported to the FDA

- Adverse Events, Product Quality, Product Use Errors, Consumer Complaints, Regulatory Misconduct, and Whistleblower Reports

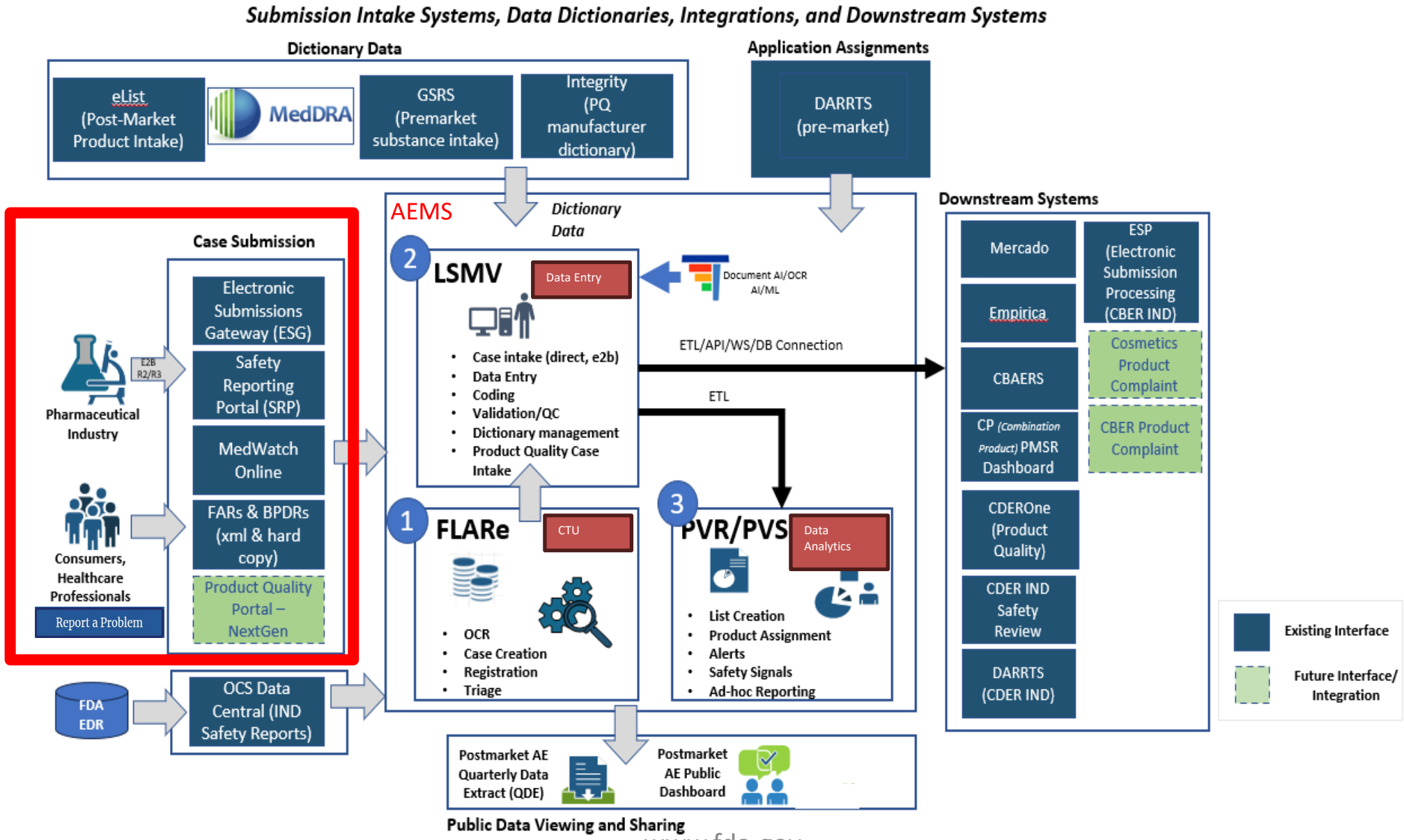
Identify the types of products that are reported to the FDA

- All FDA-regulated product categories, including medical products (drugs, biologics, vaccines, devices), tobacco, human food, cosmetics, and animal food and medicines

How Adverse Event Data Comes to FDA (CDER)



Adverse Event Monitoring System (AEMS) Landscape (CDER)



Pathways and Intake Mechanisms (CDER)



Electronic Submissions Gateway NextGen (ESG NG)

Used for Mandatory Reporting

Structured Data Format (E2BR3)

'Database to Database' Electronic Submission



Safety Reporting Portal (SRP)

Used for Mandatory and Voluntary Reporting

Rationale Questionnaire converted to E2B(R3) for submitter



MedWatch Online (MWO)

Used for Voluntary Reporting from Healthcare Professionals and Consumers and other healthcare partners (e.g., VHA, CVS, Optum)

Website Forms

MedWatch API



MedWatch Forms (3500/3500A/3500B)

Mandatory and Voluntary Reporting

Paper/PDF

Post Office/FedEx/Fax



"Report a Problem" on FDA.gov

Voluntary Reporting

Website Form

MedWatch API

Electronic Submissions Gateway (ESG NG)
Safety Reporting Portal (SRP)
(CDER)

ESG NG

- Used for Mandatory Reporting
- Large Commercial Application Holders
- Structured Data Format is E2B(R3)
- Batch Submissions
- Enhanced Schema (100K Characters Narrative, Null Values, Seriousness for Outcomes, etc.)

SRP

- Used for Mandatory Reporting
- Small Commercial Application Holders
- Structured Data Format is E2B(R3)
- Single Report Submissions
- Rationale Questionnaire (List of Values, Dictionaries for AEs, Products, Route of Administration, etc.)

MedWatch Online (MWO)
MedWatch Forms (3500/3500A/3500B)
(CDER)

MedWatch Online (Website Form)

- Voluntary Healthcare Professionals (3500) and Consumers (3500B)
- Voluntary Healthcare Partners like VHA, CVS, Optum (API)

MedWatch Forms

- Paper/PDF via US Mail and Fax (old-timers)

‘Report a Problem’ to FDA

New Centralized Reporting Portal

What is it?

- A single portal on **FDA.gov** where anyone can report a problem with an FDA-regulated product.
- For drugs, medical devices, biologics, cosmetics, cannabis, foods, tobacco products, and more.
- English and Spanish.
- Routes reports to the correct FDA expert team
- Replaces fragmented multi-site and multi-form complaint systems.
- Designed to encourage complete reporting with a streamlined, guided experience

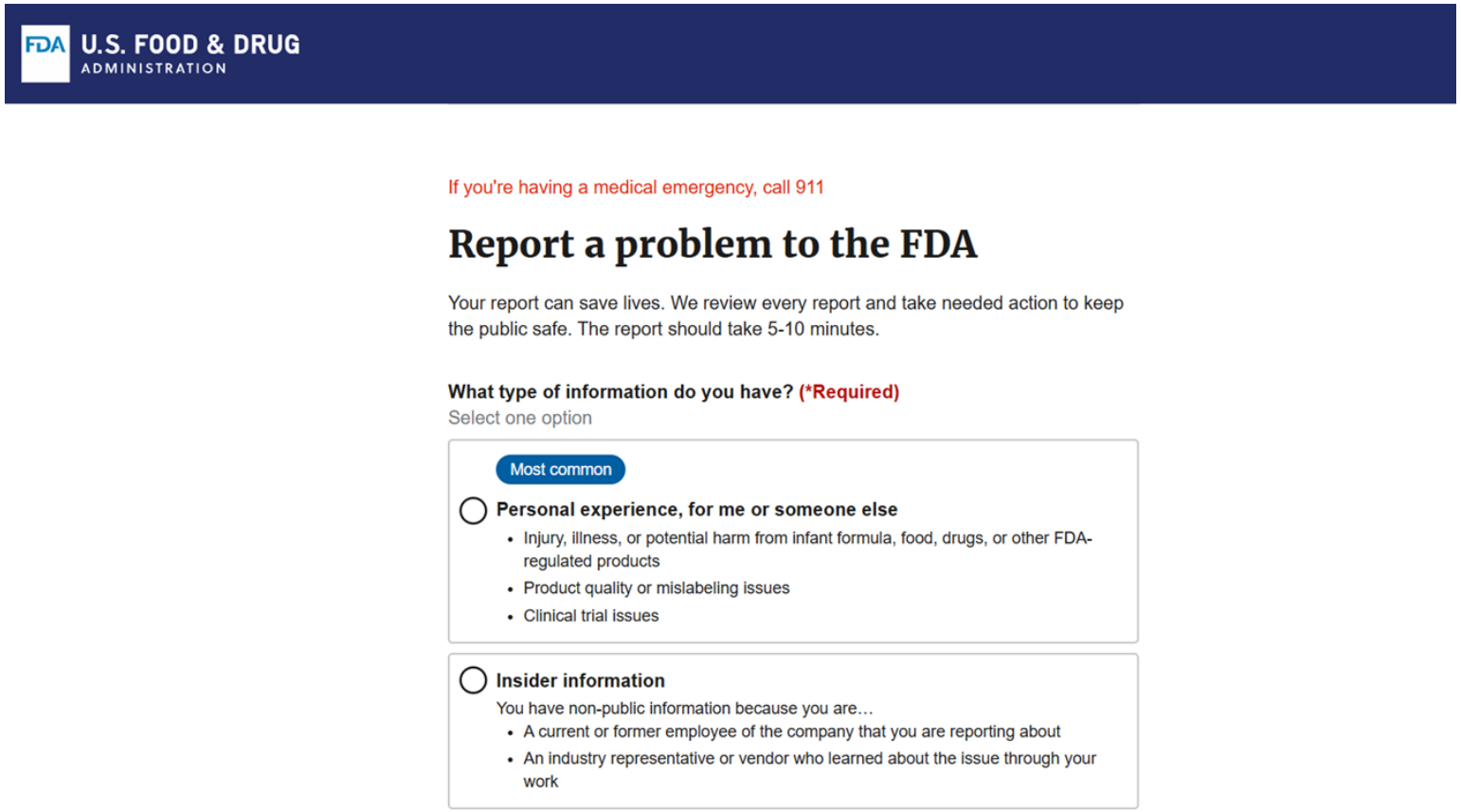
What does it mean?

- Faster safety signal detection through enhanced reporting from the public and more quickly routing to FDA experts.
- Easier reporting for patients, caregivers, and health professionals — submit reports in minutes from any device.
- Multilingual access ensures non-English-speaking families can also have their voice heard.
- May be quickly updated to direct the correct reporting pathway of a safety event of interest such as the baby wipes recall.

‘Report a Problem: https://contact.fda.gov/report-problem?utm_medium=referral&utm_source=fda_gov_homepage

‘Report a Problem’ to FDA Page

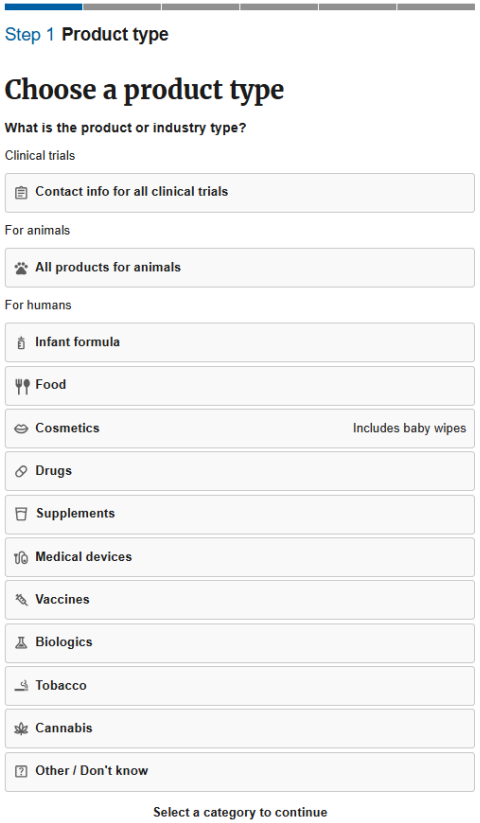
New Centralized Reporting Portal



‘Report a Problem: https://contact.fda.gov/report-problem?utm_medium=referral&utm_source=fda_gov_homepage

‘Report a Problem’ to FDA Page

New Centralized Reporting Portal



‘Report a Problem: https://contact.fda.gov/report-problem?utm_medium=referral&utm_source=fda_gov_homepage



Questions

Pediatric Advisory Committee Meeting

September 16, 2026

Open Public Hearing

All OPH Speakers, please sign in by sending an email to
PAC@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

This speaker is not affiliated with the FDA. The views expressed are those of the speaker, have not been evaluated for accuracy and do not necessarily reflect the positions of the FDA.

Open Public Hearing

Speaker #1

U.S. FOOD & DRUG ADMINISTRATION

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Open Public Hearing

Speaker #2

U.S. FOOD & DRUG ADMINISTRATION

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Open Public Hearing

Speaker #3

U.S. FOOD & DRUG ADMINISTRATION

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Lunch

Meeting will resume at 1:00 pm ET

Pediatric Advisory Committee Meeting

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Center for Drug Evaluation and Research (CDER)

Ivone Kim, MD

Center for Drug Evaluation and Research

1. Aranesp (darbepoetin alfa)

2. Dalvance (dalbavancin)

3. Fragmin (dalteparin sodium)

4. Isopto Atropine (atropine sulfate)

5. Kloxxado nasal spray, Zimhi injection, Naloxone Hydrochloride Autoinjector, Naloxone hydrochloride nasal spray, RiVive nasal spray, Rezenopy nasal spray (naloxone hydrochloride)

6. Lymphoseek (technetium Tc 99m tilmanocept)

7. Nextstellis (drospirenone/estetrol)

Center for Drug Evaluation and Research

8. Sprycel (dasatinib)

9. Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate)

10. Tecentriq (atezolizumab)

11. Veklury (remdesivir)

12. Vemlidy (tenofovir alafenamide)

13. Zelsuvmi (berdazimer)

14. Zevtera (ceftobiprole medocaril sodium)

15. Zinplava (bezlotoxumab)

Sprycel (Dasatinib)

- DPV identified a newly identified safety signal (NISS) for a potential drug-drug interaction (DDI) between dasatinib and methotrexate (MTX)
- A NISS assessment for the potential DDI between dasatinib and MTX is currently underway*
- FDA will determine what, if any, actions are appropriate after a thorough review of available data

* https://www.fda.gov/drugs/fda-adverse-event-monitoring-system-aems/october-december-2024-new-safety-information-or-potential-signals-serious-risks-identified-fda

Clarifying Questions

Voting Question and Meaning of Responses

FDA did not identify new safety signals in 14 of the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee (excluding Sprycel). As such for these 14 CDER products, FDA recommends continuing routine, ongoing postmarket safety monitoring.

Does the Pediatric Advisory Committee concur?

- Yes – the pediatric adverse event reports have not identified a new potential safety signal and routine ongoing postmarket monitoring should continue
- No – the pediatric adverse event reports have identified a new potential safety signal and additional evaluation/surveillance should be considered to evaluate this signal, in addition to routine safety monitoring
- Abstain – insufficient information to make a yes/no decision
- Recused – cannot vote due to conflicts of interest

Sprycel Voting Question and Meaning of Responses

FDA identified a new safety signal in the pediatric-focused postmarketing safety review for Sprycel. As such, FDA is conducting additional evaluation surveillance.

Does the Pediatric Advisory Committee support our further investigation of this product?

- Yes – the pediatric adverse event reports have identified a new potential safety signal and further investigation is warranted
- No – additional investigation is not necessary
- Abstain – insufficient information to make a yes/no decision
- Recused – cannot vote due to conflicts of interest

Committee Voting in Progress

Pediatric Advisory Committee Meeting

September 16, 2026

Center for Devices and Radiological Health

Douglas Silverstein, MD

Center for Devices and Radiological Health

1. Enterra Therapy System (Humanitarian Device Exemption (HDE))
2. Liposorber LA-15 System (HDE)
3. Medtronic Activa Neurostimulator for Dystonia Treatment (HDE)

Final PAC presentation. HDE withdrawn and device currently marketed under PMA P960009

4. Medtronic Contegra Pulmonary Valved Conduit (HDE)
5. Minimally Invasive Deformity Correction (MID-C) System (HDE)
6. nAbCyte Anti-AAVRh74var HB-FE Assay (HDE)

Device specifically for use with biologic, BEQVEZ™ (fidanacogene elaparvovec), which was withdrawn from the market before human use occurred; no Executive Summary will be presented

7. Pleximmune (HDE)
8. Reflect Scoliosis Correction System (HDE)
9. Sonalleve MR-HIFU (HDE)
10. The Tether – Vertebral Body Tethering System (HDE)

Clarifying Questions

Voting Question and Meaning of Responses

FDA did not identify new safety signals in the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee. As such, FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CDRH products under discussion.

Does the Pediatric Advisory Committee concur?

- Yes – the pediatric adverse event reports have not identified a new potential safety signal and routine ongoing postmarket monitoring should continue
- No – the pediatric adverse event reports have identified a new potential safety signal and additional evaluation/surveillance should be considered to evaluate this signal, in addition to routine safety monitoring
- Abstain – insufficient information to make a yes/no decision
- Recused – cannot vote due to conflicts of interest

Committee Voting
in Progress

Pediatric Advisory Committee Meeting

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Center for Biologics Evaluation and Research

Brendan Day, MD, MPH

Center for Biologics Evaluation and Research

1. Epicel (cultured epidermal autografts) (HDE*)
2. Quelimmune (HDE)

*Humanitarian Device Exemption

Clarifying Questions

Voting Question and Meaning of Responses

FDA did not identify new safety signals in the pediatric-focused postmarketing safety reviews conducted for the Pediatric Advisory Committee. As such, FDA recommends continuing routine, ongoing postmarket safety monitoring of each of the CBER products under discussion.

Does the Pediatric Advisory Committee concur?

- Yes – the pediatric adverse event reports have not identified a new potential safety signal and routine ongoing postmarket monitoring should continue
- No – the pediatric adverse event reports have identified a new potential safety signal and additional evaluation/surveillance should be considered to evaluate this signal, in addition to routine safety monitoring
- Abstain – insufficient information to make a yes/no decision
- Recused – cannot vote due to conflicts of interest

Committee Voting
in Progress

Wrap-Up

Adjournment