

Interested Parties Meeting: Implementation of the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA)

AGENDA

September 15, 2025

9:00 – 9:20 am Welcome and Opening Remarks

Dionna Green, MD

U.S. Food and Drug Administration (FDA)

9:20 – 10:20 am Session One: Interested Parties Comments

American Academy of Pediatrics (AAP)

Anjali Deshmukh, MD

International Children's Advisory Network (iCAN)

Leanne West, MS

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Aaron Pawlyk, PhD

National Organization for Rare Disorders (NORD)

Pamela Gavin, MBA

Pediatric Pharmacy Association (PPA)

M. Petrea Cober, PharmD and Rachel Meyers, PharmD

10:20 – 10:40 am Break

10:40 – 11:40 am Session Two: Interested Parties Comments

Consumer Healthcare Products Association (CHPA)

Cathy K. Gelotte, PhD

Harvard-MIT Center for Regulatory Science

Florence Bourgeois, MD, MPH

Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard

Danny Benjamin, MD, PhD

Pediatric Patient Representatives (iCAN)

Pediatric Trials Network (PTN)

Rachel G. Greenberg, MD, MB, MHS

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11:40 – 12:15 pm Session Three: Interested Parties Comments

AbbVie

David Horton, PhD and Anne Martin Robinson, Pharm D

Otsuka Pharmaceutical Development & Commercialization

Michaela Schultz, PhD and Aditi Shah, MBS

Pharmaceutical Research and Manufacturers of America (PhRMA)

Eeshan Khandekar, MSc

12:15 – 1:15 pm Lunch

1:15 – 2:10 pm Session Four: Interested Parties Comments

Hope for HIE

Betsy Pilon

International Neonatal Consortium (INC)

Kanwaljit Singh, MD, MPH, MBA

Neonatal Research Network (NRN)

Augusto Schmidt, MD, PhD

Preemie World

Deborah Discenza, MA

2:10 – 2:50 pm Session Five: Interested Parties Comments

Children's Oncology Group (COG)

Elizabeth Fox, MD

National Cancer Institute (NCI)

Malcolm Smith, MD, PhD

Kids v. Cancer

Nancy Goodman, JD

2:50 – 3:15 pm Break

3:15 – 4:15 pm Open to Public for Comments

4:15 – 4:30 pm Closing