

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

AGENDA

September 15, 2025

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

Dionna Green, MD
<i>U.S. Food and Drug Administration (FDA)</i> |
| 9:20 – 10:20 am | Session One: Interested Parties Comments

American Academy of Pediatrics (AAP)
<i>Anjali Deshmukh, MD</i>

International Children’s Advisory Network (iCAN)
<i>Leanne West, MS</i>

<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human
Development (NICHD)
<i>Aaron Pawlyk, PhD</i>

National Organization for Rare Disorders (NORD)
<i>Pamela Gavin, MBA</i>

Pediatric Pharmacy Association (PPA)
<i>M. Petrea Cober, PharmD and Rachel Meyers, PharmD</i> |
| 10:20 – 10:40 am | Break |
| 10:40 – 11:40 am | Session Two: Interested Parties Comments

Consumer Healthcare Products Association (CHPA)
<i>Cathy K. Gelotte, PhD</i>

Harvard-MIT Center for Regulatory Science
<i>Florence Bourgeois, MD, MPH</i>

Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's
Hospital and Harvard
<i>Danny Benjamin, MD, PhD</i>

Pediatric Patient Representatives (iCAN)

Pediatric Trials Network (PTN)
<i>Rachel G. Greenberg, MD, MB, MHS</i> |

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11:40 – 12:15 pm	Session Three: Interested Parties Comments AbbVie <i>David Horton, PhD and Anne Martin Robinson, Pharm D</i> Otsuka Pharmaceutical Development & Commercialization <i>Michaela Schultz, PhD and Aditi Shah, MBS</i> Pharmaceutical Research and Manufacturers of America (PhRMA) <i>Eeshan Khandekar, MSc</i>
12:15 – 1:15 pm	Lunch
1:15 – 2:10 pm	Session Four: Interested Parties Comments Hope for HIE <i>Betsy Pilon</i> International Neonatal Consortium (INC) <i>Kanwaljit Singh, MD, MPH, MBA</i> Neonatal Research Network (NRN) <i>Augusto Schmidt, MD, PhD</i> Preemie World <i>Deborah Discenza, MA</i>
2:10 – 2:50 pm	Session Five: Interested Parties Comments Children’s Oncology Group (COG) <i>Elizabeth Fox, MD</i> National Cancer Institute (NCI) <i>Malcolm Smith, MD, PhD</i> Kids v. Cancer <i>Nancy Goodman, JD</i>
2:50 – 3:15 pm	Break
3:15 – 4:15 pm	Open to Public for Comments
4:15 – 4:30 pm	Closing