

Committee on Developing a Framework to Address Legal, Ethical, Regulatory, and Policy Issues for Research Specific to Pregnant and Lactating Persons

Meeting #3



[CLICK HERE TO JOIN ZOOM MEETING](#)

Meeting ID
955 2870 2322
Passcode
943755

Phone Only
(301) 715-8592
(877) 853-5257

THURSDAY, JUNE 15, 2023

CLOSED SESSION – COMMITTEE MEMBERS ONLY

OPEN SESSION

10:15–11:15 Real World Data and Real World Evidence: Challenges and Opportunities Panel Discussion

AHIZECHUKWU EKE, *Moderator*
Director of Research, Division of Maternal-Fetal Medicine
Johns Hopkins University

Industry Registry Perspective

KRISTIN VELEY
Executive Director, Research Science
Epidemiology and Scientific Affairs, PPAS & RWE
PPD

Human Milk Biorespositories Perspective

TINA CHAMBERS
Professor of Pediatrics
University of California San Diego

FDA Perspective

TAMARA JOHNSON
Lead Medical Officer
Division of Pediatric and Maternal Health
FDA

Clinical Researcher Perspective

JONATHAN WATANABE
Associate Dean of Pharmacy Assessment and Quality
University of California Irvine

11:15–11:30 **Coffee Break**

11:30–12:15 **Discussion about Liability for Pregnant and Lactating Persons Exclusion**

LESLIE MELTZER-HENRY, *Moderator*
Professor of Law
University of Maryland

ALAN C. MILSTEIN
Shareholder & Chairman, Department of Litigation
Sherman, Silverstein, Kohl, Rose & Podolsky, P.A.

12:15–1:15 **LUNCH BREAK**

1:15–2:15 **Presentation on FDA Commissioned Paper**

JULIE TIBBETS
Partner
Goodwin Procter LLP

SARAH WICKS
Associate
Goodwin Procter LLP

2:15–2:30 **BREAK**

CLOSED SESSION – COMMITTEE MEMBERS ONLY

FRIDAY, JUNE 16, 2023

CLOSED SESSION – COMMITTEE MEMBERS ONLY

OPEN SESSION

11:30–12:00 **Product Liability Discussion**

BRUCE KUHLIK, *Moderator*
Former General Counsel
Merck & Co.

KIRKE WEAVER
General Counsel
Organon

CLOSED SESSION – COMMITTEE MEMBERS ONLY