NATIONAL ACADEMIES Sciences Engineering Medicine

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

Day One

Drug Development Inventive Programs: Experience with BPCA & PREA

Prabha Viswanathan, M.D.
Deputy Director, Office of Pediatric Therapeutics, Officer of the Commissioner, FDA

Dr. Prabha Viswanathan serves as Deputy Director of the Office of Pediatric Therapeutics (OPT), located in the Office of the Commissioner at the US Food and Drug Administration. OPT leads multiple cross-cutting programs across the FDA Centers, with the goal of giving children access to innovative, safe, and effective medical products and ensuring that the unique needs of pediatric patients are addressed throughout the lifecycle of product development. Dr. Viswanathan completed her undergraduate education in Biology and Art History at Duke University and received her medical degree from the University of Kansas School of Medicine. She completed a general pediatrics residency at Children's Hospital of Philadelphia and a pediatric infectious diseases fellowship at Children's National Hospital. Her areas of special interest include prevention and treatment of perinatal/neonatal infections, HIV, diseases affecting immunocompromised hosts, and viral respiratory illnesses. Her research portfolio centers on addressing knowledge gaps in rare pediatric diseases to promote drug development in areas of unmet medical need.

Perdita Taylor-Zapata, M.D.
Program Lead, BPCA Clinical Program, NICHD

Perdita Taylor-Zapata, M.D., is a board-certified pediatrician. She joined NICHD in 2004 as part of the Obstetric and Pediatric Pharmacology and Therapeutics Branch. She is currently the program lead for the NICHD's Best Pharmaceuticals for Children Act (BPCA) Clinical Program, a drug development program within NICHD that sponsors clinical trials to inform and improve pediatric drug labeling. Dr. Taylor-Zapata's research interests include improving pediatric inclusion in clinical trials, promoting training in pediatric clinical trial design and implementation, and increasing diversity in the field of pediatric clinical pharmacology.

Florence Bourgeois, M.D., M.P.H.
Co-Director, Harvard-MIT Center for Regulatory Science, Associate Professor of Pediatrics and Emergency Medicine, Harvard Medical School

Dr. Florence Bourgeois is Co-Director of the Harvard-MIT Center for Regulatory Science and Associate Professor of Pediatrics at Harvard Medical School. Her area of investigation focuses on applying clinical epidemiology and big data analytics to evaluate the regulation and use of medications in children and assess synthesis and integrity of clinical data to support evidence-based pediatric care. She is the Director of a Fellowship Program in Regulatory Science where she mentors students in interdisciplinary projects, including analysis of pharmaceutical development programs, prescription drug utilization, the impact of regulatory policies and incentive programs on drug and device development, and methodologies to augment postmarketing safety surveillance. At Boston Children's Hospital, Dr. Bourgeois is the Director of the Pediatric Therapeutics and Regulatory Science Initiative, which focuses on pediatric-specific drug policy and regulation and methods

to advance evidence-based use of therapeutics in children. She has served as an Expert Visitor at the European Medicines Agency, where she led an evaluation of the implementation of the EUs Pediatric Regulation and its impact on increasing pediatric drug research and product labeling. Dr. Bourgeois is a graduate of Yale University and Washington University School of Medicine in St. Louis. She completed her residency training in pediatrics and fellowship in pediatric emergency medicine, both at Boston Children's Hospital. She was a NRSA research fellow and obtained a Master in Public Health in clinical effectiveness at the Harvard School of Public Health.