Opening remarks: Kaveeta Vasisht

Kaveeta P. Vasisht, MD, PharmD is Associate Commissioner for Women's Health and the Director of the Office of Women's Health (OWH) in the Office of the Commissioner of the US Food and Drug Administration (FDA). Under her leadership, OWH works to protect and advance the health of women through policy development, scientific programs, education, stakeholder collaboration, and outreach. She serves as the principal advisor to the Commissioner and the Agency on scientific and policy issues relating to the health of women. Dr. Vasisht is double board-certified in both internal medicine and adult endocrinology and holds a Doctor of Pharmacy degree. She completed her internal medicine and endocrinology fellowship training at the University of Chicago Hospitals, where she also served on the faculty.

MC: Xiaobin Wang

Xiaobin Wang, MD, ScD, MPH is a board-certified pediatrician, maternal and child health researcher, and molecular epidemiologist. She directs the Center on Early Life Origins of Disease. Dr. Wang and her team have established three large study cohorts (Boston Birth Cohort, Chicago Family-based Cohort, and Chinese Twin Cohort). Along with extensive epidemiological and clinical data as well as related biorepositories, these cohorts are well-designed for studying a broad range of health and disease outcomes and early life precursors of pediatric and adult diseases. Dr. Wang received her MD from Beijing Medical University in Beijing, China, and a master of public health from the School of Public Health and Tropical Medicine at Tulane University in New Orleans. She also received a doctor of science degree from the Department of Maternal and Child Health at the Johns Hopkins University School of Hygiene and Public Health in Baltimore. She completed a three-year research fellowship in Environmental Epidemiology at the Harvard University School of Public Health and a residency in pediatrics at the Boston University Medical Center.

SESSION 1: Understanding the impact of data gaps for medication use during pregnancy and lactation

Catherine Sewell

Catherine Sewell, MD is currently the Acting Deputy Director and is the Deputy Director for Safety in the Division of Urology, Obstetrics and Gynecology as well as co-chair of the Drug Safety Team for Pediatrics, Rare Diseases, Obstetrics, Gynecology, Urology and Maternal Health at the US FDA. In these roles she provides leadership and technical direction to pre-market scientific review staff engaged in the evaluation of Investigational New Drug Applications (INDs) and NDA/BLA applications; provides scientific, clinical, and technical authority on all medical and scientific decisions and judgment in connection with the review and evaluation of drugs. She also advances OND's policies, research agenda, training, and collaboration across other divisions, offices and stakeholders, creation of Division level plans to meet these goals.
She further coordinates processes that span the Division's post-marketing safety activities including overseeing the development, tracking, and follow up of safety studies and clinical trials, safety labeling changes and Risk Evaluation and Mitigation Strategies (REMS) for approved drugs. Dr. Sewell is part of the process modernization effort at the FDA, aiming to improve the mechanisms for monitoring and evaluating premarket and postmarket safety signals. Additionally, she liaises with other FDA offices and other regulatory agencies, industry, professional organizations, academia, and the public. In prior roles at FDA she was a clinical reviewer and acting clinical team leader.

Kristin Darwin

Kristin Darwin, MD is a Maternal-Fetal Medicine Clinical Fellow at Johns Hopkins University. After receiving her undergraduate degree from Yale University, she attended Johns Hopkins for medical school and for OB/GYN residency. She will be giving a patient perspective during this panel, and is a mom to a spirited 18 month-old named Camille.

Irina Burd

Irina Burd, MD, PhD is a professor in the Johns Hopkins Medicine Department of Gynecology and Obstetrics. She holds a joint appointment in the Department of Neurology, where she also serves as professor. Her areas of clinical expertise include high-risk pregnancy conditions and fetal brain development. Dr. Burd was recruited to Johns Hopkins Medicine to spearhead the development of the field of fetal neurology. She is the founder and director of the Integrated Research Center for Fetal Medicine at the Johns Hopkins University School of Medicine and is the Director of the Fetal Neurosonology Program. Dr. Burd earned her undergraduate degree from Rutgers University. She completed the combined M.D./Ph.D. program at Rutgers University-Robert Wood Johnson Medical School. She completed her residency in obstetrics and gynecology at Thomas Jefferson University Hospital and performed a fellowship in maternal-fetal medicine at the University of Pennsylvania. Dr. Burd joined the Johns Hopkins faculty in 2011.

Sara Head

Sara Head, PhD, MPH is the Health Programs Coordinator in the FDA Office of Women's Health. In this role, she develops and assists OWH funding and research activities to protect and advance the health of women. Dr. Head received her PhD in Behavioral Science and Health Education from Emory University where she studied gender influences on health as well as sexual and reproductive health in the US and in international contexts. She is an alumna of CDC's Epidemic Intelligence Service and was previously with FDA's Center for Tobacco Products, HRSA's Maternal and Child Health Bureau, and USAID's Demographic and Health Surveys Program.

Christine Ladd Acosta

Christine Ladd-Acosta, PhD is an Associate Professor and Director of the genetics track in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health, with a joint appointment in Mental Health. She is also Associate Director for Genomics at the Wendy Klag Center for Autism and Developmental Disabilities and Associate Director for Epigenomic Analyses at the Environmental influences on Child Health Outcomes, Data Analysis Center (ECHO-DAC). Dr. Ladd-Acosta is cross-trained in "wet-lab" genomics/epigenomics and "dry lab" genetic epidemiology. Her research focuses on identifying risk factors for adverse health outcomes in pregnant women and children. To carry out this work, she has established productive working relationships with large research teams and collaborators including large US-based epidemiology studies (SEED, BBC, EARLI, ECHO) and international consortia (PGC, PACE, iPSYCH) and leads several funded active projects in this area.

SESSION 2: Regulatory Perspective on the Collection and Use of Real-World Data to Evaluate Medications During Pregnancy and Lactation

Susan Bersoff-Matcha

Susan Bersoff-Matcha, MD is the Deputy Director in the Office of Women's Health at FDA where she oversees the Office's scientific programs. Since coming to FDA in 2016, Dr. Matcha has worked in the Office of Medical Policy, and Office of Surveillance and Epidemiology. She has a longstanding interest on women's health and has published several peer-reviewed articles on this topic. Dr. Matcha attended Georgetown University School of Medicine, completed her internship and residency training at Emory University, and subspecialty fellowship training at Washington University School of Medicine, Division of Infectious Diseases in St. Louis, Missouri. Dr. Matcha is board certified in both Internal Medicine and Infectious Diseases.

Kenneth Quinto

LCDR Quinto is the Senior Medical Advisor in the Real World Evidence Analytics Staff in the Office of Medical Policy at FDA's Center for Drug Evaluation and Research. He oversees demonstration projects intended to support the agency's evaluation of real world evidence, evaluates real world evidence use cases, and contributes to medical policy development mandated by the 21st Century Cures Act. LCDR Quinto has held various positions at different US Department of Health and Human Services' agencies including as a medical officer at FDA's Office of Pediatric Therapeutics, a medical officer/claims analyst at the Centers for Medicare and Medicaid Services, an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention's National Center for Health Statistics while providing medical expertise in epidemiology, pediatrics, allergy and immunology, and analytical support. In 2012, LCDR Quinto was commissioned in the US Public Health Service and holds the rank of lieutenant commander. He completed his allergy and immunology fellowship and pediatric residency at the University of California, San Diego, earned his MD from the University of California, San Francisco, his MPH from University of California, Berkeley and his BS from the University of California, Los Angeles.

Leyla Sahin

Leyla Sahin, MD is an obstetrician-gynecologist who joined the FDA's Division of Pediatrics and Maternal Health (DPMH) in the Office of New Drugs, Center for Drug Evaluation and Research in 2008 following clinical practice for twelve years. She is currently serving as Acting Deputy Director for Safety, Maternal Health, for DPMH, and over the years has led various maternal health related scientific and regulatory/policy initiatives. She was a working group member on the HHS Task Force for Research Specific to Pregnant Women and Lactating Women (PRGLAC). The focus of her work involves advancing FDA's scientific and regulatory policies related to pregnancy and lactation, through all phases of drug development. Her principal area of interest is promoting the public health of pregnant and breastfeeding individuals through improved data collection.

Kira Leishear

Kira Leishear, PhD, MS serves as a Team Leader since 2017 in CDER's Office of Surveillance and Epidemiology, Office of Pharmacovigilance and Epidemiology, Division of Epidemiology I. Dr. Leishear joined the FDA in 2013 and has vast experience in numerous pregnancy safety studies, reviews, guidances, and working groups. Prior to working at the FDA, she worked as a biostatistician at the NIH (NICHD and NLM). Dr. Leishear received a PhD in Epidemiology and an MS in Biostatistics from the University of Pittsburgh.

Danijela Stojanovic

Danijela Stojanovic, PharmD, PhD is an epidemiologist on the Sentinel Program in the FDA's Office of Surveillance and Epidemiology. Her interests include maternal and pediatric health, signal identification methods, health disparities, and global health. She received her B.S. in Chemistry and a PharmD from the University of Texas in Austin and a PhD in pharmacoepidemiology from the University of Florida. Dr. Stojanovic is a Lieutenant Commander in the U.S. Public Health Service.

SESSION 3: Novel Application of RWD to Evaluate Medication Use in Pregnancy and Lactation

Ahizechukwu (Ahize) Eke

Ahizechukwu C Eke, M.B.B.Ch., M.P.H., is a specialist in maternal-fetal medicine with areas of clinical and research expertise in medical and surgical complications of pregnancy with a focus on prediction and prevention of preterm birth, pharmacokinetics, pharmacodynamics, pharmacoepidemiology, pharmacogenomics, pharmacomicrobiomics, maternal-fetal medicine, multiple pregnancies, obstetric ultrasound and HIV in pregnancy. Dr. Eke earned his undergraduate degree from Federal Government College, Wukari, Taraba State, Nigeria, and his medical degree from the College of Medicine, University of Calabar, Nigeria. He completed two obstetrics and gynecology residencies – at the Nnamdi Azikiwe University Teaching Hospital, Nigeria (2005-2010) and at Michigan State University/Sparrow hospital, which he completed in 2016, and then completed Maternal-Fetal Medicine and Clinical Pharmacology fellowships at the Johns Hopkins University School of Medicine in Baltimore, Maryland in 2019. He earned an MPH from the Harvard University School of Public Health in 2011, and a PhD in Clinical Investigation from the Johns Hopkins University School of Public Health Graduate Training Program in Clinical Investigation (GTPCI) in 2021. He is board certified in obstetrics and gynecology (OBGYN), maternal-fetal medicine (MFM) and Clinical Pharmacology. He joined the Johns Hopkins faculty in 2019.

Mili Duggal

Mili Duggal, PhD is a maternal and child health specialist who joined the CURE ID team in 2016. She has a PhD in global maternal and child health from the University of Maryland School of Public Health, and as MPH in global health from Tulane University. Dr. Duggal leads the Pregnancy and Neonatal sub-projects of the program and is excited to see the CURE platform expand to address these issues of substantial public health need. Dr. Duggal also provides critical support to many other aspects of the program.

Sonia Hernandez-Diaz

Sonia Hernandez-Diaz, MD, DrPH, MPH is Professor of Epidemiology and Director of the Pharmacoepidemiology Program at the Harvard T.H. Chan School of Public Health. Her area of interest is drug safety evaluation from non-randomized data, with a special emphasis on the design, conduct, and analysis of studies in pregnant women and their infants. She has experience developing and applying methods to case-control surveillance, ad hoc cohorts (pregnancy registries), and nested pregnancy cohorts within national and multinational healthcare databases. She is Past-President of both the International Society for Pharmacoepidemiology and the Society for Perinatal and Pediatric Epidemiology Research; and has served as a Special Government Employee for the FDA Drug Safety and Risk Management Advisory Committee, as a member of the NICHD Pregnancy & Neonatology (PN) Study Section, and as member of the Teratogenic Information Services (TERIS) Advisory Board.

Teresa Baker

Teresa Baker, MD is a Professor in the Department of Obstetrics and Gynecology at Texas Tech Health Sciences Center and co-director of the InfantRisk Center. Dr. Baker's graduated from the University of Texas Southwestern and completed her residency training at Parkland Health and Hospital System in Dallas, TX. Dr. Baker has a combined private and academic OB/GYN practice with the University Physicians at Texas Tech Health Sciences Center in Amarillo. She is interested in teen pregnancy, postpartum depression, and promoting preventive medicine for the women of the Texas Panhandle, as well as Resident and Student education and serves as the Residency Director.

Tina Chambers

Christina Chambers, PhD MPH is a Professor in the School of Medicine at UC San Diego. She is Co-Director of the Center for Better Beginnings, Program Director of MotherToBaby, and is Program Director of Mommy's Milk, a human milk biorepository for research. Dr. Chambers leads a number of national and international complex longitudinal cohort studies and clinical trials of prenatal exposures and child health and development. Her research has been instrumental in identifying previously unrecognized human teratogens, as well as ruling out substantial risk for medications and vaccines.