Optimizing Pregnancy Registries

University of Maryland Center of Excellence in Regulatory Science and Innovation
Food and Drug Administration

Public In-Person and Virtual Workshop
May 7-8, 2026 | 9:00 AM – 4:15 PM Eastern Time

Biographies

Jessica Albano, PhD, MPH
Head
EPIphany Real-World Research

Dr. Jessica Albano is Head of EPIphany Real-World Research, a pharmacoepidemiology consultancy specializing in the generation of real-world evidence with a focus on late-phase research and maternal/infant health, providing scientific and strategic guidance to clients on study design, safety surveillance, and regulatory decision making.

She holds a biochemistry degree from Earlham College, MPH from Emory University, and PhD in Epidemiology from the University of Pittsburgh and conducted research as an epidemiologist with the American Cancer Society and the University of Pittsburgh Cancer Institute. Her work as a pharmacoepidemiologist over the past 18 years has focused on evaluating the safety of drugs in the post-approval setting utilizing non-interventional research methods including prospective and retrospective study designs and primary and secondary data sources. Jessica oversaw the delivery of two-dozen pregnancy registries including single-drug, multi-drug, multi-sponsor and REMS models, presented at NIH and FDA sponsored pregnancy methods workshops, and authored a book chapter on the topic.

Dr. Albano was Primary Investigator for the Antiretroviral Pregnancy Registry (APR) from 2009-2025 and currently serves as Pharmacoepidemiology Consultant and Advisory Committee member. The APR is an international collaborative pregnancy exposure registry and FDA postmarketing requirement that has been ongoing since 1989. She plays a key role in the analysis and interpretation of APR data, promoting awareness of the registry and disseminating study results to the HIV treating community.

Kavita Shah Arora, MD, MBE, MS
Professor, Division Director for General Obstetrics, Gynecology, and Midwifery
University of North Carolina-Chapel Hill

Dr. Kavita Shah Arora is a Professor and the Division Director for General Obstetrics, Gynecology, and Midwifery at the University of North Carolina – Chapel Hill. She currently serves on the national board of directors for the American College of Obstetricians and Gynecologists and the Council on Science and Public Health for the American Medical Association. She has served as the Greenwall Fellow in Bioethics for the National Academy of Medicine, Chair of the national ethics committee of the American College of Obstetricians and Gynecologists, on the national ethics committee of the American Medical Association, on the Board of Directors of the American Society for Bioethics and the Humanities, and on the Governing Council for the Young Physicians Section of the American Medical Association.

She has authored over 150 peer-reviewed publications and has been funded by the NIH, HRSA, Greenwall Foundation, and Society for Family Planning. She was named a 40 under 40 leader in minority health by the National Minority Quality Forum and was awarded the Presidential Early Career Award for Scientists and Engineers by President Biden.

Dr. Arora received her BS with a minor in Philosophy from the Pennsylvania State University. In 2009, she graduated with both an MD from Jefferson Medical College and a Master in Bioethics from the University of Pennsylvania. She completed her residency in Obstetrics and Gynecology at Northwestern Memorial Hospital. She subsequently completed a Master in Science of Clinical Research at Case Western Reserve University.

Christina Chambers, PhD, MPH
Professor, Department of Pediatrics
Chief, Division of Environmental Science and Health
Director, Center for Better Beginnings
Associate Director, Altman Clinical & Translational Research Institute
UC San Diego

Dr. Christina Chambers is a Professor in the Department of Pediatrics, School of Medicine at UC San Diego. She is Chief of the Division of Environmental Science and Health, and Director of the Center for Better Beginnings. She is the principal investigator of MotherToBaby Pregnancy Studies, and the UC San Diego Human Milk Research Biorepository, two nation-wide longitudinal cohort studies focused on the safety of medications, vaccines, substances, infectious agents, and other environmental exposures in pregnancy and lactation. Dr. Chambers co-directs the HEALthy Brain and Child Development Study (HBCD), a nationwide research initiative focused on developmental trajectories of more than 5,000 children in various environments from prenatal life through 10 years of age. In addition, Dr. Chambers leads research and educational initiatives in the U.S. and internationally on the prevention and treatment of children with Fetal Alcohol Spectrum Disorders. She co-directs the Center for Collaboration, Engagement, Dissemination and Implementation n the Clinical and Translational Research Institute at UC San Diego which supports clinical research development in diverse populations.

Megan E. B. Clowse, MD, MPH
Professor of Medicine, Population Health Sciences, and OB/GYN
Duke University School of Medicine

Dr. Megan E. B. Clowse is an international leader in the study and management of rheumatic diseases in pregnancy. She received her medical degree from Vanderbilt Medical School, followed by residency and fellowship at Johns Hopkins. She joined the faculty of Duke University in 2005 and became the chief of their Division of Rheumatology & Immunology in 2023. She has cared for over 1000 pregnancies in women with rheumatic disease since initiating her prospective pregnancy registries in 2008. She was on the Core Leadership team for the American College of Rheumatology Reproductive Health Guidelines. Through quantitative and qualitative work, she identified that enhancing rheumatologists' knowledge and communication skills in reproductive health could be key targets to improve pregnancy outcomes. Towards this end, she has created and is testing an in-clinic intervention and program to enable rheumatologists to provide effective pregnancy planning and management to women with lupus (LupusPregnancy.org) and rheumatic disease (ReproRheum.Duke.edu).

Lee S. Cohen, MD
Director, Ammon-Pinizzotto Center for Women's Mental Health
Associate Chief of Psychiatry for Philanthropy and Departmental Communications, Massachusetts General Hospital
Edmund and Carroll Carpenter Professor of Psychiatry, Harvard Medical School

Dr. Lee Cohen is Director of the Ammon-Pinizzotto Center for Women's Mental Health, and Associate Chief of Psychiatry for Philanthropy and Departmental Communications at Massachusetts General Hospital and the Edmund and Carroll Carpenter Professor of Psychiatry at Harvard Medical School. He is a national and international leader in the field of women's mental health and was among the founders of the field of perinatal and reproductive psychiatry. His work spans the domains of research, teaching and clinical care in the area of treatment of mood and anxiety disorders with subspecialty interest in psychiatric disorders associated with female reproductive function. These include psychiatric disorders during pregnancy and the post-partum period, depression in midlife women and issues related to infertility and mental health. The research which he conducts and oversees has helped to inform the care of patients who suffer from psychiatric illness.

Dr. Cohen received his undergraduate degree from the University of Michigan in Ann Arbor and his medical degree from Albany Medical College. He completed his residency in psychiatry at MGH. After residency, Dr. Cohen completed a fellowship in psychopharmacology with a specific emphasis in reproductive pharmacology, and then founded the Center for Women's Mental Health at MGH. The program has expanded over the last two decades and now includes junior and senior faculty, research fellows, and residents from the psychiatry residency training program at the MGH. (See www.womensmentalhealth.org)

Dr. Cohen has authored or coauthored more than 350 articles, abstracts, and book chapters. His articles have been published in leading medical journals, including *American Journal of Psychiatry*, *Journal of the American Medical Association*, and *JAMA Psychiatry*. His publication on risk of using antidepressants during pregnancy received the Clinical Research Achievement Award which recognizes the top ten most informative research papers in the year's scientific literature. Dr. Cohen has been and continues to be funded by the National Institutes of Health (NIH) and other funding agencies and has mentored numerous junior faculty. He has received many awards, including the Outstanding Achievement Award for Research from the Massachusetts Psychiatric Society and the Mentorship Award for Exceptional Mentorship of Women Faculty from the Department of Psychiatry at MGH. He received the Barger Award for Mentorship from Harvard Medical School recognizing his sustained mentorship of the next generation of clinician scientists. Most recently, he received the John T. Potts, Jr., MD, Faculty Mentoring Award at the Mass General . This award was created to recognize and honor senior faculty members at MGH, in the spirit of further building a culture of mentoring. At the national level, Dr. Cohen has served on the Advisory Council to the Office of Research in Women's Health at the National Institute of Health. This office sets the agenda for research in women's health across the NIH. He has also served as the co-chair of the Reproductive Mental Health Initiative within the Office of Reproductive Health at the Department of Veterans Affairs and on the Reproductive Health Working Group at the World Health Organization. Dr. Cohen was also appointed by Governor Deval Patrick of Massachusetts to serve on the Story Commission on Postpartum Depression which sets the standards for screening and treatment of postpartum depression for women in Massachusetts.

Kourtney Davis, PhD, MSPH, FISPE
VP and Head, Global Epidemiology, Office of the Chief Medical Officer
Janssen R&D LLC, Johnson & Johnson (J&J)

Dr. Kourtney Davis is Vice President and Head, Global Epidemiology (Innovative Medicine), Office of the Chief Medical Officer at J&J, where she leads global and regional epidemiology and benefit–risk–focused teams delivering fit-for-purpose evidence to inform safety and benefit–risk decision making from R&D through to post-approval lifecycle management. She serves on the J&J Innovative Medicine R&D Development Committee and spearheaded the development of and co-chairs the J&J Pregnancy and Lactation Advisory Group (JJ-PAL), a cross-functional matrix of experts across 13 disciplines dedicated to advancing evidence on the safe use of medicines during pregnancy and lactation. She currently is serving as the PhRMA Deputy Lead for the ICH E23 Expert Working Group on Considerations for the Use of Real-World Evidence (RWE) to Inform Regulatory Decision Making with a focus on Effectiveness of Medicines. Prior to joining J&J in 2018, she spent nearly 20 years in the pharmaceutical industry leading Global Epidemiology and Real World Data & Analytics teams. She holds an MSPH and PhD in epidemiology from the University of North Carolina at Chapel Hill Gillings School of Public Health, is a Fellow of the International Society of Pharmacoepidemiology, and has extensive experience collaborating globally to advance regulatory-grade real-world evidence capabilities, including point-of-care pragmatic trials, external control methods, and novel platforms for assessing medication use in pregnancy and lactation.

Sonia Hernandez-Diaz, MD, DrPH
Professor of Epidemiology
Harvard T.H. Chan School of Public Health

Dr. Sonia Hernández-Díaz is a Professor of Epidemiology at the Harvard T.H. Chan School of Public Health, where she serves as Director of the Pharmacoepidemiology & Real World Evidence (RWE) Program. Her research focuses on examining drug safety during pregnancy using primary and secondary observational data. She has experience with case-control surveillance studies, pregnancy registries, and pregnancy cohorts nested within healthcare utilization data. Another group of research activities concerns the application of innovative methodologic concepts to increase efficiency and the validity of observational studies. In recent projects her team has emulated hypothetical target trials to evaluate medications and vaccines in pregnancy.

Tania Nayak Kamphaus, PhD
Associate Vice President, Science Partnership; Director, FNIH Patient Engagement
Foundation for the NIH, Bethesda, MD

Dr. Tania Kamphaus serves in the dual role of leading FNIH Patient Engagement efforts and providing oversight to the several programs within FNIH's Metabolic Disorders, Women's Health and Inflammation and Immunity portfolios. In her role as FNIH's Patient Engagement lead, she is responsible for establishing best practices for engaging patient voices for meaningful, end-to-end patient involvement in FNIH programs. Within Science Partnerships, she is responsible for developing multi-stakeholder public-private partnerships that include stakeholders from NIH, FDA, non-profits and life sciences companies. Dr. Kamphaus oversees three target validation programs within Accelerating Medicines Partnerships (AMP) programs in areas of Common Metabolic Diseases, Heart Failure, and Immune and Autoimmune Diseases. She also oversees projects including biomarker qualification efforts in liver diseases, pre-eclampsia, osteoporosis, and emerging programs in reproductive health. Dr. Kamphaus is trained in molecular genetics and cell biology and skilled in strategic planning and collaborative program development across basic, translational and patient-centric clinical research. Dr. Kamphaus conducted her postdoctoral fellowship at Columbia University. She has a PhD in Molecular Genetics from The Ohio State University.

Danica Marinac-Dabic, MD, PhD, MMSc, FISPE
Associate Director for Scientific Partnerships
OCEA, OPEQ, CDRH, FDA

Dr. Danica Marinac-Dabic serves as the Associate Director at the Office of Clinical Evidence and Analysis, at the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), leading the development and application of novel methods for real-world evidence and active surveillance, and collaborative efforts to advance interoperability of diverse data sources to study health technologies. Prior to this position, she was the Director of the CDRH Division of Epidemiology. Prior to coming to FDA, Dr. Marinac-Dabic garnered experience in obstetrics, gynecology, and epidemiology in the academic and hospital settings as well as teaching experience in academic environment.

Under her leadership, FDA launched Medical Device Epidemiology Network (MDEpiNet) to advance national/international infrastructure and test innovative methods to study devices throughout their life cycle. She led a large international group of experts at the International Medical Device Regulators Forum (IMDRF) to develop series of essential principles for international convergence of registry-generated data. She has been spearheading the interoperable strategically Coordinated Registry Networks via ecosystem partnership in multiple clinical areas by linking registries to medical claims, EHRs and patient generated health data. Her collaborative work includes over 125 registries across 45 countries, development of international registry consortia while advancing interoperability.

Dr. Marinac-Dabic was inducted as a Fellow of the International Society of Pharmaco-epidemiology and Therapeutic Risk Management (ISPE). She published over 100 scientific papers, serves on the steering committees of several national registries and consortia, Editorial Board of BMJ-SIT Journal, and holds an Adjunct Professor position at several academic institutions.

Gregory Pappas, MD, PhD
Associate Director for National Surveillance
OBP V, CBER, FDA

Evaluation and Safety System (BEST) through innovative partnerships, a real-world evidence approaches to generation of evidence, including the including of national specialty society registries. Dr. Gregory Pappas is on the Sentinel Executive Committee, the CDER RWE Workgroup for Registries, and the Executive Board of MDEpiNet. Dr. Pappas had also played a leadership role in establishment of NEST (National Evaluation System for health Technology), for CDRH (Center for Devices and Radiological Health) working with broad set of stakeholders including other government agencies (ONC, CMS, NIH, AHRQ), industry, researchers, patient groups, clinical specialty societies and their registries.

Before coming to FDA, Dr. Pappas directed the HIV/AIDS, Hepatitis, STD, and TB Administration for the District of Columbia, Department of Health. He has worked in over 30 countries with WHO, USAID, and CDC. He served a Professor and Chairman, Department of Community Health Sciences Aga Khan University. He was an author of the PEPFAR Five Year Plan. He served as Senior Policy Advisor to the Assistant Secretary for Health/Surgeon General, David Satcher. He directed the Office of International and Refugee Health, HHS, serving on the Executive Board of UNICEF and PAHO, and as a delegate to the World Health Assembly. Dr. Pappas received his MD and PhD (Anthropology) from Case Western Reserve in Cleveland, Ohio. He came to Washington DC, for a fellowship in Epidemiology, then as a scientist at NCHS/CDC. He is author of numerous articles, including his work in the NEJM “The increasing disparity in mortality between socioeconomic groups in the United States “and his book with Cornell University Press, “The Magic City: unemployment in a working class community.” He has served on the faculty of the Bloomberg School of Public Health, the GW School of Public Health, and Howard Medical School. Dr. Pappas was a member of the Executive Board of the American Public Health Association. His Megacities and Global Health (APHA Press 2012) with Omar Khan. Dr. Pappas has work in over 30 countries. Dr. Pappas's full CV can be viewed at https://sites.google.com/site/gregorypappasmdphd/

Aaron C. Pawlyk, PhD
Chief, Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)
Eunice Kennedy Shriver National Institue of Child Health and Human Development (NICHD)

Dr. Aaron C. Pawlyk is Chief of the Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB) in the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)'s Division of Extramural Research. OPPTB supports research and training to advance the safe and effective development and use of therapeutics for pregnant women, lactating women, and children, with an emphasis on clinical pharmacology to improve dosing, safety, and effectiveness.

Since joining NICHD as Branch Chief in August 2019, Dr. Pawlyk has led OPPTB's national extramural portfolio. He established a five-year strategic plan, expanded intra-NIH and cross-agency collaboration, and advanced data-driven recommendations to strengthen NICHD's research direction. He oversees funding mechanisms—including grants, cooperative agreements, contracts, and OTAs—and leads work at the science–policy interface, supporting activities under the Best Pharmaceuticals for Children Act (BPCA) and guiding PRGLAC follow-up and implementation, including a National Academies study on legal, ethical, and regulatory policy issues for research involving pregnant and lactating women.

Dr. Pawlyk has prioritized strengthening quantitative clinical pharmacology to close evidence gaps. Under his leadership, OPPTB envisioned the Maternal and Pediatric pRecisioN in Therapeutics (MPRINT) Hub, a national resource spanning quantitative systems pharmacology, pharmacometrics, and tool development. He also developed initiatives focused on mechanisms driving maternal–fetal and pediatric exposure and response across organ systems. In his role as the NIH point of contact for pediatric medical devices, he led OPPTB in launching a design-phase public–private partnership in pediatric medical device innovation via the Foundation for the NIH, in coordination with FDA and BARDA.

Dr. Pawlyk earned a BA in Biochemistry and Biology at the University of Pennsylvania and a PhD in Biochemistry at Texas A&M University, with training in enzymology and allosteric regulation. Prior to NIH, he built expertise in women's health and biomarker-informed product development at Wyeth and gained experience at Redpoint Bio in how excipients and palatability can affect use in children. Earlier NIH leadership at NIDDK strengthened his focus on data and knowledge resources and translational programs, including coordination of the Common Fund's Illuminating the Druggable Genome (IDG) program and stewardship of large-scale initiatives coupling multi-omics data and phenotypes to accelerate target discovery and therapeutic translation. He has authored 37 peer-reviewed publications and is recognized for building multidisciplinary teams and national-scale resources that connect mechanism, modeling, biomarkers, and implementation.

Carla Rodriguez-Watson, PhD, MPH
Director of Research
Reagan-Udall Foundation

Dr. Carla Rodriguez-Watson is the Director of Research for the Reagan-Udall Foundation for the FDA. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA.

Carla is focused on continuously developing and enhancing a portfolio of work that leverages real-world data and experiences to inform and conduct clinical and post-market medical product safety and effectiveness studies to address unmet need and improve population health. An epidemiologist by training, she brings 30 years of experience in public health informatics, surveillance and outbreak investigation; and environmental health, pharmacoepidemiology and health outcomes research to support the diverse scope of the Foundation. Moreover, her years in public health research and surveillance have underscored that the best science is team science.

Prior to her role at the Foundation, Carla's research focus was in clinical epidemiology. As a researcher at Kaiser-Permanente (2013-2019), she had the privilege to work with colleagues across many disciplines with premier real-world data (RWD) from an integrated care-delivery/insurance health system. Her work in infectious diseases was awarded the 2018 James A. Voh's Regional Quality Award and the Claudette Gravell award for excellence in HCV/HIV research. As a biostatistician with the Centers for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS) at the University of Washington (2011-2013), she and her colleagues addressed many challenges of using RWD to understand treatment patterns and health outcomes in patients with HIV, HBV, and HCV.

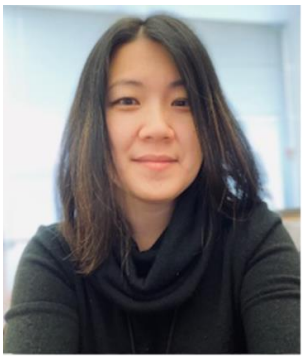
Carla's passion for public health took root over the decade she spent in outbreak investigation and developing, enhancing, and evaluating active and passive surveillance systems for the New York City Department of Health and Mental Hygiene (DOHMH), the San Francisco Department of Public Health, and Seattle-King County Public Health (1998-2009). Dr. Rodriguez-Watson was part of the team that developed the first electronically integrated vital statistics, lead, and immunization registry for the NYC DOHMH. Her work to further develop and evaluate signals generated by syndromic surveillance systems was the driving force behind her doctoral research, for which she received a CDC dissertation grant award.

Carla earned her PhD in Epidemiology from the University of Washington School of Public Health, her MPH from Columbia University Mailman School of Public Health, and her BA from Rutgers University.

Leyla Sahin, MD
Deputy Director for Safety
DPMH, ORPURM, OND, CDER, FDA

Dr. Leyla Sahin is an obstetrician-gynecologist who serves as the Deputy Director for Safety in the Division of Pediatrics and Maternal Health in the Office of New Drugs, Center for Drug Evaluation and Research at FDA. She oversees pregnancy and lactation safety activities. She joined FDA in 2008 as a medical officer after practicing obstetrics and gynecology for twelve years.

Wenjie Sun, MD, FACOG
Senior Physician
DPMH, ORPURM, OND, CDER, FDA



Dr. Wenjie Sun is a Senior Medical Officer in the Division of Pediatrics and Maternal Health at the Food and Drug Administration (FDA). As a Senior Medical Officer, Dr. Sun has completed extensive reviews of pregnancy registry and database protocols and interim and final reports and has reviewed the pregnancy and lactation sections of prescription drug labeling. Dr. Sun has provided her maternal health expertise in guidance development. She works tirelessly to advance research in pregnant and lactating individuals. Dr. Sun began working at FDA as a medical officer in 2019. She received her Bachelor of Science degree in Chemistry from Wofford College in 1999 and her medical degree from the University of South Carolina School of Medicine in 2003. She completed her residency training at Wake Forest University in 2007. Dr. Sun is a board-certified Obstetrician and Gynecologist Before joining FDA, Dr. Sun practiced obstetrics and gynecology for sixteen years.

Marie Teil, MD
Global Head, Special Patient Population
UCB Biopharma SRL

Dr. Marie Teil holds a medical degree from Lyon, a Master's degree in Statistics from Paris, and a Regulatory Affairs Certification in the US. With over three years of experience in clinical research at Sanofi, Marie embarked on a transformative journey at Mount Sinai School of Medicine in NYC in 2001. Her roles included serving as a Conflict of Interest Officer and Director of Education for the Ethics Committee. In 2004, she pioneered the creation and leadership of the Clinical Trials Office. Subsequently, in 2007, she assumed the helm of the Institute for Personalized Medicine as the Director of Operations for the Biobank.

In 2013, Marie joined UCB with a visionary purpose – to establish and spearhead the Women of Childbearing Age program. Her mission was to push the boundaries of science and elevate the standard of care for women facing severe diseases during their childbearing years. Through innovative evidence generation for pregnant and breastfeeding women, this groundbreaking program presents an exceptional opportunity to enhance the quality of life and family planning for women living with severe medical conditions.

Kaveeta P. Vasisht, MD, PharmD
Associate Commissioner for Women's Health
Director, Office of Women's Health
Office of the Commissioner, FDA

Dr. Kaveeta Vasisht is the Associate Commissioner for Women's Health and Director of the Office of Women's Health (OWH) at the US Food and Drug Administration. OWH serves to protect and advance the health of women through policy development, research, scientific programs, education, collaboration, and outreach. In her role, she advances regulatory science through understanding sex differences, promoting the inclusion of women in clinical trials, and establishing women's health research priorities at FDA. In addition, OWH works to bridge important knowledge gaps for conditions that uniquely or disproportionately impact women.

During her tenure in FDA's Office of New Drugs, Dr. Vasisht served as a medical expert on multidisciplinary teams in the review and evaluation of scientific data to make regulatory decisions on the safety and effectiveness of therapeutics. She also has extensive expertise in leading national and international regulatory policy development while working in the FDA Office of Medical Policy. Dr. Vasisht is board-certified in both internal medicine and adult endocrinology. She completed her internal medicine residency and endocrinology fellowship at the University of Chicago Hospitals, where she also served on the faculty. Dr. Vasisht received her medical degree from the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School and holds a Doctor of Pharmacy degree.

Youjin Wang PhD
Epidemiologist
SCT, RSS, OSE, CDER, FDA

Dr. Youjin Wang is an epidemiologist in the Sentinel Core Team, Regulatory Science Staff (RSS), at the FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology. In this role, she provides technical expertise on pharmacoepidemiology studies using FDA's Sentinel System to support regulatory decision-making. Dr. Wang earned her PhD in Epidemiology from the State University of New York at Buffalo and practiced as a pharmacist in South Korea and the U.S. Prior to joining the FDA in 2021, she was a research fellow at the National Cancer Institute's Division of Cancer Epidemiology and Genetics, where her work focused on genomic markers and survival outcomes after hematopoietic stem cell transplantation and translational research using pharmacoepidemiology.

Keele Wurst PhD, MS, RPh
Head of Immunology and Emerging Epidemiology
GlaxoSmithKline (GSK)

Dr. Keele Wurst is currently Head of Immunology and Emerging Epidemiology at GSK. She has been at GSK for 18 years, working across therapy areas in development, safety, pregnancy, and pediatrics. Keele is the co-chair of GSK's Pregnancy Outcomes Advisory Panel. Externally, she has been involved in the IMI Conception and TransCelerate projects, Interpretation of PV Guidance & Regulations related to Pregnancy and Breastfeeding. She is trained in clinical pharmacy with a BS in Pharmacy from the University of Pittsburgh and a MS in Pharmaceutical Policy/PhD in Pharmacoepidemiology from the University of North Carolina.

Lynne Yao, MD
Director
DPMH, ORPURM, OND, CDER, FDA

Dr. Lynne Yao is the Director, Division of Pediatric and Maternal Health (DPMH) in the Office of New Drugs, Center for Drug Evaluation and Research. Dr. Yao received a BS degree in Biology from Yale University, and an MD degree from the George Washington University School of Medicine. She is board certified in both Pediatrics and Pediatric Nephrology. Prior to joining FDA, Dr. Yao was the Director of Dialysis and Associate Pediatric Residency Program Director at the Inova Fairfax Hospital for Children in Fairfax, VA. She has been with the FDA since 2008 and has been DPMH Director since 2012. As DPMH Director, Dr. Yao oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population; and improve collection of data to support the safe use of drugs and biological products in pregnant and lactating individuals. She collaborates with numerous stakeholders both inside and outside of FDA to advance development of safe and effective therapies for children, and pregnant and lactating women.

Christopher M. Zahn, MD
Chief, Clinical Practice and Health Equity and Safety
American College of Obstetricians and Gynecologists (ACOG)

Dr. Christopher M. Zahn is currently the Chief, Clinical Practice and Health Equity and Safety, at the American College of Obstetricians and Gynecologists (ACOG). He is the former Chair of Obstetrics and Gynecology at the Uniformed Services University of Health Sciences (USUHS), and is Professor of Obstetrics and Gynecology and Pathology at USUHS. During his tenure at USUHS, he also served as Clerkship Director of the medical student program and Program Director of the Uniformed Services Residency in Obstetrics and Gynecology (USROG). He is a graduate of USUHS, and completed residency in Obstetrics and Gynecology at Wilford Hall USAF Medical Center, followed by a residency in anatomic pathology and fellowship in gynecologic pathology at Johns Hopkins University. Dr. Zahn is Board-certified in both Obstetrics and Gynecology and Anatomic Pathology. Dr. Zahn has previously served in numerous roles in ACOG, including several leadership positions at the Section and District office levels. Dr. Zahn is a former member of the Board of Directors of the American Board of Obstetrics and Gynecology and served on the ACGME Review Committee for Obstetrics and Gynecology.