Duke | MARGOLIS CENTER for Health Policy

Optimizing the Use of Postapproval Pregnancy Safety Studies

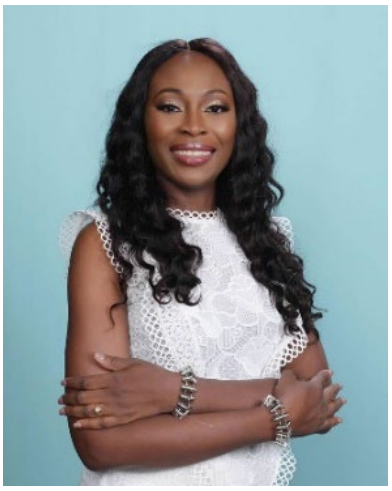
Hybrid Public Workshop

National Press Club, Washington D.C.

September 18th 10:00 AM-4:30 PM ET

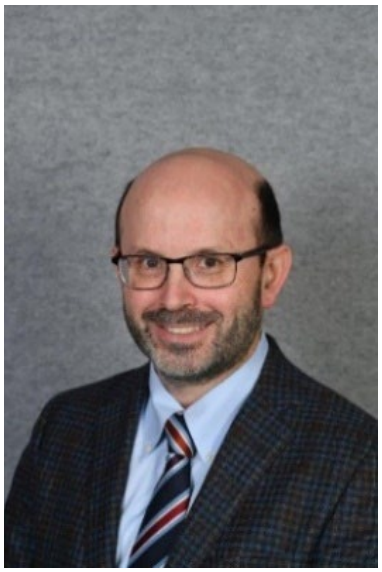
September 19th 10:00 AM-2:30PM ET

Speaker Biographies



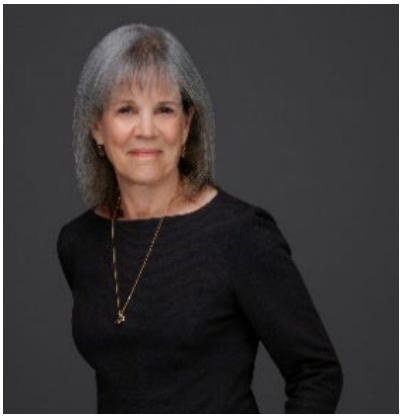
Adebola Ajao, PhD, MPH is a lead pharmacopidemiologist with the Division of Epidemiology-II, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research. She received a Bachelor of Science in Microbiology, a Master of Public Health with concentration in Epidemiology and Biostatistics, and a PhD in Molecular Epidemiology. Dr. Ajao's background is in infectious diseases, reproductive health, and health policy. Dr. Ajao has many years of experience in post-marketing safety and evaluation of regulated medical products. Her main interest is in evaluating the effectiveness and safety of gynecological products and products used in pregnancy. Dr. Ajao also has interest in health equity and understanding racial differences in health outcomes and drug safety.

Jessica Albano, PhD, MPH is Vice President, Epidemiology & Analytics, at Syneos Health. She received her undergraduate degree in biochemistry at Earlham College, MPH at Emory University, and PhD in Epidemiology from the University of Pittsburgh. She has conducted research as an epidemiologist with the American Cancer Society and the University of Pittsburgh Cancer Institute. For the past 15 years, her work as a pharmacoepidemiologist 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 has overseen the delivery of two-dozen pregnancy registries including single- and multi-sponsor models, presented at NIH and FDA sponsored pregnancy methods workshops, and authored a book chapter on the topic. Since 2009, Dr. Albano has served as the Primary Investigator for the Antiretroviral Pregnancy Registry, an international collaborative pregnancy exposure registry that has been ongoing for more than 30 years. She plays a key role in promoting awareness of the registry and helping to disseminate study results to the HIV treating community.

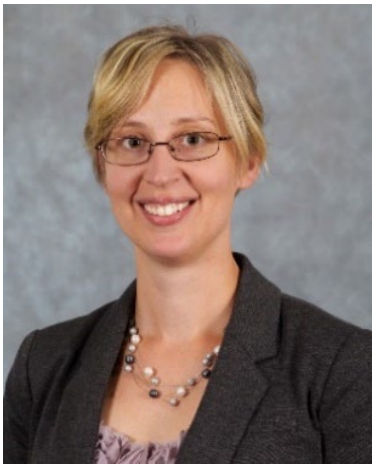


Robert Ball MD, MPH, ScM is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research, FDA. Dr. Ball shares in the responsibilities for leading OSE staff evaluating drug and biologic product safety and effectiveness using Real World Evidence, including managing the Sentinel System. Dr. Ball received his BS in Mathematics and MD from Georgetown University. He interned at the US Naval Hospital Bethesda, completed his MPH and residency in Occupational Medicine at the Uniformed Services University of the Health Sciences, and received the ScM degree in Infectious Disease Epidemiology and Vaccine Science and Policy from Johns Hopkins School of Public.

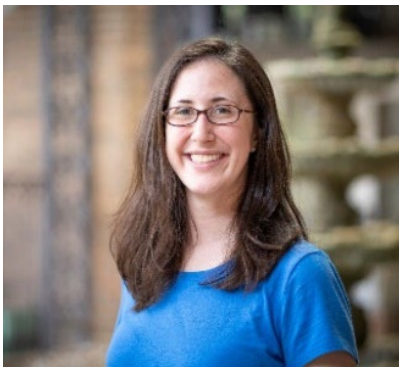
Patricia ("Trish") Bright, **PhD, MSPH** earned a Master's Degree and Ph.D. in Epidemiology from the University of North Carolina (Chapel Hill). She was a Faculty Member at the Johns Hopkins School of Medicine from 2003 to 2010, where she helped run clinical trials assessing therapeutic approaches to prevent maternal-to-child HIV transmission in developing countries. She began working at the FDA in 2010 as a Commissioner's Fellow. In 2012, she joined the Division of Epidemiology in the Center for Drug Evaluation and Research (CDER)'s Office of Surveillance and Epidemiology (OSE). She worked in the Division of Epidemiology as both a primary reviewer and as a Team Lead. She joined FDA's Sentinel Team in April 2021 and is the Associate Director and Lead for FDA's Sentinel System.



Christina Chambers, **MPH, PhD** 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 Co-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 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 Population Science and Community Engagement in the Clinical and Translational Research Institute at UC San Diego which supports clinical research development in diverse populations.

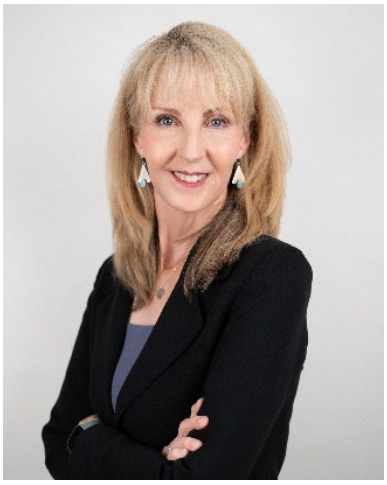


Sara Eggers PhD, directs the Decision Support and Analysis Staff within FDA's Center for Drug Evaluation and Research. This staff leverages decision science principles and tools to help structure, inform, and effectively communicate the Center's drug regulatory decision-making. Through this work, Dr. Eggers has contributed decision science expertise to initiatives regarding drug benefit-risk assessment, patient-focused drug development, product quality assessments, drug safety labeling, risk evaluation and mitigation strategies, controlled substances, and others. Before joining FDA in 2011, she conducted research and consulting in the area of decision science, stakeholder engagement, risk management, and risk communication. Dr. Eggers has a Ph.D. in Engineering and Public Policy, with an emphasis on decision science, from Carnegie Mellon University.



Joann Gruber, PhD, MSPH is a PhD-trained epidemiologist with expertise in infectious diseases and vaccines. Dr. Gruber works at the Food and Drug Administration in the Center for Biologics Evaluation and Research (CBER) in the Office of Biostatistics and Pharmacovigilance in the CBER Surveillance Program. This program coordinates the Biologics Effectiveness and Safety (BEST) Initiative which is used to conduct active post marketing safety and effectiveness surveillance studies of CBER-regulated products, including vaccines. Data from the program help inform evidence-based regulatory decisions with the goal of protecting and promoting public health.

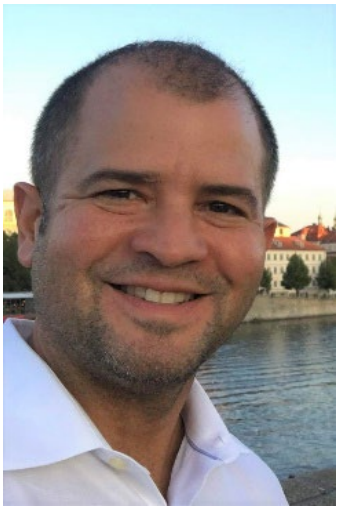
Duke | MARGOLIS CENTER *for* Health Policy



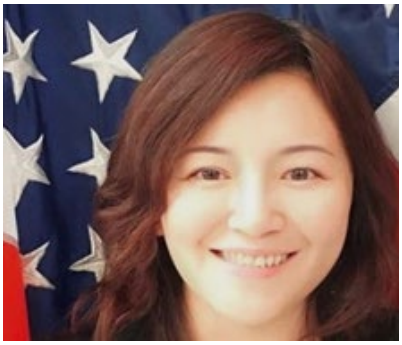
Janet R. Hardy, PhD, MSc is an accomplished epidemiologist specialized in the study of women and children's health: pregnancy registries, observational outcomes studies (RWE), burden of disease studies, medication and vaccine safety, support of pharmacovigilance, and field-based public health programming in lower middle-income countries (LMICs). She received her Master of Science degree from McGill University (pharmacoepidemiology), her doctorate from Yale University (perinatal pharmacoepidemiology), and a fellowship from the Association of Schools of Public Health (vaccine safety). With a career spanning 20 years, Dr. Hardy's expertise draws from technical methods training at world-class academic institutions and from professional experience in industry, consulting, government (US Centers for Disease Control and Prevention, CDC), and academia (former faculty member at UMass Medical School, and U. South Florida). Her recent experience as Executive Director and Head of Pharmacoepidemiology at Biohaven Pharmaceuticals, then Pfizer, included leading the cross-study and cross-regionalpharmacoepidemiology strategy, development, and execution for all Biohaven pregnancy safety post-marketing study requirements using innovative and efficient methodology. Dr. Hardy's professional history demonstrates a long-standing passion and commitment for improving the health of women and their families globally. She remains focused on goals that may be of direct clinical impact, provide evidence for positive policy change, and/or translate into meaningful and measurable public health improvement.

Sonia Hernández-Díaz, MD, DrPH 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. She is internationally recognized for her research examining drug utilization, safety and effectiveness during pregnancy. She has experience with case-control surveillance studies, pregnancy registries and pregnancy cohorts nested within healthcare utilization data. Dr. Hernandez-Diaz is the author of over 300 scientific articles and book chapters. Examples of her work include inquiries of the safety of antiepileptic drugs, antidepressants, antipsychotics, antiretrovirals, antidiabetics, opioids, and vaccines in pregnancy. Her recent projects include the emulation of hypothetical target trials to generate evidence on the comparative safety and effectiveness of treatment strategies during pregnancy. Dr. Hernandez-Diaz is also a former Chair of the US Food and Drug Administration (FDA) Drug Safety and Risk Management Advisory Committee and longstanding committee member. She is Past-President of both the International Society for Pharmacoepidemiology and the Society for Perinatal and Pediatric Epidemiology Research; former member of the NICHD Pregnancy & Neonatology (PN) Study Section, and a member of the Teratogenic Information Services (TERIS) Advisory Board. Through her service to public health institutions she has

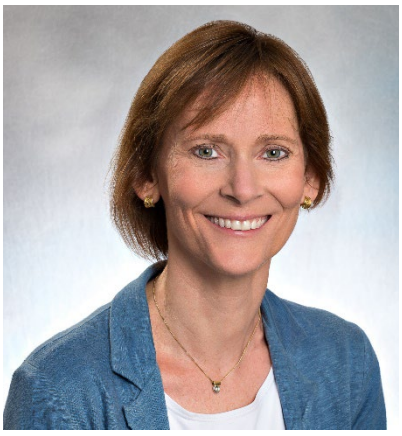
contributed to the translation of research into policy and actionable recommendations for stakeholders



José J. Hernández-Muñoz, RPh, MPH, MSc, PhD is a senior pharmacist and pharmacoepidemiologist with the Sentinel Core Team (SCT). The SCT is part of the Regulatory Science Staff, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, at the US Food and Drug Administration. Dr. Hernández-Muñoz is a member of a team of epidemiologists that oversee the development, implementation, execution, and public posting of studies involving the FDA Sentinel System. Dr. Hernández-Muñoz has special interest in the characterization of the utilization of new molecular entities upon approval and using tree-based scan statistics for post marketing surveillance.

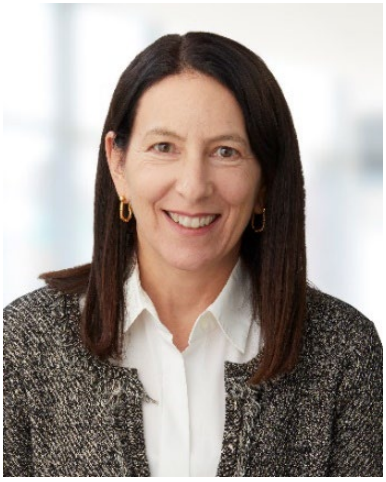


Wei Hua, MD, PhD, MS, MHS is currently Deputy Director of Division of Epidemiology-I in the Office of Surveillance and Epidemiology, CDER, FDA. She received her medical degree from China and PhD from the Johns Hopkins School of Public Health. Her areas of expertise include infectious disease epidemiology and pharmacoepidemiology with experience in both experimental and observational studies using primary and secondary data in the U.S. and through multi-site international collaborations. Over the past ten years, Dr. Hua has held multiple roles in the FDA centers for biologics and drugs leading and overseeing epidemiological research and review, including real-world evidence (RWE) and pregnancy safety, in the regulatory setting.

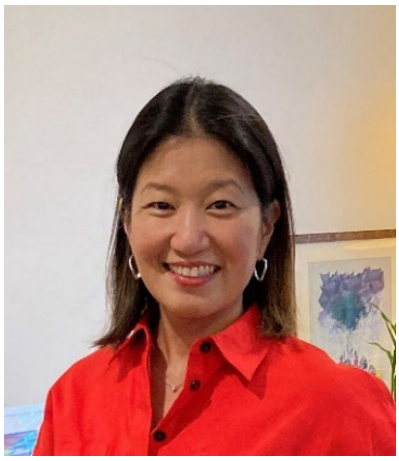


Krista F. Huybrechts, MS PhD FISPE is an Associate Professor of Medicine and Epidemiology at Harvard Medical School and Harvard T.H. Chan School of Public Health, and Adjunct Associate Professor at Boston University School of Public Health. She teaches graduate level courses in pharmacoepidemiology at both institutions. Dr. Huybrechts co-founded and co-directs the Harvard Program on Perinatal and Pediatric Pharmacoepidemiology. Her research centers on generating evidence regarding the safety and effectiveness of prescription medications during pregnancy. Her work, which is funded primarily by the National Institutes of Health, focuses on the use of advanced epidemiological and statistical methods applied mainly to large databases derived from health data collected in the context of routine medical care to help address the unique questions regarding benefit-risk trade-off for prescription medication use faced by women of reproductive age and pregnant women. Dr. Huybrechts is an Associate Editor for Pharmacoepidemiology and Drug Safety and served on the Board of Directors of the International Society of Pharmacoepidemiology (ISPE) as

Vice President Finance from 2017-2020. She currently serves on the board of Marcé of North America (MONA, Perinatal Mental Health Society) and is a voting member for the FDA Drug Safety and Risk Management Advisory Committee.

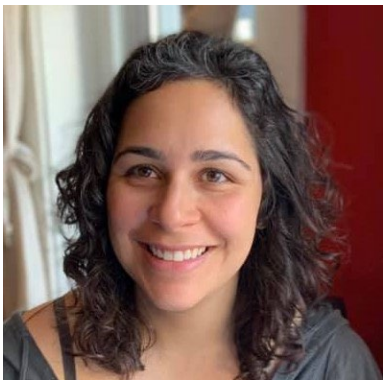


Elyse Olshen Kharbanda, MD, MPH is Executive Director of Research and a Senior Research Investigator at HealthPartners Institute. Dr. Kharbanda's research focuses on the safety of vaccines used in pregnancy, primarily through her work with the Vaccine Safety Datalink (VSD). In collaboration with the Centers for Disease Control and Prevention and several other health systems, the VSD conducts post-licensure safety surveillance for vaccines in use in the United States. Dr. Kharbanda co-leads the HealthPartners Institute Vaccine Safety Datalink (VSD) team. Dr. Kharbanda and her HealthPartners-based VSD team have and continue to lead multisite observational studies evaluating the safety of vaccines administered during pregnancy. Data from these studies have been widely disseminated through publication and presentations to the Advisory Committee on Immunization Practices (ACIP). Dr. Kharbanda completed her medical degree at Albert Einstein College of Medicine, pediatric residency at New York Presbyterian Hospital, Columbia University and adolescent medicine fellowship at Boston Children's Hospital and Boston Medical Center. She received a Master's in Public Health from Columbia University, Mailman School of Public Health, and was an Assistant Professor of Pediatrics and Public Health at Columbia University prior to joining HealthPartners Institute.

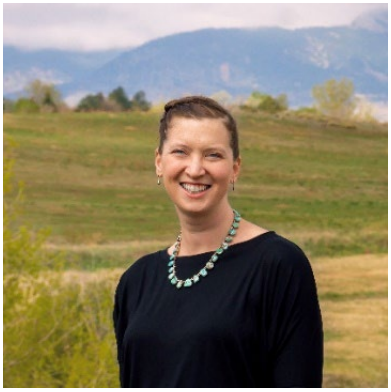


Clara Kim, PhD is a Supervisory Mathematical Statistician in the Division of Biometrics 7, Office of Biostatistics, Center for Drug Evaluation and Research. She has more than 10 years of providing statistical consultation on the design and analysis of drug safety studies, including large clinical trials, observational studies, meta-analyses. Before joining DB7, she served as an Epidemic Intelligence Service officer with the Centers for Disease Control and Prevention. Her main interest is in causal inference methods used in regulatory settings. Dr. Kim received her PhD in Biostatistics from the University of Pennsylvania.

Duke | MARGOLIS CENTER *for* Health Policy



Aida Kuzucan, PhD, PharmD is a pharmacist and pharmacoepidemiologist with the Division of Epidemiology, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research at the US Food and Drug Administration. Her tasks include conducting and critically evaluating drug-safety related observational studies to ensure they meet the best practices in epidemiology and can provide robust and actionable evidence to inform regulatory decision making. She also serves as a subject matter expert for the observational data aspects of the use of real world evidence. She is a doctoral graduate from the Department of Pharmaceutical Health Services Research at the University of Maryland, Baltimore, a former post-doctoral fellow in the T32 Epidemiology of Aging Training program at the University of Maryland, a former researcher and clinical coordinator at the Tu and Yuen Center for Functional Onco-imaging at the University of California, Irvine and a licensed pharmacist. Her research interests include real world evidence use throughout the product lifecycle and the intersection of drug-safety, health outcomes and health policy



Mariah Leach is a writer, patient advocate, and mom of three who has been living with rheumatoid arthritis since the age of 25. After learning firsthand the challenges of pregnancy and motherhood with chronic illness, she founded Mamas Facing Forward, an informational website (www.mamasfacingforward.com) and support group for women with chronic illness who are or want to become mothers.

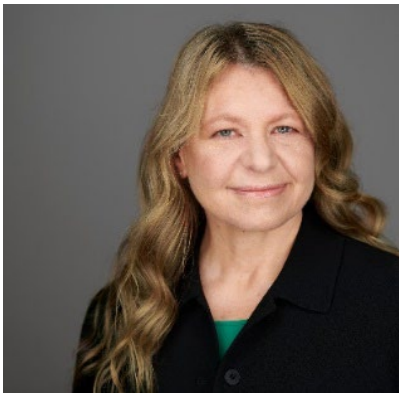
Christine Olson, MD, MPH is a U.S. Public Health Service Commissioned Corps medical officer at CDC. She's board-certified in both Obstetrics & Gynecology and Preventive Medicine, with an MPH in maternal and child health. Prior to joining CDC, she was an assistant professor and medical school clerkship director in the Maternal Fetal Medicine Division of the University of Kentucky in Lexington. Over her career in public health, she has worked at the international, national, state, and local levels in both the infectious and chronic disease areas, including international maternal morbidity and mortality (Afghanistan), immigrant and refugee health, preterm birth and infant health, perinatal quality collaboratives, and vaccine safety. She has served as an expert consultant in infection control and prevention measures in maternity care settings to WHO and on multiple federal collaborative workgroups. She has extensive experience in outbreak and emergency response, including Ebola, Zika, and COVID-19, and has formed effective and collaborative partnerships across CDC and with outside entities. She has led CDC's COVID-19 Vaccine Pregnancy Registry since 2021.

Duke | MARGOLIS CENTER *for* Health Policy

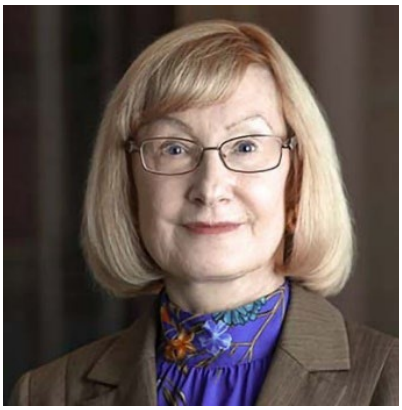
Judith Maro, PhD is an Assistant Professor in the Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute. She received her doctorate in Engineering Systems at the Massachusetts Institute of Technology (MIT). Dr. Maro's main research interest is implementation of pharmacovigilance techniques, particularly continuous near-real time sequential statistical analysis methods and data-mining / signal identification methods in distributed longitudinal databases. She is the Operations Lead for the Sentinel Operations Center (housed at Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute) as part of the U.S. Food and Drug Administration's Sentinel System. The Sentinel Operations Center is responsible for the coordination of data curation, management, and utilization activities among multiple data partner sites covering data on several hundred million patients. She is also the site Principal Investigator for Harvard Pilgrim Health Care Institute in the Centers for Disease Control and Prevention's Vaccine Safety Datalink.

Marie Teil, MD, MS is the Global Head, Woman of Childbearing Age mission, UCB Biopharma SRL Marie 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. This groundbreaking program presents an exceptional opportunity to enhance the quality of life and family planning for women living with severe medical conditions.

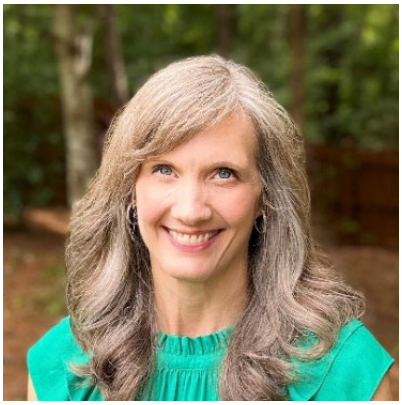
Duke | MARGOLIS CENTER *for* Health Policy



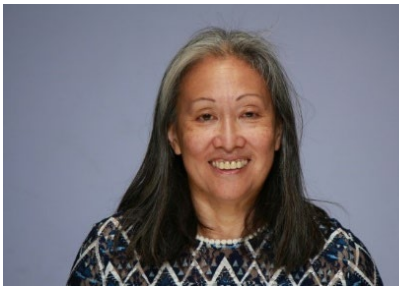
Leyla Sahin, MD is an obstetrician-gynecologist who is the Deputy Director for Safety in the Division of Pediatrics and Maternal Health in the Office of New Drugs, Center for Drug Evaluation and Research at FDA. She oversees pregnancy and lactation safety activities and leads various maternal health related scientific and regulatory/policy initiatives. She joined FDA in 2008 as a medical officer after practicing obstetrics and gynecology for twelve years.



Katherine L. Wisner , MD, M.S. obtained her M.S. in Nutrition and M.D. from Case Western Reserve University, followed by a pediatric internship and general/child psychiatry residency and post-doctoral fellowship in epidemiology at the University of Pittsburgh. She also completed fellowships in professional and biomedical ethics. Dr. Wisner's research advanced our understanding of the natural history of mood disorders across childbearing, benefit-harm decision-making for pharmacotherapy, and the pharmacokinetics of medications across pregnancy and lactation. She is internationally recognized as an expert in the treatment of mood disorders during pregnancy and the postpartum period. Dr. Wisner has received over $23 million from NIH and has 270 peer-reviewed publications (h-index=67) and 23 book chapters. Dr. was awarded the Woman in Science Award (American Medical Women's Association, 2011). From the American Psychiatric Association (APA), she received the Alexandra Symonds Award (2012) and the annual Award for Research (2017). She was honored with Distinguished Mentor Awards from the University of Pittsburgh (2012) and Northwestern University (2022). She received the Marcè International Society for Perinatal Mental Health's Medal for lifetime contributions. Dr. Wisner served on the Editorial Board of the American Journal of Psychiatry and currently on the Boards of JAMA Psychiatry and Journal of Clinical Psychiatry. She is a Fellow of the American College of Neuropsychopharmacology and a Distinguished Life Fellow of the APA. With her experience as president of the Marcé International Society for Perinatal Mental Health, she developed the business startup plan for Marcé of North America, and was its inaugural president.



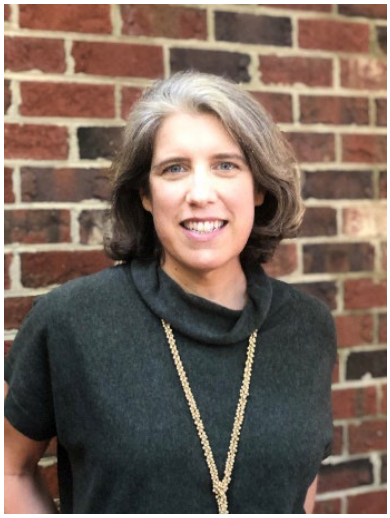
Keele Wurst, PhD, MS, RPh has spent 17 years at GlaxoSmithKline (GSK). As Head of Safety Science, Epidemiology within Value Evidence and Outcomes, she provides strategic leadership and oversight of epidemiology into safety and risk management programs across the R&D pipeline and marketed portfolio. She has extensive experience in conducting safety studies, particularly in pregnancy safety. Keele is a member of GSK's Global Safety Board, and co-chair of GSK's Pregnancy Outcomes Advisory Panel, which regularly provides consultation, evaluation of pregnancy data and recommendations for post-marketing pregnancy surveillance across project teams at GSK. She played an integral part in the development and implementation of a companywide strategy to address the FDA Pregnancy, Lactation Labeling Rule. Externally, she is involved in the IMI Conception project which aims to build and test a pan-European ecosystem for generating evidence on medication safety in pregnancy and the TransCelerate project, Interpretation of PV Guidance & Regulations related to Pregnancy and Breastfeeding. Keele received a PhD in Epidemiology specializing in pharmacoepidemiology and perinatal epidemiology from the University of North Carolina, Chapel Hill, a M. S in Pharmaceutical Policy from University of North Carolina, Chapel Hill and a B.S. in Pharmacy from the University of Pittsburgh.



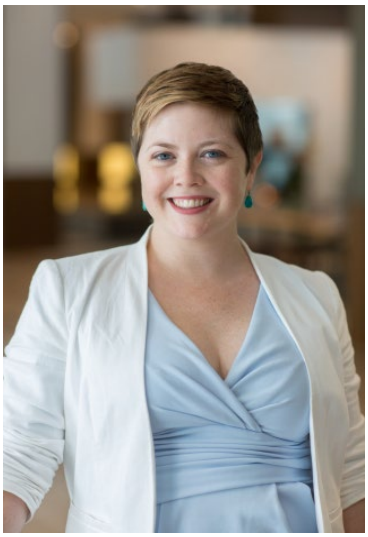
Lynne Yao, M.D., is the Director, Division of Pediatric and Maternal Health (DPMH) in the Office of New Drugs, Center for Drug Evaluation and Research. Dr. Yao received a B.S. degree in Biology from Yale University, and an M.D. degree from the George Washington University School of Medicine. She is board 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.

Moderator Biographies

Duke | MARGOLIS CENTER for Health Policy

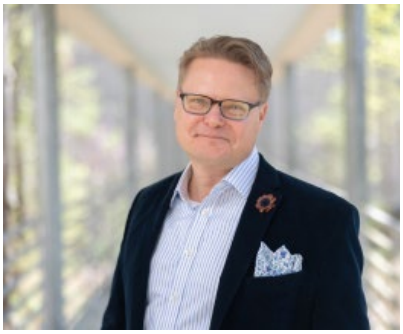


Megan Clowse, MD, MPH is a clinical rheumatologist with a long-standing research interest in understanding the real-world problems rheumatic diseases pose for our patients and identifying innovative approaches to solving these. She received her medical degree from Vanderbilt Medical School, followed by residency and fellowship at Johns Hopkins. She joined the Duke faculty in 2005.She is an international leader in the study and management of rheumatic diseases in pregnancy. She has cared for over 900 pregnancies in women with rheumatic disease since initiating her prospective pregnancy registry in 2008. She was on the Core Leadership team for the American College of Rheumatology (ACR) Reproductive Health Guidelines. Through quantitative and qualitative work, she identified gaps in rheumatologists' knowledge and communication skills as key drivers of poor pregnancy outcomes in women with lupus. To overcome these, she has created 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).

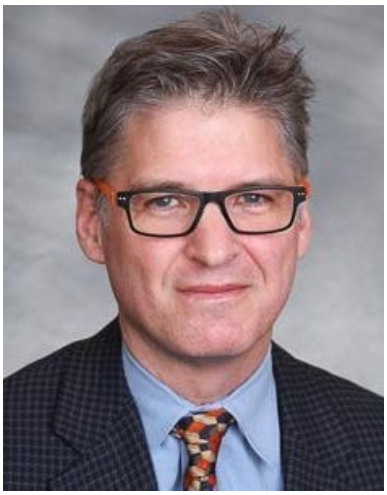


Marianne Hamilton Lopez, PhD, MPA is the Senior Research Director of Biomedical Innovation, an adjunct associate professor, and core faculty at the Duke-Margolis Center for Health Policy in Washington, DC. She leads the strategic design and direction of the Center's Biomedical Innovation portfolio, with a focus on medical products development and regulation, real world evidence, infectious disease preparedness, and payment, pricing, and coverage of drugs and medical devices. She also oversees the Value for Medical Products Consortium and partners with Duke University faculty, scholars, and external health experts to advance this work. Prior to joining Duke-Margolis, Dr. Hamilton Lopez was a senior program officer with the National Academy of Medicine's Leadership Consortium for a Value & Science-Driven Health System and provided strategic direction and oversight of the Consortium's Science and Technology portfolio and Clinical Effectiveness Research Innovation and the Digital Learning Collaboratives. She was a Senior Manager at AcademyHealth; a Public Health Community Advisor for the United States Cochrane Center; and the Federal Women's Program Manager and American Indian/Alaska Native Employment Program Manager for the National Institutes of Health.

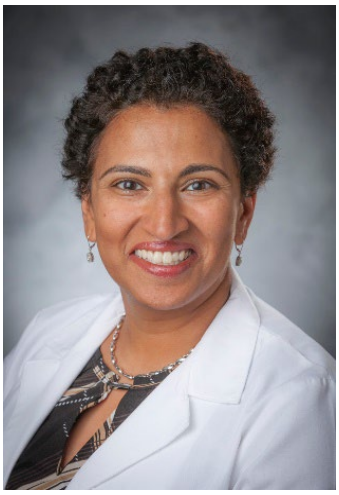
Duke | MARGOLIS CENTER for Health Policy



Gerrit Hamre, MA, is a new Research Director in Medical Product Development and Regulatory Policy at the Center. Gerrit has worked for nearly 20 years in the pharmaceutical industry with a focus on clinical research, regulatory, and commercial roles. Central to much of his career work is extensive internal and external stakeholder engagement to advance innovative, evidence-based healthcare solutions. He has often worked in the drug development and approval environment. Highlights of Gerrit's career so far have included his work in the Food and Drug Administration's Office of Legislation and as a Peace Corps Volunteer in South Africa.



Evan Myers, MD, MPH is the Walter L. Thomas Distinguished Professor in the Department of Obstetrics & Gynecology at Duke University School of Medicine. He is a Core Faculty member of the Duke-Margolis Center for Health Policy, and has appointments in the Duke Clinical Research Institute and Duke Cancer Institute. His work has primarily focused on the application of methods for evidence synthesis, especially simulation modeling, to address important clinical, epidemiological, and policy questions in women's health. He has additional experience leading data coordinating centers for clinical trials and prospective registries. He also serves as Vice Chair for Reproductive Risks for the Duke IRB, where he works with investigators, sponsors, and regulators to optimize protocols and consent forms to minimize the risk of unintended pregnancy during studies while taking into account specific considerations relevant to the study interventions and the patient population in order to avoid undue burdens on participants.



Geeta K. Swamy, MD is the Haywood Brown, MD Distinguished Professor of Women's Health in the Department of Obstetrics & Gynecology, Division of Maternal-Fetal Medicine at Duke University. She also serves as Associate Vice President for Research and Vice Dean for Scientific Integrity for Duke University and the School of Medicine. She received her Bachelor's degree in Public Health and Doctor of Medicine degree from UNC-Chapel Hill and then completed her residency in Ob/Gyn at the University of Pittsburgh. She came to Duke in 2001 as a fellow in Maternal-Fetal Medicine and joined the Duke University School of Medicine faculty following completion of her fellowship in 2004. She is a nationally and internationally recognized clinician-researcher and leader in the field of perinatal infectious diseases and maternal immunization. She has led numerous vaccine trials in pregnant women with funding from the NIH, CDC and Industry sponsors. She currently serves as Co-PI for Duke's NIAID Vaccine Treatment and Evaluation and for the CDC-funded Clinical Immunization Safety Assessment project. Dr. Swamy is also a member of the Department of Health & Human Services' National

Vaccine Advisory Committee and the American College of ObGyn Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group.