Duke | Robert J. Margolis, MD Center for Health Policy

Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials

Virtual Meeting (Zoom)
February 2 & 3, 2021

Biographies

Yodit Belew is the Associate Director for Therapeutics (acting) in the Division of Antiviral (DAV), Office of Infectious Disease (OID) at the Center for Drug Evaluation and Review (CDER), FDA. She joined the Agency in 2007 as a Medical Officer. Dr Belew has additional regulatory experiences in the Division of Pediatric and Maternal Health and the Office of New Drugs Policy. As an Associate Director, Dr. Belew provides leadership to the scientific and clinical review teams involved in the complex task of regulating and evaluating new drugs and biological products, with focus on pediatrics, maternal health, and rare diseases. She supports regulatory science research activities in the Division of Antiviral, and helps build and maintain relationships with stakeholders to advance the mission and goals of the Division. Dr. Belew graduated from Cornell University Medical College. She completed her residency in Pediatrics at Mount Sinai Hospital in New York, and fellowship in Pediatric Infectious Diseases at Children's National Medical Center in Washington, D.C. Dr Belew is board certified in both Pediatrics and Pediatric Infectious Diseases.

Christina Bucci-Rechtweg graduated with a MD from the University of Rochester School of Medicine & Dentistry and was Residency trained in Pediatrics and Fellowship trained in Pediatric Critical Care Medicine at the State University of New York @ Buffalo. She has 20 years of pharmaceutical industry experience with roles in Clinical Development & Medical Affairs as well as Regulatory and Development Policy where she was responsible for the oversight and registration of global clinical development programs. In her career she has developed and implemented clinical programs as a Global Medical Director for pediatric and women's health in phase II and III, including those with pediatric regulatory obligations in the EU and US, and is widely regarded for her negotiating skills in adult and pediatric drug development, as well as health policy and international regulatory consensus building. Christina is actively involved in numerous external organizations advancing the regulatory and development environment for pediatric and maternal health globally, including the U.S. National Advisory Council for Child Health and Human Development, ICH Pediatric Standing Advisory Cmte, ICH E11A Pediatric Extrapolation Expert Working Group, Critical Path Institute's International Neonatal Consortium, EFGCP Children's Medicines Working Party, the IQ Consortia's Pediatric Clinical Pharmacology Leadership Group, Scientific Advisor to the International Children's Advisory Network, HHS Task Force on Research in Pregnant Women & Lactating Women, as well as numerous professional societies and the trades. Christina is currently the Global Head for Pediatric and Maternal Health Policy at Novartis Pharmaceuticals.

Karim Anton Calis is a Senior Scientist and Director of Clinical Research and Compliance for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health (NIH). He also serves as Chair of the Institutional Review Board in the NIH Office of Intramural Research and a member of the NICHD Scientific Review Committee and the BPCA Research Oversight Committee. From 1989 to 2009, Dr. Calis directed the NIH drug information and pharmacotherapy consultation service and was a clinical research specialist in endocrinology and women's health at the NIH Clinical Center. His clinical practice and research in the NIH intramural program have focused on the management of endocrine disorders in children and adults. Dr. Calis has advanced training and experience in public health, clinical research, and drug development. He has expertise in study design and human subjects protection—including many years of service as chair of institutional review boards, data and safety monitoring boards, and various other NIH and extramural committees and task forces. Dr. Calis has authored numerous peer-reviewed publications, including national guidelines and best practices for data monitoring committees (DMC) to improve clinical trial oversight and enhance the safety and integrity of clinical research. He currently serves on the DMC Initiative Planning Committee and the DMC Training Subcommittee of the Society for Clinical Trials.

Prior to returning to NIH in 2017, Dr. Calis was a Senior Clinical Analyst in the Office of Medical Policy (OMP) within the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration (FDA), where he worked on medical, scientific, and regulatory policy initiatives to promote patient safety and enhance research oversight, data integrity, and clinical trial quality and efficiency. Dr. Calis also served as acting clinical team leader in the OMP Division of Clinical Trial Quality and as a medical reviewer and acting clinical team leader in the Division of Metabolism and Endocrinology Products, Office of New Drugs, where he oversaw multiple clinical development programs and conducted clinical efficacy and safety reviews of FDA-regulated drugs and biologics. Dr. Calis is a member of the FDA Drug Safety and Risk Management Advisory Committee. He earned his Bachelor of Science and Doctor of Pharmacy degrees from the University of Maryland and an MPH degree from the Johns Hopkins University School of Public Health.

Cynthia Gyamfi is board certified in both Obstetrics/Gynecology and Maternal-Fetal Medicine. As a Maternal-Fetal Medicine (MFM) specialist, she focuses on obstetric complications with a primary focus on preterm birth prevention. However, she also focuses on gestational diabetes, preeclampsia and thrombophilias in pregnancy. Her clinical practice includes caring for high-risk patients, performing detailed ultrasounds and procedures for prenatal diagnosis. She is the Director of the Maternal-Fetal Medicine Fellowship Training Program, where she oversees the training and development of future MFM physicians.

Dr. Gyamfi is also a proficient, NIH-funded researcher working on multiple clinical trials. She was the lead PI and protocol chair on the multi-center, randomized ALPS trial designed to improve neonatal outcomes in infants of women at risk for late preterm birth, published in the New England Journal of Medicine. A long-term follow-up to this study is underway. She also conducts research in the areas of preterm birth, antenatal corticosteroids, preeclampsia, CMV, maternal morbidity and health disparities, and genetic determinants of neonatal respiratory morbidity related to preterm birth. Her Masters of Science degree in Biostatistics allows her the opportunity to run analyses on existing or developed

datasets and provides a unique insight into clinical obstetric research. She is the center PI for Columbia's team of investigators in the Maternal-Fetal Medicine Units Network at the National Institutes of Health and has numerous publications in the area of prematurity, antenatal corticosteroids, health disparities, infectious diseases in pregnancy, and Jehovah's Witness care.

Aside from her clinical and research endeavors, Dr. Gyamfi served as a member of the Board of the Society for Maternal-Fetal Medicine (SMFM) and is currently on the Executive Committee of that Board, serving as the Assistant Secretary/Treasurer. She also served as a member of the SMFM Publications Committee, a national group of highly-regarded MFM specialists who write guidelines on clinical practice for MFM-subspecialists, and was their liaison to ACOG Practice Bulletins and Committee Opinions. She is a past Vice Chair of the ACOG Clinical Consensus Committee. Dr. Gyamfi is the past Chair of the SMFM Program Committee and in that role, organized the first virtual SMFM meeting in 2021. As MFM Fellowship Director at Columbia University, she oversees the training of 9 fellows, making this one of the largest training programs in the country. She has been invited to speak about her research locally, nationally, and internationally; and she is a member of AGOS.

Dr. Gyamfi's special interests include epidemiology and biostatistics as well as maternal and obstetric complications of pregnancy including prevention of preterm birth, diabetes in pregnancy, antenatal corticosteroids, chronic hypertension, thrombophilias, health disparities, infectious diseases and pregnancy in special populations such as Jehovah's Witnesses.

Kimberly Hatfield is a toxicologist and pharmacology/toxicology team leader in the Division of Pharmacology and Toxicology for Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (DPT-RPURM) supporting the Division of Urology, Obstetrics and Gynecology (DUOG) at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research (CDER). Dr. Hatfield joined the FDA in 2006 as a pharmacology/toxicology reviewer in DUOG, and has extensive experience reviewing applications for contraceptives, fertility products, biologics, drugs administered during pregnancy, drugs to treat menopausal symptoms, and products to treat a variety of urologic conditions. In addition to her review work, she is a member of the CDER Pharmacology/Toxicology Coordinating Committee, providing consultation for the review of nonclinical studies supporting pharmaceutical development, and the CDER Reproductive and Developmental Toxicology Subcommittee, providing both consultation and writing guidance for nonclinical review focusing on reproductive toxicology. She has given lectures internally at FDA and at national meetings on the topics of reproductive and developmental toxicology, most notably for the Society of Toxicology.

Prior to working at FDA, Dr. Hatfield completed her postdoctoral training at the University of Maryland Baltimore - School of Medicine in the area of reproductive toxicology, investigating the mechanisms of pesticide toxicity in the ovary, and how exposure affects female fertility and ovarian function. She received her Ph.D. in Toxicology from Texas A&M University in 2002, focusing on molecular toxicology and oxidative stress mechanisms, and her Bachelor of Science degree in Chemistry from Ursinus College in 1996.

Susan Kindig is Senior Medical Director in Global Patient Safety at Eli Lilly & Co. and leads a global team of safety physicians and scientists covering the platform of pain, neurodegeneration, psychiatry and internal medicine molecules. She completed her MD at Indiana University School of Medicine followed by a residency in OB/GYN at Bethesda Hospital, Cincinnati, OH. She then returned to the Indianapolis area where she was in private practice for 12 years. After quitting practice in 2006, she attended and completed law school at Indiana University School of Law – Indianapolis.

Maggie Little is Senior Research Scholar at the Kennedy Institute of Ethics, and Professor of Philosophy at Georgetown. Her research interests include issues in reproduction, clinical research ethics, data ethics, and the structure of moral theory. She has twice served as Visiting Scholar in residence at the National Institutes of Health Department of Bioethics, and has served on the Ethics Committee of the American College of Obstetrics and Gynecology. She is co-founder of The Second Wave Initiative, which works to promote responsible research into the health needs of pregnant women. Dr. Little is is also founder and Director of EthicsLab, a unique team of Philosophers and Designers at Georgetown University that develops new methods to help people build ethical frameworks to better address real-world problems.

Shahin Lockman is Associate Professor, Brigham and Women's Hospital and Harvard T.H. Chan School of Public Health. Dr. Lockman is an infectious-disease trained clinician and has conducted clinical trials, epidemiologic and implementation science investigation related to HIV-1 with colleagues in Botswana since 1996. One of her research focus areas is the safety and efficacy of antiretroviral drugs used for HIV treatment and prevention among pregnant and postpartum women; she is co-chair of the IMPAACT 2010 trial which evaluated the safety and efficacy of three different antiretroviral treatment regimens in pregnant and postpartum women. Dr. Lockman also conducts research on health and neurodevelopmental outcomes in HIV-exposed/uninfected children and on community-based HIV prevention, and mentors early stage investigators on a range of clinical research projects in Botswana. She is joint PI of the Botswana Clinical Trials Unit at the Botswana Harvard AIDS Institute Partnership (conducting ACTG, IMPAACT, and HPTN network trials).

Anne Drapkin Lyerly is Professor of Social Medicine and Associate Director of the Center for Bioethics at the University of North Carolina, Chapel Hill. She is also Research Professor in the Department of Obstetrics and Gynecology. A board-certified obstetrician/gynecologist and bioethicist, she studies ethically complex issues in women's reproductive health. She co-founded the ***Second Wave Initiative***, an effort to ensure that the health interests of women are fairly represented in biomedical research and drug and device policies. She is PI on the NIH-funded PHASES Project addressing the ethics of HIV research and pregnancy, was co-PI on a Wellcome Trust funded project to address the ethics research involving pregnant women in the context of Zika and public health emergencies (the PREVENT Project), and is an alumna of the Greenwall Foundation's Faculty Scholars Program and Fellowship in Bioethics and Health Policy. She has served on numerous U.S. national committees, including the American College of Obstetricians and Gynecologists Committee on Ethics, which she chaired; the National Institutes of Health Advisory Committee to the Director's

Working Group on Stem Cell Research; and the March of Dimes National Bioethics Committee. She has written dozens of articles and book chapters for academic and public audiences, including publications in journals such as *JAMA* and *The Lancet* as well as the *New York Times*. She is also the author of a book, *A Good Birth*, published by the Penguin Group/USA.

Susan McCune is the Director in the Office of Pediatric Therapeutics (OPT) in the Office of the Commissioner at the Food and Drug Administration (FDA). She joined the Agency in 2003 in the Division of Pediatric Drug Development, Office of Counter-Terrorism and Pediatric Drug Development, in the Center for Drug Development and Research (CDER). She was the Deputy Director in the Office of Translational Sciences in CDER from February, 2010, until January, 2017, when she joined OPT.
Dr. McCune received her medical degree from George Washington University following her undergraduate degree at Harvard University. She completed her internship, residency, chief residency, and neonatal fellowship at Children's National Medical Center in Washington, D.C. She is Board Certified in Pediatrics and Neonatal/Perinatal Medicine. For 15 years, while practicing academic pediatric and neonatal medicine at Johns Hopkins and Children's National Medical Center, Dr. McCune continued her molecular biology research on adrenergic receptor ontogeny and expression in models of newborn brain injury in the Lab of Developmental Neurobiology, NICHD, NIH. In addition, she has a Masters in Education Technology Leadership from George Washington University, and certificates in Public Health from Georgetown and Regulatory Science from USC.

Leslie C. McKinney is a Pharmacologist at the US Food and Drug Administration, Center for Drug Evaluation and Research, serving within the Office of New Drugs, Division of Pharmacology and Toxicology for Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (DPT-RPURM). As a primary reviewer, she is responsible for evaluating nonclinical studies that enable clinical trials and support new drug product approvals. Dr. McKinney received her doctoral degree from Washington University in St. Louis in neuroscience, and completed postdoctoral training at the University of Rochester in the area of physiology and biophysics. Prior to coming to the FDA in 2005, she worked as a staff scientist engaged in basic research at the Armed Forces Radiobiology Research Institute, and was on faculty at the Uniformed Services University of the Health Sciences at Walter Reed National Military Medical Center.

Leslie Meltzer Henry is a lawyer and bioethicist with expertise in assessing, navigating, and advising on a range of ethical and legal issues that arise at the intersection of medicine, public health, and public policy. She is a Professor of Law at the University of Maryland Carey School of Law, and a faculty member at the Johns Hopkins Berman Institute of Bioethics. Her scholarly work primarily focuses on aspects of biomedical research regulation and practice that have implications for, and are implicated by, social justice and public health. Her scholarship has addressed barriers as well as potential facilitators to including pregnant people in research, compensation schemes for research-related injuries, challenges associated with including adolescents in research, and the complexities of conducting research during pandemics. She has been an investigator on both NIH and internationally funded grants aimed at developing ethically and legally acceptable strategies for conducting research during pregnancy, and she is currently an investigator on two NIH-supported studies – one examining the ethical, legal, and social implications (ELSI) of the increasingly blurred

boundaries between infectious disease and genetics, and the second involving the use of HIV phylogenetics in clinical care and public health.

Professor Henry's research has been published in the nation's leading law reviews and medical journals, including *JAMA*, *New England Journal of Medicine, PNAS*, *AIDS*, *Hastings Center Report*, and *Ethics and Human Research*. She is an associate editor and contributor to the *Oxford Handbook for Public Health Ethics* (OUP, 2019), as well as a contributor to the *Oxford Handbook of Research Ethics* (OUP, 2020) and the *Oxford Textbook of Clinical Research Ethics* (OUP, 2008). Professor Henry has also served in an advisory capacity to a variety of federal and local agencies and commissions—including the U.S. Department of Defense, Trans-NIH Bioethics Advisory Committee, NIAID, NICHD, NIMH, and FDA—to identify limits, as well as areas of flexibility, in regulations related to the inclusion of special populations in research. Professor Henry received her J.D. from Yale Law School, Ph.D. from the University of Virginia, and M.Sc. from the University of Oxford, where she was a Wellcome Trust Fellow in the History of Medicine. She completed post-doctoral work at Johns Hopkins University as a Greenwall Fellow in Bioethics and Health Policy.

Daniel Minck is a pharmacologist in the Division of Diabetes, Lipid Disorders, and Obesity that joined the FDA in 2011. In addition to reviewing applications submitted to this division, he is a member of CDERs Reproductive and Developmental Toxicology Subcommittee and an instructor on reproductive toxicity for the Toxicology for Non-Toxicologist seminar series. Dr. Minck is also an FDA representative on the HESI Reproductive Toxicology Committee and was an FDA representative on the ICH Working Group responsible for the recent revision to the S5 guidance on the Detection of Reproductive and Developmental Toxicity for Human Pharmaceuticals. Prior to joining the FDA, Dr. Minck was the Director of Reproductive and Specialty Toxicology at Wyeth Pharmaceuticals.

Lynne Mofenson is a Board-certified pediatric infectious disease specialist; she received her M.D. from Albert Einstein College of Medicine with honors, followed by pediatric residency at Boston Children's Hospital, and Chief Residency/infectious disease fellowship at the University Massachusetts Medical School. She served as Assistant Commissioner, Division of Communicable Disease Control at the Massachusetts Department of Public Health, joining the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development in 1989. After 26 years directing research on the prevention and treatment of pediatric and maternal HIV infection in the US and globally, she retired from the NIH and currently serves as Senior HIV Technical Advisory for the Elizabeth Glaser Pediatric AIDS Foundation, where she is involved in research evaluating the implementation of many of the interventions she studied while at NIH.

Aaron C. Pawlyk joined NICHD as its OPPTB chief in 2019. His long-term research interests and experience include drug discovery and pre-clinical development, pharmacogenomics, and mathematical modeling, especially how these approaches can be applied across multiple therapeutic areas.

Prior to joining NICHD, Dr. Pawlyk served at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) as a program director and senior advisor in the Division of Diabetes, Endocrinology, and Metabolic Diseases. At NIDDK, his portfolio included drug discovery, pharmacogenomics, and drug response research. He directed the Type 1 Diabetes-Rapid Access to Interventional Development program, which offered preclinical

development contract services to outside researchers. As a program official, he managed cooperative agreement components of the Accelerating Medicines Partnership for Type 2 Diabetes and initiated and directed a trans-NIDDK program on therapeutics translation. He continues to serve as a coordinator of the NIH Common Fund program, Illuminating the Druggable Genome (IDG, https://commonfund.nih.gov/idg).

Dr. Pawlyk received his bachelor's degree from the University of Pennsylvania, where he studied biology and biochemistry. He completed his Ph.D. in biochemistry at Texas A&M University, followed by postdoctoral studies at the University of Pennsylvania. Before joining NIH, he held multiple positions in the pharmaceutical sector.

Christine P. Nguyen is the Director of the Division of Urology, Obstetrics and Gynecology in the Office of New Drugs at FDA's Center for Drug Evaluation and Research. In this capacity, she oversees a diverse group of drugs for men's and women's health. Her interests include content and policy issues related to the Pregnancy and Lactation Labeling Rule and Agency efforts to obtaining data to guide evidence-based use of prescription drugs in pregnancy. Board-certified in Obstetrics and Gynecology, Dr. Nguyen has had extensive clinical experience in obstetrics, reproductive health, and other areas of women's health. She received her Doctor of Medicine with Thesis degree from the University of California at San Francisco School of Medicine following her undergraduate degree at the University of Virginia. After completing residency in obstetrics and gynecology at the Johns Hopkins University School of Medicine, Dr. Nguyen practiced as an associate physician in a large community ob/gyn practice for several years prior to joining the FDA in the same Division in 2005.

Leyla Sahin is an obstetrician-gynecologist who joined the FDA's Division of Pediatric and Maternal Health in the Office of New Drugs, Center for Drug Evaluation and Research in 2008 following clinical practice for twelve years. She is a senior medical officer and has led various maternal health related scientific and regulatory/policy initiatives. She was a working group member on the Task Force for Research Specific to Pregnant Women and Lactating Women (PRGLAC). The focus of her work involves providing pregnancy and lactation scientific and regulatory expertise to the review divisions in the Office of New Drugs. Her principal area of interest is promoting the public health of pregnant and breastfeeding people through improved data collection of medications used in pregnant and lactating people.

Kathryn G. Schubert (Katie) is President and CEO of the Society for Women's Health Research (SWHR), where she leads the organization's efforts to promote research on sex as a biological variable and improve women's health through science, policy and education. Prior to joining SWHR in April of 2020, Katie served as Chief Advocacy Officer at the Society for Maternal-Fetal Medicine (SMFM), where she oversaw the organization's advocacy and communications activities.

Prior to joining SMFM, she was a Senior Vice President at CRD Associates. Her clients included patient advocacy organizations, physician organizations and coalitions, helping them achieve their public policy and communications goals through focused government relations strategy targeted at

Congress and federal agencies. Her areas of expertise include Medicare and Medicaid reimbursement and quality, women's and children's health and public health.

Katie previously served in key staff roles for U.S. Representative Nancy Johnson (R-CT) and Wayne Gilchrest (R-MD), and brings a unique perspective of working across party lines to achieve policy goals. She currently serves as Chair of the Board of the Maternal Mental Health Leadership Alliance and as an advisor to the John E. Lewy Fund for Children's Health. She is a past president of Women in Government Relations (WGR), the premier professional association for women in the government relations profession. She holds a Master of Public Policy degree with a concentration in health policy from The George Washington University and attended Mary Washington College in Fredericksburg, Virginia, where she earned a B.A. in Political Science. She lives in Virginia with her husband, three children, and dog George.

Catherine A. Sewell is the Deputy Director for Safety in the Division of Urology, Obstetrics and Gynecology at the US FDA. In this role, she 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 safety signals as well, and working on labeling policy. 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.

Dr. Sewell is a board-certified obstetrician/gynecologist. She graduated from Swarthmore College with Honors, the University of Pennsylvania Perelman School of Medicine and the Johns Hopkins Bloomberg School of Public Health with Honors. She also completed her Gynecology and Obstetrics residency at Johns Hopkins. She was previously the Chief of the Department of Obstetrics and Gynecology at the University of Maryland St. Joseph Medical Center, providing full-scope direct gynecologic patient care and surgery, overseeing the department's clinical care and patient safety initiatives, and mentoring and teaching medical students and DNP students. She had formerly also been on academic faculty, as Director of the Hopkins Fibroid Center in the Department of Gynecology and Obstetrics at Johns Hopkins and as Medical Director of the Jefferson Obstetrics and Gynecology Associates in the Department of Obstetrics and Gynecology at Thomas Jefferson University. Dr. Sewell has been a co-investigator for several research studies, has co-authored numerous publications and crafted documents for JHPIEGO, a non-profit health organization affiliated with Johns Hopkins.

Jeanne Sheffield is the Director of Maternal-Fetal Medicine and a Professor in the Johns Hopkins Medicine Department of Gynecology and Obstetrics. Her areas of clinical and research expertise include medical and surgical complications of pregnancy with a focus on infectious diseases and immunizations in pregnancy. Dr. Sheffield received her undergraduate degree from the University of Notre Dame and earned her medical degree from the University of Alabama at Birmingham. She did her residency in Obstetrics and Gynecology there and then completed a Maternal-Fetal Medicine fellowship at the University of Texas Southwestern Medical Center in Dallas, Texas. She is board-certified in both Obstetrics and Gynecology as well as Maternal-Fetal Medicine. Dr.

Sheffield serves on a number of national boards and committees, and currently serves as the Chair of the MFM Division of the American Board of Obstetrics and Gynecology. She works with the National Institutes of Health and the CDC consulting for clinical guideline development and is a non-federal member of the Congressional Task Force on Research Specific to Pregnant Women and Lactation (PRGLAC 1 and 2).

Catherine Spong is a Professor and Vice Chair, Department of Obstetrics and Gynecology at the University of Texas Southwestern Medical Center. She is Chief, Division of Maternal Fetal Medicine and hold the Gillette Professorship in Obstetrics and Gynecology. Her career has been dedicated to advancing public health for women, children and their families. Through an over two-decade career at the National Institutes of Health (NIH) and now in her role at UT Southwestern she has been at the forefront of advancing research and evidence for clinical practice. Dr. Spong received her M.D. from the University of Missouri-Kansas City (UMKC) in 1991. After serving as Chief Resident in Obstetrics and Gynecology at the Harbor-UCLA Medical Center, she began her career at NIH as a Maternal-Fetal Medicine Fellow, including clinical work at Georgetown University. She rose through the ranks at the NIH including leadership roles as Deputy Director and Acting Director of the National Institute of Child Health and Human Development.

Among her areas of expertise are maternal-child health, emphasizing prematurity, fetal complications, the placenta, and improving child outcomes. She is a passionate advocate for inclusion in research for underrepresented groups. She developed and facilitated research to advance understanding of stillbirth, fetal surgery for myelomeningocele, zika in pregnancy, and the Human Placenta Project. Dr. Spong is board-certified in maternal-fetal medicine, obstetrics, and gynecology. She is an Editor of William's Obstetrics, Management and Protocols of High Risk Pregnancy, and Stillbirth: Prediction, Prevention and Management. She has received numerous awards, including the Society for Maternal-Fetal Medicine Achievement Award, UMKC Alumnus of the Year, NIH Director's Awards, and a Surgeon General's Certificate of Appreciation. She has published more than 270 peer-reviewed papers and featured on national television and radio, including The Early Show, Diane Rehm Show, NPR, CNN, and Voice of America.

Kaveeta Vasisht is Associate Commissioner for Women's Health and serves as the Director of the Office of Women's Health 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 scientific programs, policy development, research, education, stakeholder collaboration, and outreach that incorporate an understanding of sex and gender differences to facilitate FDA regulatory decision making. Dr. Vasisht serves as the FDA member on the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). Prior to joining the Office of Women's Health, Dr. Vasisht served as the Deputy Director for the Division of Clinical Trial Quality in the Office of Medical Policy in the Center for Drug Evaluation and Research.

Dr. Vasisht is board-certified in both internal medicine and adult endocrinology and holds a Doctor of Pharmacy degree. She completed her internal medicine and fellowship training at the University of Chicago Hospitals, where she also served on the faculty. She obtained her medical degree from the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School.

Marta E. Wosińska is the Deputy Director, Policy of the Margolis Center for Health Policy at Duke University and Consulting Professor at the Fuqua School of Business. Widely recognized as an expert on health policy, economics, and regulation, Dr. Wosińska leads the Center's Washington, DC office. In her role, she works with Duke-Margolis leadership on developing the Center's strategy and then executes it with support of the roughly 30-person research team based in DC. Dr. Wosińska's experience spans both academia as well as the executive and legislative branches of the federal government. In 2019, Dr. Wosińska served as an economic advisor to the U.S. Senate Finance Committee, providing drug market analysis and expert guidance for the Committee's bipartisan investigative and legislative work on drug pricing. Dr. Wosińska also served for over three years as Chief Healthcare Economist in the Office of Inspector General (OIG) at the US Department of Health and Human Services. Prior to OIG, Dr. Wosińska had a seven-year tenure at the US Food and Drug Administration (FDA) where she headed the Economics Staff at the Office of Strategic Programs in the Center for Drug Evaluation and Research and served as Senior Economic Advisor to FDA's Deputy Commissioner for Medical Products and Tobacco, in both roles advising senior FDA leadership on a wide range of economic issues related to drugs and biologics. Before entering public service, Dr. Wosińska was an Assistant Professor of Marketing at the Harvard Business School, where her academic research focused on prescription drug marketing. She also was a visiting Assistant Professor at the Columbia Business School, where she developed and taught Healthcare Marketing and Marketing of Pharmaceuticals and Medical Devices. Dr. Wosińska received her PhD in economics from University of California at Berkeley and a bachelor's degree from Arizona State University.

Lynne Yao is the Director, Division of Pediatric and Maternal Health in the Office of New Drugs, Center for Drug Evaluation and Research. She has held this position since 2012 and has been with the FDA since 2008. The Division of Pediatric and Maternal Health oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population; and improve pregnancy and lactation-related information in product labeling. She collaborates with numerous stakeholders both in and out of FDA to advance development of safe and effective therapies for children, as well as pregnant and lactating women.

Dr. Yao graduated from the George Washington University School of Medicine, completed residency in Pediatrics at Walter Reed Army Medical Center, and fellowship in Pediatric Nephrology at the Georgetown University Children's Medical Center. Dr. Yao is board certified in both Pediatrics and Pediatric Nephrology.

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