Evaluating Immunosuppressive Effects of In Utero Exposure to Drug and Biologic Products

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

Public In-Person and Virtual Workshop
July 11, 2024 | 9:00 AM – 4:30 PM Eastern Time
July 12, 2024 | 9:00 AM – 1:00 PM Eastern Time

Biographies

Aaron C. Pawlyk, PhD
Chief, Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)
NIH Contact for Pediatric Medical Device Development
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Dr. Aaron Pawlyk is the Chief of the Obstetric and Pediatric Pharmacology and Therapeutics Branch at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). Dr. Pawlyk is a pharmacologist with decades of leadership experience in drug discovery and pre-clinical development, pharmacogenomics, and mathematical modeling across multiple therapeutic areas. Under his leadership, the OPPT Branch aims to assure that there are safe and effective therapeutics for children and pregnant and lactating women and that these medications are used optimally according to individual needs. To accomplish these goals, his Branch is responsible for developing and supporting a comprehensive national effort to increase the knowledge base for understanding how to appropriately treat disease during pregnancy, lactation, infancy, childhood, and adolescence using evidence-based therapeutic approaches. Dr. Pawlyk received his bachelor's degree from the University of Pennsylvania, where he studied biology and biochemistry. He completed his PhD training in Biochemistry at Texas A&M University, followed by postdoctoral studies at the University of Pennsylvania. Before joining the NIH, he held multiple positions in the pharmaceutical sector.

David McMillan, PhD, DABT
Toxicologist
DPTID | OID | OND | CDER | FDA

Dr. David McMillan is a Toxicologist in the Division of Pharmacology/Toxicology for Infectious Diseases at FDA and is assigned to the Division of Antivirals. Prior to FDA, Dr. McMillan received his PhD in Toxicology from the University of Rochester in 2013 and completed a postdoctoral fellowship at the University of Vermont in 2015. His expertise lies primarily in immunology and immunotoxicology. Dr. McMillan is the former co-chair of the FDA CDER Immunotoxicology Subcommittee, the current Treasurer of the Society of Toxicology (SOT) Immunotoxicology Specialty Section, and is the invited speaker for the "Hematopoietic and Immune Systems Toxicology" presentation within the American College of Toxicology (ACT) Advanced Comprehensive Toxicology course. He is also a regular presenter at ACT and SOT meetings and is a member of the HESI Immuno-Safety Technical Committee.

Dinesh Stanislaus, PhD
Head of Reproductive Toxicology
GSK

Dr. Dinesh Stanislaus is the head of reproductive toxicology at GSK, with over two decades of experience in the field. His work focuses on assessing risks associated with fertility and pregnancy. He played a key role in proposing a new guideline for pregnant and lactating women (ICHE21) and is a nonclinical Topic Leader in the expert working group since 2023. He holds a PhD from Oregon Health Sciences University and is actively involved in the scientific debate on strategies for data collection during pregnancy and lactation.

Edwin Lam, PharmD
Senior Scientist, Clinical Pharmacology & Pharmacometrics, Maternal Fetal Immunology
Johnson & Johnson Innovative Medicine R&D

Dr. Edwin Lam is a Clinical Pharmacologist at Johnson & Johnson Innovative Medicine R&D supporting Maternal Fetal Immunology drug development. He is also an adjunct faculty in the Department of Pharmacology and Physiology at Thomas Jefferson University, Philadelphia and is a Ready Reservist in the US Public Health Service Commissioned Corps. He received his Bachelor of Science in Pharmaceutical Sciences from the University at Buffalo, PharmD from Long Island University, and completed a NICHD-NIGMS T32 post-doctoral fellowship in adult and pediatric Clinical Pharmacology at NIH & Thomas Jefferson University. Prior to joining Johnson & Johnson in 2022, Dr. Lam was a Pharmacokineticist at the Clinical Pharmacokinetics Research Unit at the NIH supporting Phase I & II clinical pharmacology research in anti-infective, immunology, and maternal-fetal therapeutic areas.

Elisa Ochfeld, MD
Allergy/ Immunology Attending Physician
Children's Hospital of Philadelphia (CHOP)

Dr. Elisa Ochfeld is an attending physician at the Children's Hospital of Philadelphia. She completed her Allergy / Immunology fellowship at Northwestern University / Lurie Children's Hospital in Chicago in 2021. She completed an advanced research fellowship (T32 NUAIR grant), pursuing research on Kappa-deleting recombination excision circles (KRECs) in primary immunodeficiency patients as a potential indicator of B cell bone marrow output. She clinically practices in both allergy and immunology at CHOP, and specializes in areas including food challenges and oral immunotherapy, as well as the Program for Integrated Immunodeficiency and Cellular Therapy (PIICT) clinic. She has pursued research in areas including: *in-utero* exposure to immunosuppressive medications resulting in abnormal newborn screening for severe combined immunodeficiency, hematopoietic stem cell transplantation for primary immunodeficiency, and additionally is a research collaborator with the Primary Immune Deficiency Transplant Consortium (PIDTC) investigating long-term outcomes in transplanted and non-transplanted patients with primary immune dysregulatory diseases (PIRDs) and CGD.

Giorgia Berardi, MD
Clinical Trial Assessor
Clinical Trial Office at Italian Medicine Agency – AIFA

Dr. Giorgia Berardi is an MD, specialized in Rheumatology at the Catholic University of the Sacred Heart (Rome) and has been working as a clinical trial assessor for the Italian Medicine Agency for the past five years. She is also involved in the safety assessment of drugs under development. She has over ten years of hospital experience working with young patients affected by various immunological and musculoskeletal disorders, including systemic vasculitis, systemic sclerosis, SLE, myositis and polyarthritis. She is now involved as EC member in the ICH working group for the "Inclusion of pregnant and breastfeeding individuals in clinical trials". Her principal area of interest is improving care of subjects with autoimmune diseases.

Jashvant (Jash) Unadkat, PhD
Professor, Department of Pharmaceutics, School of Pharmacy
University of Washington, Seattle

Dr. Jashvant (Jash) Unadkat is a Professor in the Dept. of Pharmaceutics at the School of Pharmacy, University of Washington, Seattle. He received his bachelor's degree in pharmacy (B.Pharm.) from the University of London (1977), his PhD from the University of Manchester and his postdoctoral training at the University of California at San Francisco. He held the Milo Gibaldi Endowed Professorship in the Department from 2016-21. Dr. Unadkat's research interests are on mechanisms of transport and metabolism of drugs during pregnancy, and transport of drugs across the placental, hepatic, intestinal, and blood-brain barrier. Dr. Unadkat has published more than 250 peer-reviewed research papers. He is a fellow of AAAS, AAPS, JSSX, and the founding co-chair (1999-2001) of the focus group of AAPS on Drug Transport and Uptake. Dr. Unadkat received the AAPS Research Achievement Award in 2012 and the ISSX Scientific Achievement Award in 2023. Dr. Unadkat created and led the **UW Research Affiliates Program on Transporters** (UWRAPT), a cooperative effort between the UW School of Pharmacy and pharmaceutical companies, for ten years. He also leads **UWPKDAP**, a NIDA funded Program Project grant (P01) on drug disposition during pregnancy. Dr. Unadkat has been an Associate Editor for the *Journal of Pharmaceutical Sciences*, an Editor of *AAPS Journal*, and a member of the NIH Pharmacology study section (2000-3). Dr. Unadkat has organized or co-organized numerous national and international conferences on the role of transporters and pregnancy in the disposition of drugs.
http://sop.washington.edu/department-of-pharmaceutics/faculty-members/
https://www.washington.edu/research/research-centers/university-of-washington-research-affiliate-program-on-transporters-uwrapt/
https://sop.washington.edu/department-of-pharmaceutics/research/program-on-pharmacokinetics-of-drugs-of-abuse-during-pregnancy-uwpkdap/

Jeff Roberts, MD
Associate Vice President, Vaccine Clinical Development
Merck Research Laboratories (MRL)

Dr. Jeff Roberts joined Merck Research Laboratories (MRL) in November 2021 as Associate Vice President, Vaccine Clinical Development. In this role, he is responsible for clinical development of candidate and licensed vaccines for a variety of disease targets.

Prior to joining MRL, Jeff was Associate Director for Scientific Affairs in the Office of Vaccines Research and Review at the US FDA. His focus included emerging disease threats/medical countermeasures and use of digital health tools, alternative clinical trial designs, and real-world evidence to support product development/licensure. He also led discussions/coordination on vaccine development with other regulatory authorities. Prior to that, and for most of his 14 years at the FDA, Jeff served as Clinical Branch Chief in the Division of Vaccines and Related Product Applications (DVRPA), where he managed the clinical review activities for development programs and licensure applications for multiple products, including vaccines, allergenic products, phage therapy, and live biotherapeutics. In addition to managing the clinical review group, Jeff led several efforts to advance the regulatory science on topics like maternal immunization, human challenge models, and the use of biomarkers to enable vaccine development. Jeff received his MD degree from the University of Alabama School of Medicine. He trained in OB/GYN at the University of Colorado. He then spent several years at the National Cancer Institute at NIH doing basic research and animal modeling with HPV prior to moving to the FDA.

John M. DeSesso, PhD, Fellow ATS
Former Professor, Biochemistry and Molecular & Cellular Biology
Georgetown University School of Medicine, Washington, DC

Principal Scientist, Center for Health Sciences
Exponent, Alexandria, VA

Dr. John DeSesso is a Principal Scientist at Exponent, a scientific and engineering consulting company. He has more than four decades of post-doctoral experience specializing in developmental and reproductive toxicology, general toxicology, anatomy, and risk assessment. He has authored more than 120 papers and chapters, two of which were selected as Outstanding Published Papers Demonstrating an Application of Risk Assessment. He earned his A.B. in Chemistry from Hamilton College and his doctorate in Anatomy and Teratology from the Medical College of Virginia (now VCU School of Medicine. He serves on the editorial board for *Reproductive Toxicology* and the editorial advisory board of *Birth Defects Research*. At Georgetown University School of Medicine, he taught embryology, teratology and gross anatomy for 39 years. He has received numerous teaching awards, including six teacher of the year awards from two institutions (Georgetown University and the School of Pharmacy, Medical College of Virginia); as well as Distinguished Service Awards from the Teratology Society and FASEB. As a consultant, he interacts regularly with both EPA and FDA. He is a Past-President of the Teratology Society (now Society for Birth Defects Research and Prevention), MARTA, and the Risk Assessment Specialty Section of the Society of Toxicology.

Joseph Cafone, MD
Director, Dermatology Late Clinical Development
Johnson & Johnson Innovative Medicine

Dr. Joseph Cafone received his undergraduate degree in BioMedical Engineering from the George Washington University and medical degree from St. George's University. He completed a combined Internal Medicine / Pediatrics residency at Stony Brook University in New York and an allergy and immunology fellowship at the Children's Hospital of Philadelphia. While in training, he was a sub-investigator on multiple clinical trials, including the Phase 2/3 trials for Dupilumab in adolescents with atopic dermatitis. In 2021, he joined the Janssen Immunology Pediatric Development Team and in 2023 transitioned to role of Director within Dermatology Late Clinical Development. When he isn't working, he enjoys tracking down the best slice of pizza in South Philly with his wife and two children.

Katherine (Katie) Kratz, MD
Medical Officer
DPMH | ORDPURM | OND | CDER | FDA

Dr. Katherine (Katie) Kratz is a Medical Officer in the Division of Pediatrics and Maternal Health (DPMH) on the Maternal Health Team in the Office of Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM) at the FDA's Center for Drug Evaluation and Research (CDER). Dr. Kratz is an obstetrician/gynecologist (ob/gyn) and received her medical degree from The University of Chicago Pritzker School of Medicine in 2004. She completed her internship and residency in ob/gyn at The Johns Hopkins Hospital and a fellowship in minimally invasive gynecologic surgery at Florida Hospital. Prior to starting as a Medical Officer at FDA in 2020, Dr. Kratz practiced clinical medicine as gynecologic specialist and assistant professor at The Johns Hopkins Hospital, a generalist with the Mid-Atlantic Permanente Medical Group, and an ob/gyn hospitalist at Anne Arundel Medical Center. In DPMH, Dr. Kratz conducts scientific reviews related to the safety of drug and biologic products for pregnant, lactating, and reproductive-age individuals.

Kelly Stone, MD, PhD
Associate Director for Therapeutic Review
DPACC | OII | OND | CDER | FDA

Dr. Kelly Stone is a pediatrician and allergist/immunologist who serves as a Supervisory Physician and Associate Director for Therapeutic Review in the CDER Division of Pulmonology, Allergy, and Critical Care. In this role, he supervises regulatory review of INDs and NDAs/BLAs for products related to allergic/immunologic diseases and asthma. He serves on the FDA Pediatric Review Committee and was the recipient of a CDER Excellence in Mentoring Award and two group recognition awards for his efforts in guidance development and review of products to treat COVID-19.

Dr. Stone is a graduate of Johns Hopkins University (BA) and the University of Maryland School of Medicine (MD, PhD, Molecular and Cell Biology). He completed pediatric residency at Children's National Medical Center and fellowship training in Immunology at Children's Hospital, Boston. He served on the faculty at Children's Hospital, Boston and Children's National Medical Center, then spent 12 years at the National Institute of Allergy and Infectious Diseases where he was Deputy Chief of the Laboratory of Allergic Diseases, Director of the NIH Clinical Center Allergy and Immunology Fellowship Program, and a Senior Clinician. At NIH, he was the recipient of the NIH Clinical Center Distinguished Clinical Teacher Award, the NIH Director's Ruth Kirschstein Mentoring Award, an NIH Director's Award for scientific accomplishment, as well several NIAID Director's Awards for clinical research and administrative accomplishments. He has served on the Board of Directors of the American Academy of Allergy, Asthma, and Immunology and as a member of the FDA Pulmonary and Allergy Drugs Advisory Committee. He is the current chair of the Accreditation Council for Graduate Medical Education (ACGME) Allergy and Immunology Review Committee and chairs the ACGME Reshaping GME-the Future of Allergy and Immunology working group.

Kevin Ault, MD, FACOG, FIDSA
Professor and Chair, Department of Obstetrics and Gynecology
Western Michigan University Homer Stryker MD School of Medicine

Dr. Kevin Ault is Professor and Chair of the Department of Obstetrics and Gynecology at Western Michigan University Homer Stryker MD School of Medicine. He is an author of current maternal vaccine recommendations. He is a former member of the Center for Disease Control Advisory Committee on Immunization Practices, and a consultant to the American College of Obstetricians and Gynecologists. He is also the Vice President of the National Foundation for Infectious Diseases. His research and academic interests include infection diseases and women's health.

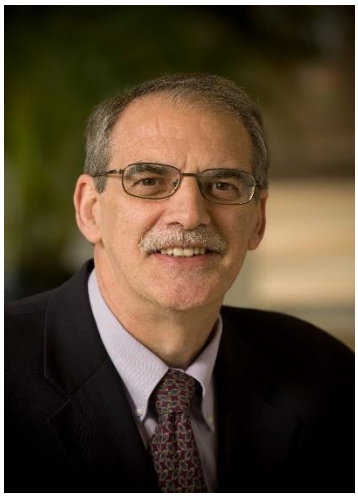
L. Latéy Bradford, MD, PhD
Family Physician, Core Faculty attending in Family Medicine Residency Program
University of Maryland Capital Region Health (UMCRH)

Dr. L. Latéy Bradford is a Family Physician and Core Faculty attending in the Family Medicine Residency Program at the University of Maryland Capital Region Health (UMCRH). Though a native of Dayton, Ohio she is a product of the University of Maryland system, with a B.S. in Biology from UMBC and a dual doctorate (MD/PHD) from the University of Maryland School of Medicine. As part of the physician scientist training program, she earned a PhD in Microbiology & Immunology using genomics and molecular epidemiology to study the vaginal microbiome and changes associated with vulvovaginal candidiasis. Following Family Medicine residency training at the University of Maryland Medical Center, where she served as Chief Resident, she joined the Family Medicine faculty at UMCRH in October 2022. Dr. Bradford provides comprehensive primary care for all members of the family, with a specialty in obstetrics and newborn care. She has a wealth of experience working with underserved communities and addressing complex healthcare needs through a social justice lens.

Laura Bozzi, MS, PhD
Associate Director, Global Epidemiology
Johnson & Johnson

Dr. Laura Bozzi is an Associate Director of Benefit-Risk Assessment in the Global Epidemiology Organization (GEO) at Johnson & Johnson (J&J) in New Jersey. Laura leads clinical and safety teams in patient preference studies and benefit-risk (B-R) assessments for regulatory submissions and internal strategic and safety decisions. She also has leadership roles as an in-house expert in B-R assessment and patient preference policy and methodology, specifically in immunology and maternal-fetal conditions. Laura has been a member of the Benefit-Risk Team and GEO since joining J&J in July 2021. Prior to J&J, Laura completed her MS in Epidemiology and PhD in Pharmaceutical Health Services Research from the University of Maryland, Baltimore.

Leslie Myatt, PhD, FRCOG
Professor, Obstetrics and Gynecology
Director of Perinatal Research, Director of the Center for Development Health, Director and Endowed Professor in Bob and Charlee Moore Institute of Nutrition and Wellness
Oregon Health & Science University, Portland



Dr. Leslie Myatt is Professor of Obstetrics and Gynecology, Director of Perinatal Research, Director of the Center for Developmental Health and Director and Endowed Professor in the Bob and Charlee Moore Institute of Nutrition and Wellness at the Oregon Health & Science University, Portland. Dr. Myatt has served as North American Editor of the journal *Placenta*, President of the Perinatal Research Society, President of the International Federation of Placenta Associations and President of the Society for Gynecologic Investigation. His primary research interests are:

1. The effects of maternal obesity, gestational diabetes and sexual dimorphism on mitochondrial respiration in the placenta and their relationship to epigenetic regulation of placental function and fetal programming
2. Autocrine/paracrine mechanisms in fetal membranes involved in parturition.

He has published over 300 papers and 375 abstracts and has served on many review panels and study sections for NIH, CIHR, and other international grant giving bodies. He was presented with the Naftolin Award for Mentorship in 2014 and the Distinguished Scientist Award in 2017 by the Society for Reproductive Investigation.

Leyla Sahin, MD
Deputy Director for Safety
DPMH | ORDPURM | 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 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.

Lily Mulugeta, PharmD
Acting Associate Director, Policy and Research
DPMH | ORDPURM | OND | CDER | FDA

Dr. Lily Mulugeta is the Acting Associate Director for Policy and Research in the Division of Pediatrics and Maternal Health at the FDA. She engages in scientific and regulatory review and research related to pediatric drug development. Dr. Mulugeta serves as a representative for the Division on the FDA Pediatric Review Committee (PeRC). Prior to joining the Division in 2017, Lily was the Scientific Lead for Pediatrics in the Division of Pharmacometrics at the FDA. Prior to joining the FDA, Dr. Mulugeta practiced as a Critical Care Specialist at Children's National Medical Center in Washington D.C. She also served as a faculty member in the Department of Pediatrics at the George Washington School of Medicine and in the Department of Pharmacy at the University of Maryland College. Dr. Mulugeta received her PharmD degree from the University of Kentucky, College of Pharmacy and completed a pediatric residency at Inova Fairfax Hospital in Falls Church, Virginia.

Lynne Yao, MD
Director
DPMH | ORDPURM | 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.

Maria Fernanda Scantamburlo Fernandes, MD

Associate VP- Global Patient Safety/Oncology
Eli Lilly and Company

Dr. Maria Fernanda Fernandes is an obstetrician and gynecologist, with over 15 years of experience in her field. Over the past seven years, she has transitioned into the pharmaceutical industry, where her focus lies primarily on patient safety. Currently, she holds the position of industry expert/deputy topic leader on the ICH21 working group, a role that focuses on the inclusion of pregnant and breastfeeding individuals in clinical trials. In addition, Dr Fernandes is a contributing member of TransCelerate, an industry consortium, where she contributes to the Pregnancy and Breastfeeding topic under the Interpretations of Pharmacovigilance Guidances & Regulations Workstream. She is a valuable resource for safety or development questions and serves as the Co-chair of the Reproductive, Pregnancy & Pediatric Safety Advisory Committee at Eli Lilly.

Marie Teil, MS
Global Head, Woman of Childbearing Age Program
UCB Biopharma SRL

Ms. 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.

Melanie E. Bhatnagar, MD
Associate Director for Pediatric Education and Outreach
OPT | OCPP | OC | FDA

Dr. Melanie E. Bhatnagar is the Associate Director for Pediatric Education and Outreach within the Office of Pediatric Therapeutics (OPT) at the U.S. Food and Drug Administration (FDA). In her role overseeing OPT's Pediatric Education and Outreach Program, Dr. Bhatnagar works to promote, enhance, and drive cross-cutting educational activities and initiatives to further knowledge on important issues pertaining to children's health and well-being. She also works to build and strengthen strategic partnerships to drive and inform scientific and policy priorities to advance children's health.

Dr. Bhatnagar has previously served as a pediatric clinical consultant in the FDA's Center for Drug Evaluation and Research (CDER) Division of Pediatrics and Maternal Health (DPMH) and as a pediatric ethicist and acting Team Leader in OPT's Pediatric Ethics Program. In those capacities, Dr. Bhatnagar supported review divisions throughout the FDA in the review of pediatric clinical investigations, including understanding agency policies and procedures, regulations, and guidance surrounding pediatric product development, and in the interpretation of the FDA's human subject protection regulations that govern research involving children.

Dr. Bhatnagar received her undergraduate degree in biology from the University of Virginia and her medical doctorate from the George Washington University School of Medicine and Health Sciences, where she also completed a scholarly concentration in medical education and leadership. She completed her pediatric residency training at the University of Maryland and is boarded in pediatrics. Prior to joining the FDA, she spent several years in private clinical practice as a general pediatrician.

Michael Keller, MD
Pediatric Immunologist, Associate Professor
Director of the Jeffrey Modell Research and Diagnostic Center for Primary Immunodeficiency Disorders
Children's National Hospital

Dr. Michael Keller is a pediatric immunologist and Associate Professor at Children's National Hospital and director of the Jeffrey Modell Research and Diagnostic Center for Primary Immunodeficiency Disorders at Children's National. His research focuses on the use of adoptive T-cell therapies for treatment of infections in immunocompromised patients, and he is the director of the Translational Research Laboratory in the Program for Cell Enhancement and Technologies for Immunotherapy at Children's National.

Mona Khurana, MD
Pediatric Team Leader
DPMH | ORDPURM | OND | CDER | FDA

Dr. Mona Khurana is board certified in general pediatrics and in pediatric nephrology. She obtained her undergraduate Bachelor of Science and Doctor of Medicine degrees from George Washington University in Washington DC. Following her internship at Nicklaus Children's Hospital and residency at Yale New-Haven Children's Hospital, she completed a fellowship in Pediatric Nephrology at Children's Hospital Boston. In 2004, she joined the faculty at Children's National Hospital in Washington DC after her fellowship where she was an Assistant Professor of Pediatrics before joining FDA in 2009. Dr. Khurana initially worked as a Medical Reviewer in the FDA's Division of Nonprescription Drug Products in the Center for Drug Evaluation and Research (CDER). She moved to the Division of Pediatrics and Maternal Health (DPMH) as a Medical Reviewer in 2015 and has been a Pediatric Team Leader in DPMH since 2016 where her efforts have primarily focused on working collaboratively with review divisions in the Office of New Drugs to assist with pediatric drug development in all therapeutic areas.

Natalie (Sparacio) Hayden, BA
Founder
Lights, Camera, Crohn's

Ms. Natalie (Sparacio) Hayden is a former TV news anchor and reporter whose mission in life is to advocate for those battling inflammatory bowel disease. She was diagnosed with Crohn's disease in July 2005, two months after graduating from Marquette University. Her award-winning blog, Lights, Camera, Crohn's, which launched in July 2016, covers everything from overcoming struggles to celebrating small victories throughout all parts of the patient journey from diagnosis and beyond.

Along with her blog, Natalie is part of the Patient Advisory Board for IBD Moms and IBD Social Circle (#IBDSC), on the Patient Engagement Research Council for Janssen Pharmaceutical, and serves on the Patient Leadership Council for the Social Health Network. She's also a patient advisor for the PIANO (Pregnancy Inflammatory Bowel Disease and Neonatal Outcomes research project), and a contributor to Everyday Health.

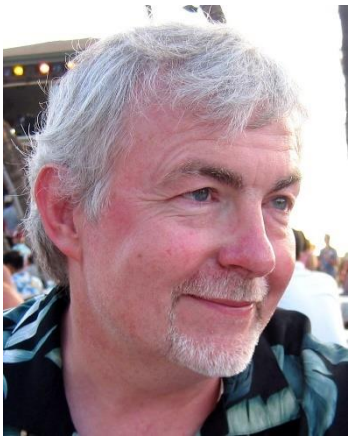
Natalie was selected as the IBD Research Insider and Patient Reporter for the Crohn's and Colitis Foundation and the American Gastroenterological Association. She is also an active volunteer and spokesperson for the Mid-America chapter of the Foundation. Natalie has been featured by Women's Health Magazine, CBS This Morning, Wall Street Journal, Prevention Magazine, Self Magazine, The Mighty, and on several podcasts. Natalie was honored with the Social Health Award's Community Cultivator Award in 2022.

Most recently, she was the U.S. Patient Ambassador for the first-ever Global Consensus Conference for Pregnancy and IBD. As an IBD mom of three children, Natalie hopes her story can comfort, educate, and inspire fellow patients.

Nick Illsley, DPhil
Principal and Senior Scientist
Placental Research Group LLC

Emeritus Professor, Pharmacology, Physiology & Neuroscience
Rutger-New Jersey Medical School

Adjunct Professor, Pharmacology & Toxicology
Ernest Mario School of Pharmacy, Rutgers University



Dr. Nick Illsley is a Principal and Senior Scientist with the Placental Research Group LLC. He is also Emeritus Professor of Pharmacology, Physiology and Neuroscience at Rutgers-New Jersey Medical School and Adjunct Professor of Pharmacology and Toxicology at the Ernest Mario School of Pharmacy at Rutgers University. He earned his BSc at the University of Bristol, U.K. and his DPhil at the University of Oxford. He founded the Placental Research Group after staff/faculty positions at the UK MRC Clinical Research Centre, University of California San Francisco, Hackensack University Medical Center, and Rutgers University. He is recognized internationally for his work in the fields of placental biology and perinatology, He held the Presidency of the International Federation of Placenta Associations from 2007-2012. He has received multi-year funding from NIH and served on review panels for both NIH and CIHR. He currently serves as editor for the journal *PLACENTA*. His research is focused on human placental transport and metabolism, hypoxia, trophoblast differentiation and invasion and aspects of these fields in pregnancy pathologies such as fetal growth restriction, preeclampsia, and placenta accreta. He is currently involved in the NIH Integrated Transporter Elucidation Center (InTEC) at Rutgers University.

Ofer Levy, MD, PhD
Staff Physician & Principal Investigator, Director, Precision Vaccines Program, Division of Infectious Diseases
Boston Children's Hospital

Professor
Harvard Medical School

Dr. Ofer Levy was born to and raised by the artist Benjamin Levy and music composer Hannah Levy in New York City, where he graduated from the Bronx High School of Science. After graduating from Yale College (B.S., *Molecular Biophysics and Biochemistry*), Dr. Levy entered the Medical Scientist (MD/PhD) Training Program at New York University School of Medicine. There he earned his PhD under the mentorship of Drs. Peter Elsbach and Jerrold Weiss, characterizing neutrophil-derived antimicrobial proteins and peptides. Inspired by his wife Sharon's example, he chose Pediatrics and completed both residency and fellowship at Boston Children's Hospital. He is currently Professor at Harvard Medical School as well as principal investigator, staff physician in Infectious Diseases and the Director of the *Precisions Vaccine Program* in the Department of Pediatrics, Boston Children's Hospital. The *Precision Vaccines Program* is an academic program that fosters international collaboration between academia, government, and industry for development of vaccine formulations optimized to protect vulnerable populations. Dr. Levy's laboratory is focused on modeling vaccine-induced human immune responses *in vitro* using a variety of platforms including three-dimensional microphysiologic systems as well as global molecular ("OMIC") approaches to accelerate and de-risk development of vaccines optimized for populations with distinct immune responses, including those at the extremes of age who suffer the most infections. He currently leads or co-leads multiple NIH/NIAID-supported studies, including (a) Adjuvant Discovery and Development Program contracts, leveraging high throughput screening to discover, characterize, and formulate novel small molecule adjuvants to enhance vaccine responses of vulnerable populations such as infants and older adults and (b) systems biology projects via the Human Immunology Project Consortium and the *Immune Development in Early Life* (IDEAL) program to define biomarkers of vaccine responsiveness, respiratory infection and asthma. Funded by the Coalition for Epidemic Preparedness Innovations (CEPI), the PVP is also leveraging systems biology to study vaccine safety. Dr. Levy pursues discovery and development of vaccines against SARS-CoV-2, influenza, HIV, RSV and pertussis as well as an opioid vaccine against fentanyl overdose. Dr. Levy serves on the U.S. Food & Drug Administration (FDA) Vaccines and Related Biologic Products Advisory Committee (VRBPAC) and participated in the Emergency Use Authorization and approval of COVID vaccines. He has given two TEDx talks and has regularly appeared in major media including *BBC*, *CNN*, *FoxNews*, *NBC Nightly News*, *National Geographic*, *The New York Times*, *Scientific American*, *USA Today* and *The Wall Street Journal*. He lives in Cambridge, Massachusetts with his wife Dr. Sharon Levy and their three children.

Raman Venkataramanan, PhD, FCP, FAAPS
Distinguished Service Professor of Pharmaceutical Sciences and Pathology
University of Pittsburgh

Director of Clinical Pharmacokinetics Laboratory, Director of Therapeutic Drug Monitoring and Toxicology
UPMC

Dr. Raman Venkataramanan is a Distinguished Service Professor of Pharmaceutical Sciences and Pathology at the University of Pittsburgh. His research focuses on optimizing drug therapy in pregnancy "prevention of preterm labor by optimizing the use of 17-hydroxyprogesterone caproate during pregnancy and optimizing buprenorphine treatment in pregnancy"; and "optimization of use of medications in organ transplant patients". He has been consistently funded for OBGYN pharmacology work for the past 18 years. Dr. Venkataramanan received is pharmacy degree from the University of Madras, India, his Master of Pharmacy from Birla Institute of Technology and Science, India, and his doctorate from the University of British Columbia, Canada; followed by a postdoctoral fellowship at the University of Washington. Dr. Venkataramanan joined the faculty at the University of Pittsburgh in 1980. He serves on the editorial board for *Therapeutic Drug Monitoring* and four additional online journals, he is the editor for the *American Journal of Analytical Chemistry,* and reviewer for ten additional journals. Raman has presented more than 200 lectures/seminars at national and international meetings. He has published over 450 papers in peer reviewed journals. Dr. Venkataramanan is a member of AAPS, ACCP, IAATDMCT, ITS, and AST. Over the years, he has mentored 35 PhD students, 10 MS students, 30 fellows, and 10 faculty members. Raman has received various awards, including most recently the Distinguished Investigator Award from ACCP and Distinguished Alumni Award, BITS, Pilani in 2024.

Robert "Skip" Nelson, MD, PhD
Executive Director, Pediatric Drug Development, Child Health Innovation Leadership Department
Johnson & Johnson

Previously (2006-2017), Dr. Robert Nelson was the Deputy Director and Senior Pediatric Ethicist in the Office of Pediatric Therapeutics at the U.S. Food and Drug Administration. Prior to joining FDA, Dr. Nelson spent 20 years in the academic practice of pediatric critical care medicine, most recently as Professor of Anesthesiology, Critical Care and Pediatrics at The Children's Hospital of Philadelphia (CHOP), and University of Pennsylvania School of Medicine. Dr. Nelson is a member of the International Council for Harmonisation (ICH) E11A Working Group developing a guideline on the use of extrapolation in pediatric drug development plans. He recently completed a four-year term as a member of the Secretary's Advisory Committee on Human Research Protections (SACHRP) and serves as the Industry Representative to the FDA Pediatric Advisory Committee. After receiving his MD degree from Yale University, Dr. Nelson trained in pediatrics (Massachusetts General Hospital), neonatology and pediatric critical care (University of California, San Francisco). He has a Master of Divinity degree from Yale Divinity School and a PhD in The Study of Religion from Harvard University, specializing in ethics.

Robert M. Califf, MD
25th Commissioner
FDA

Dr. Robert M. Califf was confirmed as the 25th Commissioner of Food and Drugs.

As Commissioner, Dr. Califf oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products.

Dr. Califf has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

This is Dr. Califf's second stint as Commissioner. He also served in 2016 as the 22nd Commissioner. Before assuming the position at that time, he served as the FDA's Deputy Commissioner for Medical Products and Tobacco.

Prior to rejoining the FDA in 2022, Dr. Califf was head of medical strategy and Senior Advisor at Alphabet Inc., contributing to strategy and policy for its health subsidiaries Verily Life Sciences and Google Health. He joined Alphabet in 2019, after serving as a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and was the founding director of the Duke Clinical Research Institute.

Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco and a fellowship in cardiology at Duke.

Rohan Lewis, PhD
Professor, Placental and Integrative Physiology
Faculty of Medicine, University of Southhampton

Dr. Rohan Lewis is Professor of Placental and Integrative Physiology at the Faculty of Medicine, University of Southampton. He completed his PhD at the University of Auckland in New Zealand, followed by postdoctoral fellowships at the Universities of Cambridge and Southampton. In 2005, he secured a faculty position at the University of Southampton, where he currently serves as Deputy Head of School Research for the School of Human Development and Health within the Faculty of Medicine.

Professor Lewis's research is centred on the placenta and how it functions to ensure a healthy birth outcome. His laboratory employs a truly interdisciplinary approach to studying placental transfer, integrating physiological experiments, multiscale 3D imaging, and computational modelling. This comprehensive approach has significantly advanced the understanding of how nutrients, hormones, and pharmacological drugs are transferred through the placenta.

Ruth Oliver, PhD
Global Quantitative Clinical Pharmacology
Data Sciences Institute, Takeda

Dr. Ruth Oliver leads the Global Quantitative Clinical Pharmacology function as part of the Data Sciences Institute at Takeda.

Ruth brings more than 25 years of experience in the field of clinical pharmacology and pharmacometrics driving drug development from discovery through life-cycle management. Ruth has lead teams and functions within large and mid-size pharmaceutical companies. Prior to Takeda, Ruth worked at UCB for 15 years where she initially focussed on early phase translational clinical pharmacology across Immunology and CNS; she then took on an expanded role as a Senior Director leading QCP and Pharmacometrics. Her last role at UCB was as Vice President, Quantitative Discovery and Development leading both pre-clinical and clinical functions (DMPK/non-clinical PK-PD/QCP/Pmx). In addition, Ruth took on various matrix leader roles as a discovery project leader, development leader and early clinical lead on different projects.

Prior to UCB, Ruth spent her early career working at GSK (Neurosciences), AZ (Oncology) and as a consultant at GloboMax (now ICON).

Ruth received her bachelor's degree in mathematics and physics (Jt Hons.) and her PhD in applied mathematics and pharmacokinetics at the University of Manchester, England, UK.

Sonaly R. McClymont, MD
Medical Officer, Pediatric Team
DPMH | ORDPURM | OND | CDER | FDA

Dr. Sonaly McClymont joined the FDA in 2021 as a Medical Officer on the Pediatric Team in the Division of Pediatric and Maternal Health (DPMH), Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER). Prior to joining the FDA, she practiced Pediatric Hospital Medicine at Children's National Hospital for 11 years. Sonaly's clinical practice and academic work focused on the care of children with medical complexity as well as newborn care and resuscitation. Sonaly has a medical degree from Thomas Jefferson University and completed pediatric residency at the University of California San Diego/Rady Children's Hospital. She received a bachelor's degree in religion from the University of Rochester with a minor degree in biology.

Tamara Johnson, MD, MS
Lead Physician, Maternal Health Team
DPMH | ORDPURM | OND | CDER | FDA

Dr. Tamara Johnson is a Lead Physician of the Maternal Health Team within the Division of Pediatrics and Maternal Health (DPMH), Office of New Drugs (OND), Center for Drug Evaluation and Research, US Food & Drug Administration. Dr. Johnson has been with the FDA for over 16 years. Initially, as a Medical Officer in the OND Division of Gastroenterology and Inborn Errors Products, she has led the DPMH Maternal Health Team for nine years. The Maternal Health Team is responsible for evaluating the safe use of drug and biologics products in pregnant and lactating individuals, and is involved in review of prescription drug labeling (including implementation of the Pregnancy and Lactation Labeling Rule (PLLR)), clinical lactation studies, and post-approval pregnancy safety studies. Dr. Johnson participates in policy and guidance development, as well as several CDER and FDA working groups. Dr. Johnson earned her Doctorate in Medicine from the Rutgers Robert Wood Johnson Medical School in New Jersey. She completed an internship at the Georgetown/Providence Hospital Family Medicine program and completed residency training in General Preventive Medicine/Public Health at the University of Maryland Baltimore.

Uma Mahadevan, MD
Lynne and Marc Benioff Professor of Gastroenterology
University of California, San Francisco

Director
UCSF Center for Colitis and Crohn's Disease Center

Dr. Uma Mahadevan is the Lynne and Marc Benioff Professor of Gastroenterology, Director of the Colitis and Crohn's Disease Center and Director of the Advanced IBD Fellowship at the University of California, San Francisco. She specializes in inflammatory bowel disease (IBD), particularly pregnancy and drug safety. She completed a medical degree at the State University of New York in Brooklyn, residency in internal medicine at Mount Sinai Medical Center in New York, Fellowship in gastroenterology at UCSF, and Advanced fellowship in IBD at the Mayo Clinic, Rochester, Minnesota. For her exceptional work in pregnancy and drug safety and her mentoring of GI fellows and junior faculty she received the AGA 2022 Immunology, Microbiology & Inflammatory Bowel Diseases (IMIBD) Section Research Mentor Award and the 2022 Sherman Prize.

Dr. Mahadevan is a fellow of the American Gastroenterological Association, for whom she was Chair for the IMIBD Section, Chair of the AGA National IBD Parenthood initiative and Director (2023) and co-Director (2022, 2017) of the AGA Postgraduate Course. She is a Fellow of the American College of Gastroenterology and served on the Educational Affairs Committee and as a member of the Advanced IBD Fellow Curriculum Committee. She was Chair of the Crohn's Colitis Foundation Clinical Research Grants committee, a member of the National Scientific Advisory Committee and Taskforce on Women in IBD, and co-chair of the annual Crohn's Colitis Congress (2020). Dr. Mahadevan is a member of the International Organization of IBD (IOIBD) for which she serves on the nominating committee.

Dr. Mahadevan is a global expert on the management of pregnancy and drug safety in the patient with IBD. She is also interested in the role of diet and IBD and has an ongoing original study in this area. Her current projects include a national prospective registry of pregnancy outcomes and drug safety in women with IBD on immunosuppressive and biologic medications (PIANO) and a clinical trial on the impact of nutritional interventions in the management of IBD (SEAMUS). She has an interest in digital health and lead the transition of the GI Division to telemedicine at the start of the pandemic in March 2020 and has developed an IBD Chatbot with the Center for Digital Health and Innovation at UCSF. Dr. Mahadevan is proud to have mentored several Advanced IBD Fellows who know hold key roles in IBD Centers around the United States.

Vani Vannappagari, MPH, PhD
Vice President & Global Head of Epidemiology and Real World Evidence
ViiV Healthcare

Dr. Vani Vannappagari is VP & Global Head of Epidemiology and Real World Evidence at ViiV Healthcare. In this role, she sets the strategy for conducting studies to collect real world evidence on treatment effectiveness, adherence and safety of the antiretroviral drugs. She also leads studies in pregnancy and registries that evaluate drug safety during pregnancy; and non-interventional studies in pediatric and adolescent populations. She is the industry co-chair of the Antiretroviral Pregnancy Registry steering committee.

Dr. Vannappagari is also an Adjunct Associate Professor at the department of Epidemiology, UNC-Chapel Hill. Prior to joining ViiV Healthcare, she was director of infectious disease epidemiology at GlaxoSmithKline leading epidemiology projects for HIV, influenza, anthrax and malaria drug development. Her work involved disease epidemiology, pharmacovigilance and post marketing drug safety, pregnancy and drug exposure registries. Dr. Vannappagari has MBBS from Karnatak Medical College, India and MPH & PhD in epidemiology from the University of North Carolina at Chapel Hill.