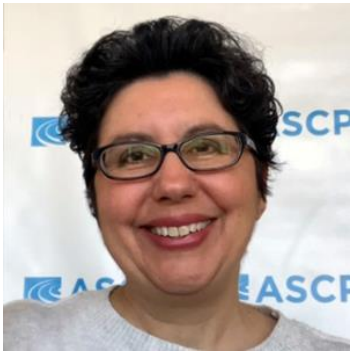
ADEPT 9: Enhancing Diversity in Therapeutics Development for Pediatric Patients

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

Public In-Person and Virtual Workshop
September 6, 2024 | 9:00 AM – 5:00 PM Eastern Time

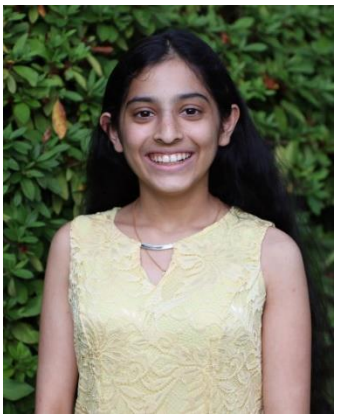
Biographies

Susan Abdel-Rahman, PharmD, MA
Chief Scientific Officer
Health Data Synthesis Institute



Dr. Susan Abdel-Rahman is a pediatric researcher, innovator, educator, and clinician with 25 years of experience in academic medicine. She is a former professor of Pediatrics and Marion Merrell Dow/Missouri Endowed Chair in Pediatric Clinical Pharmacology. She also directed Health Care Innovation for the Children's Mercy Research Institute, directed an NIH funded T32 fellowship program, and provided clinical care as part of a Clinical Pharmacology consult service before transitioning into her current as Chief Scientific Advisor for a Kansas City-based technology start-up. Dr. Rahman has held leadership roles at the regional, national and international levels including serving as Chair of Missouri Medicaid's Drug Utilization Review Board, President for the American Society for Clinical Pharmacology and Therapeutics, and Technical Advisor to the World Health Organization. As a PI she has received funding from a wide array of sources including the NIH, U.S. FDA, CDC, WHO, Pharmaceutical Industry, private foundations, and the National Endowment for the Arts. She also has numerous patents to her credit including medical devices that have been cleared by the FDA and screening tools that have been licensed to private sector companies. She continues to consult with public and private organizations in the area of pediatric pharmacology, pediatric trial design and conduct, and innovation implementation in developing countries.

Anvita Ambardekar
High School Student, Pediatric Perspective
iCAN



Ms. Anvita Ambardekar is a junior in high school from Orange County, California. She is an active member and founding member of the iCAN (International Children's Advisory Network) chapter at CHOC (Children's Hospital of Orange County), where she serves as the Funding Director. Anvita loves doing volunteer work and collaborates with various nonprofits to make a positive impact in her community.

With a strong interest in biomedical research and biotechnology, Anvita is eager to explore innovations that can transform healthcare for children. She is dedicated to raising awareness about the importance of pediatric voices in healthcare and actively participates in discussions and projects aimed at promoting these values. Recently, Anvita represented the CHOC iCAN chapter at the 2024 iCAN Summit in Bari, Italy, where she, along with other students, participated in discussions to provide feedback to healthcare/pharmaceuticals companies about clinical trials from a pediatric standpoint.

Stephen J. Balevic, MD, PhD, MHS, RhMSUS
Associate Professor of Medicine and Pediatrics,
Director of Pharmacometrics and Fit-for-Purpose Trials
Duke University/Duke Clinical Research Institute

Dr. Stephen Balevic is an adult and pediatric rheumatologist at Duke University, and a clinical researcher at the Duke Clinical Research institute where he is Director of the Pharmacometrics and Fit-for-Purpose Trials program. He completed his PhD in Pharmaceutical Sciences at the UNC Eshelman School of Pharmacy and served as an Interpersonnel Agent with the Office of Pediatric Therapeutics at the FDA. He is also the Assistant Scientific Director for the Childhood Arthritis and Rheumatology Research Alliance (CARRA) Registry.

Dr. Balevic's research interests are in precision dosing through pharmacokinetic/pharmacodynamic modeling and optimizing clinical trial design in both children and adults. He was principal investigator for the first completely decentralized trial in pediatric lupus (iPERSONAL, NCT04358302). This innovative trial was able to successfully enroll a diverse group of pediatric patients with a rare disease from across the country.

Florence Bourgeois, MD, MPH
Associate Professor, Pediatrics
Harvard Medical School

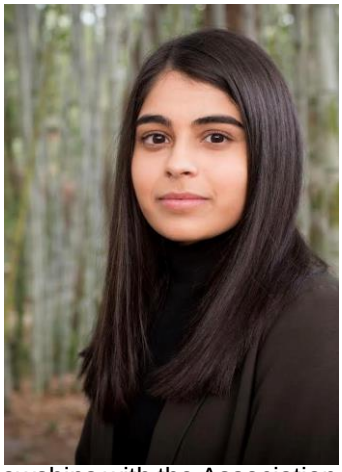
Director
Harvard-MIT Center for Regulatory Science

Directs Initiative in Pediatric Therapeutics and Regulatory Science
Boston Children's Hospital

Scientific Director, PrecisionLink Biobank for Health Discovery
Boston Children's Hospital

Dr. Florence Bourgeois' primary research focus is on the regulation and use of therapeutic products in pediatric populations and the development of novel methodologies and research infrastructure to increase evidence generation for pediatric interventions. At Harvard Medical School, she directs a fellowship program in regulatory science and leads cross-disciplinary projects in collaboration with the FDA to advance pre- and post-market evaluation of therapeutic products. Dr. Bourgeois has served as an Expert Visitor to the European Medicines Agency to analyze the EU's pediatric drug legislation and is the recipient of an Innovation in Regulatory Science Award from the Burroughs Wellcome Fund to investigate the impact of drug and device policies on product access for pediatric populations. Dr. Bourgeois is a graduate of Yale University and Washington University School of Medicine in St. Louis. She completed her residency training in pediatrics and fellowship in pediatric emergency medicine at Boston Children's Hospital. She was a NRSA research fellow and obtained a Master in Public Health in clinical effectiveness at the Harvard School of Public Health.

Sneha Dave, BA
Executive Director
Generation Patient



Sneha Dave graduated from Indiana University in May 2020, majoring in chronic illness advocacy and journalism. She created Generation Patient to develop support systems for adolescents and young adults with chronic conditions across the U.S. and internationally. She is proud to work with a team composed entirely of young adults with chronic conditions and keep Generation Patient independent of funding from the private healthcare industry. Sneha has spoken at the White House and on Capitol Hill, featured nationally on C-SPAN, and is a past contributor for U.S. News and World Report. She joined the Midwest Comparative Effectiveness Public Advisory Council, an independent appraisal committee of the Institute for Clinical and Economic Review. She also serves on the patient panel for the British Medical Journal, on a grantmaking committee with the Robert Wood Johnson Foundation, and as part of the Yale Collaboration Regulatory Rigor, Integrity, and Transparency advisory board. Sneha was awarded two academic fellowships with the Association of Health Care Journalists. For her work, the We Are Family Foundation selected her as one of the most influential teenagers in 2018 and was recognized as an American Association of People with Disabilities Emerging Leader in 2020.

Martha Donoghue, MD
Associate Director of Pediatric Oncology and Rare Cancers, Oncology Center of Excellence
Office of the Commissioner, FDA

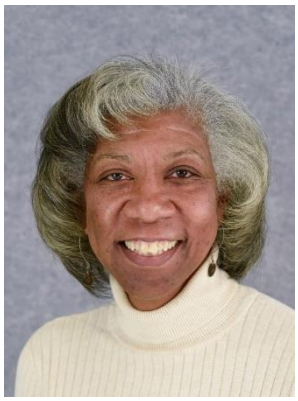
Dr. Martha Donoghue is a board-certified pediatric oncologist and pediatrician. She serves as the Associate Director for Pediatric Oncology and Rare Cancers in the Oncology Center of Excellence and the Acting Associate Director for Pediatric Oncology in the Office of Oncologic Diseases in the Center for Drug Evaluation (CDER) and Research at the FDA. In these roles, she oversees the implementation of pediatric regulations designed to facilitate the timely investigation of drugs and biological products for pediatric patients with cancer, supports and promotes consistency of regulatory work relating to pediatric oncology and rare cancer drug development across CDER and the Center for Biologics Evaluation and Research (CBER), and works with stakeholders to address challenges and foster development of drugs to treat pediatric and other rare cancers. Areas of special interest include the use of innovative clinical trial designs and real-world data to optimize drug development for rare cancers. Prior to joining FDA in 2009, Dr. Donoghue completed a fellowship in Pediatric Hematology and Oncology at the Children's National Medical Center after working for several years as a general pediatrician in private practice. She received her medical degree from Emory University and completed a residency in general pediatrics at the Georgetown University Medical Center.

Christina Edwards, MHA
Director of Clinical Trials
National Minority Quality Forum

Ms. Christina Edwards is the Director, Clinical Trials at National Minority Quality Forum's (NMQF) Center for Clinical and Social Research. She leads their MyClinical research network, which aims to increase clinical trial participation among underserved and underrepresented populations through the provision of research training to community clinicians to be Principal Investigators.

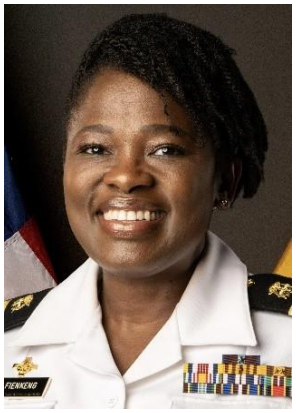
Christina has over ten years in the clinical research space working in various research settings ranging from industry-sponsored central nervous system (CNS) trials to academic research at Weill Cornell Medicine, managing a multisite, NIH funded, pediatric study. She later transitioned to the New York–Presbyterian Health System where she led industry-sponsored clinical trials for the Department of Medicine-Pulmonary and Critical Care. She began her academic career at Howard University, earning her Bachelor of Science in Biology. She later earned her Master of Health Administration from George Washington University Milken Institute School of Public Health.

Carla Epps, MD, MPH, FAAP
Senior Physician
DPMH, ORPURM, OND, CDER, FDA



Dr. Carla Epps is a board-certified pediatrician. She joined the FDA in 2009 and currently serves as a medical officer in the Division of Pediatric and Maternal Health/Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine in the Center for Drug Evaluation and Research, U.S. Food and Drug Administration. She has also served as a medical officer in the Division of Gastrointestinal and Inborn Errors Products (DGIEP), the Office of Orphan Products Development, and the Office of Pediatric Therapeutics. She has been involved in a number of FDA efforts related to pediatric drug development and rare disease drug development, including development of guidances for industry, organization of educational programs on rare diseases for FDA staff, and participation in collaborative activities between FDA and external stakeholders to facilitate development of products for pediatric patients.

CAPTAIN Mathilda Fienkeng, PharmD, MS
Director
DMPD, OMP I, OMP, CDER, FDA



CAPTAIN Mathilda Fienkeng serves as the Director of the Division of Medical Policy Development, in the Center of Drug Evaluation and Research's Office of Medical Policy at the Food and Drug Administration. In this role, CAPT Fienkeng provides leadership, oversight, and direction to a diverse staff of medical, pharmacy, public health, legal, project management and administrative professionals in the development of new and ongoing policy initiatives pertaining to human drug development, human drug approval, bioresearch monitoring, and human subject protection. She joined FDA in 2008 and has public health experience in prescription drug advertising and promotional labeling review, surveillance and enforcement, drug shortage, and domestic and international emergency response. Prior, she worked as a registered nurse and a Secondary Education Teacher. CAPT Fienkeng was commissioned in the U.S. Public Health Service in 2008 and holds the rank of Captain (O-6). She earned a Doctor of Pharmacy degree and a Master of Science in Regulatory Science from the University of Maryland School of Pharmacy, an Executive Certificate in Public Policy from Harvard Kennedy School of Executive Education, an Associate of Science in Nursing from Essex Community College, Baltimore MD, and a Bachelor of Arts in Bilingual Education from Ecole Normale Supérieure, University of Yaoundé I, Cameroon.

Dionna J. Green, MD
Director
OPT, OCPP, OC, FDA

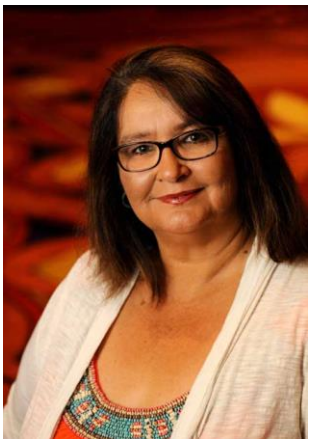
Dr. Dionna J. Green is the Director of the Office of Pediatric Therapeutics (OPT) in the Office of the Clinical Policy and Programs in the Office of the Commissioner at the US Food and Drug Administration (FDA). OPT is a congressionally mandated office whose mission is to assure access for children to innovative, safe, and effective medical products. Dr. Green leads an organization that is responsible for spearheading, coordinating, and facilitating cross-cutting activities of the FDA in the areas of pediatric health and product development, pediatric ethics, neonatology, rare diseases, pharmacovigilance, international collaboration, regulatory science, and education and outreach.

Prior to her current position, Dr. Green served as the Deputy Director of OPT. Dr. Green originally joined the FDA in 2009 and worked in the Office of Clinical Pharmacology (OCP), in the Center for Drug Evaluation and Research (CDER) as a Medical Officer with the Pediatric Clinical Pharmacology Staff where she was engaged in regulatory science research and policy work focused on identifying strategies for improving the design, efficiency, and success rates of pediatric drug development trials. She subsequently became a Medical Officer/Policy Lead with the OCP Guidance and Policy Team, which was charged with the systematic identification, development, and implementation of contemporary clinical pharmacology-related FDA guidances, policies and procedures.

Dr. Green has given numerous invited national and international presentations and published several peer-reviewed articles and book chapters on topics such as pediatric clinical pharmacology, pediatric clinical trial design, and pediatric product development and regulatory considerations.

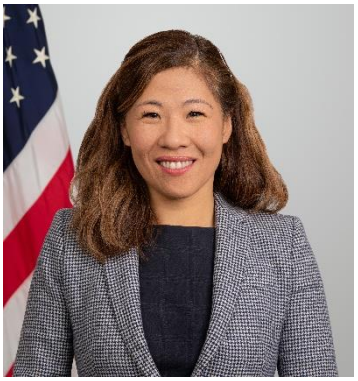
Dr. Green received her medical degree from the Howard University College of Medicine in Washington, D.C., and her clinical training in pediatric medicine from the Herman & Walter Samuelson Children's Hospital at Sinai in Baltimore. She completed a clinical pharmacology research fellowship with the Georgetown University Drug Discovery Program, and a regulatory science fellowship with the FDA Commissioner's Fellowship Program. Dr. Green is currently the President of the American College of Clinical Pharmacology (ACCP), as well as a Fellow of ACCP.

Billie Jo Kipp, PhD
Clinical Psychologist
Indigenous Innovators Collaborative



Dr. Billie Jo Kipp is a clinical psychologist and a member of the Blackfeet Tribe. Dr. Kipp worked as a research associate at the University of New Mexico Center of Alcoholism, Substance Abuse and Addiction, and she assisted New Mexico's Head Start programs through her work as a local specialist for the Academy for Educational Development's American Indian Technical Assistance Network in Washington, D.C. As an associate scientist at the University of New Mexico Masters in Public Health's School of Medicine, Department of Family and Community Medicine in Albuquerque, Dr. Kipp coordinated her department in the establishment of a range of collaborative laboratory and/or field research projects. She also worked as a child and clinical psychologist at the Laguna Behavioral Health Services in Laguna, NM; child and clinical psychologist at Sandia Behavioral Health in Bernalillo, NM; co-investigator for the Community Health Paraprofessional Diabetes Specialist Training Program's Project ECHO at the University of New Mexico; and associate director of training and education at the University of New Mexico's Center for Native American Health, Department of Family and Community Medicine in Albuquerque. Dr. Kipp has contributed to the development of an Indigenous model of education and evaluation through her tenure as a Tribal College President. Dr. Kipp was selected by the American Psychological Association as FIRSTS WOMEN OF COLOR CHANGE MAKERS NATIONAL TOUR and one of the top NATIVE AMERICAN LEADERS IN HIGHER EDUCATION and currently co-chair of the Division 18 APA Diversity Committee. Dr. Kipp's research and clinical experience, has positioned her well as an expert in Native American education, health, and wellness.

Christine S. Lee, PharmD, PhD
Acting Associate Commissioner and Director
OMHHE, OC, FDA



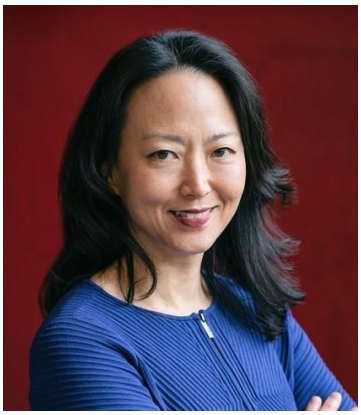
Dr. Christine S. Lee serves as the Acting Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity (OMHHE) in the Office of the Commissioner at the U.S. Food and Drug Administration (FDA). In this role, Dr. Lee provides leadership, oversight, and direction on minority health and health disparity matters for the agency and leads collaborative strategic initiatives that advance health equity, including OMHHE's Enhance Equity Initiative and the Racial and Ethnic Minority Acceleration Consortium for Health Equity (REACH) Initiative.

Dr. Lee began her FDA career in 2013 at the Center for Drug Evaluation and Research (CDER), where she held roles in Professional Affairs and Stakeholder Engagement, the Office of Surveillance and Epidemiology, and the Office of Compliance. Prior to joining the FDA, Dr. Lee worked at the Office of the Assistant Secretary for Health (OASH) at the Department of Health and Human Services (HHS). Dr. Lee received her PharmD from the University of Buffalo and her PhD in Pharmaceutical Outcomes and Policy from the University of Florida.

Lois K. Lee, MD, MPH, FAAP, FACE
Senior Associate in Pediatrics, Division of Emergency Medicine
Boston Children's Hospital

Associate Professor of Pediatrics and Emergency Medicine
Harvard Medical School

Associate Program Director for Public Policy, Sandra L. Fenwick Institute for Pediatric Health Equity and Inclusion
Boston Children's Hospital



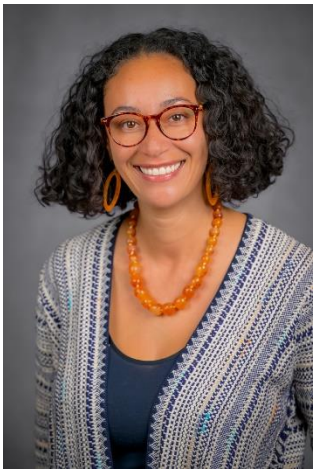
Dr. Lois Lee's work focuses on pediatric emergency medicine, injuries, health disparities, and health policy. This is grounded in her clinical work as a pediatric emergency medicine physician at Boston Children's Hospital and Associate Professor of Pediatrics and Emergency Medicine at Harvard Medical School. At Boston Children's Hospital she is the Associate Program Director for Public Policy at the Sandra L. Fenwick Institute for Pediatric Health Equity and Inclusion.

She received her MD at the Perelman School of Medicine at the University of Pennsylvania. She completed her residency in pediatrics at the Children's Hospital of Philadelphia and her pediatric emergency medicine fellowship at Boston Children's Hospital. During that time, she also received her MPH at the Harvard T. H. Chan School of Public Health. She was also the inaugural Nick Littlefield Health Policy fellow at the Network for Excellence in Health Innovation (NEHI) in 2016-2017.

Dr. Lee has published seminal research on pediatric emergency medicine, health disparities, and injury prevention, including related to firearms. With her expertise she is Chair of the AAP's Council on Injury, Violence, and Poison Prevention. She was the inaugural director of the Academic Pediatric Association's Health Policy Scholars Program, a career development program focused on health policy and advocacy. Her expertise has been recognized with her election as a member of the National Academy of Medicine in 2023. With her passion for improving the lives of children, she promotes child health through her clinical work, research, teaching, and advocacy.
Twitter: @LoisLeeMD
Lois.lee@childrens.harvard.edu

Tamorah Lewis, MD, PhD
Sellers Chair, Pharmacology and Pharmacogenetics
Division Head, Clinical Pharmacology & Toxicology
Staff Neonatologist
The Hospital for SickKids

Associate Professor, Department of Pediatrics
University of Toronto

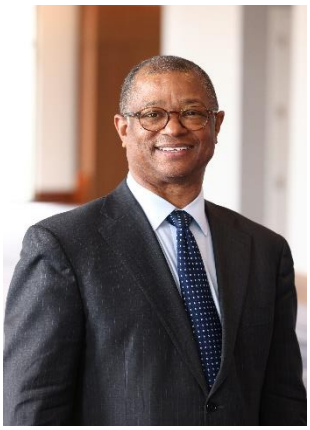


Dr. Tamorah Lewis is a physician scientist, Division Head for Clinical Pharmacology and Toxicology at SickKids. In this role, Dr Lewis helps advance the hospital-wide vision for Precision Child Health and collaborates with multiple clinical Divisions for pharmacology research. Dr Lewis also continues to provide clinical care in the level IV Neonatal ICU at SickKids.

The goals of Dr Lewis' research program are to bring precision therapeutics to the NICU population. Dr Lewis' interests include PBPK and population pharmacokinetic and pharmacodynamic investigations in neonates and children, pertaining to both drugs in common use and drugs under development. Her research focuses on the intersection between ontogeny and pharmacogenetic effects on pharmacology of drugs in infants and neonates.

In addition to her clinical and research roles, Dr Lewis is a dedicated advocate for Health Equity. Through publications and talks, she educates about the need for increased diversity in the biomedical workforce and the importance of diversity and equity in clinical research and clinical care.

Ted Love, MD
Chair of Board of Directors
Biotechnology Innovation Organization

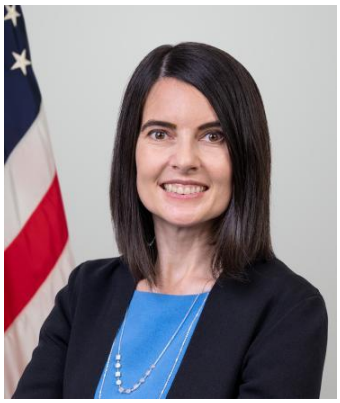


Dr. Ted Love is the chair of the Board of Directors at the Biotechnology Innovation Organization (BIO). A long-time BIO Board Member, Dr. Love most recently served as president and chief executive officer of Global Blood Therapeutics (GBT) from June 2014 until October 2023, when the company was acquired by Pfizer. During his tenure at GBT, Dr. Love led the company from a pre-clinical start-up, through the accelerated approval and launch of Oxbryta®, and into a global commercial company with an advanced pipeline of innovative therapies focused on sickle cell disease. Prior to GBT, Dr. Love was executive vice president, research and development and technical operations, at Onyx Pharmaceuticals, Inc., where he played an instrumental role in the accelerated approval of Kyprolis® for multiple myeloma, and the subsequent purchase of Onyx by Amgen. Previously, Dr. Love served as president, chief executive officer and chairman of Nuvelo, Inc., and as senior vice president, development, at Theravance, Inc.

Dr. Love began his biotech career at Genentech in 1992, where held a number of senior management positions in medical affairs and product development, and ultimately as chairman of Genentech's Product Development Committee. As vice president, product development, Dr. Love oversaw the development strategy and execution leading to approvals of Rituxan®, Herceptin®, Xolair®, TNKase®, Raptiva® and Avastin®. Prior to Genentech, Dr. Love was a member of the Department of Cardiology at the Massachusetts General Hospital.

Dr. Love currently serves on the boards of directors of Royalty Pharma and Seagen. Dr. Love holds a B.A. in molecular biology from Haverford College and an M.D. from Yale Medical School. He completed a residency in internal medicine and a fellowship in cardiology at the Massachusetts General Hospital.

Hilary Marston, MD, MPH
Chief Medical Officer
OCPP, OC, FDA



Dr. Hilary Marston serves as the primary clinical advisor to the Commissioner and oversees the Office of Clinical Policy and Programs. She leads cross-cutting initiatives that support the FDA's centers in making effective, safe, and innovative medical products available for patients.

Dr. Marston previously served as the Senior Advisor for Global COVID-19 Response on the White House COVID-19 Response Team. Her previous roles also include Director for Medical Biopreparedness and Response at the U.S. National Security Council and Medical Officer and Policy Advisor for Pandemic Preparedness at the National Institute of Allergy and Infectious Diseases, National Institutes of Health. Dr. Marston also served in positions with McKinsey & Company and the Bill & Melinda Gates Foundation.
Dr. Marston trained in Internal Medicine and Global Health Equity at Brigham & Women's Hospital. She completed her MPH at the Harvard T.H. Chan School of Public Health.

Ann W. McMahon, MD, MS, FISPE
Regulatory Scientist
OPT, OCPP, OC, FDA

Dr. Ann McMahon is a regulatory scientist from the Office of Pediatric Therapeutics at the FDA. She has a background in medicine from Case Western Reserve School of Medicine, public health from the Harvard School of Public Health, and pediatrics with a residency at the Johns Hopkins Children's Center. From there she underwent post-doctoral training at the National Institutes of Health where she was one of the inventors of the Havrix Hepatitis A Virus vaccine. After four years at the University of Chicago Children's Hospital, she joined the FDA as a medical officer. In CBER she focused on vaccine safety, followed by work with CDER on drug safety, and finally joining OPT in 2011. Her work in OPT has continued with Real World Evidence (RWE) focusing on medical product safety in pediatrics. She has contributed to Agency efforts exploring Real World Evidence in both the safety and efficacy arenas. In the last year she has led a group across offices on the topic of racial and ethnic diversity in pediatric clinical trials submitted to the FDA.

Ki Lee Milligan, MD
Executive Director, Pediatric Center for Excellence, Global Drug Development
Novartis

Dr. Ki Lee Milligan is the Executive Director, Pediatric Center of Excellence, Global Drug Development at Novartis. She obtained her MD and U.S. Air Force commission at the Uniformed Services University of Health Sciences (Bethesda, MD), pediatric residency at Saint Louis University (St Louis, MO), and allergy and immunology fellowship at National Institutes of Health (Bethesda, MD). She is a Fellow of the American Academy of Pediatrics, and Fellow of the American Academy of Allergy, Asthma and Immunology.

Her clinical trials experience from Novartis and the National Institutes of Health and diverse background, including prior U.S. military service as a combat flight surgeon, enables her to reach across cultures, public-private spaces, and special populations on behalf of advancing R&D strategies for pediatric medicines development. Ki is committed to engaging people from diverse backgrounds to strengthen the common good.

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.

Bella Oguno, MPH
Vice President, Development Operations
Nuvig Therapeutics, Redwood City, CA

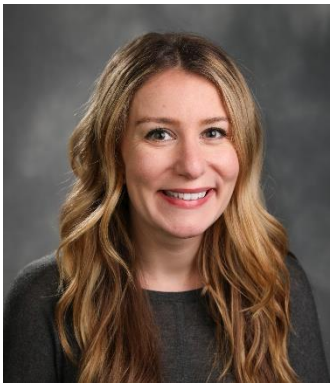
Ms. Bella Oguno is the Vice President of Development Operations at Nuvig Therapeutics, where she supports their global clinical development programs. She has more than 20 years of experience in clinical operations, developing operational strategies for multiple global and complex clinical trials. Her current focus is in rare diseases, previously she supported programs in oncology and the cardiorenal space. Prior to Nuvig, she worked at Global Blood Therapeutics (GBT), where she oversaw the execution of their sickle cell programs across multiple studies with clinical sites in North America, the European Union, Africa, the Middle East and Latin America. Prior to GBT, she held various leadership positions at Genentech and Amgen where she supported the execution of global development programs. Bella holds a BA in Sociology, Health Care and Social Issues from UC San Diego and an MPH from Benedictine University.

Melissa Penn, JD, MPH
Director of Patient Engagement R&D
Bayer Pharmaceuticals

Ms. Melissa Penn, Director of Patient Engagement R&D within Bayer Pharmaceuticals' Patient Partnership and Stakeholder Engagement global team, leverages her expertise in patient engagement to advance health and health outcomes for both pediatric and adult populations. She leads initiatives for early, meaningful, and consistent patient involvement in research and development, with a focus on enhancing diversity in clinical trials and fostering a patient-first mindset throughout the organization and treatment lifecycle. Her strategic planning supports Bayer's objectives in early research and cell and gene therapy, driving innovation and patient focused studies.

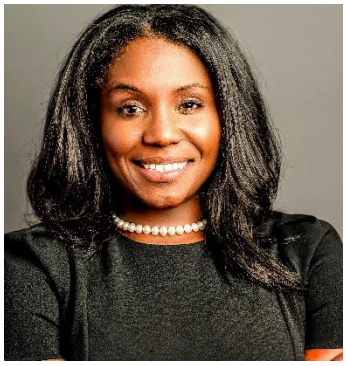
Before joining Bayer, Melissa was the first administrator of the world's largest cord blood stem cell program, making significant strides in advancing stem cell research and treatment. She founded and led the New York City Hemophilia Chapter, a not-for-profit organization dedicated to improving the health and quality of life for newly diagnosed families and previously isolated individuals with rare bleeding disorders. Additionally, Melissa founded the Hemophilia Walk in New York City, playing a pivotal role in uniting and galvanizing the national bleeding disorders community. As a sought-after collaborator, partner, and mentor, Melissa is recognized for her ability to build and foster relationships with diverse stakeholders and patient communities. She holds a JD from Rutgers University School of Law and an MPH from Columbia University School of Public Health.

Rachel Randell, MD, MSCR
Assistant Professor of Pediatrics
Duke University and Duke Clinical Research Institute



Dr. Rachel Randell is an Assistant Professor of Pediatrics at Duke University and a faculty member of the Duke Clinical Research Institute. She is a graduate and former Chief Fellow of the Eunice Kennedy Shriver National Institute of Child Health and Human Development T32 Training Program in Pediatric Clinical Pharmacology. As a Pediatric Rheumatology physician, Dr. Randell cares for children suffering from autoimmune diseases including juvenile arthritis and lupus. Dr. Randell conducts research funded by the Lupus Foundation of America and the NIH studying medication adherence, medication dosing for children, and innovative study design. She has a particular interest in direct-to-family research, an approach that uses patient-centric digital tools and design to make research participation more comfortable and convenient for children and their families

LaShell Robinson, MS
Head of Diversity, Equity & Inclusion, Clinical Research Department
Takeda



Ms. LaShell Robinson is the Head of Diversity, Equity & Inclusion in the Clinical Research Department, where her goal is to ensure that every person has access to clinical trials. Together with her team, they are committed to creating partnerships and implementing strategies that promote education, awareness, and access through Takeda's "P.A.V.E." strategic program. This program focuses on advancing diversity, equity, and inclusion in clinical research by collaborating with community stakeholders, eliminating systemic operational barriers that may hinder patient access, and expanding research opportunities to physicians and health centers traditionally let out of the system.

LaShell's experience began with volunteering at a research site. Here, she saw how clinical research could change a family's life, what it meant for physicians, and how impactful diverse representation in clinical research could be. Shortly after that, she transitioned into the industry after a seven-year stint in education. Before joining Takeda, she was part of the inaugural DEI in clinical trials team at Janssen Research & Development, a Johnson & Johnson Pharmaceutical Company. There, she served as the first Clinical Operations Lead, Diversity & Inclusion in Clinical Trials (DICT) and provided strategic and tactical support across therapeutic areas, including the COVID-19 trials. Throughout her career, she has remained committed to her initial inspiration: helping all people understand why all communities must be included in research to address health equity gaps.

LaShell grew up in Salt Lake City, where she was regularly found volunteering in the community- whether that was for voter registration, teaching religious studies at church, or serving in student government. These service-oriented activities inspire her work today.

LaShell is a proud alumna of Tuskegee University, where she earned a Bachelor of Science in both Biology & Physics. She saw firsthand the impact of history on patients' perception of clinical research, which drives her passion for educating others about clinical research and the diversity of the patient experience. LaShell holds a Master of Science in Biomedical Engineering from the University of South Florida, and she currently resides in Maryland with her family.

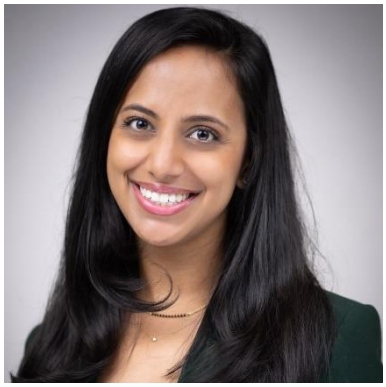
Pamela L. Simpkins, MBA, CFA
Managing Partner
Mezzopointe, LLC

Ms. Pamela Simpkins has more than 25 years of experience in the biopharma industry and nearly a decade of experience in institutional investing. She is active in US regulatory policy shaping efforts and is currently a member of FDA's Advancing the Development of Pediatric Therapeutics (ADEPT 9) Committee: Diversity in Clinical Trials. She is a member of the Conect 4 Children (c4c) public/private partnership launch team, funded, in part, by the EU Commission. In addition, she is a member of 3 biotech advisory boards supporting the advancement of new therapies for underserved patient populations. Pam is also on the advisory committee for Women of Color in Pharma (WOCIP).

Ms. Simpkins is a retiree of Johnson & Johnson (J&J) where she served as a Strategy Lead in R&D for pediatrics in the Office of the Chief Medical Officer. Prior to J&J, Ms. Simpkins led R&D Strategy & Operations for North America at Novo Nordisk. She began her biopharma career at Merck & Co., Inc. Prior to Merck & Co., Inc., she was an institutional investor at Neuberger Berman and Prudential Investment Management (now PGIM). Early in her career she practiced as a CPA. She maintains an active CFA certification.

Ms. Simpkins earned an MBA from Harvard Business School.

Puja Umaretiya, MD, MS
Assistant Professor, Division of Pediatric Hematology/Oncology
UT Southwestern, Children's Medical Center



Dr. Puja Umaretiya is an Assistant Professor in the Division of Pediatric Hematology/Oncology at UT Southwestern/Children's Medical Center in Dallas, TX. She completed pediatric residency in the Boston Combined Residency Program and subsequently completed fellowships in pediatric palliative care and pediatric hematology/oncology at Dana-Farber/Boston Children's Hospital. Her research focuses on identifying the mechanisms underlying racial, ethnic, and socioeconomic disparities for children with cancer and their families. She has leveraged clinical trial datasets and mixed methods mixed approaches to examine clinical trial equity among historically marginalized populations. She ultimately aims to develop social needs focused interventions to improve outcome inequities for children with cancer and their families. She has received awards for this work from ASCO, the National Palliative Care Research Center, and the Palliative Care Research Cooperative Group.

LaToya Williams, BA, MBA
Community Clinical Director
Inside Edge Consulting Group

Survivor Speaker
Advocate

Ms. LaToya Williams has led a remarkable life dedicated to healthcare advocacy and community empowerment. Currently serving as the Community Clinical Director at Inside Edge Consulting Group, she plays a pivotal role in advancing biopharmaceutical engagement within underrepresented communities across the nation. Her work focuses on educating and fostering trust among stakeholders to enhance participation in clinical trials, thereby ensuring that research outcomes better reflect diverse patient populations.

LaToya's journey towards this impactful career was deeply influenced by her own health battle. Diagnosed with stage 3 breast cancer at the young age of 30, and having tragically lost several family members to cancer, she emerged from her own survivorship with a profound determination to improve healthcare outcomes, particularly within communities of color. Her passion led her to champion initiatives aimed at preventing late-stage cancer diagnoses and reducing mortality rates through extensive education, awareness campaigns, and advocacy for equitable public health policies.

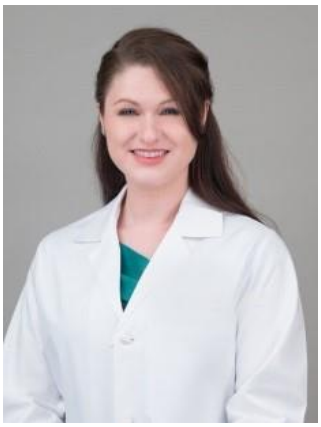
One of her significant contributions includes spearheading the expansion of a national Health Equity Ambassador program. This initiative has been pivotal in training community leaders across high-cancer-burden cities, equipping them with the knowledge and tools to educate their communities about cancer prevention and the importance of clinical trial participation.

LaToya is also a seasoned public speaker, recognized both locally and nationally for her advocacy work. She has been featured in various media outlets and has spoken at prestigious events such as CBS World News and the United Nations Non-Governmental Organization Briefing. Her inspiring story has been highlighted in publications like SELF magazine and during nationwide telecasts such as Stand-Up-To Cancer and BET News Special: I Survive.

Born and raised in Brooklyn, NY, LaToya Williams balances her professional commitments with personal interests. She enjoys playing tennis, golfing, cycling, and indulging in culinary pursuits, inspired by her love for the Food Network. LaToya holds a bachelor's degree in psychology from Grambling State University and earned her MBA from the University of Phoenix. She is a proud member of Alpha Kappa Alpha Sorority, Inc. and Women of Color in Pharma (WOCIP), where she continues to contribute her expertise and leadership.

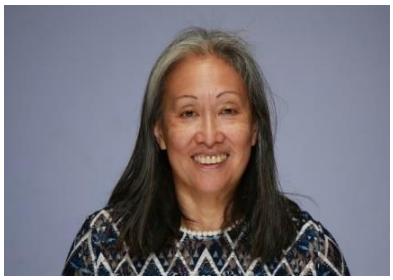
Through her tireless dedication and advocacy, LaToya Williams embodies a powerful force for change in healthcare equity, leaving an indelible impact on the lives she touches and the communities she serves.

Lauren Wood Heickman, MD
Clinical Reviewer
DDLO, OCHEN, OND, CDER, FDA



Dr. Lauren K. Wood Heickman is a Clinical Reviewer in the Division of Diabetes, Lipid Disorders, and Obesity in the Center for Drug Evaluation and Research (CDER) at the US Food and Drug Administration (FDA). Lauren is a pediatric endocrinologist with a background in type 1 diabetes clinical and translational research and joined the FDA in 2020. Lauren completed her MD and pediatric residency training in San Antonio, Texas at the University of Texas Health Science Center San Antonio and fellowship in Pediatric Endocrinology at the University of 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.