Advancing the Development of Therapeutics Through Rare Disease Patient Community Engagement
December 14, 2023 | 12:00 p.m. – 5:00 p.m. ET
Virtual Meeting
Zoom Webinar

Biographies

**Robyn Bent** is the director of the Patient-Focused Drug Development (PFDD) Program in the Center for Drug Evaluation and Research (CDER). PFDD is an effort to systematically obtain patient input and facilitate the incorporation of meaningful patient input into drug development and regulatory decision making. Prior to joining FDA, Robyn held several positions at the National Institutes of Health. Robyn has a background in pediatric oncology nursing and extensive experience in clinical trial design, conduct, and oversight. She continues to practice as a registered nurse. Robyn earned her Bachelor of Science in Nursing from The Catholic University of America and her Master of Science degree from the George Washington University.

**Danielle Boyce** is a faculty member in the informatics core of the Tufts University School of Medicine Clinical and Translational Science Institute (CTSI) as well as the Institute for Clinical Research and Health Policy Studies, Center for Advanced Research Health Informatics (CAHRI). Danielle has a master's in public health with a concentration in epidemiology and a doctorate in public administration. She is a veteran data scientist and informaticist with more than 25 years of professional experience; including more than fifteen years at Johns Hopkins University Schools of Medicine and Nursing, where she still serves as a lecturer for biomedical informatics and data science courses. Danielle also has extensive expertise in patient engagement in the research process and has held advisory roles for the Food and Drug Administration, the Centers for Disease Control and Prevention (CDC), the Critical Path Institute, the Patient-Centered Research Outcomes Insitute (PCORI), the International League Against Epilepsy, and dozens of patient advocacy groups and communities. Danielle is the leader of several grant-funded initiatives including a CDC-funded project focusing on the identification of new risk factors for amyotrophic lateral sclerosis (ALS). Danielle's work is inspired by her 13-year-old son, Charlie, who had infantile spasms and now Lennox-Gastaut syndrome.

**Teresa Buracchio, MD**, is Director of the Office of Neuroscience in the Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration (FDA). She oversees the review of new drug programs for neurologic and psychiatric diseases, including Alzheimer’s disease, Parkinson’s disease, amyotrophic lateral sclerosis, neuromuscular diseases, neurogenetic disorders, major depressive disorder, and schizophrenia. Dr. Buracchio received her medical degree from Rush Medical College and completed a residency in neurology at Rush University Medical Center, Chicago, IL. Dr. Buracchio completed fellowship training
in geriatric neurology at Oregon Health & Science University and Portland VA Medical Center in Portland, OR. Prior to joining FDA in 2013, Dr. Buracchio worked at AbbVie as an Associate Medical Director for Neuroscience Clinical Development.

Dr. Michelle Campbell is the Associate Director for Stakeholder Engagement and Clinical Outcomes in the Office of Neuroscience, Office of New Drugs (OND) in FDA’s Center for Drug Evaluation and Research. Dr. Campbell joined the FDA in 2014 and previously was a reviewer on the Clinical Outcome Assessments (COA) Staff and Scientific Coordinator of the COA Qualification Program in OND. Dr. Campbell’s focus is in patient-focused drug development and the use of patient experience data in the regulatory setting. Prior to joining FDA, Dr. Campbell spent more than 10 years conducting research in the academic-clinical setting, including five years in a neurology and developmental medicine department. Dr. Campbell earned her BA in Biology from the College of Notre Dame, her MS in Health Science from Towson University, and her PhD in Pharmaceutical Health Services Research from the University of Maryland School of Pharmacy.

Dr. Rebecca Rothwell Chiu is a supervisory mathematical statistician in the Division of Biometrics IV in the Office of Biostatistics at the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). She currently provides statistical support for the Division of Rare Diseases and Medical Genetics, focused on developing drugs and biologics intended for the prevention and treatment of rare inborn errors of metabolism. Her prior experience at the FDA includes drug development in rheumatology, COVID-19, and pediatrics. Prior to joining the FDA, Dr. Chiu received her PhD in Biostatistics from the University of Michigan at Ann Arbor.

Emma D’Agostino, Ph.D., works in medical communications and lives with cystic fibrosis. She serves as a patient advocate for the Cystic Fibrosis Foundation and a consumer representative for the FDA, and is passionate about including the patient perspective in clinical research and communicating clinical science to the patient community.

Jennifer Farmer is the Chief Executive Officer of the Friedreich’s Ataxia Research Alliance. Jennifer has a Master’s degree in Genetic Counseling and prior to joining FARA she worked at the University of Pennsylvania and Children’s Hospital of Philadelphia. As a genetic counselor, Jennifer developed a special interest in neurogenetic conditions and then went on to establish and coordinate clinical and research programs for individuals and families diagnosed with Friedreich Ataxia (FA) and other neurodegenerative diseases. Having established relationships with the families who founded FARA and sharing in their vision to treat and cure FA she joined the organization full time in 2006. Jennifer has led FARA's efforts to
establish clinical research infrastructure and clinical trial readiness, grown the research grant program from funding <1M annually to >9M annually, led efforts to engage bio-pharma industry in FA drug discovery and development, and ensured highly efficient and transparent organizational growth and development. In her current role at FARA as CEO, she helps to carry out the strategic mission of the organization through leading FARA’s research and partnership initiatives.

Dr. Lili Garrard is a Master Scientist and the technical lead of the Patient-Focused Statistical Scientists (PFSS) group within the Division of Biometrics III, Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). Dr. Garrard is an expert in patient-focused drug development (PFDD)-related scientific and policy issues, and she is recognized both internally and externally for her contributions to the field. Over the years, Dr. Garrard has provided statistical and psychometrics expertise on the development and implementation of clinical outcome assessments (COAs) across therapeutic areas in CDER and other FDA Centers. Prior to joining FDA, Dr. Garrard was the RN (registered nurse) survey director at the National Database of Nursing Quality Indicators (NDNQI). Dr. Garrard received a PhD in Biostatistics from the University of Kansas Medical Center, and both an MS degree and a BS degree in Mathematics from the Michigan Technological University.

Dr. Lili Garrard

Dr. Karin Hoelzer directs Policy and Regulatory Affairs for the National Organization for Rare Disorders (NORD®). In this role, Karin provides strategic direction to advance NORDs federal policy and regulatory priorities. She works closely with key rare disease partners across the pharmaceutical and biological space to ensure the policy landscape supports innovative approaches and new treatments to help rare disease patients, and adequately incorporates patient preferences and perspectives in therapy development. Her role also involves extensive legislative and communication engagements to advance rare disease policy priorities.

Dr. Karin Hoelzer

Dr. Hoelzer is a health policy, risk analysis, and biomedical research expert, with extensive intellectual property and regulatory expertise across most FDA-regulated products. Most recently, she worked at Maximus, Inc. where she established and led a new health data analytics division to provide more timely data and better insights to government clients in support of the public health response to the COVID-19 pandemic.

Prior to working at Maximus, Inc., Dr. Hoelzer served as Senior Officer for Health Programs at The Pew Charitable Trusts where she led policy and regulatory efforts to improve the federal oversight of a variety of FDA-regulated products. Dr. Hoelzer joined Pew from the Food and Drug Administration (FDA), where she served as Risk Analyst. In this role, she assessed and quantified the expected impact of changes to FDA policy and regulatory practice.

Prior to joining FDA in 2010, Dr. Hoelzer worked as Biomedical Researcher for Cornell University. She received a PhD in comparative biomedical sciences from Cornell University and a Doctor of Veterinary Medicine degree from the University of Veterinary Medicine in Hannover (Germany). Since 2014, she is also a registered patent agent with the U.S. Patent and Trademark Office, and remains active in the biomedical research space. This includes serving as Editor in Chief for a major peer-reviewed
international biomedical research journal and as the Executive Director for the professional association representing veterinarians in DC.

**Joseph P. Horrigan, MD**, is a pediatric neuropsychiatrist and has specialized in the treatment of children with complex neurodevelopmental disorders for more than 30 years. Dr. Horrigan has served in various roles associated with the pharmaceutical and biotech industries. At GlaxoSmithKline, he co-founded and led the company-wide Medicines for Children Advisory Network that collaborated with all therapeutic areas in the company. Dr. Horrigan served as Assistant Vice President and Head of Medical Research for Autism Speaks, the largest science and advocacy organization in the U.S. devoted to autism spectrum disorders (ASD). He subsequently served as Vice President of Clinical Development and Medical Affairs for Neuren Pharmaceuticals, leading that company’s pioneering clinical development efforts in neurodevelopmental disorders such as Rett syndrome. Dr. Horrigan is currently the Chief Medical Officer for AMO Pharma Ltd., a British-American biopharmaceutical company that is focusing on orphan neuromuscular and neurodevelopmental disorders with significant unmet medical needs. Dr. Horrigan received his Sc.B. degree from Brown University and his medical degree from the University of Rochester. Dr. Horrigan has been a longstanding scientific advisor to FRAXA, he is on the Board of Directors of the International Rett Syndrome Foundation, and he is a member of the Angelman Syndrome Foundation Scientific Advisory Committee. Dr. Horrigan is also a Consulting Associate Professor at the Duke University Center for Autism and Brain Development in Durham, North Carolina. At Duke, he evaluates and treats patients in Duke’s tertiary care autism clinic.

**Collin Hovinga, PharmD, MS, FCCP**, serves as Vice President of the Rare and Orphan Disease Programs at the Critical Path Institute overseeing the Critical Path for Rare Neurodegenerative Diseases public-private partnership and C-Path’s Rare Disease Cures Accelerator-Data and Analytics Platform. Dr. Hovinga completed his Bachelor of Science Degree in Biology and Doctor of Pharmacy degrees from Creighton University in Omaha, Nebraska. After which he pursued a Residency and Fellowship in Pediatric Pharmacotherapy with emphasis in Pediatric Neuroscience at the University of Tennessee, Memphis, LeBonheur Children’s Medical Center. He has a Masters of Epidemiology from the University of Tennessee Health Science Center. Dr. Hovinga has been active in studying factors that influence the efficacy and safety of medications in children and in rare/orphan diseases. Dr. Hovinga is recognized as an expert in trial design, real world data and clinical pharmacology and has served as an advisor to NIH/NINDS and FDA SGE (CNS/PNS and DSRM).

**Kelley Kidwell, Ph.D.,** is a Professor and Associate Chair of Academic Affairs of Biostatistics at the University of Michigan School of Public Health. She is an expert in large and small sample sequential, multiple assignment, randomized trial (SMART) design and analysis. She is the primary investigator of current FDA and PCORI contracts, also had previous FDA and PCORI methods contracts, all related to SMART design, and has been a co-investigator on many NIH and industry funded, clinical trial grants. Her current focus is on advancing small sample clinical trial design and methods and incorporating patient treatment preferences into clinical trials.
Connie Lee, Psy.D. is the founder and CEO of the Alliance to Cure Cavernous Malformation, formerly Angioma Alliance, a patient research and advocacy organization that strives to inform, support, and mobilize those with cerebral cavernous malformations (CCM) and drive research for better treatments and a cure. The organization develops and executes strategic, creative, high-return interventions as a model for rare diseases. Dr. Lee’s achievements with the Alliance have included the development of a robust scientific program, an extensive Center of Excellence network, model DEI programs, and mentorship of 21 international sister organizations. The Alliance to Cure received the 2023 NORD Abbey S. Meyers Leadership Award and is a member of the CZI Rare As One Network.

Kerry Jo Lee is the Associate Director for Rare Diseases in the Division of Rare Diseases and Medical Genetics, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER). In this role she leads the Rare Diseases Team, a multidisciplinary rare disease programming and policy team that works to promote their mission to facilitate, support, and accelerate the development of drugs and therapeutic biologics for rare diseases and serves as the program management office for CDER’s Accelerating Rare diseases Cures (ARC) Program. Dr. Lee joined the FDA as a medical officer in 2014 with the former Division of Gastroenterology and Inborn Errors Products, OND, CDER. Dr. Lee then moved to a position as a clinical advisor for the Office of New Drug Policy, CDER, where she served as a lead in the areas of benefit-risk assessment, modernization efforts (including the integrated review for marketing applications), and real-world data/evidence programming before serving in her current position. Dr. Lee is a pediatric gastroenterologist/hepatologist and a graduate of Princeton University and the New York University School of Medicine with an honors degree conferred in microbiology. She completed her residency in pediatrics at the Children’s Hospital of Los Angeles followed by a post-doctoral clinical fellowship in Pediatric Gastroenterology, Hepatology, and Nutrition at Columbia University College of Physicians and Surgeons in New York. Dr. Lee maintains a steadfast interest in international policy and bioethics and worked for several years at the former National Bioethics Advisory Commission on reports advising the executive branch on ethical and policy issues in both international and domestic clinical trials.

Dr. Thomas F. Miller is Vice President & Global Head, Acute, Chronic and Pediatric Disease Nucleus in Bayer’s Pharmaceutical Division, a role he assumed earlier this year. He joined Bayer in 2017 to create and effectuate their Pediatric Clinical Development function. In total, Dr. Miller’s career in the life science industry spans more than 27 years, with a primary focus on the development of therapeutics, medical devices and combination products for pediatric and rare disease patients. Prior to joining Bayer, Dr. Miller served in the capacity of Chief Executive Officer of Therabron Therapeutics, Inc. with oversight of all operational functions for the company (R&D, manufacturing, quality, regulatory affairs, etc.). While at Therabron, he oversaw their clinical program through Phase 2 completion for their lead molecule (orphan pediatric disease) and secured both the Rare Pediatric Disease and Fast Track designations for this program. Prior to Therabron, Dr. Miller served in the capacity of Chief Operating Officer of Discovery Laboratories, Inc. During his tenure, the company successfully secured marketing authorization for their first approved therapeutic, successfully registered their first medical device and advanced multiple rare disease pipeline programs into the clinic. Earlier, Dr. Miller served in operational roles of increasing responsibility at Pfizer, Novartis, BASF Pharma, and Johnson & Johnson. He received his doctorate from the Temple University School of Medicine, his MBA from Fairleigh Dickinson
University and his bachelor’s degree from Fairfield University. Dr. Miller has authored several peer-reviewed publications, given numerous presentations at scientific symposia and is an inventor with an issued and licensed patent in the field of pediatric respiratory drug delivery.

Monica Morell is a statistical reviewer and psychometrician on the Patient-Focused Statistical Scientists (PFSS) Group at the Division of Biometrics III, Office of Biostatistics (OB), Office of Translational Sciences (OTS), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Dr. Morell’s group provides statistical and psychometric reviews on the development and use of clinical outcome assessments (COAs) across multiple therapeutic areas. Prior to joining FDA, Dr. Morell was a clinical research coordinator at the Sylvester Comprehensive Cancer Center’s Department of Radiation Oncology. Dr. Morell received a PhD in Measurement, Statistics, and Evaluation from the University of Maryland.

Jennifer Panagoulias, RAC is the Head of Regulatory and Policy for the Foundation for Angelman Syndrome Therapeutics (FAST) and the Co-Director of the Angelman Syndrome Biomarkers and Outcome Measures Consortium (ABOM). Jennifer has worked in drug development for over 20 years, primarily focused on advancing global development programs for the treatment of rare neurological diseases. She spent 16 years in Regulatory Affairs at Genzyme where she held various roles including Global Therapeutic Head, Regulatory Affairs Neurology. At Genzyme, she supported global registration efforts for Myozyme (alglucosidase alfa), an enzyme replacement therapy for children and adults with Pompe disease, a rare, genetic, neuromuscular disorder. Jennifer has experience in working with global regulatory agencies including the US FDA, the European Medicines Agency, and the Pharmaceutical and Medical Device Agency in Japan. She has help key leadership roles in Regulatory Affairs supporting the development of oligonucleotide drugs at Wave Life Sciences and was part of the founding team at GeneTx Biotherapeutics advancing an ASO specific for the treatment of Angelman syndrome.

Dr. Tejashri Purohit-Sheth has over 21 years of FDA experience and is currently the Director of the Division of Clinical Evaluation General Medicine in the Office of Therapeutics in the Center for Biologics Evaluation and Research at the Food and Drug Administration where she oversees Clinical and Clinical Pharmacology Staff for review of a variety of indications to include rare diseases. Prior to the recent re-organization, she was the Division Director for the Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT) in the Office of Tissues and Advanced Therapies (OTAT) where she provided supervisory oversight for all of the clinical and pharmacology/toxicology reviews of submissions to OTAT. She previously served as the Clinical Deputy Director in DAGRID/ODE/CDRH/FDA as well as Division Director (Acting) and Branch Chief in Office of Scientific Investigation in CDER/FDA and as a Medical Officer in the Division of Pulmonary and Allergy Products (CDER/FDA).

She completed an Internal Medicine Residency at Naval Medical Center Portsmouth followed by a fellowship in Allergy/Immunology at Walter Reed Army Medical Center. Following fellowship, she took over as Service Chief of the Allergy/Immunology clinic at National Naval Medical Center in Bethesda, MD. Following her end of obligated service as an active duty Naval Officer, she transferred her
commission to the U.S. Public Health Service and began her FDA career. She retired from Public Health Service following close to 29 years of service as an active duty Uniformed Service Officer.

**Dr. John W. Sleasman** is Professor of Pediatrics and Division Chief of the Division of Allergy and Immunology where he is also co-director of the Duke Diagnostic Immunology Laboratory, and medical director the Duke’s Jeffrey Modell Diagnostic and Research Center for Primary Immune Deficiencies Diseases. As of 2021, he co-directs Duke’s thymus implantation program for infants and children with congenital athymia. Over the past 25 years, Dr. Sleasman’s research has focused on studies of the pathogenesis, diagnosis, and treatment of primary and secondary immune deficiency disorders including HIV in children and adolescents. He has over 150 peer-reviewed publications, books and book chapters; most related to basic and clinical research to human immunology.

**Peter Stein, M.D.,** is the Director of CDER’s Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters.

A nationally-recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late stage development, diabetes, and endocrinology at Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience.

Dr. Stein holds a bachelor’s degree in history from the University of Rochester in New York and a medical degree from University of Pennsylvania. He trained at Yale University and Yale-New Haven Hospital in internal medicine and in endocrinology and metabolism.

**Saira Sultan** represents a range of health care stakeholders, and joins us today as the lead policy consultant for Haystack Project, a nonprofit umbrella organization enabling ultra rare disease patient groups to highlight and address systemic reimbursement obstacles to patient access. Haystack Project’s core mission is to evolve health care payment and delivery systems with an eye toward spurring innovation and quality of care. Saira’s work for Haystack focuses on tangible, feasible, pragmatic solutions for a community of over 140 patient groups for whom unmet needs are high and delays in treatment can be catastrophic.

Saira has represented corporate, nonprofit, and government interests in the legislative and regulatory health policy arena for almost 30 years in Washington, D.C. She has had repeated success in designing business solutions by identifying and creating advocacy opportunities and translating them into strategic legislative and regulatory results. Saira has run a small boutique consulting practice for the last decade, capitalizing on her years of experience working with market access, medical, health outcomes, and commercial teams in pharmaceutical companies, including at Pfizer and Sanofi. She has also led policy, lobbying and advocacy functions for drug and device companies as well as provider organizations.

Focusing in areas such as rare and extremely rare diseases, oncology, sickle cell, pain, addiction, cell and gene therapy and more, Saira has worked extensively with CMS, FDA and Capitol Hill. Her insight and
skill in working cross-functionally in a corporate environment, as well as with advocacy organizations and key trade associations serves her clients well. Saira's leadership at the Association of Community Cancer Centers allowed her to build strong relationships with the oncology community and gain insights into the evolution of oncology care. She continues to work closely with many oncology organizations, identifying emerging trends that have led to repeated success in tackling coverage, coding and payment of marketed and pipeline Part B and D products. The Government Affairs and Policy team at ACCC, under Saira's direction, raised significant revenue, improved the Association's profile, as she became a sought after speaker on oncology policy issues.

Complementing her 10 years on the pharmaceutical side, Saira's time at Medtronic gives her an in-depth understanding of the unique needs of the device industry. Representing Medtronic at a time when CMS was completely revamping device reimbursement in hospital outpatient departments, gave her the opportunity to work closely with CMS and key stakeholders. Saira built a successful coalition of varied stakeholders that ensured reimbursement for Class III devices reflecting their value to patients.

Additionally, Saira brings House and Senate experience, including work on the Ways and Means Committee, and roles as senior legislative counsel for Senator Mike DeWine (R-OH) and Chief Counsel to one of the Senate Healthcare Subcommittees. She handled all healthcare issues under the Senate HELP Committee's jurisdiction, including extensive negotiations with FDA and industry on the Balanced Budget Act of 1997 and the first reauthorization of the Prescription Drug User Fee Act. She spearheaded passage of the first Better Pharmaceuticals for Children.

Saira holds a JD from the University of Virginia in Charlottesville, VA.

Dr. Nicole Verdun received her undergraduate degree from Duke University and her medical degree from the University of Chicago Pritzker School of Medicine. She then completed a Pediatrics Residency at Children’s Memorial Hospital-Northwestern University and a Pediatric Hematology-Oncology Fellowship at the Children’s Hospital of Philadelphia (CHOP). After practicing as a hematologist with a focus on hemostasis and thrombosis, Dr. Verdun joined FDA in 2012, first in the Office of Hematology Oncology Products as a medical officer and a liaison for sickle cell therapeutics and anticoagulants, and then Therapeutic Biosimilars. She was appointed as the Deputy Director of the Office of Blood Research and Review in the Center for Biologics Evaluation and Research (CBER) in October 2016 and was promoted to Office Director in 2018. In 2023, Dr. Verdun was selected as the Super Office Director of the Office of Therapeutic Products, overseeing 6 Offices dedicated to the regulation and approval of Cell and Gene therapies in the United States. She oversees both a research and regulatory portfolio in CBER. She is also on staff at Children’s National Medical Center.

Robert (Bobby) Wiseman Jr. is a native of San Francisco, California and currently resides in Sacramento, CA. He attended St. Ignatius College Prep, University of California – Berkeley (Professional Development Program), University of California – Davis (Applied Behavioral Sciences) and the traditional-untraditional school of life. He is currently a Master of Divinity (MDiv) and Master of Arts (MA) Candidate 2026 at the Pacific School of Religion, with a concentration in both Social Justice and Social Transformation. He has personal lived experience with a number of chronic, long-term financially and psych-socially expensive-challenging-motivating clinical diagnosis. He is a combination of his family of birth, family of choosing, travels to various places around both the US and the world.
Bobby has had the true pleasure of working in collaboration with those who have been termed challenging, non-compliant, traditional, and non-traditional. In his 52 years of life, he has had the priceless gift of having both comfortable and uncomfortable conversations; being a parent, son, uncle, true friend and advocate. He has effectively and successfully lived with a few chronic, manageable health conditions. He has navigated systems, structures, ideology, emotions, and feelings with a sense of seeing “what can be.”

Bobby is enthusiastic about creating meals from farmer’s market finds, thrift store re-crafting, and hours with I Love Lucy, Golden Girls and Boomerang. Bobby has been called a social justice advocate, a catalyst for change as well as a person that seeks to gain/increase knowledge by ACTUALLY hearing from those with different viewpoints and landscapes and having REAL understanding, clarity, and communication. For those who need more understanding, clarity pertaining to Bobby here are a few components:

- A direct outcome of his parents, grandparents, siblings, friends, and communities of faith, relationship, and connection
- Minister & Founding Member – Ekklesia Deliverance Center, Church of God in Christ Inc – Orangevale, CA
- Ordained Deacon – United Church of Christ – Bishop Yvette Flunder, Presiding Prelate – The Fellowship of Affirming Ministries/Founding Pastor/Senior Pastor – City of Refugee, UCC (Oakland, CA)

**Duke-Margolis Moderators**

**Victoria “Tori” Gemme** is a Research Associate for the Biomedical Innovation team. She comes to Duke-Margolis from the Cystic Fibrosis Foundation where, as a Senior Specialist, she oversaw a wide-ranging policy portfolio covering basic science research, drug development, antimicrobial resistance, organ transplant, and among other topics. Victoria graduated from Vassar College with a Bachelor’s degree in neuroscience, from Suffolk University with a Master’s in Ethics and Public Policy, and from Quantic School of Business and Technology with a Master’s in Business Administration.

**Dr. Marianne Hamilton Lopez** is the Senior Research Director of Biomedical Innovation, an adjunct associate professor, and core faculty at the Duke-Margolis Center for Health Policy in Washington, DC. She leads the strategic design and direction of the Center’s Biomedical Innovation portfolio, with a focus on medical products development and regulation, real world evidence, infectious disease preparedness, and payment, pricing, and coverage of drugs and medical devices. She also oversees the Value for Medical Products Consortium and partners with Duke University faculty, scholars, and external health experts to advance this work.

Prior to joining Duke-Margolis, Dr. Hamilton Lopez was a senior program officer with the National Academy of Medicine’s Leadership Consortium for a Value & Science-Driven Health System and provided strategic direction and oversight of the Consortium’s Science and Technology portfolio and
Clinical Effectiveness Research Innovation and the Digital Learning Collaboratives. She was a Senior Manager at AcademyHealth; a Public Health Community Advisor for the United States Cochrane Center; and the Federal Women’s Program Manager and American Indian/Alaska Native Employment Program Manager for the National Institutes of Health.

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

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