Public Workshop to Enhance Clinical Study Diversity

A public meeting to fulfill FDORA Section 3603 requirements and to solicit input on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the prevalence of the disease or condition among demographic subgroups

November 29-30, 2023 | 10:00 a.m.—2:00 p.m. EDT

Speaker Biographies

Opening Remarks, Day 1

Karen Hicks is the Deputy Director of the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) at the United States Food and Drug Administration (FDA). She oversees regulation and policy development for CDER and participates in cross-cutting agency initiatives. She works closely with the Office of the Commissioner and other Centers to promote diversity and inclusion of underrepresented populations in clinical trials. Dr. Hicks joined the FDA in 2003 and previously served as a Team Leader in the Division of Cardiovascular and Renal Products and as a Deputy Director in the Division of Nonprescription Drugs II. She has led two large multi-stakeholder initiatives to standardize data collection for cardiovascular trials. Dr. Hicks received her undergraduate degree from Duke University, MS degree from Georgetown University, and MD degree from the Georgetown School of Medicine. She completed her internship and residency in Internal Medicine and fellowship in Cardiovascular Disease at Walter Reed Army Medical Center. She completed her Interventional Cardiology training at The Johns Hopkins Hospital and subsequently was Director of the Cardiac Catheterization Laboratory at Madigan Army Medical Center.

Keynote Speaker, Day 1

Patrizia Cavazzoni is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. The Center’s mission is to ensure that safe, effective and high-quality drugs are available to the public. To achieve this, CDER regulates the medical products under its jurisdiction throughout their lifecycle, oversees the development of new and generic drugs, evaluates applications to determine whether drugs should be approved, monitors the safety of drugs after they are marketed, conducts research to advance regulatory science and takes enforcement actions to protect the public from harmful products. Dr. Cavazzoni joined the FDA in January 2018 as CDER’s Deputy Director for Operations where she has led several key initiatives on behalf of the organization.
She also served as Acting Principal Deputy Commissioner of Food and Drugs from January 2019 to February 2019. Dr. Cavazzoni received her medical degree at McGill University and completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa. During her training, she was an investigator in clinical trials of novel antipsychotic and antidepressant medications and became a research collaborator within the International Group for The Study of Lithium Treated Patients. She subsequently received a full-time appointment to the Faculty of Medicine at the University of Ottawa and joined the Mood Disorders Program at the Royal Ottawa Hospital, where she treated patients suffering from severe mood disorders, taught students and conducted research on genetic predictors of bipolar disorder as part of a multidisciplinary international collaborative effort, authoring numerous peer-reviewed scientific publications. After her tenure in academic medicine, Dr. Cavazzoni worked in the pharmaceutical industry for several years and held senior executive positions in clinical development, regulatory affairs, and safety risk management in large companies across multiple therapeutic areas, until she joined the FDA. Dr. Cavazzoni obtained certification by the American Board of Neurology and Psychiatry in 1997 and 2008 and was a fellow of the Canadian Royal College of Physicians and Surgeons from 1997 until 2023. She is a fellow of the Canadian College of Neuropsychopharmacology and a recipient of the American College of Psychiatrists’ Laughlin Fellowship.

**Session 1**

**Rear Admiral Richardae Araojo** serves as the Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity at the U.S. Food and Drug Administration (FDA). In this role, RDML Araojo provides leadership, oversight, and direction on minority health and health disparity matters for the Agency. RDML Araojo previously served as the Director of the Office of Medical Policy Initiatives in FDA’s Center for Drug Evaluation and Research (CDER), where she led a variety of broad-based medical and clinical policy initiatives to improve the science and efficiency of clinical trials and enhance professional and patient labeling. RDML Araojo joined FDA in 2003, where she held several positions in CDER. RDML Araojo received her Doctor of Pharmacy Degree from Virginia Commonwealth University, completed a Pharmacy Practice Residency at University of Maryland, and earned a Master’s degree in Pharmacy Regulation and Policy from the University of Florida.

**Lola A. Fashoyin-Aje** is a medical oncologist and Deputy Director in the Division of Oncology 3 (DO3) in the Office of Oncologic Diseases (OOD) at the Center for Drug Evaluation and Research- Food and Drug Administration (FDA). In this role, she provides clinical, scientific, and regulatory policy guidance and oversight to multidisciplinary teams reviewing drugs and biologics under development for the treatment of solid tumor malignancies. Dr. Fashoyin-Aje is also an Associate Director at the FDA Oncology Center of Excellence at the FDA, where she leads initiatives to address clinical and regulatory science and policy issues impacting oncology drug development. Prior to joining the FDA, Dr. Fashoyin-
Aje completed her undergraduate and graduate training at Columbia University and Yale University, respectively, and received her M.D. degree from the University of Rochester School of Medicine and Dentistry. She completed postgraduate training in internal medicine and medical oncology at Johns Hopkins.

Eldrin Lewis is the Simon H. Stertzer, MD Professor of Medicine and Chief of Cardiovascular Medicine at Stanford University School of Medicine. He moved from Harvard University to assume the role as Chief of Cardiovascular Medicine and in this role has expanded the clinical reach of the division to both the East Bay and South Bay, expanded the faculty to 97, increased the diversity of the faculty and trainees, and expanded the clinical research and clinical trial capacity to dovetail with the existing basic and translational research. He has an interest in preventing the development of and progression of heart failure by investigating novel strategies and therapies for treating early heart failure and co-morbid illnesses that are risk factors for heart failure. He performs quality of life research to better understand how to improve these outcomes and include them into medical decision making. As an advanced heart disease specialist, he specializes in the management of patients with advanced heart failure, heart transplantation, and those with mechanical circulatory support devices. His work has included understanding the biological and social factors that influence patient reported outcomes and progression of disease from risk factors (e.g., diabetes, chronic kidney disease and hypertension) to heart failure with over 200 publications. He is leading an effort to understand how to enhance the diversity of participants in clinical trials and is on numerous steering committees. He holds numerous leadership positions in national organizations, including Chair of Scientific Publishing Committee for the American Heart Association, Immediate Past Chair of Clinical Cardiology Council, and Chair of Research Committee for Association of Black Cardiologist.

Laura Mauri is the Senior Vice President, Chief Scientific, Medical, and Regulatory Officer at Medtronic. In this role, Laura leads the global company’s scientific, medical, clinical research and regulatory affairs functions and is a member of the Medtronic Executive Committee. Her strategic responsibilities include driving the integration of medical and scientific intelligence to inform business decisions and delivering a transformative approach to patient safety and patient engagement. Laura is an interventional cardiologist who practiced at the Brigham and Women’s Hospital for 15 years as an internationally renowned investigator and Professor of Medicine at Harvard Medical School and an expert in trial design, strategy and data analysis. Laura received her A.B. from Harvard College and her M.D. from Harvard Medical School, both magna cum laude, and her M.Sc. (Clinical Epidemiology) from Harvard School of Public Health.

Allison Cuff Shimooka serves as the Chief Operating Officer of TransCelerate BioPharma Inc. In this role, Allison is responsible for translating TransCelerate’s strategic vision into operational plans in close partnership with the leadership team, member companies, and Board of Directors. She is also responsible for advancing TransCelerate’s engagement strategy. Prior to joining TransCelerate,
Allison was the Senior Vice President of Strategy and Product Innovation for Optum Life Sciences, which offers end-to-end real-world evidence solutions including data, analytics, and consulting. Previously, Allison held a variety of leadership roles across her 17-year tenure with the Advisory Board Company, a membership-based best practice, technology, and strategy company. Prior to joining the Advisory Board, Allison worked in strategy at PPL Therapeutics, a biotechnology company in Edinburgh, Scotland, and at LEK Consulting, advising biotechnology, medical device, and health services companies on a variety of strategic issues. Allison received her MBA in health care management from the Wharton School of Business at the University of Pennsylvania, where she was named a Palmer Scholar. She received her undergraduate degree in chemistry cum laude from Dartmouth College.

Ricki Fairley is a Stage 3A Triple Negative Breast Cancer Survivor/Thriver, and her personal purpose, passion, mission, ministry and blessing is to bring focus, attention, research and action to eradicating Black Breast Cancer, and supporting and coaching what she calls her “Breasties” through their breast cancer experience. Ricki is an award-winning seasoned marketing veteran that has transformed her strategic acumen into breast cancer advocacy. Ricki recently co-founded Touch, The Black Breast Cancer Alliance to address Black Breast Cancer as a unique and special disease state, with the overall goal of reducing the mortality rate for Black women. Ricki founded and serves as co-host for “The Doctor Is In,” a weekly live web series on the BlackDoctor.org Facebook page. She is a founding member of #BlackDataMatters, in partnership with Ciitizen to encourage and elevate the importance of Black Women participating in clinical trial research. She serves on the Board of Trustees for the Triple Negative Breast Cancer Foundation where she spearheads the Marketing Committee and directs multicultural outreach. She is a board member for the Center for Healthcare Innovation, a non-profit research and educational institute making healthcare more equitable. She also serves as an Ambassador and Advisor for the Live Humanly Campaign and works with companies to provide the patient advocate voice for breast cancer drug development. She serves on the National Accreditation Program for Breast Centers (NAPBC) Advocacy and Outreach Committee. She writes regularly for BlackDoctor.org, Black Health Matters, the Cincinnati Herald and the Black Press.

Session 2

Dionne Price is the Deputy Director of the Office of Biostatistics in the Office of Translational Sciences, Center for Drug Evaluation and Research, FDA. In this role, Dr. Price provides leadership to statisticians involved in the development and application of methodology used in the regulation of drug products. She currently leads cross-cutting, collaborative efforts across FDA to advance and facilitate the use of innovative trial designs in pharmaceutical drug development. Dr. Price received her MS in Biostatistics from the University of North Carolina at Chapel Hill and a PhD in Biostatistics from Emory University. Dr. Price is an active member of the American Statistical Association (ASA) and the Eastern
North American Region of the International Biometrics Society. She is a Fellow of the ASA and the 2023 President of the ASA.

Scott Halpern is the John M. Eisenberg Professor of Medicine, Epidemiology, and Medical Ethics and Health Policy at the University of Pennsylvania, and a practicing critical care doctor. He is the founding Director of the Palliative and Advanced Illness Research (PAIR) Center, which generates evidence to advance policies and practices with the goals of improving the lives of all people affected by serious illness and removing the barriers to health equity that commonly face seriously ill patients. He is also Director of the NIH-funded Penn Roybal Center on Palliative Care in Dementia, and the American Heart Association-funded BETTER Center (Behavioral Economics to Transform Trial Enrollment Representativeness), which works to promote diverse participation in clinical trials. He is an elected member of the American Society of Clinical Investigation, the Association of American Physicians, and the Hastings Center.

Dooti Roy is the Director of Global Biostatistics and Data Sciences at Boehringer Ingelheim and leads a team of talented statisticians and data scientists who develop and implement cutting-edge clinical research and statistical visualization tools. She has more than 8 years of experience in the biopharmaceutical industry, where she has successfully created and led numerous cross-functional collaborations to solve complex problems and deliver high-quality results. Her current research focus is on the applications of Bayesian statistics, artificial intelligence, and machine learning in drug development, which she believes are the key drivers of innovation and efficiency in this field. She also has an adjunct faculty appointment at the University of Connecticut, where she teaches a unique summer program that she designed to introduce students to the essential biostatistical topics needed as a clinical trialist. She is passionately engaged on the topic of clinical trial diversity, inclusion, justice, and equity for the past several years primarily driven by her own experience in the industry and by her personal experience as a care giver. Dooti has a PhD in Statistics from the University of Connecticut and is originally from Kolkata, India.

Roberta (Bobbi) Bogaev Chapman is the Vice President for Heart Failure at Abiomed in Danvers, Massachusetts where she leads the Women’s Heart Initiative and works collaboratively on all Abiomed sponsored clinical trials, education, patient advocacy and developing best practices for patients with heart failure. Dr. Bogaev received her mechanical engineering degree from Virginia Tech and her medical degree and training from the University of Virginia. She is board certified in cardiology and advanced heart failure. Dr. Bogaev served as the Medical Director of the Heart Transplant program at Methodist Hospital in San Antonio and the Texas Heart Institute in Houston, Texas where she was faculty at Baylor College of Medicine and directed the heart failure fellowship training program. Prior to joining Abiomed, she served as Medical Director of the Advanced Heart Failure Program and Chief of Cardiology for Bon Secours Mercy Health in Richmond, Virginia. She has authored peer review articles, book chapters, and abstracts in the fields of heart failure, mechanical circulatory support, and sex
specific outcomes. She spent two years during her fellowship in basic science research and has been actively involved in translational and clinical research for the past twenty years. Dr. Bogaev advocates for women with heart disease and is an avid supporter of the AHA’s Go Red campaign, serving on multiple AHA boards and Go Red executive leadership teams in San Antonio, Houston and Richmond, Virginia. She and one of her LVAD patients, “The Bionic Bride” made several appearances on the Today Show, showcasing the advanced technology of continuous flow pumps. She is passionate about the prevention of heart disease, early treatment of heart failure and cardiogenic shock, and optimizing outcomes for patients who require mechanical circulatory support. Dr. Bogaev is committed and dedicated to helping patients live long, fulfilling lives.

Thomas R. Fleming is Professor and former Chair of the Department of Biostatistics at the University of Washington in Seattle, Member of the Fred Hutchinson Cancer Research Center. Dr Fleming has authored or coauthored several books and nearly 300 research articles in peer-reviewed journals, many regarding the development of state-of-the-art methods for the design, conduct and analysis of clinical trials, and many others reporting the results of landmark trials, including the 2011 publication in NEJM on prevention of transmission of HIV. This research, on which he was senior author, was recognized by Science Magazine to be the scientific “Breakthrough of the Year”. He has chaired or served on Data Monitoring Committees for more than 250 clinical trials. For more than 30 years he has served as a Special Government Employee for FDA, as a regular member of several FDA Advisory Committees and as an invited voting member on more than 100 occasions. Dr Fleming has received numerous awards and was elected to membership in the Institute of Medicine of the National Academies in 2012, which became the National Academy of Medicine in 2015.

Michel Reid leads a team that supports the full GSK R&D (medicines and vaccines) and Viiv R&D (HIV therapies) portfolios to enhance diversity in clinical trials, to ensure GSK delivers science that helps the most people possible, by being ambitious for patients. Under his leadership, the team has been instrumental to promote health equity and to help improve health outcomes for a diverse population of underrepresented patients. To lead with transparency, he published a peer-reviewed retrospective study for GSK clinical trials over a span of 17 years that investigated the historical representation of U.S.-based participants and compared demographics with real-world disease epidemiology data. Prior to this role, Michel served as Director in GSK’s US Pharmaceuticals Commercial Insights team focusing on Vaccines. There, he was responsible for leading the design and execution of purpose-built market analysis and market research, producing innovative insights that continue to drive the commercial organization. Before joining GSK in 2018, Michel spent over 15 years in marketing agencies and consultancy, providing business strategy, and communications design, strategy, and analysis for clients in a variety of industries and across a wide range of pharmaceutical therapeutic areas and customer groups. Michel holds a degree in Mechanical Engineering from Carnegie Mellon University. Michel lives in Burlington, NJ, USA with his wife Jennifer and three daughters, Azarin, Bonnie, and Piper. Talk to him about cars, computers, or cryptocurrencies, as those are his favorites.
Larissa Avilés-Santa is the director of the Division of Clinical and Health Services Research at National Institute on Minority Health and Health Disparities (NIMHD) at the National Institutes of Health. In this capacity, she leads a multi-disciplinary team, and has led and/or supported the development of multiple new scientific initiatives in a wide range of topic areas. Prior to joining NIMHD, she worked at the National Heart, Lung, and Blood Institute as the project director (2006-2019) for the Hispanic Community Health Study/Study of Latinos, the most comprehensive study on Hispanic/Latino health in the United States to date. In 2015, she founded the NIH Hispanic Health Research Scientific Interest Group. In 2017, Dr. Avilés-Santa was the field coordinator of the post-hurricanes Irma and María recovery of the health and social services in Puerto Rico during the first six and a half months of work coordinated by HHS. In this capacity, she had the opportunity to lead a diverse group of volunteer federal employees and local contractors in the performance of needs assessments and the proposal of multiple recovery strategies. Dr. Avilés-Santa earned her medical degree from the University of Puerto Rico School of Medicine, and completed a residency in internal medicine at the University Hospital in San Juan and a fellowship in endocrinology at the University of Texas Southwestern Medical Center. She also earned a Master’s degree at the University of Texas School of Public Health.

Rose Blackburne is a globally recognized leader in product development and a board-certified Obstetrics/Gynecology physician with over 25 years of experience in healthcare. She currently serves as the Global Vice President and Therapeutic Area Head of General Medicine Clinical Research at PPD, a Thermo Fisher Scientific company. Dr. Blackburne has been instrumental in obtaining approvals for pharmaceuticals, vaccines, medical devices, and diagnostic tests. She also serves as the Industry Representative Alternate to the FDA Patient Engagement Advisory Committee (PEAC), providing advice on medical device regulation and developing guidance and policies. With over 18 years of experience in Clinical Research & Development, Dr. Blackburne has held numerous global leadership positions in CROs, focusing on Ph I-IV programs across therapeutic areas. She is passionate about Diversity, Equity and Inclusion and Women’s Health policies, and has led numerous initiatives to improve inclusion of underrepresented participants in clinical trials. Dr. Blackburne holds a medical degree from Morehouse School of Medicine, an MBA from the University of Virginia Darden Graduate School of Business and has a certificate in Health Policy from Harvard University Kennedy School of Government.

Anne Drapkin Lyerly is Professor of Social Medicine, Research Professor of Obstetrics and Gynecology and core faculty in the Center for Bioethics at the University of North Carolina, Chapel Hill. A board-certified obstetrician/gynecologist and bioethicist, she studies ethically complex issues around gender and reproductive medicine. She has led multiple projects developing ethics guidance around research in pregnancy: she is principal investigator on the NIH-funded PHASES Project and PREPARE...
Project addressing the ethics of HIV research and pregnancy and pregnant adolescents, respectively; and was co-PI on the Wellcome Trust funded PREVENT project on research, pregnancy and public health emergencies. She chaired the American College of Obstetricians and Gynecologists Committee on Ethics and has served as advisor for the US Food and Drug Administration, National Institutes of Health and the World Health Organization. She is a fellow of the Hastings Center, an alumna of the Greenwall Faculty Scholars Program, and was recently elected as a member of the Johns Hopkins Society of Scholars. She has written dozens of articles and book chapters, including publications in JAMA and The Lancet as well as the New York Times. She is author of A Good Birth, published by the Penguin Group/USA.

Michele Kipke is a Professor of Pediatrics and Population and Public Health Sciences at the Keck School of Medicine and Associate Vice President for Strategic Health Alliances in the Office of the Senior Vice President of Health Affairs at the University of Southern California (USC). In addition, she co-directs USC’s Southern California Clinical and Translational Science Institute. A nationally known public health researcher and policy expert, Dr. Kipke has been intimately involved in the HIV/AIDS epidemic since its onset in the U.S. in the mid-1980’s and has made significant scientific contributions to the field of HIV prevention since that time. Early in her career, she studied risk for HIV exposure among injection drug users, developed and conducted the first formal evaluation of an HIV prevention intervention for adolescents in Harlem, and evaluated one of the first needle exchange programs. During the past three decades, Dr. Kipke has conducted NIH-funded behavioral epidemiologic research with at-risk youth populations, as well as health services and health outcomes research to characterize inequities in health in diverse pediatric populations. During the COVID-19 pandemic, Dr. Kipke has led a USC-wide effort, called VaccinateLA, which includes a digital and multi-media campaign, and community navigation services delivered to residents in low vaccination communities in Los Angeles County, as well as in 34 states throughout the United States. Through this effort, over 400,000 individuals have been vaccinated to date. Targeted public health interventions are also being developed to increase pediatric vaccinations. To date, Dr. Kipke has authored over 100 publications and lectured nationally and internationally.

Jennifer Jones-McMeans is the Divisional Vice President of Global Clinical Affairs for Abbott’s Vascular Business based in Santa Clara, California. Since joining Abbott as a clinical research scientist more than 16 years ago, Jennifer has worked on gaining approval of numerous vascular devices, in the USA and around the world. Through her work, Jennifer has become one of the leading experts in clinical trial design strategy for vascular devices. Jennifer’s journey began while working on her PhD at the University of Maryland, College Park, where her early research focused on evaluating the differences in genes and biomarkers between African Americans and Caucasians who were pre-hypertensive when they were put on an exercise regimen. As a post-doctoral fellow in the Division of Hypertension at University of Texas Southwestern Medical Center focused on clinical trials evaluating anti-hypertensive therapies, Jennifer also worked on the Barbershop Hypertension Program, training barbers to measure the blood pressure of their male customers and connecting those with high blood pressure with trusted
contacts in the healthcare community. Following the completion of her post-doctoral fellowship, she chose to take her experience and knowledge to Abbott. Jennifer is taking a proactive approach to the design and implementation of clinical trials. In the spirit of continuous improvement, her goal is to make clinical trials more equitable, accessible and inclusive of diverse patient populations so that participants in clinical trials more accurately reflect those burdened with vascular diseases.

**Dawn Corbett** is the National Institutes of Health (NIH) Inclusion Policy Officer in the Office of Extramural Research (OER), where she provides leadership and coordination for trans-NIH efforts to ensure the inclusion of women, members of racial and ethnic minority groups, and individuals across the lifespan in NIH-defined clinical research. Prior to joining OER in 2017, Ms. Corbett held positions at the National Institute of Mental Health for 14 years, where she oversaw program activities to increase diversity, efficiency, and transparency in the mental health clinical research portfolio. Ms. Corbett has a master’s degree in public health from the Johns Hopkins Bloomberg School of Public Health and a bachelor’s degree in political science from the University of Illinois at Urbana-Champaign.

**Session 3B**

**David Resnik** is a Bioethicist at the National Institute of Environmental Health Sciences, National Institutes of Health. Dr. Resnik has published over 300 articles and ten books on various topics on ethical, philosophical, and legal issues in science, technology, and medicine and is a Fellow of the American Association for the Advancement of Science. He serves on several editorial boards and is an Associate Editor of the journal Accountability in Research.

**Willyanne DeCormier Plosky** is a Program Director at the Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard, where she focuses primarily upon initiatives within the Diversity, Equity, and Inclusion in Clinical Research portfolio. Previously she worked for Management Sciences for Health, the World Bank, Avenir Health, UNICEF, and USAID in the areas of health economics, maternal and child health, disability rights, HIV/AIDS, and humanitarian response. She has also served for five years on the Board of Directors for All Farmers, an organization that supports refugee and immigrant families to access arable urban land and farmers markets.

**Kellie Malloy Foerter** joined BMS in 2020 with 25+ years of clinical research experience, she is currently serving as Vice President and Head of Global Trial Management for Immunology, Cardiovascular and Neuroscience, as well as Head of Global Biospecimen and Imaging Management. Before joining BMS, she served as a Chief Operation Officer at Oncosec Medical, Inc. Prior to that, she served on the Clinical Executive Leadership Team at Syneos Health and lead multi-therapeutic business units with 1000+ cross-functional teams. Kellie has a BS from St. Joseph’s University, and a
masters in Bioethics from The Ohio State University. She is active in her community and has participated in BMS’ Coast to Coast for Cancer twice.

**Ari Ne-eman** is a PhD Candidate in Health Policy at Harvard University and a Visiting Scholar at the Lurie Institute for Disability Policy at Brandeis University. He previously served as executive director of the Autistic Self Advocacy Network from 2006 to 2016 and as one of President Obama’s appointees to the National Council on Disability from 2010 to 2015.

**Alison Barkoff** leads the US Department of Health and Human Services’ Administration for Community Living or ACL and performs the duties of the ACL Administrator and the Assistant Secretary for Aging. In her role at ACL, Alison provides executive leadership and coordination for ACL programs nationwide and serves as an advisor to HHS Secretary Becerra on issues that impact people with disabilities and older adults. Alison is a lifelong advocate for community living who has worked tirelessly at the forefront of national efforts to expand the home and community-based services that make community living possible for so many people. She has appeared before Congress and the US Commission on Civil Rights and has been part of countless coalitions of people with disabilities, older adults, and advocates, often in her role as a civil rights attorney. She has served as Special Counsel for Olmstead Enforcement in the Civil Rights Division of the US Department of Justice; held leadership roles with the Centers for Medicare & Medicaid Services and the Department of Labor; and she previously directed advocacy efforts at both the Center for Public Representation and the Bazelon Center for Mental Health Law.

**Closing Remarks, Day 1**

**Sally Okun** is the Executive Director of the Clinical Trials Transformation Initiative (CTTI). Ms. Okun coordinates with the Executive Committee in the development and execution of strategies to accomplish CTTI’s mission. She provides senior oversight and management of CTTI operations and organizes efforts to leverage the participation of member organizations and external stakeholders. Prior to joining CTTI, Ms. Okun led a consultancy firm that specialized in projects related to patient and public involvement in research, care, policy, and socially accountable ethics. From 2013 to 2019, she served as vice president of the online patient research network PatientsLikeMe (PLM) where she was responsible for the company’s patient advocacy initiatives, contributed to health policy discussions at the national and global level, and was PLM’s liaison with government and regulatory agencies, including the U.S. Food and Drug Administration (FDA), Center for Medicare and Medicaid Services (CMS), and the European Medicines Agency (EMA). Ms. Okun joined PLM in 2008 as the manager of Health Data Integrity and Patient Safety, where she oversaw the site’s medical ontology including the curation of patient-reported health data, the patient voice vocabulary, and the development of an integrated Drug
Safety and Pharmacovigilance Platform. Prior to 2008 Ms. Okun, a registered nurse, practiced as a community-based palliative care specialist and held other clinical positions for over three decades.

Opening Remarks, Day 2

**CDR 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. She provides leadership, oversight, and direction to a diverse staff of medical, pharmacy, nursing, 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 to joining FDA, she worked as a registered nurse and a Secondary Education Teacher. CDR Fienkeng was commissioned in the U.S. Public Health Service in 2008 and holds the rank of Commander. She earned a Doctor of Pharmacy degree and a Master's 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 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.

Session 3C

**Paul Appelbaum** is the Elizabeth K. Dollard Professor of Psychiatry, Medicine, and Law, and Director, Center for Law, Ethics, and Psychiatry, Department of Psychiatry, Columbia University. His research focuses on ethical, legal and social issues related to advances in genetics, as well as mental health law. The author of many articles and books on law and ethics in clinical practice and research, Dr. Appelbaum is a Past President of the American Psychiatric Association and chairs the DSM Steering Committee. A graduate of Columbia College and Harvard Medical School, he has been elected to the National Academy of Medicine.

**Patricia A. Areán** is the director for the Division of Services and Interventions Research at the National Institute of Mental Health. She is an international expert on the design of randomized clinical trials for behavioral and digital interventions, and implementation strategies. She is a former professor in the University of Washington’s Department of Psychiatry and Behavioral Sciences, co-director of the NIMH funded ALACRITY Center, the CREATIV and the MHATS Digital Laboratories. Dr. Areán is a leading behavioral scientist, with an expertise cross-cultural mental health, geriatric psychology, assessment
and treatment of depression and anxiety, the use of Human Centered Design for adapting psychosocial interventions and in the use of technology to conduct surveys, user experience research and clinical trials to scale. She has published on the recognition and treatment of depression and anxiety, methods for recruiting and retaining large and representative numbers of adults into longitudinal research, and acceptability of using digital methods for the purpose of screening and treating mental illnesses.

**Allissa Torres** is the Director of Mental Health Equity at Mental Health America (MHA). Her role ensures that MHA centers equity in every part of its work. Allissa spearheads projects such as the BIPOC Mental Health Month campaign in July and advises on many other campaigns throughout the year. Allissa has over 10 years of experience working with mental health nonprofits on local, regional, and national levels. Allissa holds two degrees, a Master of Social Work from the University of Southern California and a Bachelor of Arts in Psychology from Arizona State University. She is passionate about all things equity and especially is interested in the intersection of social justice and mental health. She is a firm believer in community-centered care, grassroots advocacy, and liberation-based practice. Allissa’s lived experience as a Latina woman with mental health diagnoses drives much of her passion in this field.

**Scott Kim** is a Senior Investigator in the Department of Bioethics, National Institutes of Health. Prior to joining NIH, he was Professor of Psychiatry and Co-Director of the Center for Bioethics and Social Sciences in Medicine at the University of Michigan. He received his MD from Harvard and PhD in moral philosophy (on Kantian ethics) from the University of Chicago, and trained in adult psychiatry at the Massachusetts General Hospital. He combines philosophical, clinical, and empirical research approaches to address several bioethical topics, including: ethical issues in human subjects research, decision-making capacity, surrogate consent, theory of informed consent, and end of life issues (especially euthanasia and physician-assisted suicide—for which he served on the Council of Canadian Academies Expert Panel on Medical Assistance in Dying). Dr. Kim’s work has been supported by the NIMH, NINDS, NIA, NHGRI, Michael J. Fox Foundation, American Association for Geriatric Psychiatry, and the Greenwall Foundation. His work has appeared in *New England Journal of Medicine*, *Nature*, *JAMA*, and other key journals, as well as being covered in popular media, such as the New York Times and the Atlantic. His book *Evaluation of Capacity to Consent to Treatment and Research* (Oxford, 2010) is available in English and Japanese.

**Eric Lenze** is the Wallace & Lucille Renard Professor of Psychiatry and chair of the department of Psychiatry at Washington University School of Medicine. Dr. Lenze earned his MD and completed psychiatry residency at Washington University School of Medicine. He then completed a geriatric psychiatry fellowship and a research fellowship at University of Pittsburgh, in the Late-Life Mood Disorder center headed by Dr. Chip Reynolds. For over 20 years he has led a research program that advances evidence-based medicine for depression, anxiety, and cognitive disorders in older adults. His research has been consistently funded by the NIH, as well as the patient-centered outcomes research
Innovation Through Collaboration

http://www.ctti-clinicaltrials.org

Craig Tendler is Vice President and Global Head of Clinical Development, Diagnostics, and Medical Affairs for the Oncology Therapeutic area at Johnson & Johnson Innovative Medicine. In this position, he is responsible for creating and overseeing robust development plans, including optimal integration of biomarkers and diagnostics, and comprehensive data generation activities for all products in the oncology portfolio, from proof of concept through registration and lifecycle management. He works closely with teams in early development and the disease areas of focus to implement a seamless end-to-end oncology clinical research strategy that incorporates compelling science, broad clinical trial access to diverse populations, and addresses areas of high unmet medical need. Prior to this role, Craig served as Vice President of Medical Affairs for Tibotec Therapeutics and then Ortho-Biotech, where he led medical affairs teams in lifecycle management and data generation for the Janssen Virology and Oncology franchises. Craig has overseen and coordinated more than 30 major drug approvals by national regulatory agencies, including at least ten NDAs by the US Food and Drug Administration (FDA). He and his have team worked in collaboration with the FDA and the European Medicines Agency to secure the worldwide approvals of Janssen’s treatments in prostate cancer, hematologic malignancies, as well as for lung and bladder cancer. Further, together with his team, Craig has been instrumental in achieving 12 FDA breakthrough designations for accelerating the early development of promising investigational medicines intended for the treatment of serious oncology conditions. Prior to joining Janssen, Craig served as the Vice President of Oncology Clinical Research and Chair of the Oncology Licensing Committee at the Schering-Plough Research Institute. In addition to his pharmaceutical industry experience, he has served as Assistant Professor of Pediatrics/Hematology-Oncology at the Mount Sinai School of Medicine in New York City and as a research fellow at the National Cancer Institute in Bethesda, Maryland. Craig earned his undergraduate degree from Cornell University, and graduated from the Mount Sinai School of Medicine, New York City, with high honors and induction into the Alpha Omega Alpha Medical Society.

Craig Lipset is an advisor, educator, advocate and innovator focused on novel solutions for clinical trials and medicine development. He is the founder of Clinical Innovation Partners, providing advisory and board leadership with pharma, tech and investors. Craig is Co-Chair for the Decentralized Trials &
Research Alliance and Vice President of the Foundation for Sarcoidosis. He is Adjunct Assistant Professor in Health Informatics at Rutgers University, and serves on the Advisory Council for HL7 Project Vulcan and External Stakeholder Board for IMI Trials at Home.

Laura Esserman is Professor of Surgery and Radiology at the University of California, San Francisco (UCSF) and director of the UCSF Breast Care Clinic. Her work in breast cancer spans the spectrum from basic science to public policy issues, and the impact of both on the delivery of clinical care. Dr. Esserman is recognized as a thought leader in cancer screening and over-diagnosis, as well as innovative clinical trial design. She led the creation of the University of California-wide Athena Breast Health Network, a learning system designed to integrate clinical care and research as it follows 150,000 women from screening through treatment and outcomes. The Athena Network launched the PCORI-funded Wisdom Study, which tests a personalized approach to breast cancer screening in 100,000 women. She is also a leader of the innovative I-SPY TRIAL model, designed to accelerate the identification and approval of effective new agents for women with high risk breast cancers. In 2020, she got FDA approval for an I-SPY COVID trial, designed to rapidly screen and confirm high impact treatments to reduce mortality and time on ventilators.

Luther T. Clark is Executive Director, Patient Innovation & Engagement, Global Medical and Scientific Affairs at Merck. In this role, he is responsible for (1) collaborating with key internal and external stakeholders to increase the voice of patients, directly and indirectly, in decision-making; (2) supporting implementation of the global clinical trial diversity, inclusion and equity strategic plan; and (3) representing Merck externally, expanding bi-directional scientific exchange and connectivity with key patient and professional leaders and organizations. Dr. Clark co-leads a team that champions diversity, equity and inclusion in clinical research and chairs Merck's Patient Engagement, Diversity and Health Literacy Investigator Initiated Studies Research Committee. Prior to joining Merck, Dr. Clark was Chief of the Division of Cardiovascular Medicine at the State University of New York Downstate Medical Center (SUNY Downstate) and founding Director of the National Institutes of Health (NIH) funded Brooklyn Health Disparities Research Center. Dr. Clark earned his Bachelor of Arts degree from Harvard College and his Medical degree from Harvard Medical School. He is a Fellow of the American College of Cardiology (FACC) and the American College of Physicians (FACP). He has authored more than 100 publications and edited (as well as being principal contributor) the textbook Cardiovascular Disease and Diabetes (McGraw-Hill). Dr. Clark has received numerous awards and honors, including the Harvard University Alumni Lifetime Achievement Award for Excellence in Medicine.

Alanna A. Morris is Associate Professor of Medicine in the Division of Cardiology at Emory University School of Medicine and the Emory Cardiovascular Clinical Research Institute. Currently she serves as the Director for Heart Failure Research. Dr. Morris received her undergraduate degree in Biology from Xavier University of Louisiana, and her medical degree from the Harvard Medical School. She completed her residency at Brigham and Women’s Hospital in Boston, Massachusetts. Subsequently,
she came to Emory University to complete fellowships in general cardiology, and advanced heart failure and transplant. Her clinical time is spent as faculty in Emory’s Center for Heart Failure Therapy and Transplantation. Her research program focuses on studying mechanisms that underlie race- and gender disparities in heart failure risk and progression, as well as execution of clinical trials in patients with heart failure.

Ivor Horn is Chief Health Equity Officer at Google where she leads a cross-functional team that provides health equity leadership to ensure that health-related products, research and other initiatives are diverse, fair, accessible and inclusive. Dr. Horn is a pediatrician and health services researcher who has over 25 years of experience in health equity and social determinants of health addressing the needs of marginalized communities. Prior to her role at Google, Dr. Horn served as Chief Medical Officer at Accolade. Before Accolade, she served as Medical Director of the Center for Diversity and Health Equity at Seattle Children’s Hospital, and Professor of Pediatrics at the University of Washington School of Medicine. A nationally recognized leader in health equity, social determinants of health and healthcare innovation, Dr. Horn has served on advisory panels for the National Institutes of Health, the Robert Wood Johnson Foundation, the American Academy of Pediatrics and the Office of the National Coordinator. Dr. Horn currently serves as a Board Trustee for Boston Children’s Hospital, on the Advisory Board of the Harvard Public Health Journal and a Board Director for Care Academy. She holds an MD and MPH and has authored several peer-reviewed journal publications on health communication and health equity.

Session 5A

James E.K. Hildreth is the 12th president and chief executive officer of Meharry Medical College, the nation’s largest private, independent historically black academic health sciences center. Dr. Hildreth obtained a B.A. in chemistry from Harvard University and was selected as the first African-American Rhodes Scholar from Arkansas. He obtained a Ph.D. in immunology from Oxford University where his studies focused on the biology of virus-specific cytotoxic T cells. Dr. Hildreth also became an expert in monoclonal antibody technology and cell adhesion molecules while at Oxford. He obtained an M.D. from Johns Hopkins University School of Medicine and took a leave of absence from medical school for a postdoctoral fellowship in pharmacology at Johns Hopkins.

Paula Boyles is the Clinical Trial Data Sharing External Demand Program Lead, at Pfizer, currently living and working in CT, USA. She has 16 years’ experience at Pfizer working in both the USA and UK, focusing on the implementation and support of clinical trial and regulatory applications. Paula received a Pfizer Recognition Award for her role in the introduction of electronic data capture at clinical study sites globally. After a career break to raise her family, Paula returned to Pfizer where she applies her clinical trial knowledge and passion for doing the right thing, to drive positive changes to the way
Cynthia Chauhan's experience as a support advocate and a research advocate at the local, regional, national and international levels is augmented by her professional experience as a social worker. Cynthia has been an active research advocate for twenty-two years and was an active support advocate for about fifteen years. Cynthia has HFpEF stage 3 and kidney failure stage 4 and because there are currently limited treatment options for HFpEF, she regularly participates in clinical trials. Additionally, Cynthia has other significant comorbidities including glaucoma, dry amd, multiple arthritis, peripheral neuropathy, and is a survivor of renal cell carcinoma and breast cancer and lives with chronic pain. She has undergone multiple procedures including but are not limited to multiple joint replacements, multiple trabeculectomies, right nephrectomy, breast lumpectomy and radiation therapy. She is currently enrolling in a clinical trial and have participated in 12 clinical trials including a pericardiectomy. Cynthia believes continuous research is important to enable us to live longer healthy lives. The way to move treatments forward is through clinical trials. Not all trials are successful, but all clinical trials move us down a path to success. Cynthia’s personal extensive history of health issues gives her a deep understanding of the challenges patients face.

Tarek Hammad is the Vice President and Head of Medical Safety for Marketed Products at Takeda Pharmaceuticals. Prior to this, he held notable positions in leading pharmaceutical companies, including Sanofi and Merck KGaA, where he served as the Therapeutic Area Strategy Lead and Head of Signal Detection and Benefit-Risk Assessment, respectively. He also served as an Executive Director of Pharmacoepidemiology in US Merck. Before transitioning to the industry, Dr. Hammad enjoyed a distinguished 13-year career at the United States FDA, where he progressively took on more responsibilities, culminating in his role as the Deputy Division Director of Pharmacoepidemiology at the Office of Surveillance and Epidemiology (OSE), CDER. He received several prestigious awards during his tenure at the FDA, including the FDA Distinguished Service Award and the Frances Kelsey Excellence in Drug Safety Award. Throughout his career, Dr. Hammad has made substantial contributions to the scientific community through teaching, publications, as a peer reviewer for major scientific journals, and working with public-private consortia dedicated to advancing innovation in drug development (e.g., the Innovation in Medicine Initiative (IMI) and the Council for International Organizations of Medical Sciences (CIOMS)). His expertise extends to his participation in the ICH Expert Working Group (EWG M4E(R2)) on “Enhancing the Format and Structure of Benefit-Risk Information.” His reputation as an expert in drug safety, pharmacoepidemiology, and benefit-risk assessment is nationally and internationally recognized. As a sought-after speaker, Dr. Hammad is frequently invited to webinars, symposia, public workshops, and scientific conferences, where he shares his insights. He has also assumed roles as a session chair and member of scientific program committees. Alongside his professional accomplishments, Dr. Hammad has held various academic appointments and authored over 80 peer-reviewed articles, letters to the editor, and book chapters.
Barbara E. Bierer, a hematologist-oncologist is Professor of Medicine at Harvard Medical School and the Brigham and Women’s Hospital (BWH). Dr. Bierer co-founded and now leads the Multi-Regional Clinical Trials Center of BWH and Harvard (MRCT Center, www.mrctcenter.org), a collaborative effort to improve standards for the planning and conduct of international clinical trials to harmonize policies for and approaches to clinical trial regulation. In 2017, the MRCT Center launched the non-profit organization, Vivli (www.vivli.org), a global clinical research data sharing platform. In addition, she is the Director of the Regulatory Foundations, Ethics, and the Law program at the Harvard Catalyst, the Harvard Clinical and Translational Science Award, working across the academic spectrum to enable the clinical trial enterprise from study planning through recruitment to data acquisition and dissemination. She is the Director and PI of SMART IRB (www.SMARTIRB.org), a national effort to align single site IRB review of multi-site trials. She serves as Faculty in the Center for Bioethics, Harvard Medical School, and as Affiliate Faculty in the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. From 2003 – 2014, Dr. Bierer served as Senior Vice-President, Research at the Brigham and Women’s Hospital (BWH). During her tenure, Dr. Bierer founded and served as Executive Sponsor of the Brigham Research Institute and the Brigham Innovation Hub (iHub), a focus for entrepreneurship and innovation in healthcare. She has authored approximately 300 publications. Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.

Tesheia H. Johnson is the Chief, Clinical Research Strategy and Development Officer for the Yale Center for Clinical Investigation (YCCI) and the Director of Clinical Research for Yale School of Medicine, where she provides leadership and direction in the area of clinical research. She is co-founder, along with the community leaders of the AME Zion Church and Junta for Progressive Action, of the Yale Cultural Ambassadors Program, launched more than ten years ago with a mission to catalyze the sustainable advancement of patient diversity, equity, and inclusion in clinical research. Ms. Johnson is nationally recognized for her expertise in the design and setup of clinical research programs.

Ileana L Piña is Professor of Medicine at Thomas Jefferson University and the Chief Quality Officer for the Cardiovascular Line, Philadelphia, and Clinical Professor of Medicine at Central Michigan University, Mount Pleasant, Michigan, USA. Dr Piña also serves as Senior Fellow and Medical Officer to the Food and Drug Administration’s Center for Devices and Radiological Health. Dr Piña earned her undergraduate degree in chemistry from the University of Miami in Florida. She completed her medical degree and cardiology fellowship at the University of Miami School of Medicine; an internal medicine residency at the University of South Florida, Tampa, where she was Chief Resident; and fulfilled a surgery internship at the University of Miami Hospitals and Clinics. She earned a Master's degree in public health from Case Western Reserve University School of Medicine in Cleveland, Ohio, while
pursuing a VA Quality Fellowship. Dr Piña has been actively involved in gender, racial and ethnic issues in healthcare delivery. She is the author/co-author of more than 250 publications. She is currently a member of the Advocacy and Scientific Committees of the American Heart Association (AHA) and on the Board of Directors National AHA. Dr Piña’s research interests include transition of care in heart failure patients, and the role of natriuretic peptide-guided management for patients hospitalized for heart failure, biomarkers of myocardial stress and fibrosis in chronic heart failure, and heart failure differences by sex, race and ethnicity.

B. Angeloe Burch, Sr. is the CEO of the African American Community Collaborative, Inc. He has a Bachelor of Arts, MDiv and a PhD in Philosophy of Religion. Dr. Burch is the President of the Durham, NC NAACP, Parliamentarian for the State NAACP, Chair of the Religious & Human Affairs for the Durham Committee on the Affairs of Black People and Board member of PCORI. He is the Chair of the Families and Communities Rising Board of Directors, Member of the Criminal Justice Advisory Committee, and OCHIN Project for COVID Research for Minority populations. He is a 33rd degree Grand Inspectors General in the United Supreme Council Southern Jurisdiction.

Reed V. Tuckson is Managing Director of Tuckson Health Connections, LLC, a vehicle to advance initiatives that support optimal health and wellbeing. Currently, Dr. Tuckson's focus is on his role as a Co-Convener of the Coalition For Trust In Health & Science which is dedicated to bringing together the entire health related ecosystem to address mistrust and misinformation. In addition, he continues to advance his work as a co-founder of the Black Coalition Against COVID, a multi-stakeholder and interdisciplinary effort working to mitigate the COVID-19 pandemic in Washington, D.C. and nationally by coordinating the four historically Black medical schools, the NMA, the National Black Nurses Association, the National Urban League, and BlackDoctor.org. Previously, he enjoyed a long tenure as Executive Vice President and Chief of Medical Affairs for UnitedHealth Group, a Fortune 20 Health and wellbeing company. A recognized leader in his field, Dr. Tuckson is honored to have been appointed to leadership roles at the National Institutes of Health; National Academy of Medicine; numerous Federal Advisory Committees; and corporate, non-profit and academic boards.

Perla Nunes is a native of Ecuador and has over 30 years of experience in research. Her career began at Hoffman-LaRoche in Nutley, NC, where she worked in drug discovery. In NC she worked in the Department of General Surgery Research at the Cannon Research Center of Atrium Health, focusing on preclinical and clinical research areas related to oncology and immunology. From 2009-2020, Ms. Nunes worked at Duke University (CTSI) overseeing community engagement, outreach, recruitment, and retention efforts of diverse patient populations for clinical research studies. In 2020, Perla joined Javara, an Integrated Research Organization (IRO), and was responsible for the development and implementation of community outreach strategies and engagement for their healthcare partners. One of her objectives was to bring awareness and drive the participation of minority populations in clinical research. In 2021, she joined Greater Gift as Director of Outreach. Greater Gift is a non-profit
organization whose mission is to increase awareness of clinical research, especially among underrepresented populations. In 2023, Ms. Nunes started consulting and worked at North Carolina Central University (NCCU), a Historically Black Colleges and Universities (HBCU) as Director of Community Health Outreach at the Julius L. Chambers Biomedical Biotechnology Research Institute (JLC-BBRI). JCL-BBRI conducts multidisciplinary and interinstitutional research focused on health issues that disproportionately affect minority and underserved populations.

Billy A. Caceres is an Assistant Professor of Nursing at Columbia University and a nationally recognized expert on social and structural determinants of cardiovascular health. He is a board-certified nurse and nurse practitioner with expertise in cardiology. His contributions to cardiovascular health and health equity research have been recognized with awards from the National Institute of Health and the American Heart Association.

Kali Zhou is a transplant hepatologist and Assistant Professor in the Division of Gastrointestinal and Liver Diseases, Keck School of Medicine at the University of Southern California. She received her medical degree from Feinberg School of Medicine at Northwestern University, is a Fulbright scholar, and completed a T32 gastroenterology/transplant hepatology fellowship at the University of California, San Francisco, where she also received a Master’s in Clinical Research. Her current research program focuses on disparities in liver cancer and utilizing novel geospatial approaches to improving cancer equity and outcomes for multi-ethnic populations (NIH/NIMHD K23).

Session 6

Nakela L. Cook is the executive director at PCORI. She is a cardiologist and health services researcher with a distinguished career leading key scientific initiatives engaging patients, clinicians and other health care stakeholders at some of the nation’s largest health research funders. Cook leads PCORI’s research, engagement, dissemination and implementation, and research infrastructure development work. She also provides oversight to a growing number of programs and initiatives designed to create a more efficient, effective, equitable and patient-centered system of health. Under her leadership, and with extensive engagement of stakeholders, PCORI established a bold strategic vision to address the challenges, including social determinants of health, facing patients and communities in our nation’s complex, fast-changing health system. Prior to her current role, Cook served as senior scientific officer and chief of staff at the National Heart, Lung, and Blood Institute (NHLBI), the third largest institute of the National Institutes of Health. At NHLBI, she spearheaded the development and implementation of its strategic plan as well as initiatives in cardiovascular outcomes, precision medicine, data science, sickle cell disease and women’s health. Cook earned her medical degree from Harvard Medical School and a Master of Public Health in health care policy and management from Harvard School of Public Health. She completed her clinical training at Massachusetts General Hospital in Boston and is an
alumna of the Commonwealth Fund/Harvard University Fellowship in Minority Health Policy. Throughout her career, Cook has worked to enhance diversity and equity in research and care delivery and has been a leader in efforts to reduce disparities in health access and outcomes. She has received numerous awards for her excellence in clinical teaching and mentorship as well as her leadership of complex scientific initiatives and programs.

Peter Marks received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women’s Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development and is an author or co-author of over 100 publications. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in 2016. Over the past several years he has been integrally involved in the response to various public health emergencies, and in 2022 he was elected a member of the National Academy of Medicine.

Jeffrey Shuren is the Director of the Center for Devices and Radiological Health (CDRH) at FDA. He previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, Dr. Shuren joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detaillee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. From 1998 to 2003, he served as a Staff Volunteer in the National Institutes of Health’s National Institute of Neurological Disorders and Stroke Cognitive Neuroscience Section supervising and designing clinical studies on human reasoning. Dr. Shuren returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009.

Peter Stein 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 the University of Pennsylvania. He trained at Yale University and Yale-New Haven Hospital in internal medicine and in endocrinology and metabolism.
Marc Theoret is a hematologist/oncologist and serves as Deputy Director of the Food and Drug Administration’s (FDA) Oncology Center of Excellence (OCE). He is also Acting Supervisory Associate Director in the Office of Oncologic Diseases in the FDA’s Center for Drug Evaluation and Research. In his various roles, Dr. Theoret has led the reviews of numerous breakthrough therapies, new molecular entities, and novel biologics. He has contributed extensively to initiatives—regulatory, scientific, and policy efforts—in cancer therapeutic development, in particular immuno-oncology therapeutics, and has consistently provided FDA leadership in this field to wide-ranging external partners. Dr. Theoret earned his medical degree from the Penn State College of Medicine. He completed his internship and residency training in Internal Medicine at the Beth Israel Deaconess Medical Center in Boston, and fellowship training in Hematology and Oncology at the National Cancer Institute in Bethesda.

Meghan McKenzie works in Patient Inclusion and Health Equity in Genentech’s Chief Diversity Office. She develops strategies to drive greater inclusion of racial and ethnically representative patient populations in clinical research and to advance health equity. Gaining patient, clinician and community insights early in program development is integral to developing what is important to patients and improving access to medicines and treatments for all patients, regardless of race, ethnicity, sexual orientation, gender identity, age, socioeconomic status and ability/disability. She has over 25 years of clinical development experience working at sites and in industry, and spanning multiple diseases, including oncology, ophthalmology, immunology, neurology, infectious and rare diseases. Meghan received her Master's Degree in Human Biology at San Francisco State University and her Bachelor’s Degree in Economics at University of North Carolina, Chapel Hill.

Concluding Remarks, Day 2

Karen Hicks is the Deputy Director of the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) at the United States Food and Drug Administration (FDA). She oversees regulation and policy development for CDER and participates in cross-cutting agency initiatives. She works closely with the Office of the Commissioner and other Centers to promote diversity and inclusion of underrepresented populations in clinical trials. Dr. Hicks joined the FDA in 2003 and previously served as a Team Leader in the Division of Cardiovascular and Renal Products and as a Deputy Director in the Division of Nonprescription Drugs II. She has led two large multi-stakeholder initiatives to standardize data collection for cardiovascular trials. Dr. Hicks received her undergraduate degree from Duke University, MS degree from Georgetown University, and MD degree from the Georgetown School of Medicine. She completed her internship and residency in Internal Medicine and fellowship in Cardiovascular Disease at Walter Reed Army Medical Center. She completed her Interventional Cardiology training at The Johns Hopkins Hospital and subsequently was Director of the Cardiac Catheterization Laboratory at Madigan Army Medical Center.