Duke | MARGOLIS INSTITUTE for Health Policy

Sixteenth Annual Sentinel Initiative Public Workshop

November 7, 2024 | 9:00 a.m. – 4:15 p.m. ET
Hybrid In-Person and Virtual Workshop
National Press Club, Washington, D.C. & Zoom Webinar

Speaker Biographies

Steve Anderson is currently the Director of the Office of Biostatistics and Pharmacovigilance (OBPV) at the FDA Center for Biologics Evaluation and Research (CBER). In 2001, he was hired by CBER as the Associate Director for Risk Assessment to establish a program in quantitative risk assessment for biologic products. He has conducted collaborative studies using the FDA Sentinel system and CMS data to evaluate the safety of blood products and vaccines and worked to integrate use of these data systems into CBER's regulatory processes to improve biologic product safety evaluations and surveillance. In 2018 his office launched the CBER Biologics Effectiveness and Safety (BEST) Initiative to expand and enhance CBER access to new data sources, methods, tools, expertise and infrastructure to conduct surveillance and epidemiologic studies for biologic 2 products. Dr. Anderson earned a Master's Degree in Public Policy (MPP) at Georgetown University and while there developed the first quantitative risk assessment for antimicrobial resistant pathogens in cattle. Dr. Anderson received his PhD from the University of Cincinnati where he worked on biochemistry, drug resistance, pathogenicity and genomics of unique tropical disease pathogens. He has published a number of articles in biologic product safety, risk assessment, epidemiology, infectious diseases, biologics safety, and genomics and protein structure/targeting.

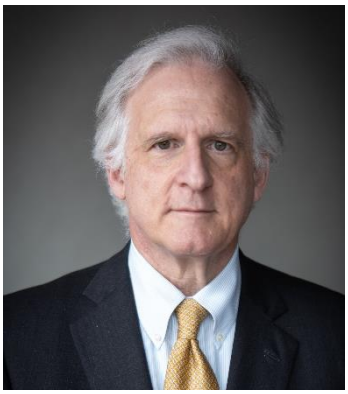
Robert Ball is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research, Food and Drug Administration (FDA) where he shares in responsibilities leading OSE in the premarket and postmarket regulation of drugs and therapeutic biologics through adverse event surveillance, pharmacoepidemiology, risk management, and medication error prevention. OSE also evaluates drug and biologic product safety and effectiveness using Real World Evidence, including managing the Sentinel System. From 2008-2013, he served as the Director, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, FDA where he led statistical and epidemiological evaluation of vaccines, blood,

cell, tissue, and gene therapy products. Dr. Ball received his BS in Mathematics and MD from Georgetown University. He interned at the US Naval Hospital Bethesda, completed his MPH and residency in Occupational Medicine at the Uniformed Services University of the Health Sciences, and received the ScM degree in Infectious Disease Epidemiology and Vaccine Science and Policy from Johns Hopkins School of Public.

Andrew Bate is Vice President & Head of Safety Innovation & Analytics at GSK, leads the development of next generation Safety capability, and is a member of the Global Safety Leadership team. Previously, Andrew was in the Global Epidemiology Leadership team at Pfizer for a decade and, prior to that, at the WHO Collaborating Centre for International drug Monitoring for more than 12 years, where he led the Research function. Andrew has contributed to several international initiatives and partnerships, including participating in The Council for International Organizations of Medical Sciences (CIOMS) on Working Group VIII on safety signal detection as the WHO nominated representative, as a Scientific Advisory Board member of OMOP (Observational Medical Outcomes Partnership) from 2009 to 2013, and as a member of the FDA Science Board Subcommittee on Pharmacovigilance (2010 to 2011). Andrew was a co-PI for the IMEDS Evaluation Pilot, the first evaluative access and use of the data across FDA's Sentinel Data Network by a non-FDA entity. Currently, Andrew sits on the Transcelerate BioPharma Pharmacovigilance Steering Committee and Integrated Leadership Team for GSK, was the Executive Sponsor the Intelligent Automation initiative, and he currently co-sponsors the Modernizing Pharmacovigilance workstream. Andrew is a member of CIOMS XIV on Artificial Intelligence in Pharmacovigilance. Andrew holds a master's degree in chemistry from Oxford and a PhD in Clinical Pharmacology from Umea University, Sweden.

Patricia Bright earned a Master's Degree and Ph.D. in Epidemiology from the University of North Carolina (Chapel Hill). She was a Faculty Member at the Johns Hopkins School of Medicine from 2003 to 2010, where she helped run clinical trials assessing therapeutic approaches to prevent maternal-to-child HIV transmission in developing countries. She began working at the FDA in 2010 as a Commissioner's Fellow. In 2012, she joined the Division of Epidemiology in the Center for Drug Evaluation and Research (CDER)'s Office of Surveillance and Epidemiology (OSE). She worked in the Division of Epidemiology as both a primary reviewer and as a Team Lead. She joined FDA's Sentinel Team in April 2021 and is the Associate Director and Lead for FDA's Sentinel System.

Patrizia Cavazzoni is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. 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. 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 is a fellow of the Canadian Royal College of Physician and Surgeons. She is a fellow of the Canadian College of Neuropsychopharmacology and a recipient of the American College of Psychiatrists' Laughlin Fellowship.



Gerald J. Dal Pan currently serves as the Director of the Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research, where since 2005 he has been responsible for the Center's programs in adverse event surveillance and analysis, pharmacoepidemiology, risk management, and medication error prevention. In this capacity, he is involved in both the premarket and postmarket regulation of drugs and therapeutic biologics, and in the implementation of the drug safety provisions of the Food and Drug Administration Amendments Act and other initiatives. He is a member of the World Health Organization Advisory Committee on the Safety of Medicinal Products, and has served on working groups of the Council of International Organization of Medical Sciences (CIOMS) and the International Council on Harmonisation (ICH). He received his MD from Columbia University College of Physicians and Surgeons and his Master of Health Science in Clinical Epidemiology from the Johns Hopkins University School of Hygiene and Public Health. He completed residency training in Internal Medicine at the Hospital of the University of Pennsylvania and in Neurology at the Johns Hopkins Hospital. He is board certified in both Internal Medicine and Neurology. He joined FDA in 2000 as a medical reviewer in the Center's Office of New Drugs. Before working at FDA, he was a faculty

member in the Department of Neurology at Johns Hopkins and worked in the pharmaceutical industry.

Rishi J. Desai is an Associate Professor of Medicine at Harvard Medical School and an Epidemiologist in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. His research focuses on understanding the use of medications and resulting outcomes in routine care patients with chronic diseases. He has a special interest in methodological investigations to improve inference from non-randomized studies of medication effects. He has authored >170 original research publications. He is the Operations Chief for the FDA Sentinel Innovation Center. His work has been funded by the National Institute of Aging, National Heart, Lung, and Blood Institute, and Food and Drug Administration.

Hussein Ezzeldin is a Senior Digital Health Expert in the Office of Biostatistics and Pharmacovigilance (OBPV). During the 10 years with OBPV, he has worked on a wide range of modeling, risk assessment, policy, and research projects. Currently, he is the team lead for the digital health technology review team (DHTRT), supporting the use of DHTs in regulatory submissions. In addition, Dr. Ezzeldin supports the Biologics Effectiveness and Safety Innovative Methods Initiative (BEST IM), which aims to develop new and innovative methods for a semi-automated adverse events (AEs) reporting system for CBER-Regulated Biological Products. Also, Dr. Ezzeldin has a passion for advancing the science of patient input, and he is leading the natural history study for metachromatic leukodystrophy, HOME. Dr. Ezzeldin led the development of the open-sourced SHAPE (Survey of Health And Patient Experience) platform, a versatile Data Collection platform for Patient-Centered Studies.

Richard Forshee is the Deputy Director of the Office of Biostatistics and Pharmacovigilance in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. He works on a wide range of issues related to the risks and benefits of biologic medical products. Dr. Forshee has led many award-winning benefit-risk assessments. He is also active in Real World Evidence studies of vaccine safety and effectiveness. In 2020, the Society for Risk Analysis selected Dr. Forshee for the Outstanding Practitioner Award. He has won numerous other awards including the FDA Award of Merit, the FDA Service Award, and the CBER Hope Hopps Memorial Award.

Joann Gruber is a PhD-trained epidemiologist with expertise in infectious diseases and vaccines. Dr. Gruber works at the Food and Drug Administration in the Center for Biologics Evaluation and Research (CBER) in the Office of Biostatistics and Pharmacovigilance in the CBER Surveillance Program. This program coordinates the Biologics Effectiveness and Safety (BEST) Initiative which is used to conduct active post marketing safety and effectiveness surveillance studies of CBER-regulated products, including vaccines. Data from the program help inform evidence-based regulatory decisions with the goal of protecting and promoting public health.

Mao Hu is a Policy Researcher at Acumen, LLC, where he manages projects for the BEST Data Coordination Center. His research interests include the assessment of the safety and effectiveness of vaccines, non-vaccine biologics, drugs, and other products using real world data sources from the Centers for Medicare & Medicaid Services and commercial insurance organizations in the BEST Initiative. He also works on the development and application of pharmacoepidemiologic methods for casual inference and analytics in distributed data networks such as the BEST Initiative.

Jamal T. Jones is an epidemiologist on the Sentinel Core Team within FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology. In this role, Dr. Jones provides scientific oversight and review of Sentinel modular program reports, pharmacoepidemiologic study protocols, web pages dedicated to individual medical product analyses and overarching medical product study pages, and other documents related to the implementation and execution of the Sentinel System. Dr. Jones is tasked with guiding project direction to meet FDA needs for Sentinel studies and communicating with key stakeholders. Dr. Jones primarily conducts studies on medical product utilization and to characterize various data elements in the Sentinel Distributed Database as well as electronic health record data aggregators. Dr. Jones is also involved in studies utilizing Sentinel analytic tools for safety signal identification and evaluation. Prior to joining the Sentinel Core Team, Dr. Jones served as an epidemiologist at FDA's Center for Tobacco Products where he performed scientific review of premarket tobacco product applications and conducted studies assessing tobacco product use behaviors and smoking cessation. He previously conducted health services research to prevent HIV among persons with increased risk for HIV acquisition – with an emphasis on HIV pre-exposure prophylaxis uptake in the United States – at the Centers for Disease Control and Prevention.

Patricia Lloyd is a health statistician who joined the CBER Surveillance Team within CBER's Office of Biostatistics and Pharmacovigilance (OBPV) in February 2021. She has worked on COVID-19 vaccine safety surveillance and vaccine effectiveness studies. Prior to this role she was a supervisory statistician at the DC Department of Health, leading COVID-19 surveillance activities and analyses of health disparities using mortality, natality, and hospital discharge data. Dr. Lloyd also served as a health statistician with the Centers for Disease Control and Prevention at the National Center for Health statistics in the Data Linkage Program, leading the data linkage project of population health surveys with administrative data from the US Department of Housing and Urban Development. Dr. Lloyd earned her PhD in epidemiology at the George Washington University (2014) and Masters in Biostatistics from Harvard School of Public Health (2004).

Yun Lu is the Deputy Division Director at Division of Analytics and Benefit-Risk Assessment (DABRA), FDA/CBER/Office of Biostatistics and Pharmacovigilance (OBPV). Dr. Lu joined the FDA in 2010 as a Mathematical Statistician, and she has extensive experiences with real-world evidence reviews and post-marketing vaccine safety and effectiveness studies using claims data.

Danica Marinac-Dabic serves as the Associate Director at the Office of Clinical Evidence and Analysis, at the Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), leading the development and application of novel methods for real-world evidence and active surveillance and advancing the interoperability of diverse data sources to study health technologies. Prior to this position, she was the Director of the CDRH Division of Epidemiology. Prior to coming to FDA, Dr. Marinac-Dabic garnered experience in obstetrics, gynecology, and epidemiology in the academic and hospital settings as well as teaching experience in academic environment. Under her leadership, FDA launched Medical Device Epidemiology Network (MDEpiNet) to advance national/international infrastructure and test innovative methods to study devices throughout their life cycle. She led a large international group of experts at the International Medical Device Regulators Forum (IMDRF) to develop series of essential principles for international convergence of registry-generated data. She has been spearheading the interoperable strategically Coordinated Registry Networks via ecosystem partnership in multiple clinical areas by linking registries to medical claims, EHRs and patient generated health data. Her collaborative work includes over 125 registries across 45 countries, development of international registry consortia while advancing interoperability. Dr. Marinac-Dabic was inducted as a Fellow of the International Society of Pharmaco-epidemiology and Therapeutic Risk Management (ISPE). She published over 100 scientific papers, serves on the steering committees of several registries and consortia, Editorial Board of BMJ-SIT Journal, and holds an Adjunct Professor position at several academic institutions.

Frederic S. Resnic is the Chairman of the Division of Cardiovascular Medicine at Lahey Hospital and Medical Center, the Medical Director of the Beth Israel Lahey Health Cardiovascular Service Line (North Region) and a Professor of Medicine at the University of Massachusetts, School of Medicine. Dr. Resnic received his undergraduate degree from Duke University in Electrical Engineering, his medical degree from Mount Sinai School of Medicine in New York and a Master's degree in Medical Informatics from the Massachusetts Institute of Technology. He completed his medical training in Internal Medicine, Cardiovascular Medicine and Interventional Cardiology at Brigham and Women's Hospital in Boston, where he served as a faculty member at and ultimately as the Director of the Cardiac Catheterization Laboratory until moving to Lahey Clinic in 2012. Dr. Resnic remains an active interventional cardiologist and is an expert in treating patients with complex coronary artery disease. His research has focused on developing the methods to monitor the safety of medical devices, as well as in assessing the overall quality of procedural related medical care. Dr. Resnic has led NIH and FDA funded research programs exploring the automated surveillance of medical device and medication safety. He has published over 100 original articles and book chapters related to the quality and safety of medical procedures and devices in leading academic. In addition, Dr. Resnic has served in multiple leadership positions within the American College of Cardiology and is the incoming Chair for the ACC National Cardiovascular Data Repository Oversight Committee.

Mary Beth Ritchey has spent her career dedicated to better understanding medical product safety and effectiveness in clinical practice. In her current role as the Chief Scientific Officer for CERobs Consulting, she provides scientific and operational leadership for real-world evidence (RWE) strategy and evidence generation to inform health care decisions by regulators, payers, clinicians, and patients. Dr. Ritchey's career has encompassed roles within government and industry, and she understands the nuanced perspectives of each. Before re-joining CERobs in 2023, she was the Chief Epidemiologist for the US FDA Center for Devices and Radiological Health (CDRH), providing guidance and oversight related to clinical evidence generation and real-world evidence policies and programs. She holds a part-time Associate Research Professor appointment in the Center for Pharmacoepidemiology and Treatment Sciences at Rutgers University and is the current President of the International Society for Pharmacoepidemiology (ISPE). She has more than forty peer reviewed publications and co-edited a textbook on pragmatic clinical trials (2021). Dr. Ritchey holds bachelor's degrees in chemistry

(Duke University) and nursing (University of North Carolina [UNC] Chapel Hill) as well as Masters and Doctoral degrees in epidemiology from UNC Gillings School of Global Public Health.

Sebastian Schneeweiss is a Professor of Medicine and Epidemiology at Harvard Medical School and Chief of the Division of Pharmacoepidemiology, Department of Medicine, Brigham and Women's Hospital. His research focuses on assessing the effectiveness and safety of biopharmaceuticals in clinical practice. He has developed analytic methods to improve the accuracy of estimating causal treatment effects of new drugs using complex digital healthcare databases. His work is published in >500 articles and is used for regulatory and coverage decision making around the globe. He is funded by NIH, PCORI, IMI, and FDA where he is also a voting consultant. He is Principal Investigator of the FDA Sentinel Innovation Center and co-leads the RCT-DUPLICATE initiative to understand when and how real-world evidence studies can reach causal conclusions.

Merianne Rose T. Spencer recently joined the Office of Biostatistics and Pharmacovigilance at the FDA's Center for Biologics Evaluation and Research as a health statistician this past year. For the past decade, Dr. Spencer previously worked on a range of health topics spanning healthcare services, mortality, injuries, and other patient-centered outcomes at the Division of Analysis and Epidemiology's National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention. She also previously supported methods development examining unstructured data, namely, the literal text on death certificate records for near real-time mortality surveillance. Prior to these roles, Dr. Spencer had worked in the private sector as a health services researcher focusing on healthcare utilization, cost of hospital services, and comparative effectiveness research. She obtained her Ph.D. in Health Services Research at the University of Maryland, College Park, and her M.P.H. in Epidemiology from the Milken Institute School of Public Health at George Washington University.

Darren Toh is an Endowed Professor in the Department of Population Medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute. He is a pharmacoepidemiologist with an interest in the comparative safety and effectiveness research of medical products. His research focuses on 1) assessing the risks and benefits of medical products using electronic data collected as part of routine healthcare delivery, and 2) developing and applying privacy-protecting analytic methods to conduct multi-center studies in distributed data networks. Dr. Toh is Principal Investigator of the Operations Center of the FDA-funded Sentinel System, a congressionally mandated national medical product safety surveillance program. He is also Principal Investigator of projects funded by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Patient-Centered Outcomes Research Institute, and the Food and Drug Administration. Dr. Toh received his pharmacy training at the National Taiwan University and his doctoral degree in Epidemiology from the Harvard School of Public Health.

Amarilys Vega currently serves as the Director of the Regulatory Science Staff (RSS) in the Office of Surveillance and Epidemiology, CDER. She oversees a team of scientists responsible for the management of programs that provide the scientific underpinnings to OSE's regulatory decisions (e.g., FAERS, Drug Utilization Data and Sentinel). RSS is also responsible for the evaluation, development and management of new data sources, tools, and methods to assess product safety and for the management of OSE acquisitions program and extramural budget. Prior to joining RSS, she served as the Deputy Division Director of the Division of Epidemiology and as a medical reviewer in the divisions of Risk Management and Epidemiology. She received a Doctor of Medicine degree from the University of Puerto Rico, completed a Pediatric Internship and Residency at the University Pediatric Hospital, San Juan, Puerto Rico and earned a Master of Public Health (concentration in epidemiology and biostatistics) from Johns Hopkins Bloomberg School of Public Health.

Patrice Verpillat is the Head of the Real-World Evidence (RWE) Workstream at the European Medicines Agency (EMA). He is a medical doctor, specialist in epidemiology. Before joining the EMA, he has worked during 20 years in the pharmaceutical industry where he had positions in several international companies, always dealing with real world data (RWD) and non-interventional studies (NIS) in order to bring RWE into research, access and life-cycle product management. Dr. Verpillat has published over 70 articles in Medline referenced journals. He has been involved in many organisations such as ENCePP, ICH M14 working group, European pharma association (efpia) and ISPE.

Carla Zelaya is an epidemiologist who joined the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Office of Biostatistics and Pharmacovigilance (OBPV) in August 2023. Dr. Zelaya is in the CBER Surveillance Program (CSP). This program coordinates the Biologics Effectiveness and Safety (BEST) Initiative which is used to conduct active post marketing safety and effectiveness surveillance studies of CBER-regulated products, including vaccines. Prior to this role, Dr. Zelaya was a health statistician with the Data Linkage Program, at the Centers for Disease Control, National Center for Health Statistics. Dr. Zelaya has a PhD in Infectious Disease Epidemiology from Johns Hopkins Bloomberg School of Public health (2008) and a MSc in Control of Infectious Disease from the London School of Hygiene and Tropical Medicine (2002) and brings to the team 20 years research experience in epidemiological study design, exposure and outcome measurement, and health access and utilization research.

Moderator Biographies

Victoria Gemme is an Assistant Research Director for the Biomedical Innovation team. She works with the medical products development and regulations team, specifically leading the Institute's FDA PDUFA cooperative agreement work. Over her time at Duke-Margolis, Victoria has worked on projects spanning a range of topics including rare disease drug development, prescription drug promotion regulation, development and regulation of psychedelics for therapeutic use, hepatitis C elimination, and value-based payment approaches for medical products among other topics. Prior to joining

Duke-Margolis, Victoria was a senior specialist at the Cystic Fibrosis Foundation, where she oversaw a wide-ranging policy portfolio covering basic science research, drug development, antimicrobial resistance, and organ transplant 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.

Gerrit Hamre is a Research Director in Biomedical Regulatory Policy at the Duke-Margolis Institute for Health Policy. Gerrit has worked for nearly 20 years in the pharmaceutical industry, focused 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 health care solutions. This has primarily occurred in the drug development and approval environment, incorporating input from government agencies, academic centers, manufacturers, advocacy groups, health care providers and payers, technology companies, standard setting organizations, and others. Particularly rewarding career years occurred working in the Food and Drug Administration's Office of Legislation and as a Peace Corps Volunteer in South Africa, prior to he and his wife moving to Durham, North Carolina in 2015.

Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence (RWE) at the Duke-Margolis Institute for Health Policy in Washington, DC, strategically leading and managing the Institute's RWE Collaborative. As an engagement expert, researcher, bioethicist, and policy practitioner, her work centers on conducting research to address implementation and ethical, legal, and social implications issues at the intersection of health policy and innovation. She also engages Duke University faculty, scholars, students, and external health experts to advance the Institute's biomedical innovation work and training and education opportunities.

Trevan Locke is an Assistant Research Director at Duke-Margolis working on issues related to biomedical innovation. He oversees Duke-Margolis' involvement as a founding member of the Advancing Clinical Trials at the Point of Care Coalition and workstreams on evidence generation for Duke-Margolis' Real-World Evidence Collaborative. Previously, he worked as a Regulatory Science and Policy Analyst at the American Association for Cancer Research on regulatory issues impacting cancer care and the development of cancer therapies, including considerations for equitable clinical trial enrollment. Dr. Locke completed a Bachelor of Engineering in Chemical and Biomolecular Engineering at Vanderbilt University and a PhD in Chemical and Biochemical Engineering at Rutgers University, where his research focused on the development of nanoparticles for the delivery of chemotherapy to treat cancer.

Mark McClellan is Director and Robert J. Margolis, M.D., Professor of Business, Medicine and Policy at the Duke-Margolis Institute for Health Policy at Duke University. He is a physician-economist who focuses on quality and value in health care, including payment reform, real-world evidence and more effective drug and device innovation. At the center of the nation's efforts to combat the COVID-19 pandemic, the author of COVID-19 response roadmap, and co-author of a comprehensive set health policy strategies for COVID vaccines, testing, and treatments, Dr. McClellan and his Duke-Margolis colleagues are now focused on health policy strategies and solutions to advance the resilience and interconnectedness of 21st Century public health and health care. Mark is a former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration, where he developed and implemented major reforms in health policy. Dr. McClellan is an independent board member on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and Prognom IQ; co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network; and serves as an advisor for Arsenal Capital Group, Blackstone Life Sciences.

Christina Silcox is the Research Director for Digital Health at the Duke-Margolis Center for Health Policy, working on policy solutions to advance innovation in health and health care and improve regulation, reimbursement, and long-term evaluation of medical products, with a focus on digital health. Dr. Silcox's portfolio includes multiple areas in digital health policy and real-world evidence, with an emphasis on medical devices. Currently, she is concentrating on challenges to regulating and adopting artificial intelligence-enabled software, using mHealth to collect real-world data, and characterizing real-world data quality and relevancy. Her projects have included the use of patient-generated health data in medical device evaluations, the exploration of value-based payments for medical devices, and the convening of the National Evaluation System for health Technology (NEST) Planning Board. Before she joined Duke-Margolis, Dr. Silcox was a senior fellow at the National Center for Health Research, focused on federal regulation of and policies for medical products. She earned an M.S. from the Massachusetts Institute of Technology (MIT) in Electrical Engineering and a Ph.D. in Medical Engineering and Medical Physics from the Harvard-MIT Division of Health Sciences and Technology (HST).