Duke | Robert J. Margolis, MD Center for Health Policy

Fifteenth Annual Sentinel Initiative Public Workshop

November 8, 2023 | 9:00 a.m. – 5:00 p.m. ET
Hybrid Meeting
National Press Club, Washington D.C. & Zoom Webinar

Biographies

Margaret Anderson is a Managing Director with Deloitte Consulting where she brings biomedical program, policy, and patient engagement experience in Federal Health and nonprofit area. She recently led high-impact COVID-19 projects across federal health space focused on public-private partnerships, community response, risk mitigation, and overall impacts of the pandemic on nonprofit. She serves as the Chief Marketing Officer of the Federal Health Sector at Deloitte. Prior to Deloitte, she served as Executive Director of FasterCures and oversaw programs advancing the science of patient input, examining the metrics for consortia, and policy related to federal research and regulatory paradigms. She also worked on HIV/AIDS strategy and other public health issues at the American Public Health Association and in a consulting capacity for CDC's HIV/AIDS programs in the early part of the epidemic response. She currently serves on the Boards of Act for NIH, Allen Institute, FasterCures, and Friends of Cancer Research. She was recently appointed to the National Cancer Advisory Board by President Biden. Margaret was a founding board member and past president of the Alliance for a Stronger FDA and the NIH National Center for Advancing Translational Sciences Advisory Council and the Cures Acceleration Network Review Board. She previously served on the boards of the National Health Council, United for Medical Research, the FDA's Science Board, Science Looking Forward Committee, and the National Academy of Medicine's Forum on Drug Discovery, Development and Translation. She attended University of Maryland and majored in Political Science and holds a Master's in Science Policy from the George Washington University.

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.

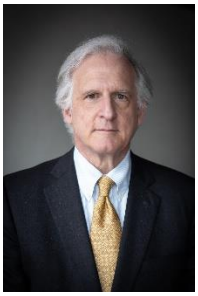
Robert Ball is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research, FDA. Dr. Ball shares in the responsibilities for leading OSE staff evaluating drug and biologic product safety and effectiveness using Real World Evidence, including managing the Sentinel System. 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.

Patricia ("Trish") Bright is the Associate Director and Lead for FDA's Sentinel System. She 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.

Jeffrey Brown Chief Scientific Officer at TriNetX and Lecturer (part-time) at Harvard Medical School (HMS), is an internationally recognized expert in the use of real-world data to support the evidentiary needs of regulatory agencies and medical product sponsors and an expert in the assessment of data quality of real-world data resources. He focuses on the value of collaborative research with an emphasis on federated networks. He has expertise in assessing the fitness-for-use of real-world data and matching questions to methods to data to generate robust evidence. Dr. Brown has over 15 years of experience facilitating large-scale, multi-institutional observational research through use of distributed health data networks to support a learning health system and the use of electronic health data to support decision-making. In his previous role as Associate Professor at Harvard Medical School he served as the Lead Data Scientist for the FDA Sentinel Operations Center and as a member of the Sentinel Operations Center Executive Committee, Principal Investigator of the analytic coordinating center for Innovation in Medical Evidence Development and Surveillance (IMEDS) program and the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC). While at Harvard he also served as PI of several industry-sponsored multi-site pharmacoepidemiologic studies to support FDA and EMA regulatory requirements.

Yoganand Chillarige is a Senior Research Manager at Acumen LLC, where he leads Acumen's collaboration with FDA and CDC. As the Lead of the Acumen BEST Coordinating Center, Mr. Chillarige oversees the development, maintenance, and effective use of a distributed data network with multiple data partners to support FDA's product safety surveillance efforts. Mr. Chillarige is an expert in the integrated use of data from a broad range of sources including administrative claims, provider databases, surveys, and medical records, and has over 10 years of experience conducting

epidemiologic studies that monitor and evaluate the uptake, safety, and effectiveness of medical products and procedures.



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.

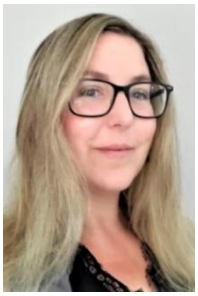
Richard Forshee is the Deputy Director of the Office of Biostatistics and Pharmacovigilance in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. He works on a wide range of issues related to the risks and benefits of biologic medical products. Dr. Forshee has 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.

Phil Goodney is a vascular surgeon, health services researcher, Vice Chair of Research in the Department of Surgery, Director of the Center for the Evaluation of Surgical Care at Dartmouth (CESC), and Co-Director of the VA Outcomes Group at Veterans Affairs Medical Center in White River Junction, Vermont. His research interests include outcomes assessment using both quantitative and qualitative methods, clinical trials, patient preferences, and shared decision making. He received a Career Development Award from the National Heart, Lung, and Blood Institute in 2010, the Lifeline Research Award from the Society for Vascular Surgery (SVS), and research funding from VA HSR&D, PCORI, FDA and others. He was elected to the American Surgical Association in 2016, and serves on multiple editorial boards of surgical, cardiovascular, and health services journals. Within the Vascular Quality Initiative, the SVS's quality improvement program, Goodney is Chair of the Research Advisory Committee. He leads the development of the Vascular Implant Surveillance and Interventional Outcomes Network (VISION), a claims/registry-based surveillance distributed research network which links Medicare data to the SVS's national registry to allow timely tracking of short- and long-term outcomes across 407 hospitals and practices across the United States. Goodney also leads a 20-

site, cluster-randomized trial of a decision aid for military veterans facing treatment for an abdominal aortic aneurysm, PROVE-AAA. Goodney earned a BS from the University of Connecticut, an MD from the University Of Connecticut School Of Medicine, and an MS from The Dartmouth Institute for Health Policy and Clinical Practice.

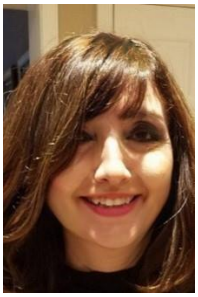
Joann Gruber is a PhD-trained epidemiologist with expertise in infectious diseases and vaccines. Dr. Gruber works at the Food and Drug Administration in the Center for Biologics Evaluation and Research (CBER) in the Office of Biostatistics and Pharmacovigilance in the CBER Surveillance Program. This 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.



Melissa Kampman is a Manager and Senior Epidemiologist in Health Canada's Marketed Health Products Directorate where her team focuses on data analytics and real world evidence. Her training is in pharmacoepidemiology and pharmacovigilance. Her main areas of interest are population health, study design methodology for pharmacoepidemiologic research, drug safety and effectiveness, real world evidence, and regulatory policy and decision-making.

Patricia (Patsy) 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).



Danica Marinac-Dabic serves as the Associate Director of 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 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 12 clinical areas by linking registries to medical claims, EHRs and patient generated health data.Dr. Marinac-Dabic was inducted as a Fellow of the International Society of Pharmaco-epidemiology and Therapeutic Risk Management (ISPE). She serves on the Advisory Board of the Council of Medical Specialty Societies, Executive Operations Committee of MDEpiNet, Active Surveillance Task Force of National Evaluation System for Health Technology, National Breast Implants Registry Steering Committee, Oxford-based IDEAL Collaborative, Editorial Board of BMJ-SIT Journal and holds an Adjunct Professor position at several academic institutions.

Anna McCollister is a health technology entrepreneur, strategic consultant, and reform advocate. Her work focuses on facilitating innovative engagement of health care constituents in critical aspects of health research; care and treatment; data governance; evidence development; and policy reform. In 2022, Anna was appointed by the GAO to serve on the federal Health Information Technology Advisory Committee (HITAC), which advises the Office of the National Coordinator for Health IT on federal health IT policy. Additionally, Anna serves on two FDA advisory committees and non-profit advisory boards, helping to facilitate patient-centered design of products, policy, and research. Previously, Anna served as Chief Advocate for Participatory Research at the Scripps Research Translational Institute (SRTI), where she had the opportunity to be a Co-Primary Investigator for the "All of Us" Research Program, a centerpiece of the National Institutes of Health's Precision Medicine Initiative. Since 2019, Anna has advised C-Suite leaders and developed strategic approaches for engaging stakeholders, including patients and advocacy groups, in critical aspects of corporate and public policy. Anna's passion for innovation in healthcare is rooted in her personal experiences living with type 1 diabetes. She is a co-founder of the global patient-led hacker movement, #WeAreNotWaiting, which helped accelerate diabetes device data access, connectivity, and interoperability. Anna has founded two health technology startups: VitalCrowd, a Web-based platform for crowdsourcing the design of health research, and Galileo Analytics, a visual data exploration and analytics company aimed at understanding and democratizing access to complex health data.

David Moeny is the Acting Deputy Director for the Office of Pharmacovigilance and Epidemiology at the Food and Drug Administration. He is a pharmacist and epidemiologist with experience in clinical pharmacy practice, public health, drug utilization, regulatory pharmacoepidemiology, and international collaborations. He brings significant experience in leading large internal and external projects, coalition building, and bringing diverse teams together to protect and promote the public health. He is the Rapporteur for the International Council of Harmonization's M14 expert working group to establish of a new ICH guideline on "General principles on plan, design, and analysis of pharmacoepidemiological studies that utilize real-world data for safety assessment of medicines."

Daniel Morales is a senior clinical epidemiologist within the Data Analytics Taskforce at the European Medicines Agency (EMA). Prior to this he was a European Commission appointed Independent Scientific Expert to the EMA Pharmacovigilance Risk Assessment Committee (PRAC) that monitors approved medicines in Europe. Dr. Morales background is in clinical general practice (family medicine) and academia, having conducted a wide range of academic real world evidence studies at the University of Dundee. He has previously been a member of the steering group of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance and Chair of the EMA PRAC impact group responsible for strategy to measure the impact of pharmacovigilance interventions. He is currently EMA lead of the European Specialised Expert Community for Real World Evidence.

Jennifer Nelson is Director of the Biostatistics Division at Kaiser Permanente Washington Health Research Institute and an Affiliate Professor of Biostatistics at the University of Washington. Her research focuses on methods to quantify post-market safety and effectiveness for vaccines and drugs, with an emphasis on addressing statistical challenges of using electronic health record data from large health care systems. Since 2009, she has provided strategic direction for the U.S. Food and Drug Administration's (FDA's) Sentinel Network that facilitates rapid safety surveillance for FDA-regulated medical products. Over the past two decades, she has also led statistical advancements for the Centers for Disease Control and Prevention (CDC) sponsored Vaccine Safety Datalink (VSD) project, a national collaboration that has monitored vaccine safety in the U.S. since 1990. From 2021-2023 she was an invited member of the CDC's Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Safety Technical Work Group, comprised of medical and public health national experts who informed recommendations on the use of COVID-19 vaccines in the U.S. She has also served an Associate Editor for the journal Vaccine since 2018. Her 2013 paper that adapted group sequential monitoring methods to a real-world observational vaccine safety data setting was one of the American Journal of Epidemiology's Articles of the Year. She received her PhD in Biostatistics at the University of Washington in 1999, earned the VSD's Margarette Kolczak Award for outstanding biostatistical contributions in the field of vaccine safety in 2009, and is an elected Fellow of the American Statistical Association.

Lauren Peetluk is an Epidemiologist at Optum. In her current role, Dr. Peetluk applies rigorous methods to design and execute pharmacoepidemiologic studies across a range of therapeutic areas, including vaccine safety and effectiveness. In addition to her role at Optum, Dr. Peetluk is adjunct faculty at Vanderbilt University. Dr. Peetluk has a PhD in Epidemiology from Vanderbilt University and an MPH in Epidemiology and Biostatistics from Boston University School of Public Health. Prior to joining Optum Epidemiology, Dr. Peetluk worked as a research instructor in the Divisions of Infectious Diseases and Epidemiology at Vanderbilt University Medical Center. Her previous research focused on understanding the drivers of unfavorable tuberculosis treatment outcomes, specifically developing prognostic models for tuberculosis treatment outcomes and applying causal inference methods to examine the impact of clinical characteristics on end of treatment outcomes.

Silvia Perez-Vilar is a senior epidemiologist at the Division of Epidemiology-I, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research. Before joining CDER in 2019, she held positions as epidemiologic reviewer in the Center for Biologics Evaluation and Research (CBER), scientific researcher at the Erasmus University Medical Center (The Netherlands), supervisory pharmacist for international clinical trials in FISABIO (Spain), and international professional consultant at the World Health Organization (WHO) (Switzerland) and at the Pan American Health Organization (PAHO/WHO) (United States). She has over 40 peer-reviewed publications and over 80 presentations at national and international scientific conferences focusing on safety and effectiveness of FDA-regulated products.

Heather Rubino is the Head of Safety Surveillance Research (SSR) at Pfizer, Inc.. Heather is responsible for providing strategic and innovative approaches utilizing real world data in the post-approval setting that will support and inform safety signal identification and characterization and assess the effectiveness of additional risk minimization measures for marketed products. Additionally, in her capacity she oversees Pfizer's business processes related non-interventional studies and post approval safety studies and represents Pfizer in various external working groups, including the BeCome, COVID R&D Alliance, PhRMA, and ISPE, among others. Prior to Pfizer, Heather managed the Surveillance and Surveillance Systems program for the Bureau of Epidemiology at the Florida Department of Health. There, she lead the development of the epidemiology informatics capacity to leverage existing data sources, provided the informatics expertise to inform how to best capture data, and the epidemiologic methods experience to establish analytic standards and best practices to transform data into meaningful public health action. Heather also deployed to Guinea with the Centers for Disease Control and Health Protection to work for the CDC Guinea country office, WHO, Guinea ministry of health, and other public health partners on Ebola, polio, measles, mumps, rubella, and to establish surveillance infrastructure for 14 priority diseases. Heather has a deep passion for pharmacoepidemiology and innovation!

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.

John Seeger is a pharmacoepidemiologist and Chief Scientific Officer for Epidemiology at Optum who has conducted dozens of studies addressing regulatory drug safety issues across a wide range of drugs and disease conditions. Most of this work has involved the use of health insurance claims databases, and Dr. Seeger's methodologic expertise focuses on research issues encountered in such settings. He has worked extensively with propensity scores that seek to mitigate confounding by collapsing covariates, and he teaches several courses on propensity scores in pharmacoepidemiology. Throughout this work, Dr. Seeger has remained keenly aware of the limitations of research using administrative data and has supplemented the platform of insurance claims with additional data where appropriate, including laboratory test results, surveys, medical record reviews, and more recently has expanded into work involving electronic health record data. Dr. Seeger is an Adjunct Assistant Professor of Epidemiology at the Harvard T.H. Chan School of Public Health. He has been active within the International Society of Pharmacoepidemiology (ISPE) and is a Past President and Fellow of the Society.

Darren Toh is DPM 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.

Susan C. Winckler is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post in May of 2020, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, industry leaders, and consumers with a neutral forum to address domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, she served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations, and allied groups. Ms. Winckler earned a BS from the University of Iowa College of Pharmacy and her JD magna cum laude from Georgetown University Law Center. She is an APhA Fellow, an elected member and Chair of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025), a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council.

Janet Woodcock is the FDA's Principal Deputy Commissioner. In this role she works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and helps oversee the agency's day-to-day functions. She served as the Acting Commissioner of Food and Drugs from Jan. 20, 2021, until Feb. 17, 2022. Dr. Woodcock began her FDA career in 1986 at the Center for Biologics Evaluation and Research (CBER) where she served as the Director of the Division of Biological Investigational New Drugs and as Acting Deputy Director. She later became Director of CBER's Office of Therapeutics Research and Review, which oversaw the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure. In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), leading the Center's work that is the world's gold standard for drug approval and safety. In 2004, Dr. Woodcock became the FDA's Deputy Commissioner and Chief Medical Officer. Later she took on other executive leadership positions in the Commissioner's Office, including Deputy Commissioner for Operations and Chief Operating Officer. In 2007, Dr. Woodcock returned as Director of CDER until she was asked to be the therapeutics lead for "Operation Warp Speed" in early 2020. This entailed supporting the development, evaluation, and availability of treatments such as monoclonal antibodies and antiviral drugs for patients with COVID-19. Dr. Woodcock holds a Bachelor of Science in chemistry from Bucknell University (Lewisburg, PA), and a Doctor of Medicine from the Feinberg School of Medicine at Northwestern University Medical School (Chicago). She is board certified in internal medicine.

Richard Wyss is an Assistant Professor of Medicine at Harvard Medical School and a Lead Investigator in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital. His research focuses on the development of analytic methods for causal inference and their application to large electronic healthcare databases for evaluating the comparative effectiveness and safety of pharmaceutical drugs. Dr. Wyss has been involved with the US Food and Drug Administration's Sentinel Initiative since 2015. His work with Sentinel has focused on the application of machine learning methods for causal inference in post-market safety surveillance. Dr. Wyss received his doctorate in epidemiology from the University of North Carolina at Chapel Hill and his Bachelor's and Master's degrees in statistics from Brigham Young University.

Moderators

Gerrit Hamre has worked for nearly twenty 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 healthcare 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 Center for Health Policy in Washington, DC, strategically leading and managing the Center's RWE Collaborative. As an engagement expert, researcher, bioethicist, and policy practitioner, her work centers on addressing implementation and ethical, legal, and social implications issues at the intersection of health policy and innovation. She also partners with Duke University faculty, scholars, students, and external health experts to advance the Center's biomedical innovation work. She is presently adjunct faculty at rural Ohio University, teaching graduate courses in the Department of Interdisciplinary Health Science's Health Policy Certificate program, and has taught graduate courses within the Masters of Health Care Innovation program at the University of Pennsylvania's Perelman School of Medicine. As of January 2023, she serves on the Board of Directors for Public Responsibility in Medicine and Research (PRIM&R) and is part of executive leadership for the National Alliance Against Disparities in Patient Health (NADPH). Prior to joining Duke-Margolis, Dr. Hendricks-Sturrup was Health Policy Counsel and Lead at the Future of Privacy Forum (FPF), leading the organization's health and genetic data initiatives and workgroup. Prior to FPF, she served in several administrative and scientific roles at various industry, health care, and academic institutions. To date, she has published several commentaries and original research papers in high-quality, peer-reviewed journals. Dr. Hendricks-Sturrup is also an accomplished health and science journalist, having completed a comparative effectiveness research fellowship with the Association of Health Care Journalists in 2017. Dr. Hendricks-Sturrup received her Bachelor of Science in Biology from Chicago State University, her

Master's in Pharmacology and Toxicology from Michigan State University, her Master's in Legal Studies from the University of Illinois, and her Doctor of Health Science from Nova Southeastern University. She completed a predoctoral internship with the National Health Service in London, UK, and postdoctoral research training within the Department of Population Medicine at Harvard Pilgrim Health Care Institute and Harvard Medical School.

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 the Robert J. Margolis Professor of Business, Medicine, and Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University. Dr. McClellan is a doctor and an economist who has addressed a wide range of strategies and policy reforms to improve health care, including payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and strategies for more effective biomedical innovation. At the center of the nation's efforts to combat the pandemic, Dr. McClellan is the co-author of a roadmap that details the steps needed for a comprehensive COVID-19 response and safe reopening of our country. His current work on responding to the COVID-19 public health emergency spans virus containment and testing strategies; reforming health care toward more resilient models of delivering better, more equitable care; accelerating the development of therapeutics and vaccines, and building a more robust global response to the pandemic. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. He also has a highly distinguished record in public service and academic research.

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 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 a 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).