Your Treatment and Your Community: Advancing Evidence and Policy for Medical Products that Impact Others

Virtual Public Workshop
March 20, 2025 | 1:00 - 5:00 pm ET

Speaker Biographies

Blythe Adamson is an infectious disease epidemiologist and economist. A former member of the White House COVID Task Force on Healthcare Resilience and lead data scientist in the West Wing, she currently serves on the COVID Sports and Society Working Group, advises public and private institutions on safe reopening plans for large-scale in-person gatherings including all major sports leagues, theme parks, retailers, and universities, and is an advisory board member to both NBA-Yale SalivaDirect and Testing for America. Dr. Adamson founded Infectious Economics in 2017 to provide thought leadership to policy makers and industry leaders on cost-effective strategies to prevent the transmission of viruses. Dr. Adamson holds degrees in microbiology, epidemiology, and pharmaceutical economics with a focus on infectious disease prevention. Dr. Adamson has held roles at the Bill and Melinda Gates Foundation Institute for Disease Modeling, the HIV Vaccine Trials Network, and Flatiron Health.

Haider Andazola advises on coding, coverage and reimbursement strategies at under the Medicare and Medicaid programs for Manatt Health clients navigating health care's most complex regulatory requirements. Haider provides guidance on engaging with Centers for Medicare & Medicaid Services (CMS) to help companies ensure compliance with Federal requirements while simultaneously achieving their business objectives. Haider's strategic regulatory and public policy practice spans across the healthcare industry to include life science companies, hospitals, physician practices and health plans. Additionally, Haider maintains an active pro bono practice representing immigrants and their families in accessing legal status in the U.S.

Mara G. Aspinall is a healthcare leader and pioneer with 35 years of experience in diagnostics, personalized medicine and genomics. She is a Partner at Illumina Ventures, the premier venture firm focused on genomics. Aspinall is also Editor of the popular Sensitive & Specific: The Testing Newsletter and annual Diagnostics Year in Review. Previously, Aspinall served as CEO of Ventana Medical Systems and President of Genzyme Genetics and Genzyme Pharmaceuticals. With a passion for education, she co-founded the Biomedical Diagnostics Master Degree program at Arizona State University, the only program dedicated to diagnostics as an independent discipline. During COVID, Aspinall was an Advisor to The Rockefeller Foundation. Mara was named one of "100 Most Inspiring People in Life Sciences" by PharmaVOICE and holds an MBA from Harvard Business School.

Natalie Dean is an Associate Professor in the Department of Biostatistics and Bioinformatics at Emory's Rollins School of Public Health. Her primary research area is in methods for infectious disease epidemiology and vaccine study design, with a focus on emerging pathogens. She co-directs the Emory Alliance for Vaccine Epidemiology and the Summer Institute in Statistics and Modeling of Infectious Diseases. During the COVID-19 pandemic, Dr. Dean was active in science communication, with op-eds in the New York Times, Washington Post, and Stat News. She was honored as a member of the Committee of Presidents of Statistical Societies' Leadership Academy and as recipient of the 2024 Communications Award from the Joint Policy Board of Mathematics.

Lee A. Fleisher is Emeritus Professor of Anesthesiology and Critical Care at the University of Pennsylvania Perelman School of Medicine and continues to practice clinically. He is also the Founding Principal and CEO at Rubrum Advising, LLC. He serves as a Visiting Fellow of the Duke-Margolis Institute for Health Policy, Senior Advisor of the Bipartisan Policy Center and FasterCures of the Milken Institute. He is a member of the Steering Committee of CHAI (Coalition of Health AI), consultant to the FDA Digital Health Advisory Committee and a member of the HITAC of the ONC. From July 2020-July 2023, he was the Chief Medical Officer and Director of the Center for Clinical Standards and Quality for the Centers for Medicare and Medicaid Services. In this capacity, he was responsible for executing all national clinical, quality, and safety standards for healthcare facilities and providers, as well as establishing coverage determinations for items and services that improve health outcomes for Medicare beneficiaries. From 2004 through July 2020, he was the Robert D. Dripps Professor and Chair of Anesthesiology and Critical Care and Professor of Medicine at the University of Pennsylvania. In 2007, he was elected to membership of the National Academy of Medicine of the National Academy of Sciences and served on Committees including the Board of Health Services of the NAM.

Scott Gottlieb is a senior fellow at the American Enterprise Institute (AEI). He returned to AEI in 2019 after serving as the 23rd commissioner of the Food and Drug Administration (FDA). At AEI, he continues his work on improving public health through entrepreneurship and medical innovation and on expanding regulatory approaches to maintain patient and physician autonomy. Dr. Gottlieb is also a special partner with the venture capital firm New Enterprise Associates and serves on the boards of Pfizer, Illumina, Aetion, and Tempus.

Joe Franklin is special counsel at Covington & Burling whose practice includes emerging medical technologies, research uses of real world and clinical trial data, and the deployment of artificial intelligence in healthcare and biopharma. He brings experience in both government and the health tech sector to advise clients on the unique challenges and opportunities posed by evolving regulatory frameworks for novel technologies. Joe was at Verily, Alphabet's precision health company, from 2021-2024, where his roles included Chief Counsel for Regulatory and Strategic Affairs. During his years of federal service, Joe held several senior policy roles at FDA, including as policy director for FDA Principal Deputy Commissioner Amy Abernethy. At FDA, Joe played a central role in the Agency's technology and data modernization strategy and had responsibilities for a broad portfolio of regulatory and scientific programs. While in FDA's Center for Drug Evaluation and Research (CDER), Joe built and led the biosimilars policy staff in the Office of New Drugs (OND). Joe was FDA's Deputy Chief of Staff in 2015. While serving in FDA's Office of the Chief Counsel, Joe advised CDER and the Office of the Commissioner on biosimilars, emergency use authorizations, user fees, and controlled substances, among other issues. During the COVID-19 pandemic, Joe worked within the HHS General Counsel's Immediate Office to advise on the federal response.

Peter Marks 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.

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.

Susan Sobolov is currently President and Chief Operating Officer for RIGImmune Inc. joining in May 2022, bringing over 25 years of experience in drug discovery and development. She has expertise across multiple therapeutic areas, including oncology, neuroscience, rare diseases, ophthalmology, and infectious diseases. Before joining RIGImmune, Dr. Sobolov was the Chief Operating Officer at Caelum Biosciences, where she led the development of anselamimab for light chain amyloidosis until Caelum was acquired by Alexion, AstraZeneca Rare Disease. Prior to that, she served as Vice President of Strategy, Portfolio, and Program Management at Fortress Biotech, overseeing the advancement of a number of its subsidiary companies, including Mustang Bio (CAR-T and cell therapy), Avetis (complement gene therapy), Tamid (gene therapy for MPS1), and Checkpoint Therapeutics (PDL1 UNLOXCYT™ and Olafertinib). Earlier in her career, Dr. Sobolov held leadership roles at Pfizer, Vertex, Novartis, and Alexion, where she contributed to more than 35 clinical programs, including four successful global regulatory submissions. Throughout her industry career, she has co-authored over 40 scientific publications and patents. Dr. Sobolov is an Entrepreneur-in-Residence at the University of Connecticut's Technology Incubator Program, advising multiple companies on growth and strategy. She is also the cofounder of the Women in Bio Connecticut chapter. She earned her M.S., M.Phil, M.S., and Ph.D. in organic chemistry from Yale University, and completed an American Cancer Society postdoctoral fellowship in enzymology and molecular biology at Harvard Medical School.