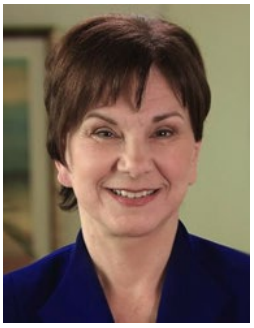
Annual Public Meeting of the Board of Directors
May 12, 2021

Speaker Bios

Janet Woodcock, MD
Commissioner of Food and Drugs (Acting), U.S. Food and Drug Administration



Janet Woodcock, MD, began her long and distinguished FDA career in 1986 with the agency's Center for Biologics Evaluation and Research (CBER) as Director of the Division of Biological Investigational New Drugs. She also served as CBER's Acting Deputy Director, and later as Director of the Office of Therapeutics Research and Review.

In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), overseeing the center's work that is the world's gold standard for drug approval and safety. In that position, she has led many of the FDA's groundbreaking drug initiatives. She has also served in other leadership roles at the FDA, including as Deputy Commissioner and Chief Medical Officer.

With the onset of the COVID-19 public health emergency last year, Dr. Woodcock was asked to lend her expertise to "Operation Warp Speed" the initiative to develop therapeutics in response to the pandemic. Dr. Woodcock was named Acting Commissioner of Food and Drugs on January 20, 2021.

Ellen V. Sigal, PhD
Board Chair, Reagan-Udall Foundation for the FDA

Ellen V. Sigal, PhD, is Chairperson and Founder of Friends of Cancer Research (Friends), a think tank and advocacy organization based in Washington, DC that drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients.

Dr. Sigal serves on the Board of the Foundation for the National Institutes of Health, where she chairs its Public Private Partnerships Committee. In 2010, Dr. Sigal was appointed to a six-year term on the Board of Governors of the Patient Centered Outcomes Research Institute (PCORI) as a representative of patients and health consumers.

Dr. Sigal, a founding board member, joined the Reagan-Udall Foundation for the FDA Board of Directors in 2008.

Georges C. Benjamin, MD, FACP, FNAPA, FACEP (E), Hon FRSPH
Food & Nutrition Board Committee Chair, Reagan-Udall Foundation for the FDA

Georges C. Benjamin, MD, Executive Director of American Public Health Association (APHA) since 2002, is leading the Association's push to make America the healthiest nation in one generation. He came to APHA from his position as Secretary of the Maryland Department of Health and Mental Hygiene, following four years as its Deputy Secretary for Public Health Services. As Secretary, Dr. Benjamin oversaw the expansion and improvement of the state's Medicaid program.

At APHA, Dr. Benjamin also serves as publisher of The Nation's Health, the association's official newspaper, and the American Journal of Public Health. He is the author of more than 100 scientific articles and book chapters. In April 2016, President Obama appointed Dr. Benjamin to the National Infrastructure Advisory Council.

Dr. Benjamin, a founding board member, joined the FDA Foundation Board of Directors in 2008.

Lori Bickel, JD
Regulatory Counsel, Office of Medical Policy, CDER, FDA

Lori Bickel, JD, is a Regulatory Counsel with the Office of Medical Policy in the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA). Lori has been with FDA over 10 years, and in her time with the Agency has worked on various policy matters including: Expanded Access, Labeling, Expedited Programs, and Clinical Trial Eligibility. Before joining FDA, she worked for healthcare organizations including the American Pharmacists Association, the Healthcare Distribution Management Association, and the American Physical Therapy Association. Lori earned her law degree from DePaul University in Chicago, Illinois, and a BA in Political Science and Philosophy from Saint Mary's College in Notre Dame, Indiana.

Jacqueline Corrigan-Curay, JD, MD
Acting Center Deputy Director for Operations, Office of Medical Policy, CDER, FDA

Jacqueline Corrigan-Curay, JD, MD, is the Acting Center Deputy Director for Operations. She also serves as Director of CDER's Office of Medical Policy (OMP). As Acting Deputy Center Director for Operations, Dr. Corrigan-Curay directs the Center and Agency-level priority and initiative programs and leads GDUFA III reauthorization negotiations. As Director of OMP, Dr. Corrigan-Curay leads the development, coordination, and implementation of medical policy programs and strategic initiatives. She works collaboratively with other CDER program areas, FDA centers, and stakeholders on enhancing policies to improve drug development and regulatory review processes.

Dr. Corrigan-Curay brings to the position a unique legal, scientific policy, and clinical background with expertise in risk and scientific assessment, and clinical trial design and oversight. Before joining FDA, she served as supervisory medical officer with the Immediate Office of the Director, National Heart, Lung and Blood Institute (NHLBI) at the National Institutes of Health (NIH). She also served in director and acting director roles with the Office of Biotechnology Activities (OBA), Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She has held positions as an attending physician with the VA Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and a practicing attorney in Washington, D.C.

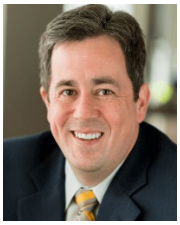
Sally J. Greenberg, JD
Board Member, Reagan-Udall Foundation for the FDA

Sally J. Greenberg, JD, joined the National Consumers League (NCL) as Executive Director on October 1, 2007. Sally has testified before Congress on consumer protection issues, including on airline passenger rights, product safety, fraud, and excessive fees on car rentals, consumer rip-offs in calling cards and in support of protections for farmworker children. Ms. Greenberg is the NCL's primary spokesperson on a variety of issues.

Ms. Greenberg came to NCL from Consumers Union, where she worked from 1997-2007 on product liability and food safety issues, along with auto and product safety. Previously, Ms. Greenberg worked at the U.S. Department of Justice Foreign Claims Settlement Commission and prior to that, she spent a decade serving as the Eastern States Civil Rights Counsel for the Anti-Defamation League, based in Boston.

Ms. Greenberg joined the FDA Foundation Board of Directors in 2012.

Adrian F. Hernandez, MD, MHS
IMEDS Board Committee Chair, Reagan-Udall Foundation for the FDA



Adrian F. Hernandez, MD, MHS, is a cardiologist who serves as the Vice Dean for Clinical Research at the Duke University School of Medicine. Dr. Hernandez has devoted his career to research to improve population health, focusing on understanding health outcomes, and closing the gap between clinical efficacy and effectiveness. An expert in trial design, use of electronic health data, health services, and regulatory science, Dr. Hernandez has led efforts to create more pragmatic clinical trials that get closer to what patients and clinicians experience every day. Presently, he is the Coordinating Center Principal Investigator for PCORI's National Patient-Centered Clinical Research Network (PCORnet), NIH's Health System Collaboratory, and other pragmatic clinical trials to generate real world evidence. He is also the Coordinating Center Principal Investigator for the Baseline Health System Consortium which aims to change how clinical research is performed to integrate people in and outside of the health system, accelerate research, and improve efficiency.

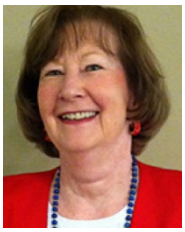
Dr. Hernandez joined the FDA Foundation Board of Directors in 2019.

RADM Denise Hinton
Chief Scientist, FDA

RADM Denise Hinton is FDA's Chief Scientist. In this capacity, she is responsible for leading and coordinating FDA's cross-cutting scientific and public health efforts. The Office of the Chief Scientist works closely with FDA's product centers, providing strategic leadership and support for FDA's regulatory science and innovation initiatives, including the Advancing Regulatory Science Initiative, FDA's Technology Transfer Program, scientific professional development, scientific integrity, and the Medical Countermeasures Initiative (MCMi).

RADM Hinton previously served as Deputy Director of the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER), where she concurrently served as Acting OMP Director from 2014 to 2016. There, she led the development, coordination, and implementation of medical policy programs and strategic initiatives, including the efficient integration of rapidly evolving science and new technologies into the drug development and regulatory review processes. RADM Hinton's work involved close collaboration with other CDER program areas, FDA product centers, and a broad variety of stakeholders.

Kay Holcombe, MS
Board Secretary, Reagan-Udall Foundation for the FDA



Kay Holcombe formerly served as Senior Vice President for Science Policy at BIO, the Biotechnology Innovation Organization. During her time at BIO, she worked with the BIO CEO and Board, BIO's health policy, reimbursement, government affairs, and alliance development staff to formulate, develop, and advance BIO principles, programs, and strategies relating to health policy matters that are of interest to and affect BIO member companies.

Prior to this, as Senior Policy Advisor and Vice President for Government Relations at Genzyme, a Sanofi Company, Ms. Holcombe worked to develop and implement corporate policies and appropriate responses to government initiatives in the regulatory and health policy arenas.

Ms. Holcombe, a founding board member, joined the Reagan-Udall Foundation for the FDA Board of Directors in 2008.

Robin McKinnon, PhD, MPA
Senior Advisor for Nutrition Policy, Center for Food Safety and Applied Nutrition, FDA

Robin McKinnon, PhD, is a Senior Advisor for Nutrition Policy at FDA's Center for Food Safety and Applied Nutrition (CFSAN). Dr. McKinnon works to advance nutrition-related activities across CFSAN, including FDA's Nutrition Innovation Strategy. Prior to joining FDA, Dr. McKinnon was a Health Policy Specialist at the National Cancer Institute (NCI), National Institutes of Health. At NCI, Dr. McKinnon led policy-relevant research initiatives on diet, obesity and physical activity. Dr. McKinnon has a Ph.D. in Public Policy and Administration from the George Washington University and a Master's in Public Administration from Harvard University.

Lorrie McNeill
Director, Office of Communication Outreach and Development, CBER, FDA

Lorrie McNeill is the director of the Office of Communication, Outreach and Development in FDA's Center for Biologics Evaluation and Research. Prior to becoming office director, she was the director of the Division of Communication and Consumer Affairs in CBER. She has been with the Center since 1992, and with FDA since 1990. Prior to coming to FDA, she worked as a public health advisor for the Centers for Disease Control and Prevention in Atlanta and Baltimore. She holds a BA degree in industrial relations from the University of North Carolina at Chapel Hill.

Richard L. Schilsky, MD, FACP, FSCT, FASCO
Vice Chair of the Board, Reagan-Udall Foundation for the FDA

Richard L. Schilsky, MD, FASCO, formerly served as Chief Medical Officer of the American Society of Clinical Oncology (ASCO) and is Professor emeritus at the University of Chicago. An international expert in gastrointestinal malignancies and cancer pharmacology, Dr. Schilsky has published more than 300 scientific articles, reviews, and commentaries. He has served on a number of peer review and advisory committees for the NCI including as a member and chair of the NCI Board of Scientific Advisors and as a member of the Clinical and Translational Research Advisory Committee. Dr. Schilsky also served as a member and chair of the Oncologic Drugs Advisory Committee of the FDA. Dr. Schilsky has served as a member of the Board of Directors of ASCO and of the Conquer Cancer Foundation of ASCO and as ASCO President 2008-2009.

Dr. Schilsky joined the Reagan-Udall Foundation for the FDA Board of Directors in 2013.

Gina Valo
White House Presidential Innovation Fellow, FDA

Gina Valo currently serves as a White House Presidential Innovation Fellow at FDA where she leads strategic initiatives to advance the agency's technology and data modernization action plans. In response to the COVID-19 public health emergency, Ms. Valo has focused on the use of external data sources to understand real-world performance of diagnostics and increase supply chain visibility for medical products.

Ms. Valo is an experienced leader in enterprise software delivery and data integration with expertise in developing people, processes, and technology within high-growth organizations. She has previously held cross-functional and executive leadership roles across a variety of industries and companies including Google, Square, and Opower (acquired by Oracle), and continues to work as an independent consultant to early stage technology startups.

Susan C. Winckler, RPh, Esq.
CEO, Reagan-Udall Foundation for the FDA

Susan C. Winckler, RPh, Esq., is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, Ms. Winckler served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. She directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters.

As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), Ms. Winckler managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges, and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.