



2024 Annual Public Meeting
Reagan-Udall Foundation for the FDA Board of Directors
May 7, 2024

Speaker Biographies

Robert M. Califf, MD, MACC

Commissioner of Food and Drugs, U.S. Food and Drug Administration



Dr. Robert M. Califf was confirmed earlier this year as the 25th Commissioner of Food and Drugs. As Commissioner, Dr. Califf oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products.

Dr. Califf has had a long and distinguished career as a physician, researcher, and leader in the fields of science and medicine. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

This is Dr. Califf's second stint as Commissioner. He also served in 2016 as the 22nd Commissioner. Before assuming the position at that time, he served as the FDA's Deputy Commissioner for Medical Products and Tobacco.

Panelists

William Flynn, DVM, MS

Deputy Director, Center for Veterinary Medicine, U.S. Food and Drug Administration



Dr. William Flynn received a master's degree in Veterinary Preventative Medicine in 1987 and a doctoral degree in Veterinary Medicine in 1991 from the Ohio State University. Following several years of private veterinary practice, Dr. Flynn joined the Food and Drug Administration's Center for Veterinary Medicine (CVM) in 1993. He served in various capacities in CVM's Office of New Animal Drug Evaluation with a focus primarily on issues related to therapeutic drugs for food-producing animals. From 2003 to 2008, he served as Director of CVM's Policy and Regulations Staff and is currently CVM's Deputy Director for Science Policy.

Jim Jones, MS

Deputy Commissioner for Human Foods, U.S. Food and Drug Administration



Jim Jones joined the U.S. Food and Drug Administration in September 2023 as the agency's first Deputy Commissioner for Human Foods.

In this new executive position, which reports directly to the FDA Commissioner, Jones leads the charge in setting and advancing priorities for a proposed, unified Human Foods Program (HFP), which includes food safety, chemical safety and nutrition activities. He will exercise decision-making authority over all HFP entities, including resource allocation, risk-prioritization strategy, policy, major response activities involving human foods, and related Office of Regulatory Affairs activities. He currently oversees the leadership of the agency's Center for Food Safety and Applied Nutrition and Office of Food Policy and Response until the proposed HFP reorganization is implemented.

He has decades of leadership experience and a track record of forging partnerships among diverse segments of stakeholders and achieving dynamic results to improve public health.

Jones spent most of his career as a federal regulator of pesticides, toxic substances, chemical safety, and pollution prevention at the U.S. Environmental Protection Agency (EPA) and spent much of his more than 30-year tenure involved in leadership and decision-making related to food safety. He held positions of increasing responsibility at EPA and made public health-based decisions grounded in sound science, public policy, and law. As a principal architect of the 2016 overhaul of the Toxic Substances Control Act, Jones led discussions with members of Congress, industry and environmental groups that resulted in a law reshaping how chemical safety is managed in the U.S. He also led several national-level sustainability programs, including the Environmental Preferable Purchasing Program and the Presidential Green Chemistry Awards Challenge.

Peter Marks, MD, PhD

Director, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration



Dr. Peter Marks is the director of the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. The center is responsible for assuring the safety and effectiveness of biological products, including vaccines, allergenic products, blood and blood products, and cellular, tissue, and gene therapies.

Dr. Peter Marks received his graduate degree in cell and molecular biology and his medical degree at New York University. Following this, he completed an Internal Medicine residency and Hematology/Medical

Oncology fellowship at Brigham and Women's Hospital in Boston, where he subsequently joined the attending staff as a clinician-scientist and eventually served as Clinical Director of Hematology.

He then moved on to work for several years in the pharmaceutical industry on the clinical development of hematology and oncology products prior to returning to academic medicine at Yale University where he led the Adult Leukemia Service and served as Chief Clinical Officer of Smilow Cancer Hospital. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in 2016. Dr. Marks is board certified in internal medicine, hematology and medical oncology, and is a Fellow of the American College of Physicians. In 2022, he became a Member of the National Academy of Medicine, one of the highest honors in the fields of health, science and medicine.

Michele Mital

Deputy Director, Center for Tobacco Products, U.S. Food and Drug Administration



Michele Mital currently serves as the deputy director of the Center for Tobacco Products (CTP) within the U.S. Food and Drug Administration (FDA). In this position, Ms. Mital is responsible for assuring that CTP accomplishes its public health goals and for operationalizing the center's vision and mission as it implements the Family Smoking Prevention and Tobacco Control Act. Ms. Mital works closely with CTP senior leadership and with key FDA and U.S. Department of Health and Human Services (HHS) leadership and external stakeholders on matters that affect center goals, policies, programs, and strategic initiatives.

From 2013-2018, Ms. Mital served as CTP's associate director for Program Coordination. As a member of the center's senior leadership team, Ms. Mital provided strategic advice and counsel on programmatic and management matters.

Ms. Mital is a graduate of the University of Maryland at College Park and has more than 25 years of experience working at the FDA. She began her career as a policy analyst in FDA's Office

of Tobacco Programs where she led a team of analysts who were responsible for working with state and territorial government officials to enforce FDA's 1996 tobacco regulation.

Jeffrey Shuren, MD, JD

Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration



Dr. Jeffrey Shuren is the Director of the Center for Devices and Radiological Health (CDRH) at the U.S. Food and Drug Administration. The center is responsible for assuring the safety, effectiveness, and quality of medical devices; assuring the safety of radiation-emitting products (such as cell phones and microwave ovens); and fostering device innovation.

Dr. Shuren received his bachelor's and medical degrees from Northwestern University under its Honors Program in Medical Education. He completed his medical internship at Beth Israel Hospital in Boston, his neurology residency at Tufts New England Medical Center, and a fellowship in behavioral neurology and neuropsychology at the University of Florida. He subsequently joined the faculty of the University of Cincinnati. He received his juris doctorate from the University of Michigan. He is board-certified in neurology and a member of the Maryland state bar.

Dr. Shuren held various policy and planning positions within the FDA's Office of the Commissioner from 1998 to 2009, including Medical Officer in the Office of Policy; Assistant Commissioner for Policy; Associate Commissioner for Policy and Planning; Special Counsel to the Principal Deputy Commissioner; and Acting Deputy Commissioner for Policy, Planning, and Budget.

Dr. Shuren became the Acting Director of CDRH beginning in September 2009 and was appointed the permanent Director in January 2010. During his tenure, Dr. Shuren has envisioned and implemented initiatives to modernize the regulation of medical devices through a holistic, patient-centric, customer service-focused, total product life cycle approach to oversight and the organizational structure of CDRH.

Marta Sokolowska, PhD

Deputy Center Director, Substance Use and Behavioral Health

Center for Drug Evaluation and Research, U.S. Food and Drug Administration



Dr. Marta Sokolowska is the Deputy Center Director for Substance Use and Behavioral Health in FDA's Center for Drug Evaluation and Research (CDER). She serves as the center's executive-level leader responsible for advancing FDA's public health response to the non-medical use of substances with abuse potential. With expertise in science-based assessment and management of drug abuse risks, Dr. Sokolowska advises senior FDA officials on shaping scientific and policy interventions and executing strategies pertaining to the use of controlled substances and

behavioral health programs.

Dr. Sokolowska joined CDER in 2018 as Associate Director for Controlled Substances in the Office of the Center Director. In 2020, she began leading the Controlled Substances Program (CSP), which comprises the Controlled Substance Staff (CSS) and the Controlled Substances Initiatives (CSI) group. CSS provides consultation throughout FDA on evaluation of abuse potential of drugs and advises on all matters related to domestic and international drug scheduling. The strategy group pursues activities and policies to identify, mitigate, and manage emerging issues with controlled substances to minimize risks associated with problematic use while enabling appropriate access to these products for medical use.

Dr. Sokolowska is a recognized expert in drug abuse liability and scheduling strategies. She has facilitated numerous initiatives to improve public health by advancing the science of assessing drug abuse liability. Prior to joining FDA, Dr. Sokolowska held senior clinical and medical leadership roles in the pharmaceutical industry. She earned her doctoral degree in psychology from McMaster University in Canada.

Douglas Stearn, JD

Deputy Associate Commissioner, Regulatory Affairs, U.S. Food and Drug Administration



Douglas Stearn is the deputy associate commissioner for regulatory affairs in the FDA Office of Regulatory Affairs (ORA), overseeing inspections, compliance, enforcement, field laboratory operations, import operations, and strategic planning, among other areas.

Mr. Stearn's last position was deputy director for regulatory affairs for the FDA Center for Food Safety and Applied Nutrition. In this role, he directs oversight and responsibility for regulatory programs overseeing the food supply under FDA jurisdiction, including compliance functions and regulatory programs involving food safety, outbreak response, and dietary supplements for over five years.

Previous roles include director of the FDA Office of Enforcement and Import Operations between 2013 and 2018, where he oversaw the execution of the agency's import operations and compliance activities. Between 2009 and 2013, he was the assistant director and then deputy director of the Office of Compliance in the FDA Center for Drug Evaluation and Research (CDER).

Prior to joining CDER, Mr. Stearn directed the ORA Division of Compliance Policy for almost two years. Before joining the FDA, Mr. Stearn was a trial attorney in the U.S. Department of Justice's Office of Consumer Litigation for more than fifteen years. In this role, he litigated numerous civil and criminal cases referred by the FDA and other consumer protection agencies.

Foundation Leadership

Richard L. Schilsky, MD, FACP, FSCT, FASCO

Board Chair, Reagan-Udall Foundation for the FDA



Dr. Richard Schilsky is the former Chief Medical Officer with the American Society of Clinical Oncology and Professor emeritus at the University of Chicago. Dr. Schilsky earned his medical degree at the University of Chicago Pritzker School Of Medicine in 1975. Following a residency in Internal Medicine at the University of Texas Southwestern Medical Center and Parkland Memorial Hospital, he received training in Medical Oncology and Clinical Pharmacology at the National Cancer Institute from 1977 to 1981. He then served as Assistant Professor of Medicine at the University of Missouri-Columbia School of Medicine from 1981-1984 when he returned to the University of Chicago. At the University of Chicago, Dr.

Schilsky rose to the rank of Professor of Medicine (tenured) and served as Director of the University of Chicago Cancer Research Center (1991-99), as Associate Dean for Clinical Research (1999-2007) and as Chief of the Section of Hematology-Oncology (2009-2012). From 1995-2010, Dr. Schilsky also served as Chairman of the Cancer and Leukemia Group B, an NCI-sponsored national cancer clinical trials group.

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 Food and Drug Administration. Dr. Schilsky has served as a member of the Board of Directors of the American Society of Clinical Oncology (ASCO) and of the Conquer Cancer Foundation of ASCO and as ASCO President 2008-2009.

Susan C. Winckler, RPh, Esq.

Chief Executive Officer, Reagan-Udall Foundation for the FDA



Susan C. Winckler 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, she 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. Winckler 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), she 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.