2022 Annual Public Meeting
Reagan-Udall Foundation for the FDA Board of Directors
May 16, 2022
Speaker Biographies

Robert M. Califf, MD, MACC
Commissioner of Food and Drug, 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

Janet Woodcock, MD
Principal Deputy Commissioner, U.S. Food and Drug Administration

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). At CBER, she served as 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. There she conceived and implemented many of the FDA's drug initiatives, including introducing the concept of risk management as a new approach to drug safety; modernizing drug manufacturing and regulation through the Pharmaceutical Quality for the 21st Century Initiative; advancing medical discoveries from the laboratory to consumers more efficiently under the Critical Path Initiative; launching the Safety First and Safe Use initiatives designed to improve drug safety management within and outside the FDA, respectively; developing the Sentinel Network for drug safety and spearheading CDER efforts on patient-focused drug development.

Andi Lipstein Fristedt
Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration

Andi Lipstein Fristedt is the Deputy Commissioner for Policy, Legislation, and International Affairs. In this role, she provides strategic policy direction to advance the FDA's mission and vision of protecting and promoting public health and oversees the agency's engagement with Congress and global partners and state, local, territorial, and tribal policymakers.

Ms. Fristedt worked for nearly a decade in various capacities with the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP), first as a senior advisor to Chairman Tom Harkin and later to Ranking Member and Chair Patty Murray. In addition to serving as the Senate's top Democratic public health staffer beginning in 2012, she was the HELP Committee's Deputy Health Policy Director from 2017 until she joined the FDA in 2021. Ms. Fristedt spearheaded the Senate Democratic response to COVID-19, developing extensive policy proposals with respect to COVID-19 therapeutics, diagnostics, and vaccines. During her time in the Senate, Ms. Fristedt also led the drafting or negotiation of a wide range of public health legislation that was signed into law, including two reauthorizations of the Pandemic and All-Hazards Preparedness Act, legislation increasing the legal age of tobacco sale to 21, and key provisions of the 21st Century Cures Act, the Lower Health Care Costs Act, and the SUPPORT for Patients Act. Ms. Fristedt began her federal service at the Centers for Disease Control and Prevention's Washington, DC office where she led the agency's engagement with Congress on key issues, including HIV/AIDS and viral hepatitis. She first joined CDC as a Presidential Management Fellow.

James Sigg
Deputy Commissioner for Operations & Chief Operating Officer, U.S. Food and Drug Administration

James “Jim” Sigg is the Food and Drug Administration's (FDA) Deputy Commissioner for Operations and Chief Operating Officer. In this role, he maintains oversight of FDA’s operations worldwide to include ethics, equal employment opportunity, human resources, safety and security, facilities, acquisition, and financial management oversight of $6 billion.

More specifically, Mr. Sigg has led several key initiatives on behalf of and in support of FDA to include but not limited to:

- Leading FDA’s operational response to the COVID-19 pandemic to ensure a safe and operable FDA’s workforce.
- Expanding FDA’s recruitment strategy to hire at an unprecedented rate and mitigate attrition during a global pandemic.
- Leading and facilitating HHS’ call to deploy over 250 volunteers to support the Unaccompanied Children Mission of minors entering the United States without immigration status, and
- Collaborating with the Office of Regulatory Affairs (ORA) to reduce harm from opioid addiction and abuse through advancing high priority International Mail Facility (IMF) expansion needs, further protecting the safety and health of families.

Mr. Sigg has been with the FDA for over 30 years. He previously served as the Associate Director for Management, Executive Officer, and Director of the Office of Management in the Center for Biologics Evaluation and Research (CBER). In these roles, he managed CBER’s annual budget of $300 million and provided executive leadership in the areas of workforce development, budget formulation and execution, resource management, program planning and evaluation, and other administrative services that support CBER’s public health mission. Mr. Sigg advised CBER’s Director and senior executives on Center-wide administrative functions including financial management, human resources, and procurement. Under his leadership, he strategically managed the move of over 1,100 employees and contractors, 70 laboratories and approximately 14,000 research animals from eight locations to the FDA White Oak Campus with no disruption to critical regulatory and administrative operations.

Mr. Sigg earned a Bachelor of Science in Business Management from Saint Francis College. He has been the recipient of three Commissioner’s Special Citation awards for his contributions in leading improvements in human resources efforts and has received multiple awards and citations for his extraordinary leadership in managing fiscal responsibilities and staffing.

Frank Yiannas, MPH
Deputy Commissioner for Food Policy and Response

Frank Yiannas is the Deputy Commissioner for Food Policy and Response, a position he assumed in December of 2018. He is the principal advisor to the FDA Commissioner in the development and execution of policies related to food safety, including implementation of the landmark FDA Food Safety Modernization Act (FSMA). His leadership role within the Agency covers a broad spectrum of food safety priorities, such as outbreak response, traceback investigations, product recall activities, and supply chain innovation across the full spectrum of FDA-regulated products.

Mr. Yiannas is, in effect, the Agency's chief ambassador to reduce food safety risks and achieve high rates of compliance with FDA food safety standards, working to develop innovative collaborations with external partners and stakeholders and effective relationships with government and industry leaders, as well as consumer groups.

A renowned food safety expert and author, Mr. Yiannas came to FDA from leadership roles with two industry giants: Walmart and the Walt Disney Company. Through his career, he's been recognized for his role in elevating food safety standards and building effective food safety management systems based on modern science and risk-based prevention principles.

At Walmart, which he joined in 2008 and served for over a decade, Mr. Yiannas was the Vice President for Food Safety. In this role, he led the effort to make Walmart the first U.S. retailer to require suppliers to achieve certification against one of the Global Food Safety Initiative (GFSI) benchmarked food safety schemes. More recently, he has become a globally recognized pioneer in using blockchain technology to create a more digital and transparent food system. His work has shown that by leveraging technology, the amount of time taken to trace the origin of a food back to source can be reduced from weeks and days down to seconds. Based on his work, other major food companies are now exploring the use of this technology.

His experiences in the food safety arena have also made him an advocate for the promotion of a Food Safety Culture to protect the world's food supply, arguing that science and policy alone are not enough. Advancing food safety also requires an understanding of organizational culture and principles of human behavior. Engaging on this level to help shape an organization's culture is the subject of his books Food Safety Culture, Creating a Behavior-based Food Safety Management System, and Food Safety = Behavior, 30 Proven Techniques to Enhance Employee Compliance.

At Disney, where he worked for 19 years, he was the Director of Safety and Health. During his tenure, Disney received the prestigious Black Pearl Award for corporate excellence in food safety from the International Association for Food Protection.

The recipient of numerous awards, in 2007, he received the National Science Foundation's International Lifetime Achievement Award for Leadership in Food Safety. He is also the recipient of the Collaboration Award by FDA in 2008 and he was named the 2015 Industry Professional Food Safety Hero Award by STOP Foodborne Illness, a consumer advocacy group.

Mr. Yiannas is a past president of the International Association for Food Protection and a past vice-chairman of the Global Food Safety Initiative. He is also an adjunct Professor in the Food Safety Program at Michigan State University, and in 2017 was awarded the MSU Outstanding Faculty Award.

A microbiologist, Mr. Yiannas received a B.S. in microbiology from the University of Central Florida and a Master of Public Health degree from the University of South Florida.

Meeting Moderator

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.