Optimizing FDA's Use of and Processes for Advisory Committees

Public Meeting: June 13, 2024

Speakers' Biographies

Robert M. Califf, MD, MACC, Commissioner of Food and Drugs. President Joe Biden nominated Dr. Califf to head the U.S. Food and Drug Administration and Dr. Califf was sworn in on February 17, 2022. Previously, Dr. Califf served as Commissioner of Food and Drugs from February 2016 to January 2017. As the top official of the FDA, Dr. Califf is committed to strengthening programs and policies that enable the agency to carry out its mission to protect and promote the public health. Dr. Califf served as the FDA's Deputy Commissioner for Medical Products and Tobacco from February 2015 until his first appointment as Commissioner in February 2016.

Prior to rejoining the FDA, Dr. Califf was head of medical strategy and Senior Advisor at Alphabet Inc., contributing to strategy and policy for its health subsidiaries Verily Life Sciences and Google Health. He joined Alphabet in 2019, after serving as a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,300 publications in the peer-reviewed literature.

Dr. Califf became a Member of the National Academy of Medicine (formerly known as the Institute of Medicine (IOM)) in 2016, one of the highest honors in the fields of health and medicine. Dr. Califf has served on numerous IOM committees, and he has served as a member of the FDA Cardiorenal Advisory Panel and the FDA Science Board's Subcommittee on Science and Technology. Dr. Califf has also served on the Board of Scientific Counselors for the National Library of Medicine, as well as on advisory committees for the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Environmental Health Sciences and the Council of the National Institute on Aging.

While at Duke, Dr. Califf led major initiatives aimed at improving methods and infrastructure for clinical research, including the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by the FDA and Duke. He also served as the principal investigator for Duke's Clinical and Translational Science Award and the NIH Health Care Systems Research Collaboratory Coordinating Center.

Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco and a fellowship in cardiology at Duke.

Namandjé N. Bumpus, PhD, Principal Deputy Commissioner, FDA. In this role she works closely with FDA leadership to develop, advance and implement key public health initiatives, as well as to oversee the agency's day-to-day functions. Chief among those priorities is the proposed reorganization unifying the Human Foods Program, creating a new model for the Office of Regulatory Affairs, and strengthening the entire agency. Dr. Bumpus has played an integral leadership role in the Implementation and Change Management Group and will provide seamless transition for this critical modernization effort.

As the FDA's Chief Scientist since August 2022, Dr. Bumpus has overseen and quickly elevated the research foundation, science and innovation that provides vital support for the FDA's public health mission. This includes leading the agency's implementation of the Modernization of Cosmetics Regulation Act. She has continued to raise the cache of the FDA's regulatory science within the agency and to the outside world, in part by being a champion of plain language, a staunch advocate for truth-telling in public health, and a formidable scientist.

Before joining the FDA, Dr. Bumpus was the E.K. Marshall and Thomas H. Maren Professor and chair of the Department of Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine. She served previously as associate dean for basic research in the Johns Hopkins University School of Medicine. Dr. Bumpus' research has focused on drug metabolism, pharmacogenetics, bioanalytical chemistry, and infectious disease pharmacology. Dr. Bumpus joined the faculty at Johns Hopkins in 2010 as an assistant professor. She earned a bachelor's degree in biology at Occidental College in 2003, a doctorate in pharmacology at the University of Michigan in 2007 and completed a postdoctoral fellowship in molecular and experimental medicine at The Scripps Research Institute in La Jolla, California, in 2010.

Dr. Bumpus currently serves as president of the American Society for Pharmacology and Experimental Therapeutics. She previously served as chair of the National Institutes of Health Xenobiotic and Nutrient Disposition and Action study section.

Her many honors include the Leon I. Goldberg Award from the American Society for Clinical Pharmacology and Therapeutics, the James Gillette Award from the International Society for the Study of Xenobiotics, the John J. Abel Award in Pharmacology from the American Society for Pharmacology and Experimental Therapeutics and the Presidential Early Career Award for Scientists and Engineers, which is the highest honor bestowed by the U.S. government on early career scientists and engineers. Dr. Bumpus is an elected fellow of the American Association for the Advancement of Science. She became a Member of the National Academy of Medicine, Class of 2022, one of the highest honors in the fields of health, science and medicine.

Dayle Lewis Cristinzio. Director, Stakeholder Engagement, Office of External Affairs, FDA. Ms. Cristinzio has more than 25 years of experience in public health policy development and advocacy as a Congressional staffer, representing health care clients in the private sector as a government affairs representative, and in various roles at the FDA. Ms. Cristinzio joined the FDA in 2015 and served as the head of the Office of Legislation for two years where she managed the team through passage of the

21st Century Cures legislation and the FDA's user fee reauthorizations act of 2017. She joined the Office of External Affairs at the FDA in 2017 to lead the Stakeholder Engagement Staff and works closely with the FDA centers and offices across the entire Agency. The Stakeholder Engagement Staff's mission is to build relationships with health professional organizations, patient groups, consumers, academia, and industry trade stakeholders, communicate timely agency policy announcements, and create strategic collaborations to better inform FDA's work.