REAGAN-UDALL FOUNDATION FOR THE FDA

Advancing Rare Disease Therapies Through an FDA Rare Disease Innovation Hub

Hybrid Public Meeting
October 16, 2024; 10AM – 2:30PM (eastern time)

Speakers

Namandjé N. Bumpus, PhD
Office of the Commissioner, FDA

Dr. Namandjé N. Bumpus became the FDA's Principal Deputy Commissioner on Feb. 1, 2024. 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.

Patrizia Cavazzoni, MD
Center for Drug Evaluation and Research, FDA

Dr. Patrizia Cavazzoni is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. The Center's mission is to ensure that safe, effective and high-quality drugs are available to the public. To achieve this, CDER regulates the medical products under its jurisdiction throughout their lifecycle, oversees the development of new and generic drugs, evaluates applications to determine whether drugs should be approved, monitors the safety of drugs after they are marketed, conducts research to advance regulatory science and takes enforcement actions to protect the public from harmful products. Dr. Cavazzoni joined the FDA in January 2018 as CDER's Deputy Director for Operations where she has led several key initiatives on behalf of the organization. She also served as Acting Principal Deputy Commissioner of Food and Drugs from January 2019 to February 2019.

Kerry Jo Lee, MD
Center for Drug Evaluation and Research, FDA

Dr. Kerry Jo Lee is the Associate Director for Rare Diseases in the Division of Rare Diseases and Medical Genetics (DRDMG), Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORPURM), Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER). In this role she leads CDER's Rare Diseases Team, a multidisciplinary rare disease programming and policy team that works across CDER to promote their mission to facilitate, support, and accelerate the development of drugs and therapeutic biologics for rare diseases. Dr. Lee also serves as Program Manager of CDER's Accelerating Rare Disease Cures (ARC) Program. Dr. Lee is a pediatric gastroenterologist/hepatologist who joined the FDA as a medical officer in 2014. Through her previous roles in CDER/OND, Dr. Lee has served as a lead in the areas of benefit-risk assessment, modernization efforts (including the integrated review for marketing applications), and real-world data/evidence programming in CDER drug review and policy.

Peter Marks, MD, PhD,
Center for Biologics Evaluation and Research, FDA

Dr. Peter Marks serves as 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. Marks and center staff have committed themselves to facilitating the development of biological products and providing oversight throughout the product life cycle. 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.

Julie Tierney, JD
Center for Biologics Evaluation and Research, FDA

Julie Tierney is the Deputy Center Director for Strategy, Policy and Legislation for the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER). Ms. Tierney has held several senior roles in the Office of the Commissioner and CBER during her tenure at FDA. Most recently, from January 2021 through December 2023, she served as the FDA Chief of Staff. She also served as Chief of Staff for CBER and FDA's detailee to the U.S. Senate Health, Education, Labor & Pensions (HELP) Committee as a Senior Health Policy Advisor. Ms. Tierney joined the FDA as an Associate Chief Counsel for Drugs in the Office of Chief Counsel.

Prior to working at the FDA, Ms. Tierney practiced food and drug law at private law firms. She received her J.D. from Georgetown University Law Center and her undergraduate degree in Biology and History from Johns Hopkins University.

Moderator

Susan C. Winckler, RPh, Esq.
Chief Executive Officer, Reagan-Udall Foundation for the Food and Drug Administration

Prior to accepting the Foundation post in May of 2020, 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 on public policy/regulation, business strategy, investments, and other matters. A pharmacist and attorney by training, she was, earlier, CEO of the Food & Drug Law Institute. As Chief of Staff for the FDA (2007-2009), 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. She is an APhA Fellow, an elected member (2015-2020, 2020-2025) and Chair (2018- present) of the United States Pharmacopeial Convention (USP) Board of Trustees, and a member of the Purgo Scientific, LLC board.