Rare Disease Framework Initiative
Hybrid Public Meeting
Wednesday, October 28, 2026 | 1pm - 5pm (Eastern)

Speaker Bios

Amy Comstock Rick, JD
Director, Rare Disease Innovation Hub, FDA



Amy Comstock Rick, JD, is CDER's Associate Director for Rare Disease Strategy and the Director of Strategic Coalitions for FDA's Rare Disease Innovation Hub (the Hub). She serves in a cross-cutting role across FDA's Center for Drug Evaluations and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to facilitate implementation of the Hub. She also works closely with both centers to develop and carry out a rare disease strategic agenda. Ms. Rick, with support from staff in CBER's and CDER's rare disease programs, is the Hub's primary point of engagement for parties external to FDA.

Most recently, Ms. Rick served as Principal Consultant at Leavitt Partners, focusing on health policy matters, with a primary focus on rare disease and medical product development. Before Leavitt Partners, she served as President and Chief Executive Officer of the Food and Drug Law Institute (FDLI), a non-profit organization dedicated to providing an innovative, open, balanced exchange of ideas and viewpoints across the field of food and drug law.

Before joining FDLI, Ms. Rick was Chief Executive Officer of the Parkinson's Action Network. Ms. Rick also served as President of the Coalition for the Advancement of Medical Research and on the Boards of Directors for Research America, the National Health Council, and the American Brain Coalition.

Ms. Rick had previous federal service as a career attorney at the U.S. Department of Education in 1988, focusing primarily on the field of government ethics. She was the Senate-confirmed Director of the U.S. Office of Government Ethics from 2000 to 2003 and Associate Counsel to the President in the White House Counsel's Office from 1998 to 2000. She received a bachelor of arts degree from Bard College and a juris doctor degree from the University of Michigan.

Michael Davis, MD, PhD
Director, Center for Drug Evaluation and Research, FDA



Dr. Michael Davis is the Center Director of the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER). CDER'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 – overseeing the development of new and generic drugs, evaluating applications to determine whether drugs should be approved, monitoring the safety of drugs after they are marketed, conducting research to advance regulatory science, and taking enforcement actions to protect the public from harmful products.

Dr. Davis was previously the Deputy Center Director of CDER, serving on the senior leadership team supporting the Center Director by providing executive leadership on strategic initiatives that advanced CDER's mission.

Dr. Davis completed a Medical Scientist Training Program (MD, PhD in pharmacology) at Case Western Reserve University, psychiatric residency training at the Semel Institute for Neuroscience and Human Behavior at UCLA, and a clinical research fellowship at the West Los Angeles VA Mental Illness Research, Education, and Clinical Center. His research interests focused on the development of novel therapeutics for schizophrenia. Following completion of his fellowship in 2014, he was a Staff Psychiatrist at the Michael E. DeBakey VA Medical Center in Houston, TX, and an Assistant Professor in the Baylor College of Medicine Department of Psychiatry and Behavioral Sciences. Dr. Davis is licensed to practice medicine and is board certified in psychiatry.

From 2016–2022, Dr. Davis served in CDER's Office of New Drugs (OND) as a Clinical Team Leader in the Division of Psychiatry, where he led multidisciplinary teams in the review of drugs for the treatment of psychiatric disorders, as well as contributed to regulatory science and policy development. In this role, he received numerous honors and awards, including the Division of Psychiatry Annual Awards for Individual Supervisor and for Collaboration, and the FDA Outstanding Service Award for leadership in advancing science in psychiatric drug development. Dr. Davis also presented nationally and internationally on regulatory topics such as estimands, digital health technologies, and issues related to development of psychedelic-based therapies. After leaving the agency in 2022, Dr. Davis served from 2022-2025 as Chief Medical Officer for a nonprofit medical research organization developing psychedelic drugs for the treatment of major depressive disorder and post-traumatic stress disorder. In 2025, Dr. Davis returned to the agency.

Kyle Diamantas, JD
Acting Commissioner of Food and Drugs, FDA



Kyle Diamantas, JD is the Acting Commissioner of Food and Drugs. Prior to becoming Acting Commissioner, as the FDA's Deputy Commissioner for Food, Mr. Diamantas lead the agency's Human Foods Program. In that role he oversaw all FDA nutrition and food safety activities, exercising authority over all Human Food Program entities and operations, including resource allocation, risk-prioritization strategy and decision making, policy initiatives, and major response activities involving human foods. Mr. Diamantas also oversaw food resources in the agency's Office of Inspections and Investigations. He also served since February 2026 as a Senior Counselor for the Food and Drug Administration in the U.S. Department of Health and Human Services.

As the FDA's top food executive, Mr. Diamantas set the strategic direction and operations for food policy in the U.S., while serving as a critical liaison between the agency, HHS, and The White House. He also represented the agency on food activities and matters in dealings with foreign governments and international organizations.

Mr. Diamantas has extensive experience working with various federal and state agencies and policy makers, scientific organizations, consumer advocacy groups, and industry stakeholders. He has wide-ranging experience on matters spanning regulatory, compliance, investigative, enforcement, rulemaking, and legislation. Mr. Diamantas holds a juris doctor from the University of Florida Levin College of Law and a bachelor's in pre-law political science from the University of Central Florida.

Karim Mikhail, BPharm, MSc
Director, Center for Drug Evaluation and Research, FDA



Karim Mikhail serves as the FDA's Director of the Center for Biologics Evaluation and Research (CBER). He joined the FDA in 2025 as a Senior Advisor in the Office of the Commissioner where he led U.S. competitiveness reforms, spanning multiple disciplines from accelerating early clinical development to on-shoring of biopharmaceutical manufacturing. He brings over two decades of leadership experience in leading both large pharmaceutical companies and small biotechnology startups across therapy areas including cardio-metabolism, respiratory, immunology, neuroscience, oncology, women's health, and anti-infectives.

Mr. Mikhail has lived and worked across eight countries on three continents, with trilingual fluency. He has an unparalleled international perspective and deep understanding of the drug development ecosystem from multiple perspectives—regulatory, commercial, and scientific. His clinical development experience spans a range of therapeutic areas, providing deep understanding of the drug development lifecycle from bench to bedside to market.

Mr. Mikhail holds a Master of Science in Biopharmaceutical Management from École supérieure de commerce de Paris (ESCP Business School) and a Bachelor of Pharmacy & Pharmaceutical Sciences from Cairo University. His Six Sigma Executive Belt certification reflects his commitment to operational excellence. Mr. Mikhail is a distinguished thought leader in pharmaceutical innovation and entrepreneurial business strategy.

Moderator

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 Food and Drug Administration. Prior to accepting the Foundation post, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, and other stakeholders with a neutral forum to address domestic and global issues. 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. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her law degree magna cum laude from Georgetown University Law Center. She is an APhA Fellow, served as an elected member of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025) and Chair of that Board from 2019 to mid-2025. In 2023, she received the Distinguished Alumni Award of the Food and Drug Administration Alumni Association and, separately, was awarded the Osterhaus Medal for Lifetime Achievement by the Univ. of Iowa College of Pharmacy.