Demand Forecasting for Controlled Substances

Hybrid Public Meeting

Rooftop Meeting Space | 1333 New Hampshire Ave NW | Washington, DC 20036

August 27, 2025

2 – 5pm *(eastern)*

Speaker Biographies

Amar Bhat, PhD
Chief Operating Officer
Reagan-Udall Foundation for the FDA

Amar Bhat, PhD, is the Chief Operating Officer of the Reagan-Udall Foundation for the FDA, a non-profit organization created by Congress to advance the mission of the U.S. Food and Drug Administration. Dr. Bhat joined the Foundation in May 2018 as the Director of Business Planning and Programs, with a portfolio that focused on new initiatives, program development and strategic planning. From April 2019 to May 2020, he served as Interim Executive Director. Prior to joining the Foundation, Dr. Bhat held a variety of executive positions in health and science policy, both in industry and government.

While at NIH and HHS, Dr. Bhat negotiated dozens of bilateral agreements and developed an in-depth knowledge of the health systems around the world. He worked closely with FDA, CDC, and other U.S. Government agencies on a number of high-profile activities such as the Global Fund and PEPFAR, as well as the U.S. Government's response to various epidemics and natural disasters. Through these various roles, Dr. Bhat also developed a keen understanding of the role of regulatory science and the development of experimental therapies into commercial products.

Dr. Bhat has a doctoral degree in Public Policy from The George Washington University where his research focused on developing methods for measuring the economic impacts of biomedical research. Dr. Bhat also received a master's degree in public policy and a bachelor's degree in chemistry from Duke University.

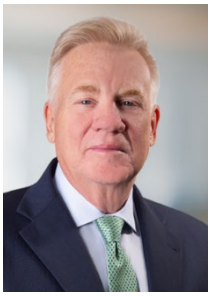
Laura Bray, MBA
Chief Change Maker
Angels for Change

Laura Bray is the Chief Change Maker and founder of Angels for Change, the only U.S.-based, volunteer-driven, nonprofit patient advocacy organization solely dedicated to ending drug shortages. She founded the organization in October 2019 after her daughter, Abby, faced three life-threatening drug shortages during treatment for pediatric cancer. Drawing on her expertise in supply chain management, business acumen, and personal experience navigating critical medication shortages, Laura leads Angels for Change with a passionate, patient-first approach.

Under her leadership, Angels for Change has launched several nationally recognized programs, including the Drug Shortage Hotline—the only hotline in the country that allows patients, physicians, and pharmacists to report shortages and be connected to care. The hotline has a 98% success rate in helping ensure patients receive the care they need during shortage events.

Laura's work has helped provide access to life-saving medications for hundreds of thousands of patients. She has become a leading voice in national efforts to end drug shortages, earning recognition from CNN as "leading the national movement to end drug shortages." Her advocacy extends to the highest levels, including testifying before Congress, serving on the White House Drug Shortages Task Force, and co-founding the End Drug Shortages Alliance.

John A. Gilbert, Jr., JD
Director
Hyman, Phelps, and McNamara



John A. Gilbert, Jr. counsels and advises clients on legal and regulatory issues involving controlled substances, prescription drugs, & precursor chemicals. His expertise extends to international, federal and state laws and regulations governing the scheduling, manufacturing, distribution, dispensing, import and export of controlled substances drugs and precursor chemicals. Mr. Gilbert has advised numerous companies at all levels of the drug supply chain on legal, regulatory and enforcement matters involving the Controlled Substances Act (CSA) and state laws governing controlled substances and precursor chemicals. Mr. Gilbert frequently conducts investigations and inspections related to compliance with federal and state laws and has handled numerous civil litigation matters involving violations of federal and state laws including actions before the DEA Office of Administrative Law Judges and civil actions initiated by U.S. Attorney Offices in federal court.

Mr. Gilbert has extensive experience in scheduling and regulation of controlled substances under the international drug control treaties and issues related to the United Nations Drug Control Program. He has advised and represented clients on matters related to the World Health Organization's Expert Committee on Drug Dependence, the International Narcotics Control Board and the U.N. Commission on Narcotic Drugs.

Mr. Gilbert also advises clients on compliance with federal and state requirements on licensing, pedigree, track and trace, and drug sampling requirements, including regulations associated with the Drug Quality and Security Act. Before joining the firm in 1995, Mr., Gilbert was an attorney in the DEA's Office of Chief Counsel, Diversion/Regulatory Section. He also served as law clerk to the DEA's Chief Administrative Law Judge as part of the U.S. Department of Justice's Honors Program.

Nicolette A. Louissaint, PhD, MBA
Chief Policy Officer
Healthcare Distribution Alliance

Dr. Nicolette Louissaint serves as the Chief Policy Officer for the Healthcare Distribution Alliance. In this role, she leads the organization's work to build policy solutions that reinforce the role of pharmaceutical distributors in the healthcare ecosystem.

She previously served as the executive director and president of Healthcare Ready, a 501(c)(3) organization that focuses on strengthening the United States' healthcare supply chain preparedness and response before, during and after natural disasters and disease pandemics. Prior to this, Nicolette served as the Senior Advisor to the US State Department's Special Coordinator for Ebola and as a Foreign Affairs Officer at the US Department of State in the Bureau of Economic and Business Affairs.

She served on the Federal Emergency Management Agency's (FEMA) National Advisory Council, as chair of the Equity Working Group. She serves on the Board of Directors for Project HOPE and the YMCA of Central Maryland. Nicolette earned Bachelor of Science degrees in Chemical Engineering and Biological Sciences from Carnegie Mellon University, a PhD in Pharmacology and Molecular Sciences from Johns Hopkins University School of Medicine, and an MBA from the University of Baltimore.

Marta Sokolowska, PhD
Deputy Center Director for 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.

Emily Tucker, PhD
Dean's Assistant Professor
Department of Industrial Engineering
Clemson University

Emily Tucker is an assistant professor in the Department of Industrial Engineering at Clemson University. Her research focuses on applying operations research to societal problems, including health care policy, operations, and supply chain resiliency, with methods that include stochastic optimization and mathematical programming. Through collaborations with clinical partners, she has studied policies to reduce drug shortages in the United States and worldwide; expectations of kidney transplant recipients; nurse scheduling; disaster relief efforts; and national HIV/AIDS policy. She has active collaborations with the Emergency Department at Prisma Health. Tucker received her PhD and MSE in industrial and operations engineering from The University of Michigan. She was part of the National Science Foundation Graduate Research Fellowship, and her dissertation work was awarded the University of Michigan Richard and Eleanor Towner Prize for Outstanding PhD Research. Before graduate school, she worked as a research health economist at RTI International and received her bachelor's degree in industrial engineering from North Carolina State University.

Jillanne S. Schulte Wall, JD
Senior Director, Health & Regulatory Policy
Office of Government Relations
American Society of Health-System Pharmacists

Jillanne Schulte Wall is the Senior Director of Health & Regulatory Policy for the American Society of Health-System Pharmacists (ASHP) in Bethesda, MD. She serves as ASHP's primary liaison to federal regulatory agencies and, in conjunction with other members of the Government Relations team, develops and communicates of ASHP's positions on federal and state laws, regulations, and guidance related to the profession of pharmacy. Additionally, Jillanne works closely with stakeholders in pharmacy, medicine, manufacturing, and patient advocacy on legislative and regulatory issues of importance to ASHP members. Prior to joining ASHP, Jillanne was the Director of Regulatory Affairs for the American Pharmacists Association in Washington, DC. She began her career as a healthcare attorney at Feldesman Tucker Leifer Fidell LLP in Washington, DC, where she advised healthcare clients on corporate, regulatory, and transactional issues, with a particular emphasis on optimizing performance after the implementation of the Affordable Care Act.

Lowell M. Zeta, JD
Deputy Commissioner for Strategic Initiatives and Special Counsel
U.S Food and Drug Administration

Lowell M. Zeta, JD, is the Deputy Commissioner for Strategic Initiatives at the U.S. Food and Drug Administration and serves as Special Counsel for FDA in the Office of the Chief Counsel (OCC), which is the Food and Drug Division of the U.S. Department of Health and Human Services' (HHS) Office of the General Counsel.

In this dual role, Mr. Zeta provides legal and strategic counsel to the FDA Commissioner and Agency leadership to advance strategic regulatory initiatives, drive cross-agency innovation, and strengthen oversight across all FDA-related product areas including drugs, biologics, food, medical devices, cosmetics, veterinary products, and tobacco products. He serves as the point-person ensuring that strategic initiatives and priorities, at all levels of the organization, are authorized under the Federal Food, Drug, and Cosmetic Act (FDCA) and other applicable laws and regulations, and are in line with the FDA Commissioner's priorities and the broader goals of HHS and the Administration.

Mr. Zeta is responsible for collaborating with the FDA Commissioner to identify opportunities to improve regulatory programs, to develop innovative strategies to emerging and ongoing issues, and to implement new programs and solutions to achieve the FDA's mission objectives. He works closely with FDA leadership and provides executive oversight for operations and regulatory process improvements. His responsibilities include providing analyses and recommendations on innovative regulatory initiatives and programs, ensuring the alignment of the key functions of strategy planning, and driving change and overseeing change management during implementation to maximize efficiency and public health benefit.

As Special Counsel for FDA, Mr. Zeta provides legal counsel and strategic counsel on high-priority regulatory and administrative actions and cross-cutting legal issues involving emerging technologies such as artificial intelligence, domestic manufacturing and foreign inspections, and risk management for regulations, guidance, and policy development, which often involves complex legal analyses of intricate statutory provisions. He works closely with OCC litigators and counselors to advise FDA officials on strategy planning and risk mitigation approaches, new and pending regulations and draft legislation, and complex compliance and enforcement matters to advance FDA's mission of promoting and protecting the public health.

Mr. Zeta was previously with the FDA (2020-2021), serving as a Senior Advisor to the Commissioner, and provided leadership on key public health initiatives, including the Pandemic Recovery and Preparedness Plan (PREPP) initiative to strengthen the FDA's response to public health emergencies. Prior to his return, Mr. Zeta was a senior partner at a global law firm in Washington, D.C., focusing on regulatory and commercial strategies, enforcement and administrative matters, compliance and investigations involving the pharmaceutical and biotech industries. In addition, he has extensive experience, and is a frequent speaker and published writer on FDA and healthcare priorities. Mr. Zeta previously served as a Food and Drug Law Journal advisory board member where he was responsible for peer-review of publications in the Food and Drug Law Journal, covering scholarly work on legislation, regulations, court decisions, and public policies affecting FDA regulated industries. Mr. Zeta completed his undergraduate studies at the University of Iowa and earned his juris doctor and postgraduate degree in law and health policy from Creighton University and Georgetown University, respectively.

Meeting Moderator

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

Susan C. Winckler is CEO of the Reagan-Udall Foundation for the FDA (Foundation). The Foundation is the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post in May of 2020, 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, industry leaders, and consumers with a neutral forum to address domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, she served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations, and allied groups. Ms. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her juris doctorate magna cum laude from Georgetown University Law Center. She served as an elected member United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025) and Chair of that Board from 2019 to mid-2025. She is an APhA Fellow, a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council.