Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest

Hybrid Public Meeting
Thursday, June 27, 2024, from 9 am – 4 pm Eastern Time
1333 New Hampshire Avenue NW; Rooftop Meeting Room
Washington, DC, 20036

Speaker Biographies

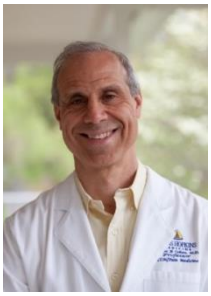
Ilisa Bernstein, PharmD, JD
President
Bernstein Rx Solutions

Ilisa Bernstein, PharmD, JD, FAPhA, is President of Bernstein Rx Solutions, LLC, assisting clients in understanding and maneuvering through drug and pharmacy regulatory policy and compliance issues, strategies, and advocacy. She brings over 35 years of experience and expertise in the government, non-profit, and private sector in achieving successful outcomes and advancing innovation. Dr. Bernstein spent nearly 5 years at the American Pharmacists Association (APhA). For 13 months, she served as the 14th CEO and Executive Vice President of APhA, the first woman to lead as CEO in the 172-year history of the association. She led all operations and strategies for APhA, the Board of Pharmacy Specialties, and the APhA Foundation. She joined APhA in 2019 as Senior Vice President for Pharmacy Practice & Government Affairs and guided APhA as the voice of pharmacists in all practice settings. For over 30 years, Dr. Bernstein held several senior leadership positions at the U.S. Food and Drug Administration (FDA). Notably, she was deputy director of FDA's Office of Compliance in the Center for Drug Evaluation & Research, leading policies, compliance, and enforcement for drugs and for 19 years she had several senior policy advisor roles in the Office of the Commissioner. She started at FDA as a clinical pharmacology reviewer. Recognized for her achievements, she proudly received the 2023 Distinguished Alumni Lifetime Achievement Award from the University of Michigan College of Pharmacy and was chosen as one of the 2023 Top 50 Most Influential Leaders in Pharmacy. Dr. Bernstein was also senior associate director of worldwide regulatory affairs for Pfizer and completed a post-doctoral clinical residency at the National Institutes of Health. She earned her Doctor of Pharmacy from the University of Michigan College of Pharmacy and her Juris Doctor from American University Washington College of Law.

Gail Bormel, RPh, JD
Director, Office of Compounding Quality and Compliance
FDA Center for Drug Evaluation and Research

Gail Bormel is the Director of the Office of Compounding Quality and Compliance and has worked in FDA's CDER Office of Compliance for over 20 years. Before joining FDA, Ms. Bormel worked as Associate Legal Counsel for Legislative and Regulatory Affairs at the United States Pharmacopeia, as an attorney at Hyman, Phelps, & McNamara, P.C., and as a state regulator with the Massachusetts Department of Public Health. Ms. Bormel holds degrees in pharmacy from the University of Maryland School of Pharmacy and law from the National Law Center, George Washington University.

Steven P. Cohen, MD
Professor of Anesthesiology and Vice Chair of Research and Pain Medicine and Professor of Neurology, Physical Medicine & Rehabilitation, Psychiatry and Neurological Surgery
Northwestern University Feinberg School of Medicine



Dr. Cohen has published over 400 peer-reviewed articles and book chapters in journals such as Lancet, JAMA, BMJ, CMAJ, Anesthesiology, Pain and New England Journal of Medicine, Cecil Textbook of Medicine, Harrison's Principles of Internal Medicine and UpToDate. Among his major contributions are the development of an FDA-approved denervation technique for treating sacroiliac joint pain, developing the IV ketamine test, helping set up the first pain clinic in a war zone, inventing the IV ketamine test, performing the first studies evaluating the epidural administration of biological agents for pain, serving as Senior Investigator on the congressionally-mandated study evaluating compounded topical creams for chronic pain and serving as Principal Investigator on the largest NIH-HEAL grant involving over 2-dozen sites. He has served as Chair on international committees developing guidelines on ketamine for acute and chronic pain management, lumbar and cervical facet joint guidelines, and pain management during COVID. His work was instrumental in the passage of the 2008 Military Pain Care Act. Most recently in May 2024, he chaired the largest medical conference, on pain, in Ukraine since the war with Russia. In addition to his academic work, Dr. Cohen is a retired Colonel in the U.S. Army.

Fran Cunningham, PharmD
Director
VA Center for Medication Safety (VAMedSAFE)

Dr. Cunningham's work focuses on assessing new agents where safety data is lacking, and older medications that exhibit emerging safety signals requiring evaluation. She designed the VAMedSAFE Drug Safety Quality Improvement programs which aids in tracking multiple ADEs and drug safety initiatives at the national level. Under her direction, the Center became VA's comprehensive pharmacovigilance program contributing to VA national decisions and provider awareness of drug and vaccine safety issues. Dr. Cunningham's group has worked independently and with other researchers to perform several medication safety

and pharmacoepidemiologic studies. Dr. Cunningham serves as the VA's federal Interagency representative for medication and vaccine safety. Her work has led to national awards for her contributions in pharmacovigilance and medication safety including the Mark A. Wolcott National Award for Leadership in Healthcare: Medication Safety and the Arthur S Fleming Award, given for her national work in medication safety.

A.J. Day, PharmD
Compounding Steering Committee
National Community Pharmacists Association

Dr. A.J. Day is a clinical pharmacist and Vice President of Clinical Services at PCCA in Houston, TX. His practice focus areas include regulatory affairs, QA/QC, compounding supply chain, pediatric compounding, veterinary compounding, aseptic compounding, and pain management. Over the course of his career A.J. has had the privilege of providing CE and non-CE presentations to thousands of physicians, pharmacists, and veterinarians around the world. He has provided expert testimony to FDA on behalf of the Compounding profession on multiple occasions. He has published ten articles covering a variety of clinical topics and was the recipient of the 2022 Compounding Advocacy Champion Award. A.J. serves on the National Community Pharmacists Association Compounding Steering Committee, and previously served on the Board of Directors for the Alliance for Pharmacy Compounding, IACP Foundation, and Texas Pharmacy Foundation. He is active with several pharmacy groups including ASHP, APhA, NCPA, and The Society of Veterinary Hospital Pharmacists (SVHP). He served 10 years in the Texas State Guard, Houston Medical Response Group. As a preceptor for colleges of pharmacy across the country, A.J. coordinates and supervises PharmD. students in their final year of studies. He studied chemistry at the University of Texas at Austin and obtained his Doctor of Pharmacy from the University of Houston College of Pharmacy.

Michael DiStefano, PhD
Assistant Professor, Center for Pharmaceutical Outcomes Research
Department of Clinical Pharmacy
University of Colorado Anschutz Medical Center

Mike DiStefano is an Assistant Professor in the Center for Pharmaceutical Outcomes Research and the Department of Clinical Pharmacy at the University of Colorado Anschutz Medical Center. His research is primarily focused on health technology assessment, prescription drug policy, and direct-to-consumer pharmaceutical advertising. He is particularly interested in the ethical considerations that arise in each of these research areas. Prior to joining the University of Colorado, he worked at the Johns Hopkins Bloomberg School of Public Health where he also completed his PhD in Health Policy.

Megan Ehret, PharmD, MS, BCPP
Professor of Practice, Sciences, and Health Outcomes Research
Co-director, Mental Health Program
University if Maryland, Baltimore, School of Pharmacy

Dr. Ehret is a graduate of the University of Toledo where she completed her PharmD degree, and she went on to complete a Psychiatric Pharmacy Residency. She then completed a Psychopharmacology and Pharmacogenomics Fellowship at Nova Southeastern University. After training, she received her initial faculty appointment at the University of Connecticut and gained tenure during her stay there. Currently, her role is a Professor and Co-Director of the Mental Health Program at the University Of Maryland School Of Pharmacy. She has the privilege of working with the State of Maryland Medicaid in evaluating antipsychotic use. She is a Past-President of AAPP and is the current BCPP Recertification Director. Dr. Ehret has worked with the State of Maryland to establish regulations permitting community pharmacists the authority to administer maintenance injections. Dr. Ehret has publications and book chapters describing psychotropic medication adherence and the role of pharmacogenomics in medication selection.

Lisa Harding, MD
Assistant Clinical Professor, Department of Psychiatry
Yale University School of Medicine

Dr. Lisa Harding is a Board-Certified Psychiatrist and depression expert who is specially trained in providing all treatment types for depression. She completed her residency in Psychiatry as the Chief of Interventional Psychiatry at the Yale School of Medicine. She has completed over 4000 procedures in Electroconvulsive therapy (ECT), IV Ketamine, Spravato and Transcranial Magnetic Stimulation (TMS). She is also experienced in managing complex medication regimen and skilled in various psychotherapy methods. She is also very active in the American Psychiatric Association as a Foundation Ambassador and was once a Diversity Leadership Fellow as well as an American Academy of Psychiatry and the Law Rappeport Fellow, both of which are distinguished national fellowship awards offered to the top 1% of resident psychiatrists.

Boris Heifets, MD, PhD
Associate Professor, Department of Anesthesiology, Perioperative & Pain Medicine &
Department of Psychiatry & Behavioral Sciences
Stanford School of Medicine

Dr. Boris Heifets has an active neuroanesthesia practice, he directs both clinical and basic neuroscience research programs, bridging neuroscience, psychiatry and anesthesiology. His research is focused on deconstructing the neural mechanisms involved in an emerging class of rapid-acting psychiatric therapies, like ketamine, MDMA and psilocybin. His lab investigates these compounds' neuroplastic potential, and is working to develop therapeutics that are precise, safe, and scalable. He is an associate professor in the Department of Anesthesiology, Perioperative & Pain Medicine, and, by courtesy, in the Department of Psychiatry & Behavioral Sciences at the Stanford School of Medicine.

Eric Hermes, MD
National Director, Psychopharmacology and Somatic Treatments
VA's Office of Mental Health
Associate Professor, Department of Psychiatry
Yale University School of Medicine

Dr. Hermes is a psychiatrist and health services researcher who studies implementation and quality improvement in mental health.

Caroline Huang, PhD
Senior Science Policy Advisor, Center for Drug Evaluation and Research
Food and Drug Administration

Caroline J. Huang, PhD, is a Senior Science Policy Advisor in FDA's Controlled Substances Program, Controlled Substances Initiatives team (CSP/CSI), in the Center for Drug Evaluation and Research. In this role, she oversees stakeholder engagement and strategic collaborations and communications across drug classes, as well as coordinating FDA's controlled substances research portfolio. Prior to joining CSP/CSI in August 2020, Dr. Huang spent a year as a Staff Fellow in FDA's Office of Women's Health, where she covered issues related to COVID-19 and managed the team's social science portfolio. She also completed a Bioethics Fellowship with the NIH Clinical Center, where she researched chronic pain and opioid use disorders and served as a bioethics consultant. She holds an SB in Brain and Cognitive Sciences from the Massachusetts Institute of Technology and a PhD (DPhil) in Public Health from the University of Oxford, where she was a Rhodes Scholar.

Mikhail Kogan, MD
Associate Professor, Division of Geriatrics and Palliative Care
Medical Director, Center for Integrative Medicine
George Washington University

Dr. Kogan received his medical degree from Drexel University, College of Medicine. He completed Social Internal Medicine Resident program at Montefiore, Albert Einstein School of Medicine and Geriatric Fellowship at George Washington University. Currently he serves as medical director of the GW Center for Integrative Medicine, associate professor of medicine in division of Geriatrics and Palliative Care, associate director of the Geriatrics Fellowship Program and co-host of GW Integrative Medicine Podcast. Dr. Kogan is founder and board member of AIM Health Institute, a 501(c)(3) non-profit organization in the Washington, D.C. metropolitan area that provides integrative medicine services to low-income and terminally ill patients regardless of their ability to pay.

Michelle Leff, MD, MBA
Senior Medical Advisor/Acting Deputy Director
Center for Substance Abuse Prevention
Substance Abuse and Mental Health Services

Dr. Michelle Kim Leff, CAPT, is a Senior Medical Advisor in the Center for Mental Health Services (CMHS/SAMHSA). Previously, she served as the Acting Deputy Director and Senior Medical Advisor in the Center for Substance Abuse Prevention (CSAP/SAMHSA). Her CMHS portfolio includes mental health promotion, child and family services for Certified Community Behavioral Health Clinics (CCBHCs), and emerging therapeutics in behavioral health. She is passionate about child, adolescent, and young adult behavioral health with a particular interest in mental health promotion and substance use prevention. She also has a strong interest in operations management and organizational health. She has worked in a variety of community, clinical, and research settings and served 30 years as Medical Officer in the US Army and US Public Health Service. Board-certified in both general psychiatry and child/adolescent psychiatry, CAPT Leff received her A.B. (bachelors degree) from Harvard University, her medical degree from New York University School of Medicine, and her master's in business administration from The Wharton School, University of Pennsylvania. She was a recipient of the Health Professionals Scholarship Program; and completed her internship, residency, and fellowship training at US Army Medical Centers (Brooke Army Medical Center and Walter Reed Army Medical Center). During her nine years as an active-duty Medical Corps Officer, she supervised inpatient psychiatry units, outpatient psychiatry clinics, an overseas alcohol treatment facility, and consulted with the Department of Defense Dependents Schools – serving military members and their family members.

Seth Mailhot. JD
Partner
Husch Blackwell

Seth Mailhot is a Partner and lead of the FDA Regulatory Practice Group in Husch Blackwell's Washington D.C. office. His 14 years working in the FDA has provided him a unique perspective when counseling clients on a broad range of matters involving the FDA. Seth's practice includes representation of the medical device, pharmaceutical, dietary supplement, tobacco and food industries, and covers both premarket and post-market issues. His practice is focused on development of premarket submission strategies, and FDA enforcement of good manufacturing practices, both domestically and abroad.

Brittany O'Brien, PhD
Associate Professor, Menninger Department of Psychiatry and Behavioral Sciences
Baylor College of Medicine

Dr. Brittany O'Brien is an Associate Professor at Baylor College of Medicine (BCM) in the Menninger Department of Psychiatry & Behavioral Sciences. She completed post-doctoral training with the department in the Mood and Anxiety Disorders Program at BCM studying pharmacological treatments for patients with chronic and treatment resistant mental illness. Her research investigates the efficacy and effectiveness of ketamine, psilocybin, and other glutamatergic modulators and she has served as coinvestigator on several small proof of concept RCTs, 2 multi-site PCORI funded effectiveness trials, as well as state, industry and foundation supported clinical research studies. She presents nationally and internationally on real world outcomes of patients receiving intravenous (IV) ketamine in community settings. In her clinical work with patients, she aims to deliver and expand access to evidence-based psychotherapy for patients with chronic, treatment resistant mood and trauma-related disorders in community based, outpatient settings. She is also actively involved in education and training, overseeing the Mood and Trauma Related Disorders pre-doctoral psychology internship training program at the Baylor Psychiatry Clinic.

Joseph Palamar, PhD, MPH
Associate Professor, Department of Population Health
NYU Langone Health

Dr. Joseph Palamar is an Associate Professor of Population Health at NYU Langone Health and Deputy Director of the National Drug Early Warning System (NDEWS). He has authored over 200 papers focusing on the epidemiology of drug use with a particular focus on new psychoactive substances and on "club drugs" such as ketamine. He has authored dozens of papers focused on ketamine with a particular focus on trends in recreational use, poisonings involving ketamine, and law enforcement seizures of ketamine. He has received funding for four research grants from the National Institute on Drug Abuse including a new grant that funds him to investigate the rapidly changing ketamine landscape in the United States.

Sandhya Prashad, MD
Founder and President
American Society of Ketamine Physicians, Psychotherapists, and Practitioners Clinical Assistant Professor, Department of Psychiatry and Behavioral Sciences
Baylor College of Medicine

Dr. Sandhya Prashad is a board-certified psychiatrist specializing in interventional modalities for treatment resistant disorders with a particular interest and expertise in ketamine therapy. She completed both medical school and psychiatry residency at Baylor College of Medicine. She has been in private practice in the Houston area since 2011 and has been utilizing intravenous ketamine since 2016. In addition to treatment with ketamine and esketamine, Dr. Prashad also offers deep TMS and ketamine assisted psychotherapy in her practice. Dr. Prashad has also been appointed as a clinical assistant professor at Baylor College of Medicine in the Menninger Department of Psychiatry and Behavioral Sciences. Dr. Prashad is involved on an international level with furthering awareness and education regarding the safe and effective use of ketamine. She is a founder and the current president of the American Society of Ketamine Physicians, Psychotherapists and Practitioners (ASKP3, www.ASKP.org) Dr. Prashad presents frequently on a national level both to the public and to other physicians regarding the use of ketamine for psychiatric disorders. She also serves on several advisory panels for ketamine related research and her private practice is a site for a PCORI funded trial comparing IV ketamine to intranasal Spravato.

Jessica Poole, DNAP, CRNA
Trustee and Director of State Government Affairs
Pennsylvania Association of Nurse Anesthetists

Dr. Jessica Poole graduated from the Excela Health School of Anesthesia Program, an affiliate of Saint Vincent College in Latrobe, Pennsylvania. After practicing for several years, she was awarded a Doctorate in Nurse Anesthesia Practice from La Roche University in 2017. She has years of healthcare leadership experience and has practiced in multiple settings including, hospitals, ambulatory surgery centers and office settings. She has held different leadership positions at the state and national level. Dr. Poole has previously served as a committee member on the National Board of Certification and Recertification for Nurse Anesthetists, a Trustee and Director of State Government Affairs on the Pennsylvania Association of Nurse Anesthetists, Chair of the Practice Committee for the American Association of Nurse Anesthetists and a member of the State Organizational Developmental Committee. She also served on the Pennsylvania Department of Health task force that promulgated guidelines to ensure safety surrounding subanesthetic administration of Ketamine.

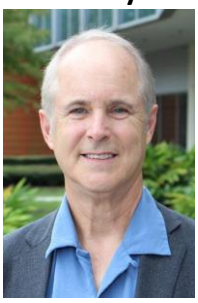
Richard Quaresima
Assistant Director, Division of Advertising Practices
Federal Trade Commission

Rick Quaresima has been an Assistant Director for the FTC's Division of Advertising Practices since 2005, concentrating on supervising enforcement actions involving deceptive health claims. Prior to becoming Assistant Director, he was counsel to two Directors of the FTC's Bureau of Consumer Protection, and the agency's inaugural Criminal Liaison Unit Chief.

Lisa Robin
Chief Advisory Officer
Federation of State Medical Boards

Lisa Robin is Chief Advocacy Officer at the Federation of State Medical Boards (FSMB). She currently leads the FSMB Washington, DC office. Ms. Robin earned her bachelors and masters degrees from Texas Christian University. During her tenure with the FSMB, Ms. Robin has been active in policy development and promulgation on issues pertinent to medical regulation, with a special focus on telemedicine and license portability and regulatory structure and function. In addition to policy development, Ms. Robin, as an executive member of the C-Suite, is involved with the overall administration of the FSMB and is directly responsible for FSMB's state and federal government affairs and policy, communications/public affairs and the FSMB Research and Education Foundation.

Mark Rogge, PhD, FCP
Adjunct Professor, Center for Pharmacometrics and Systems Pharmacology
University of Florida



Dr. Rogge serves as a lecturer and discussion leader for the Model-Informed Drug Development program, is a co-mentor for students, and serves as Chair for the Dean's Regulatory Science Working Group. He also serves as a Senior Vice President of Translational Science and Early Development for Atlas Ventures company advancement. He is an active member of the American College of Clinical Pharmacology where he serves as a Regent and leads the Public Policy Committee. Prior to joining the UF faculty, he worked at Takeda Pharmaceuticals as Global Head and Vice President of Quantitative Translational Science. There, he served on the research senior leadership team, on portfolio joint steering committees, and the scientific advisory board for the Tri-Institutional Therapeutics Discovery Institute. His undergraduate work was completed at the University of Wisconsin (Pharmacy). He later received his M.S. and Ph.D. from the University of Michigan (Pharmaceutics). He is the author of more than 50 peer-reviewed publications, the Co-Editor of Preclinical Drug Development, a member of FDA's Pharmaceutical Science and Clinical Pharmacology Advisory Committee, and several Scientific Advisory and Drug Safety Monitoring Boards.

Gerard Sanacora, MD
Associate Professor, Department of Psychiatry
Yale University

Dr. Sanacora is the George and Ester Gross Professor of Psychiatry, Director of the Yale Depression Research Program, and Co-Director of Yale's Interventional Psychiatry Program. Dr. Sanacora's work employs both preclinical and clinical research methodologies in attempts to expand our understanding of the underlying pathophysiology of neuropsychiatric disorders and mechanisms of effective treatment actions, with the goal of ultimately developing novel diagnostic and treatment approaches. He has served as PI on numerous NIH, foundation, and industry sponsored studies ranging from rodent models of pathogenesis, through mechanistic neuroimaging studies introducing novel methods to assess brain metabolism, to large multicenter phase III clinical trials. His personal experience over the arc of this journey has provided him with unique perspectives on the challenges that impede the successful application of neuroscience advances to clinical practice. Most recently, Dr. Sanacora has focused on fostering responsible dissemination efforts, providing leadership to consensus statements and national educational efforts relating to the clinical utility and concerns associated with these novel therapeutic options. In recognition of these efforts, he recently received the 2022 Association for Clinical and Translational Sciences award for Team Science in addition to previous awards including the Anna-Monkia Stiftung international award for investigation of the biological substrate and functional disturbances of depression, the Joel Elkes Research Award for Outstanding contributions to Psychopharmacology from the American College of Neuro-pychopharmacology.

Eric Schwenk, MD, FASA
Professor, Anesthesiology and Orthopedic Surgery
Thomas Jefferson University

Dr. Schwenk is a fellowship-trained regional anesthesiologist and director of the acute pain management service at Thomas Jefferson University Hospital in Philly. He is a professor of anesthesiology and perioperative medicine and orthopedic surgery at the Sidney Kimmel Medical College at Thomas Jefferson University. His clinical interests include offering opioid alternatives for perioperative analgesia and improving outcomes after orthopedic surgery. He is an expert in the use of ketamine infusions for acute pain. His research interests include the efficacy and mechanisms of ketamine in refractory headache, adverse effects of ketamine, persistent post-surgical pain, and ambulatory total joint replacement. He is an active member of several committees within the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine and a member of the editorial board for Regional Anesthesia and Pain Medicine. He is a North Carolina Tar Heel and fan of all Philly sports.

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.

Jenni Wai, RPh, MBA
Chief Pharmacist
Ohio Board of Pharmacy

Jenni Wai is a distinguished pharmacist, regulatory expert, and Chief Pharmacist at the Ohio Board of Pharmacy, where she plays a pivotal role in ensuring the safety, integrity, and accessibility of pharmaceutical care across the state. With a career dedicated to upholding the highest standards of pharmacy practice and healthcare, Jenni is a trusted authority in regulatory affairs and a catalyst for positive change within the profession. In her role as Chief Pharmacist at the Ohio Board of Pharmacy, Jenni leads a team of dedicated professionals responsible for overseeing pharmacy licensure, compliance, and enforcement activities. With a keen understanding of state and federal regulations governing pharmacy practice and drug distribution, she works tirelessly to safeguard public health and promote best practices within the profession. Jenni's career spans both the public and private sectors, with experience in community, hospital, and consulting pharmacy. Her diverse background provides her with a comprehensive understanding of the challenges and opportunities facing pharmacists in today's complex healthcare landscape. As a speaker, Jenni brings a wealth of knowledge, experience, and expertise to her presentations, making her a sought-after voice in the field of pharmacy regulation. Her talks are characterized by their clarity, relevance, and practical insights, offering

attendees valuable guidance on navigating the ever-changing regulatory environment. Jenni earned her Bachelor of Science in Pharmacy (BSP) degree from Ohio Northern University before obtaining her Master of Business Administration (MBA) with a focus on healthcare management.

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 Food and Drug Administration. 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 is an APhA Fellow, an elected member and Chair of the United States Pharmacopeial Convention (USP) Board of Trustees (2015-2020, 2020-2025), a member of the Purgo Scientific, LLC board, and a member of the Virginia Commonwealth University School of Pharmacy National Advisory Council.