REAGAN-UDALL FOUNDATION for the Food and Drug Administration

A Practical Research Agenda for Treatment Development for Stimulant Use Disorder

Virtual Public Workshop

Speaker Bios

Session 1: Efforts to Promote Treatment Development for Stimulant Use Disorder

Janet Woodcock, MD
Acting Commissioner, U.S. Food and Drug Administration (FDA)

Dr. Janet Woodcock began her long and distinguished FDA career in 1986 with the agency's Center for Biologics Evaluation and Research (CBER) as Director of the Division of Biological Investigational New Drugs. She also served as CBER's Acting Deputy Director, and later as Director of the Office of Therapeutics Research and Review. In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), overseeing the center's work that is the world's gold standard for drug approval and safety. In that position, she has led many of the FDA's groundbreaking drug initiatives. She has also served in other leadership roles at the FDA, including as Deputy Commissioner and Chief Medical Officer. With the onset of the COVID-19 public health emergency last year, Dr. Woodcock was asked to lend her expertise to "Operation Warp Speed" the initiative to develop therapeutics in response to the pandemic. Dr. Woodcock was named Acting Commissioner of Food and Drugs on January 20, 2021. Dr. Woodcock has received numerous honors during her distinguished public health career, including: a Lifetime Achievement Award in 2015 from the Institute for Safe Medication Practices; the Ellen V. Sigal Advocacy Leadership Award in 2016 from Friends of Cancer Research; the Florence Kelley Consumer Leadership Award in 2017 from the National Consumers League; the 2019 Biotechnology Heritage Award from the Biotechnology Innovation Organization and Science History Institute; and the 2020 Lifetime Achievement Award from NORD. She is also an avid and accomplished gardener.

Nora D. Volkow, MD
Director, National Institute on Drug Abuse

Dr. Nora Volkow is the Director of the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health, which supports most of the world's research on the health aspects of drug use and addiction. Dr. Volkow's scientific research was instrumental in demonstrating that drug addiction is a disease of the human brain and, as NIDA Director, her work has promoted research that improves the prevention and treatment of substance use disorders. As a research psychiatrist, Dr. Volkow pioneered the use of brain imaging to investigate the effects of addictive drugs. Her studies documented disruption of the dopamine system in addiction with its consequential functional impairment of frontal brain regions involved with motivation, executive function and self-regulation. She has also made important contributions to the neurobiology of obesity and ADHD, and has published more than 830 peer-reviewed articles, written more than 100 book chapters and non-peer-reviewed manuscripts, co-edited a Neuroscience Encyclopedia and edited four books on neuroimaging for mental and addictive disorders.

Session 2: Optimizing Clinical Trial Design for Stimulant Use Disorder

PRESENTERS

David McCann, PhD

Associate Director, Division of Therapeutics and Medical Consequences, National Institute on Drug Abuse

Dr. David McCann is Associate Director of the Division of Therapeutics and Medical Consequences within the National Institute on Drug Abuse (NIDA). He received a B.S. in Pharmacy (1981) from the Albany College of Pharmacy and his Ph.D. (1988) from the Department of Pharmacology and Experimental Therapeutics at the State University of New York at Buffalo. His postdoctoral research was conducted as a Staff Fellow/Sr. Staff Fellow at the NIDA Intramural Research Program in Baltimore, MD. In 1992, he joined the NIDA Extramural Program, where his hands-on experience in both behavioral and receptor pharmacology helped to shape NIDA's preclinical medications discovery program. He has served as Chief of the Medications Discovery and Toxicology Branch, as Acting Division Director, and as Acting Chief of the Clinical/Medical Branch. In his current position, his primary responsibility is to facilitate the discovery and development of medications to treat substance use disorders through oversight of the Division's contract program and by establishing NIDA/private sector collaborations. He has served as a consultant to the U.S. Food & Drug Administration and the World Health Organization for domestic and international drug scheduling and has served the U.S. Department of State as a technical expert during meetings of the United Nations Commission on Narcotic Drugs.

Madhukar Trivedi, MD

Founding Director, Center for Depression Research and Clinical Care, University of Texas Southwestern Medical Center

Dr. Madhukar Trivedi is a Professor of Psychiatry, Chief of the Division of Mood Disorders, and founding Director of the Center for Depression Research and Clinical Care at UT Southwestern Medical Center, where he holds the Betty Ho Hay Distinguished Chair in Mental Health and the Julie K. Hersh Chair for Depression Research and Clinical Care. Certified by the American Board of Psychiatry and Neurology, Dr. Trivedi focuses on developing and validating biosignatures of depression. He also conducts research on pharmacological, psychosocial, and nonpharmacological treatments for depression. He has been a principal investigator on numerous translational research projects and clinical trials. He serves on the editorial board of CNS Spectrums, Clinical Medicine: Psychiatry, Journal of Clinical Psychiatry, Journal of Affective Disorders, Psychiatric Annals and Asian Journal of Psychiatry. Dr. Trivedi currently serves as Deputy Editor of the American Journal of Psychiatry and as president of the American Society of Clinical Psychopharmacology (ASCP). He is a member of numerous other organizations, including the American College of Neuropsychopharmacology, American College of Psychiatrists, American Medical Association, American Psychiatric Association, Dallas County Medical Society, Society of Biological Psychiatry, Texas Medical Association, and the Texas Society of Psychiatric Physicians. Named a Texas

Monthly Super Doctor multiple times, he has received numerous accolades, including the Gerald L. Klerman Award from the National Depressive and Manic-Depressive Association Scientific Advisory Board, the Psychiatric Excellence Award from the Texas Society of Psychiatric Physicians, the Gerald Klerman Senior Investigator Award, the American Psychiatric Association Award for Research, and the Mood Disorders Research Award from the American College of Psychiatrists. Dr. Trivedi was listed by Thomson Reuters' World's Most Influential Scientific Minds as one of the nation's most highly cited researchers in psychiatry every year since 2014.

PANELISTS

Maryam Afshar, MD
Senior Medical Officer, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Photo Not Available

Dr. Maryam Afshar is a Senior Medical Officer in the Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP) in Office of Neuroscience (ON), Office of New Drug (OND), Center for Drug Evaluation and Research (CDER) at FDA. Prior to joining FDA in 2016, she had conducted many clinical research studies in major psychiatric disorders and substance use disorders, in particular, stimulant use and alcohol use disorder. She has practiced as a psychiatrist for 20+ years and held faculty appointments at University of Toronto, Boston University and University of Texas.

Sarah Akerman, MD
Executive Medical Director, Medical Affairs, Alkermes

Dr. Sarah Akerman is a psychiatrist and executive medical director in medical affairs at Alkermes. In this role, she oversees the medical strategy for the neuroscience pipeline and psychiatry franchise, which includes treatments for substance use disorders, schizophrenia, and bipolar disorder. She received a Bachelor of Arts from Tufts University and a Doctor of Medicine from the University of Miami Miller School of Medicine where she was a member of the Alpha Omega Alpha Honor Medical Society. She completed a psychiatry residency, served as chief resident and completed addiction clinical and research fellowships at the Dartmouth Geisel School of Medicine. Following fellowship, she served an assistant professor of psychiatry at Dartmouth, established a treatment program for pregnant women with substance use disorders, and received a Dartmouth SYNERGY Scholars research award. Dr. Akerman is a diplomate of the American Board of Psychiatry and Neurology and is board certified in both general and addiction psychiatry.

Jessica Hulsey
Founder and CEO, Addiction Policy Forum

Jessica Hulsey is founder and CEO of the Addiction Policy Forum, a national nonprofit organization dedicated to elevating awareness around substance use disorders and helping patients and families in crisis. APF works to end the stigma surrounding addiction while translating science and providing services in all 50 states. Ms. Hulsey has more than 25 years' experience in the field of prevention, treatment, and policy solutions to address substance use disorders. She serves on the National Advisory Council on Drug Abuse and is a Board Member for the federal DEA Educational Foundation (Drug Enforcement Administration, US Department of Justice). She lives in Maryland and is mom to three beautiful boys -- Conner, Jack and Tyler.

Frances R. Levin, MD
Kennedy-Leavy Professor of Psychiatry, Columbia University

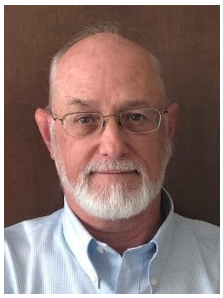
Dr. Frances Rudnick Levin is the Kennedy-Leavy Professor of Psychiatry at Columbia University and the Chief of the Division on Substance Use Disorders at NYSPI/CUIMC. Dr. Levin, working with Columbia University faculty, inaugurated the university-wide Center for Healing of Opioid and Other Substance Use Disorders: Enhancing Intervention Development and Implementation (CHOSEN) in 2020 and serves as one of the senior Directors. She is the Principal Investigator several NIH grants including a long-standing T32 Substance Abuse Research Fellowship. Her current research interests include pharmacologic interventions for opioid, cocaine and marijuana use disorders, and treatments targeting adults with substance use disorders and attention-deficit hyperactivity disorder (ADHD). She is a past President of the American Academy of Addiction Psychiatry and past Chair of the APA Council on Addiction Psychiatry.

Maria Sullivan, MD, PhD
Vice President, Clinical Development, Pear Therapeutics

Dr. Maria Sullivan serves as Vice President, Clinical Development at Pear, leading the Translational, Clinical, and Clinical Operations teams. She previously served as the Addiction Franchise Lead at Alkermes, where for 6 years she led a clinical research team conducting late-stage trials focused on initiation of opioid antagonist treatment, and also served as Executive Medical Director, Medical Affairs. Throughout her clinical research career, she has explored the efficacy of potential new therapeutics to improve care for patients suffering from addiction. Dr. Sullivan was an independent NIDA-funded Principal Investigator for 20 years at Columbia University and the New York State Psychiatric Institute, receiving continuous funding to carry out clinical studies focused on developing novel pharmacotherapies and behavioral treatments for opioid dependence and nicotine dependence. She was a member of the board of directors of the American Academy of Addiction Psychiatry and Chair, Clinical Expert Committee, for the SAMHSA-sponsored Prescribers' Clinical Support System (PCSS). She continues to serve on the voluntary faculty at Columbia University as Associate Professor of Clinical Psychiatry in the Division of Substance Use, Department of Psychiatry. She is also a board-

certified and practicing Addiction Psychiatrist. Dr. Sullivan is the author of more than 100 peer-reviewed articles and book chapters and Co-Editor, Addiction in the Older Patient (Oxford University Press, 2016). She completed her education and training at Harvard, the University of Chicago, George Washington Medical School, and Columbia University.

Robert Walsh
Chief, Regulatory Affairs Branch, Division of Therapeutics and Medical Consequences, National Institute on Drug Abuse



Mr. Walsh joined NIDA in 1987 where he ran the NIDA Drug Supply Program. Before that, he was a Forensic Chemist for the Pennsylvania State Police Crime Lab outside of Philadelphia, PA. In 1988 he became one of the founding members of the Medications Development Division, now called the Division of Pharmacotherapeutics and Medical Consequences. In his role as Chief of the Regulatory Affairs Branch, he manages and directs the overall activities of the Branch, including Investigational New Drug (IND) Applications and Drug Master File (DMF) submissions. He is responsible for ensuring that all clinical trials are performed in compliance with all applicable regulatory requirements. He provides guidance to NIDA investigators and development partners on regulatory issues and consults on clinical support contracts, importation of compounds from foreign sources, and Drug Enforcement Administration registration of contract testing facilities. He served as the NIDA Project Manager for the development of LAAM. He also served as the NIDA Project Director for the development of Subutex (buprenorphine), and as Study Director for the NIDA/VACSP study of office-based buprenorphine treatment. He has served as Project Director for the development of other potential drug abuse treatment agents. Mr. Walsh is a division liaison to the Food and Drug Administration, Drug Enforcement Administration, and other governmental regulatory agencies. He provides Project Management consultation to division staff and collaborators. Mr. Walsh has a total of 34 years of experience at NIDA - three years in NIDA's Division of Preclinical Research prior to the establishment of DTMC in 1989.

Session 3: Identifying Clinically Meaningful and Patient-Centric Endpoints

PRESENTERS

Brian Kiluk, PhD

Associate Professor of Psychiatry, Yale School of Medicine

Dr. Brian Kiluk is Associate Professor of Psychiatry at Yale School of Medicine where he directs a program of research that includes the development and evaluation of alternatives to abstinence as endpoints for substance use disorder clinical trials. He is Principal Investigator of multiple NIH-funded research grants through the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism, and his work has been widely published and featured at national scientific meetings. Dr. Kiluk has led several publications using data from previously completed clinical trials that support functional outcomes including DSM diagnostic criteria as a meaningful indicator of treatment outcome, and he has an active NIDA-funded project to develop and validate a patient-reported measure of disorder severity.

PANELISTS

Deborah Hasin, PhD

Professor of Epidemiology, Columbia University

Dr. Deborah Hasin is Professor of Epidemiology at Columbia University in the Vagelos College of Physicians and Surgeons, Department of Psychiatry, and in the Mailman School of Public Health, Department of Epidemiology. She is also a Research Scientist with the New York State Psychiatric Institute. Dr. Hasin's research has covered general population and clinical studies of substance use and substance use disorders, including alcohol and cannabis, and on the comorbidity associated with these conditions. She has also conducted extensive research on the reliability and validity of measures of alcohol and drug use disorders; these had a substantial impact on the definitions of these disorders found in DSM-5. Dr. Hasin's research has been supported by multiple grants from the National Institute on Drug Abuse Health (NIDA) and the National Institute of Alcohol Abuse and Alcoholism (NIAAA) totaling over $50 million in research funding since 1990. To date, she has authored over 500 peer-reviewed publications and book chapters, and she has made over 150 presentations and invited talks since 2000. Dr. Hasin was a member of the Substance Use Disorders (SUD) Workgroup for DSM-5 (2008 to 2013) and was lead author of the 2013 paper in the American Journal of Psychiatry presenting the decisions of the DSM-5 SUD workgroup and the evidence underlying these decisions. She also recently served as Text Editor for the revised Substance Use Disorders chapter of DSM-5 (DSM-5-TR) (TR=Text Revision). She has been the principal investigator and director of the NIDA-funded pre- and post-doctoral training program in substance use epidemiology at Columbia since the inception of this training program in 2012. Many of Dr. Hasin's mentees gone on to successful careers of their own, wining many awards from scientific organizations, receiving NIH and other funding, and serving as faculty at numerous universities.

Ivan Montoya, MD, MPH
Acting Director, Division of Therapeutics and Medical Consequences, National Institute on Drug Abuse

Dr. Ivan Montoya is the Acting Director of the Division of Therapeutics and Medical Consequences (DTMC) of the National Institute on Drug Abuse (NIDA) and Chair of the National Institutes of Health (NIH) HEAL Initiative in Medications Development for Opioid Use Disorders Program. He leads a large program of research that supports the development of pharmacological and non-pharmacological treatments for Substance Use Disorders (SUDs). He is a psychiatrist and has a Master's in Public Health (M.P.H.) degree from Johns Hopkins University. He completed a Post-Doctoral Fellowship at the Intramural Research Program of NIDA and was the Director of the Practice Research Network of the American Psychiatric Association. He has published extensively in the areas of etiology, prevention, treatment (pharmacological and non-pharmacological), and medical consequences of SUDs. He is the editor of a book summarizing the science on biologics (vaccines, monoclonal antibodies, and enzymes) to treat SUDs and another book focusing on the science of Cannabis Use Disorders. He has received numerous awards including the NIH Director's Award and the Michael Morrison Award from the College on Problems of Drug Dependence (CPDD).

Michelle Peavy, PhD
Research Scientist, University of Washington

Dr. Michelle Peavy is a licensed clinical psychologist, Master Addiction Counselor, and holds the Washington State credential as a Substance Use Disorder Treatment Professional. She currently holds a position as a Research Scientist at the University of Washington's Addictions, Drug & Alcohol Institute. Prior to this, she spent 10 years on the frontlines of the opioid epidemic at an Opioid Treatment Program, where she undertook clinical, supervisory, and administrative roles, as well as directing implementation of new clinical programming and managing research projects.

David S. Reasner, PhD
Division Director, Division of Clinical Outcome Assessment, U.S. Food and Drug Administration

Dr. David S. Reasner is the Division Director, Division of Clinical Outcome Assessment, at FDA within the U.S. Department of Health and Human Services. The Division of Clinical Outcome Assessment (DCOA) comprises multidisciplinary measurement experts and is located in the Office of Drug Evaluation Sciences (ODES) - Office of New Drugs (OND), in FDA's Center for Drug Evaluation and Research (CDER). DCOA integrates the patient voice into drug development through COA endpoints that are meaningful to patients, valid, reliable, and responsive to treatment. He earned his undergraduate Psychology degree from Duke University and went on to complete a Ph.D. in Biopsychology at Cornell University as well as post-doctoral training in Neuroscience at the Worcester Foundation for Experimental Biology.

Philip Rutherford
Faces and Voices of Recovery

Philip Rutherford is the Chief Operating Officer at Faces & Voices of Recovery. He is a recovery coach, a passionate member of the Recovery Community and possesses a self-described Doctorate from the school of Hard Knocks. As COO, he is responsible for multiple lines of business within the Faces & Voices ecosystem. Phil is credited with a significant role in conception, design, launch and facilitation of the Recovery Data Platform (RDP). This cloud-based platform is the first of its kind and has quickly become a valuable asset in longitudinal data collection for Peer-Based Services. Phil has a BA in Psychology with a specialization in Substance Use Disorders. Phil's prior experience as Director at a Recovery Community Organization offered front-row seat into the world of Peer Based Recovery Supports. Prior to that, he spent most of his career in corporate sales, marketing, and management at Microsoft, Micron Electronics, and companies within the Taylor Corporation. Phil is an active member of the Recovery community and has considerable experience in the areas of Substance Use Disorders, Recovery, Reentry, and Cultural Competency.

Celia Winchell, MD
Associate Director for Therapeutic Review, Addiction Medicine, in the Division of Anesthesiology, Addiction Medicine, and Pain Medicine, U.S. Food and Drug Administration

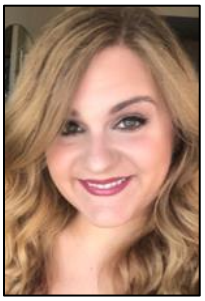
Photo Not Available

Celia Winchell is the Associate Director for Therapeutic Review, Addiction Medicine, in the Division of Anesthesiology, Addiction Medicine, and Pain Medicine in FDA's Center for Drug Evaluation and Research. Dr. Winchell holds a Bachelor's degree in Psychology and Social Relations from Harvard University, and a Medical degree from the University of Virginia. She completed residency in Psychiatry at Johns Hopkins Hospital. Since 1995, she has served as a reviewer at FDA, with regulatory responsibility for commercial development programs and academic research investigations involving medications to treat addictive disorders.

Session 4: Future Directions for Stimulant Use Disorder Research

PANELISTS

Nicole Caffiero, PharmD, BCACP
Clinical Program Senior Advisor, Cigna



Dr. Nicole Caffiero earned her Doctor of Pharmacy in 2014 followed by a PGY1 Community Practice Residency at the University of Utah and a PGY2 in Ambulatory Care at Kaiser Permanente Colorado (KPCO). She then gained board certification and joined Kaiser Permanente of the Mid-Atlantic States (KPMAS) where she practiced as a Clinical Pharmacy Specialist in Primary Care actively managing a panel of patients with chronic diseases. She also became an integral part of implementing a utilization management program that leverages technology to proactively evaluate, strategize, and plan for optimal use of selected pipeline specialty drugs. Her final role at KPMAS was a Project Manager in Drug Use Management which included serving as P&T Formulary Co-Chair, analyzing prescribing and financial trends and in turn implementing action plans, programs and initiatives to help the pharmacy department reach its goals. In March 2021, she joined Cigna as a Clinical Program Senior Advisor where she designs clinical programs as part of the pharmacy clinical development team to improve outcomes of Cigna customer lives and in turn decrease the total cost of care. In this role, She has focused on programs to improve safety in customers with opioid use disorder and increase access to medication-assisted treatment which led her to be a part of AMCP's Substance Use Disorder Workgroup. Dr. Caffiero's areas of expertise include chronic disease state management, managed care pharmacy and her publications include analyzing pharmacy programs. Outside of pharmacy, she loves traveling and spending time outdoors with her dog.

Brandee Izquierdo, MPA
Executive Director, SAFE Project

Brandee Izquierdo is the Executive Director of SAFE Project. Her drive and determination are built on making an impact within behavioral health, promoting long-term recovery, and ensuring communities are educated and have the tools necessary to combat the addiction epidemic. Before leading the SAFE Project team, she worked for Faces & Voices of Recovery as the Director of Advocacy and Outreach. In addition, she served as the Associate Director of Special Populations with Behavioral Health System Baltimore and as the Director of Consumer Affairs for the state of Maryland's Behavioral Health Administration. In these leadership roles, she has led advocacy efforts to expand access to behavioral health services while providing technical assistance both nationally and internationally. Izquierdo's knowledge and passion for service work extend beyond behavioral health. With a Master's degree in Public Administration, She is a Doctoral Candidate in Public Administration with a focus on Organizational Change Management.

Denise Leclair, MD
Clinical Development Head, Global Health, Non-communicable diseases, Novartis

Dr. Denise Leclair is the CD for Non-Communicable Diseases, working in the Global Health therapeutic area at Novartis. She has extensive drug development experience, especially in patient safety, working in different therapeutic areas, including psychiatry, neuroscience, ophthalmology and recently in addiction medicine. Dr. Leclair graduated from Duke Medical School, with a Residency from Georgetown University in Family Medicine, and a Fellowship in Medical Editing. She currently leading a team exploring adaptive development in transplant medicine as well as cardiovascular and neuroscience.

F. Gerald Moeller, MD
Division Chair of Addictions, Department of Psychiatry, Virginia Commonwealth University

Dr. F. Gerard Moeller received his MD from the University of Texas Health Science Center in Houston and attended the University of Texas Health Science Center at San Antonio for his internship and residency in psychiatry. He also completed a fellowship in clinical psychopharmacology research at the University of California in San Diego. Currently Dr. Moeller is Professor and Division Chair of Addictions in the Department of Psychiatry. He also holds appointments in the departments of Pharmacology and Toxicology and Neurology. He is Director of the VCU Institute for Drug and Alcohol Studies, Director of the VCU C. Kenneth and Dianne Wright Center for Clinical and Translational Research, PI of the VCU CTSA award, and Associate Vice President for Clinical Research at VCU.

Pamela D. Scott, MS
Assistant Director for the Neuromodulation Psychiatry Team, U.S. Food and Drug Administration

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Ms. Pamela Scott has been with FDA for 31 years and currently serves as the Assistant Director for the Neuromodulation Psychiatry Team. She currently leads a team of 11 people in handling pre-market, post-market, and quality system activities for neuromodulation devices indicated primarily for psychiatric and neurodevelopmental disorders. She began her career as Scientific Reviewer in ODE's Dental Devices Branch where she served for 12 years as a Lead Reviewer and in the dual role for 5 years as the Designated Federal Officer for the Dental Products Panel. She also served for 5 years as a Compliance Officer focused on quality systems and enforcement of the medical device laws and regulations. Ms. Scott also served for 8 years as a Senior Science Health Advisor in the Office of the Center Director at the Center for Devices and Radiological Health (CDRH) in FDA. As a Senior Science Health Advisor she coordinated and managed public health issues for a wide range of medical devices, including collaboration between premarket, post market, compliance, and scientific activities. In this position Ms. Scott lead CDRH efforts in addressing issues related to reprocessing of reusable medical devices from 2009 through 2016 and reducing the risk of tubing misconnections since 2010. Ms. Scott is a Biomedical Engineer and with a Bachelor's of Science from Brown University and a Master's of Science from The Catholic University of America.

Marta Sokolowska, PhD
Associate Director for Controlled Substances, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Dr. Marta Sokolowska is the Associate Director for Controlled Substances in FDA's Center for Drug Evaluation and Research (CDER). In this position, she oversees 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.

Nora D. Volkow, MD
Director, National Institute on Drug Abuse
(See Session 1)

Moderators

Carla Rodriguez-Watson, PhD
Director of Research, Reagan-Udall Foundation for the FDA

Dr. Carla Rodriguez-Watson is the Director of Research and oversees the Innovation in Medical Evidence Development and Surveillance (IMEDS) program at the Reagan-Udall Foundation for the FDA. A transformational public-private partnership, IMEDS mobilizes data providers, drug manufacturers, researchers, and the FDA to accelerate research and answer critical patient safety and public health questions. Dr. Rodriguez-Watson brings to the Foundation 25 years of experience in public health research in local, national, and international settings. An epidemiologist, Dr. Rodriguez-Watson's research focus is in the use of real-world, big-data for public health surveillance and the epidemiology of viral hepatitis and HIV, influenza, substance abuse, liver and kidney disease. Her methodological areas of focus include the development and evaluation of surveillance systems, comparative effectiveness, multi-level modeling, predictive modeling, and test accuracy. Dr. Rodriguez-Watson earned her PhD in Epidemiology from the University of Washington School of Public Health, her MPH from Columbia University Mailman School of Public Health, and her BA from Rutgers University. She is currently associate faculty in the Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health.

Susan C. Winckler, RPh, Esq.
CEO, Reagan-Udall Foundation for the FDA

Susan C. Winckler, is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, she 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. Winckler directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters. As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), she 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 in a series of positions of increasing responsibility.