REAGAN-UDALL FOUNDATION FOR THE FDA

Advancing Treatments for Post-Traumatic Stress Disorder

Hybrid Public Meeting
September 6, 2024; 1-3:30PM (eastern time)

Speakers & Panelists

Bernard A. Fischer, MD
U.S. Food and Drug Administration, HHS

Dr. Fischer is a psychiatrist and the Deputy Director of the Division of Psychiatry in the Office of New Drugs at the U.S. Food and Drug Administration (FDA). He is involved in the regulatory oversight of all psychiatric drug development activities conducted under investigational new drug applications (INDs) and the review of all new drug applications (NDAs) for marketing a psychiatric drug in the United States. Prior to the FDA, he spent more than 10 years in academic medicine at the Maryland Psychiatric Research Center (MPRC) and the Department of Veterans Affairs. Dr. Fischer earned his medical degree from the Medical College of Virginia. He completed a 5-year research/clinical residency in psychiatry at the University of Maryland/Sheppard Pratt followed by a post-doctoral fellowship in mental illness research at the MPRC. He holds a master's degree in biomedical ethics and has been board certified in both psychiatry and addiction medicine. He has authored or co-authored more than 50 scientific publications.

Neeraj 'Jim' Gandotra, MD
Substance Abuse and Mental Health Services Administration, HHS

Dr. Neeraj Gandotra serves as the Chief Medical Officer for SAMHSA. Dr. Gandotra began his addiction career in public health by training within an underserved community in Washington D.C., where he developed his perspective of how a nationwide approach to local addiction treatment is greatly needed. Later, as medical director of Addiction Treatment Services at Johns Hopkins, he directed and delivered care through implementation of department initiatives and medical center resources. Dr. Gandotra was tasked with both administrative and supervisory roles for all providers and clinics within Addiction Treatment Services.

At Johns Hopkins, he was responsible for developing program policy and procedure based on new research findings with the goal of improving outcomes and reducing risk for patients with substance use disorder. In addition, he had managed the administration and clinical treatment within an OTP multidisciplinary team setting. He provided physician support for research conducted at the Behavioral Pharmacology Research Unit, related to various conditions co-occurring with substance use disorders.

Dr. Gandotra has also worked as a Medical Director for federally qualified health centers, where it was necessary to develop policies sensitive of the specific catchment area cultural and ethnic needs. Immediately prior to joining SAMHSA, Dr. Gandotra served as the Chief Medical Officer for a large nationwide addiction treatment network, where he has developed national strategies specifically aimed at reducing risk, improving outcomes, and provider development. He is familiar with the development and utilization of medical services budgets, nuances of regulations and code across various states, and most importantly provider perspectives as he delivered direct patient care.

In addition to his clinical work, Dr. Gandotra is a member of the American Society of Addiction Medicine and American Academy of Addiction Psychiatry. Dr. Gandotra has worked with the Maryland State Attorney General on cases of physician misconduct, specifically those involving prescriptions of controlled substances. Dr. Gandotra also has been a consultant for the NFL player's assistance program for substance use disorders and for the Nuclear Regulatory Commission. Dr. Gandotra received his Bachelor of Science in Biology at University of Maryland, his Doctor of Medicine from the Universidad Iberoamericana (UNIBE) School of Medicine and completed his Psychiatric residency at Howard University. He completed an Addiction Psychiatry Fellowship at Yale University School of Medicine. Dr. Gandotra had served on the faculty at Johns Hopkins University and Howard University Hospital for a decade.

Elyse Katz, PhD
U.S. Department of Defense

Dr. Elyse Katz has a background in clinical and biomarker development, working in academic, industry, and government spaces. In her current role at Tunnell Government Services, Inc., Dr. Katz provides Senior Product Management Support to the Warfighter Brain Health Project Management Office at the U.S. Army Medical Materiel Development Activity (USAMMDA) and has played a pivotal role in facilitating the development of innovative therapeutics and diagnostics for psychological health conditions and traumatic brain injury. Through this work, Dr. Katz is committed to improving the lives of active-duty service members and veterans.

Dr. Katz's expertise extends across the entire clinical development lifecycle, from early-stage research to Phase 4 clinical trials. Her focus on the integration of biomarkers within clinical development programs has been instrumental in de-risking these efforts and increasing the probability of technical and regulatory success for new drugs and diagnostics in neuroscience and neurology disease areas.

Paula P. Schnurr, PhD
U.S. Department of Veterans Affairs

Dr. Paula P. Schnurr, PhD, is Executive Director of the VA National Center for PTSD. She is Professor of Psychiatry at the Geisel School of Medicine at Dartmouth.

She has written or co-edited over 300 chapters, books, and journal articles. Dr. Schnurr is editor-in-chief of the Clinician's Trauma Update-Online. She also is a Fellow of the American Psychological Association, past-president of the ISTSS, and former Editor-in-Chief of the Journal of Traumatic Stress.

Miriam J. Smyth, PhD
U.S. Department of Veterans Affairs

Miriam J. Smyth, PhD, currently serves as the Acting Director of the Clinical Science Research & Development Service (CSR&D).

Dr. Smyth joined the VA in 1995 as a researcher with the Durham Geriatric Research, Education and Clinical Center (GRECC). Following transfer of her VA-funded research program to the Baltimore VA Medical Center, she conducted research in prostate cancer and, additionally, was one of the two local site PIs for the Million Veteran Program. In 2006, she transitioned to research administration in the Research & Development Service at the VA Maryland Health Care System. She was the Deputy Associate Chief of Staff for Research and Development at the time of her departure from Baltimore to assume the position of Strategic Planning Manager/CSR&D at VA's Office of Research and Development in 2015. She served as Acting Director/CSRD 2017-2018 and Deputy Director/CSRD 2019-2022.

Marta Sokolowska, PhD
U.S. Food and Drug Administration, HHS

Marta Sokolowska, Ph.D., 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.

Leith J. States, MD, MPH, MBA, FACPM
Office of the Assistant Secretary for Health, HHS

Dr. States serves as the Acting Director of the Office of Science and Medicine and Chief Medical Officer to the Assistant Secretary for Health, in the Office of the Assistant Secretary for Health (OASH) at the US Department of Health and Human Services (HHS). In these roles, he leads a diverse portfolio addressing critical and emerging areas of public health interest for OASH and the Immediate Office of the HHS Secretary, including behavioral health, mental health, substance use disorder, and emerging public health threats. He has been a leader within HHS around efforts to reconsider scheduling considerations regarding cannabis and has worked closely across HHS Divisions to address potential therapeutic roles for psychedelics and entactogens. Before HHS, he spent nine years on active duty as a Navy Medical Officer serving in roles including Battalion Surgeon of a Marine infantry battalion, Public Health Emergency Officer for Navy Medicine West, and Officer in Charge of a Forward Deployable Preventive Medicine Unit. A native of Long Beach, California, States received his MD from the UCSD School of Medicine, completed residency training and an MPH at Loma Linda University, and earned an MBA from the George Washington University. He is board certified in preventive medicine and a Fellow of the American College of Preventive Medicine.

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.