REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Understanding Fatal Overdoses to Inform Product Development and Public Health Interventions to Manage Overdose

March 8, 1-4:45 PM ET

March 9, 1-4:45 PM ET

Speaker Bios

Keynote Speaker

Robert M. Califf, MD, MAAC

Commissioner of Food and Drugs, U.S. Food and Drug Administration

Dr. Robert M. Califf was confirmed earlier this year as the 25th Commissioner of Food and Drugs. As Commissioner, Dr. Califf oversees the full breadth of the FDA portfolio and execution of the Federal Food, Drug, and Cosmetic Act and other applicable laws. This includes assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices; the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation; and the regulation of tobacco products. He is a nationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, and a leader in the growing field of translational research, which is key to ensuring that advances in science translate into medical care.

This is Dr. Califf's second stint as Commissioner. He also served in 2016 as the 22nd Commissioner. Before assuming the position at that time, he served as the FDA's Deputy Commissioner for Medical Products and Tobacco. Prior to rejoining the FDA in 2022, Dr. Califf was head of medical strategy and Senior Advisor at Alphabet Inc., contributing to strategy and policy for its health subsidiaries Verily Life Sciences and Google Health.

Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco and a fellowship in cardiology at Duke.

Panelists

Alice Bell, LCSW

Overdose Prevention Project Coordinator, Prevention Point Pittsburgh

Alice Bell is the Overdose Prevention Project Coordinator for Prevention Point Pittsburgh. She has distributed naloxone at PPP's syringe service sites, since 2005 and coordinates PPP's naloxone distribution and data collection. She provides training on Harm Reduction Strategies to Reduce Overdose and is an advocate for drug policy reform, and working to promote harm reduction practices at the local, state and national level. She is co-facilitator for the Opiate Safety with Naloxone Network (OSNN).

Sessi Kuwabara Blanchard

Policy Community Organizer, VOCAL-NY

Sessi Kuwabara Blanchard works and organizes for drug users' health and power. She organized VOCAL-NY's Users Union, a grassroots membership-based group campaigning for statewide access to overdose prevention centers, as well as DISH! (Do It Safe, Heaux!), a mutual-aid collective of trans women who do sex work and use crystal meth. Additionally, she has worked as a journalist reporting on drug policy, both as a staff writer at Filter (filtermag.org), one of the web's only journalistic publications dedicated to covering harm reduction, and as a freelance contributor to The Intercept, The Nation, VICE, The Appeal, and others. Returning to her experience working in harm reduction service provision as a peer, she is currently a harm reduction specialist at a community mental health organization, as she prepares to start law school in Fall 2023.

Albert Dahan, MD, PhD

Professor of Anesthesiology, Leiden University Medical Center

Albert Dahan is chairman of the LUMC Institutional Review Board and vice-chair of the Research Advice Committee of the LUMC. He is founder and heads the Anesthesia & Pain Research Unit, a non-profit organization that performs outcomes-research in anesthesia and pain medicine. Dr. Dahan is also a board member of PainLess.

Nabarun Dasgupta, PhD, MPH
Senior Scientist, Injury Prevention Research Center Innovation Fellow, UNC Gillings School of Global Public Health

Dr. Nabarun Dasgupta is a pioneer in community-based naloxone access. He co-founded Project Lazarus, a groundbreaking Appalachian overdose prevention program. He is the Board Chair of the Remedy Alliance/For The People, a national non-profit ensuring affordable naloxone reaches harm reduction programs. He has served as an advisor to US FDA, CDC, and the World Health Organization on opioid epidemiology. His team's work can be found at OpioidData.org.

Zachary Dezman, MD, MS
Medical Officer, U.S. Food and Drug Administration

Zachary Dezman, MD, MS, is a medical officer in the Division of Anesthesiology, Addiction Medicine, and Pain Medicine within the Center for Drug Evaluation and Research at the Food and Drug Administration. He is also a Clinical Associate Professor in the Departments of Emergency Medicine and Epidemiology and Public Health at the University of Maryland School of Medicine. Dr. Dezman is an author on 60 peer-reviewed publications, many of which focus on the impact of substance abuse. Dr. Dezman championed making fentanyl testing standard within the University of Maryland Medical System, the first hospital system in the state to do so, and provided testimony to the US Senate relating to the burden of illicit fentanyl use on Marylanders. His work has been featured in the Washington Post, Baltimore Sun, and Forbes Magazine. Dr. Dezman is a practicing emergency physician in downtown Baltimore, Maryland.

CAPT Jennifer Fan, PharmD, JD
Acting Director, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration

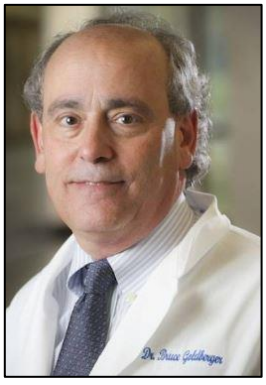
CAPT Jennifer Fan, Pharm.D., J.D. is a Commissioned Officer in the U.S. Public Health Service (USPHS) and returns as the Acting Center for Substance Abuse Prevention (CSAP) Director at the Substance Abuse and Mental Health Services Administration (SAMHSA). CAPT Fan served many different roles at SAMHSA from 2007-2021 including Acting CSAP Deputy Director; Special Assistant for the CSAP Director; Office of National Drug Control Policy (ONDCP) Liaison for the Drug-Free Communities Support Program Grants; CSAP Subject Matter Expert on Opioids and Prescription Drug Misuse; and Public Health Advisor/Pharmacist for SAMHSA Legislative and Regulatory Affairs, CSAP Division of Workplace Programs, and the Center for Substance Abuse Treatment (CSAT) Division of Pharmacologic Therapies. During her time at SAMHSA, CAPT Fan served as the Senior Editor for the Surgeon General's Spotlight on Opioids Report and was instrumental in creating SAMHSA's Strategic Prevention Framework for Prescription Drugs (SPF Rx) grants and the Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO). Previous to

joining and returning to SAMHSA, CAPT Fan worked at the U.S. Food and Drug Administration in the Office of Medical Policy (Division of Clinical Trial Quality and the Division of Drug Marketing, Advertising, and Communications) and the Office of Generic Drugs (Division of Bioequivalence). She also worked at the Centers for Medicare and Medicaid Services in the Division of Ambulatory Services (Hospital and Ambulatory Policy Group) on Medicare Part B Reimbursement. CAPT Fan received her Pharm.D. from the University of Maryland School of Pharmacy and her J.D. from the University of Baltimore School of Law.

Phillip Fiuty
Harm Reduction Program Director, The Mountain Center

Phillip Fiuty began providing community syringe and naloxone distribution in rural southern Santa Fe county in the early 1990's. He was a harm reduction volunteer for the AIDS Resource Center of Wisconsin from 1999 to 2001, a harm reduction outreach specialist for Albuquerque Healthcare for the Homeless from 2001 to 2002, and the Harm Reduction Program Manager for the New Mexico Dept. of Health from 2002 to 2006. His independent work has included harm reduction and research for methamphetamine and stimulant use, safe access to medical cannabis, and the use of ayahuasca and ibogaine for the treatment of SUD. He is currently the Harm Reduction Program Director for The Mountain Center serving Santa Fe, Rio Arriba and Taos counties in northern New Mexico, and a consultant, trainer and administrator for the federal PDO, SOR, FR-CARA and HRSA overdose and OUD grants in NM, Santa Fe and Rio Arriba counties, and is the Consumer Health Advocate appointee to the Governor's Overdose Prevention and Pain Management Advisory Council. He does independent work as the Network Coordinator for Rio Arriba County's SAMHSA and NAACHO rural overdose prevention grants, and as an overdose trainer and consultant with the NMDOH OD2A team.

Bruce Goldberger, PhD
Professor and the Chief of the Division of Forensic Medicine, Department of Pathology, Immunology and Laboratory Medicine, University of Florida College of Medicine



Dr. Bruce Goldberger is a Professor and the Chief of the Division of Forensic Medicine in the Department of Pathology, Immunology and Laboratory Medicine in the College of Medicine at the University of Florida in Gainesville, Florida. Dr. Goldberger holds a joint Professor position in the Department of Psychiatry Division of Addiction Medicine. Dr. Goldberger is the Medical Director of UF Health Pathology Laboratories Clinical Toxicology Laboratory, the Director of the William R. Maples Center for Forensic Medicine, and the Program Director of the Florida Emergency Mortuary Operations Response System. Dr. Goldberger is the Technical and Administrative Director of the Forensic Toxicology Laboratory at the University of Florida which provides toxicological services to Medical Examiner Offices and State and local law enforcement agencies throughout the State of Florida. Dr. Goldberger has been qualified as an expert witness more than 380 times in Federal, State, Military and Canadian courts of law. Dr.

Goldberger is an opioid consultant for the Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention and is a member of the White House Office of National Drug Control Policy Emerging Threats Committee. Dr. Goldberger received a Bachelor of Arts Degree in Zoology from Drew University in Madison, New Jersey and Master of Science and Doctor of Philosophy Degrees in Forensic Toxicology from the University of Maryland School of Medicine in Baltimore, Maryland. Dr. Goldberger is a Fellow of the American Board of Forensic Toxicology and the AACC Academy.

Angela G. Huskey, PharmD, CPE
Senior Vice President and Chief Clinical Officer, Millennium Health

Angela G. Huskey, PharmD, CPE is Senior Vice President and Chief Clinical Officer for Millennium Health, an accredited specialty laboratory with expertise in clinical drug testing and drug use trends data. In this role, Dr. Huskey leads all clinical aspects of drug testing for substance use treatment, pain management, behavioral health, and primary care. Additionally, she has spearheaded the use of aggregated and de-identified urine drug test (UDT) results to monitor the shifting landscape of drug use nationally. The use of this rich data source allows clinicians, first responders, and those responsible for public health to be quickly informed about these changes to help prevent overdoses and save lives. Dr. Huskey led her MH colleagues and a team of experts in the development of a real-time surveillance system called the Emerging Threat Intelligence (ETI) Program™ to provide meaningful, real-time insights into dangerous and evolving trends in drug use nationwide and use these findings to aid the development of rapid health responses. Since the creation of the ETI Program, Millennium Health has entered collaborations with the CDC, U.S. Department of Health and Human Services and the Ohio Department of Public Safety as well as multiple academic partners. Formerly a pain and palliative care clinician, Dr. Huskey is a nationally recognized expert on drug testing and its role in clinical care. Her passion for its use in the care of individuals and in public health applications is driven by her clinical background and personal experience of caring for a loved one with a substance use disorder (SUD).

Christopher M. Jones, PharmD, DrPH, MPH
Director of the National Center for Injury Prevention and Control, Centers for Disease Control and Prevention

Christopher Jones currently serves as the Director of the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention. In this role, he oversees all aspects of the Center's scientific, policy, program, and management and operations activities and provides executive leadership over multiple national prevention programs that advance injury and violence prevention, including substance use and overdose prevention, suicide prevention, youth violence and adverse childhood experiences prevention, and core state injury and violence prevention activities.

Jermaine Jones, PhD

Associate Professor of Clinical Neurobiology, Columbia University Department of Psychiatry

Dr. Jones was born in Henderson, Texas, and attended college at the University of Virginia majoring in Psychology and Biology. Throughout his post-secondary education, he was involved in several summer undergraduate research internships at Carnegie Mellon, the Univ. of Illinois and Johns Hopkins. While obtaining his doctoral degree at American University, he found a balance between behavioral and biological investigations that best fit my interests. Dr. Jones' research in Dr. Anthony Riley's Psychopharmacology Laboratory focused on understanding alcohol's effects on cocaine-induced affective responses, along with neuropharmacological mediation of cocaine's aversive effects and their impact on its abuse liability. Working under Dr. George Uhl and Scott Hall at the Molecular Neurobiology Division at NIDA, he also researched the genetic contribution to cocaine's aversive effects. Dr. Jones' graduate training provided an opportunity to learn from two well-respected substance abuse investigators. Under the tutelage of Dr. Riley, he learned the importance of information gained by integrating behavioral assays into pharmacological research. Through his time with Drs. Uhl/Hall, he developed an appreciation for the influence that genetic factors have on behavioral responses to drugs.

Mark Lysyshyn, MD, MPH

Deputy Chief Medical Health Officer, Vancouver Coastal Health

Dr. Mark Lysyshyn works for Vancouver Coastal Health as Deputy Chief Medical Health Officer and Medical Health Officer for Vancouver. He has been co-leading the public health response to the COVID-19 and overdose emergencies. He is a specialist in Public Health and Preventive Medicine and a Clinical Assistant Professor at the UBC School of Population and Public Health.

Carin King Malley, MD

Clinical Instructor of Emergency Medicine and Medical Toxicology, University of Pittsburgh Medical Center

Dr. Carin King Malley is a clinical instructor of Emergency medicine and Medical Toxicology at the University of Pittsburgh. Dr. Malley received her Bachelors of Science in Engineering from MIT and her MD from Oakland University William Beaumont School of Medicine. She completed her residency in Emergency Medicine and fellowship in Medical Toxicology at UPMC. Her current research interests include inpatient treatment of alcohol and opioid withdrawal, and treatment of hepatotoxicity due to acetaminophen overdose. Clinically, she is passionate about providing addiction medicine and toxicology services to underserved populations in the ED and hospital settings.

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

Dr. Iván 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).

Srikanth C. Nallani, PhD
Senior Clinical Pharmacologist, U.S. Food and Drug Administration

Dr. Nallani joined the Agency in 2003 after doctoral, and post-doctoral training at the University of Cincinnati, College of Pharmacy. Through his work as a senior clinical pharmacologist in the Division of Neuropsychiatric Pharmacology, he supports offices in CDER such as Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP), Office of Surveillance and Epidemiology (OSE), Office of Generic Drugs, and CDER Controlled Substances Program (CSP). Dr. Nallani has extensive scientific and regulatory knowledge pertaining to the clinical pharmacology of opioids, opioid antagonists, analgesics, anesthetics, and treatments for various substance use disorders; as well as the clinical pharmacology issues pertaining to pediatrics and maternal health, and drug-drug interactions.

Yngvild K. Olsen, MD, MPH
Director for the Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration

Dr. Yngvild Olsen serves as the Director for the Center for Substance Abuse Treatment (CSAT). She has a long history of working within the addiction treatment field to expand access to care and enhance quality. She began her career as the Medical Director for the Johns Hopkins Hospital's outpatient substance use treatment services while a full-time Assistant Professor in the Department of Medicine at the Johns Hopkins School of Medicine. She subsequently served as the Deputy Health Officer for Maryland's Harford County Health Department, where she led a modernization of publicly funded substance use treatment services in collaboration with State and

local partners. She next served as the Vice President of Clinical Affairs for the Baltimore Substance Abuse Systems, then the local addiction authority for Baltimore City. Dr. Olsen has also served as Medical Consultant to the Maryland Behavioral Health Administration, as a clinical expert to the Maryland Addiction Consultation Service at the University of Maryland School of Medicine, and as an advisor on addiction interventions to the Baltimore City Health Department. From 2011 to 2021, she served as Medical Director for the Institutes for Behavior Resources/REACH Health Services, a comprehensive outpatient substance use disorder treatment program in Baltimore City. After graduating from Harvard Medical School, Dr. Olsen completed residency training in internal medicine and served as primary care chief resident at Boston Medical Center. She completed a Fellowship in General Internal Medicine at Johns Hopkins, during which time she received a Master in Public Health degree from the Johns Hopkins Bloomberg School of Public Health.

Jessica Paulsen

Associate Director for Digital Health in the Office of Product Evaluation and Quality, U.S. Food and Drug Administration

Jessica Paulsen is the Associate Director for Digital Health in the Office of Product Evaluation and Quality (OPEQ) in the Center for Devices and Radiological Health (CDRH) at the FDA. She provides executive leadership and strategic oversight of OPEQ's digital health review practices and policy implementation. She also leads the Center's Digital Health Focal Point Program which aims to promote communication, collaboration, and consistency in digital health product reviews across CDRH. She previously served as the Director for the Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices in CDRH. She earned her B.E. in Biomedical Engineering and Engineering Management from Vanderbilt University.

Jesse Pines, MD

National Director of Clinical Innovation, US Acute Care Solutions

Jesse Pines MD, is the National Director of Clinical Innovation at US Acute Care Solutions. Dr. Pines most recently served as director of the Center for Healthcare Innovation & Policy Research and a professor of Emergency Medicine in the George Washington (GW) University School of Medicine and Health Sciences and a professor of Health Policy and Management at GW Milken Institute School of Public Health (MISPH). He also was the principal investigator for Urgent Matters, a program that disseminates information on best practices in emergency care for eight years. Dr. Pines has been awarded funding from multiple organizations including the Agency for Health Care Research and Quality, the Robert Wood Johnson Foundation, the National Institutes of Health, the Department of Homeland Security, the Centers for Medicare and Medicaid Services, Emergency Medicine Foundation, American College of Emergency Physicians, and the American Geriatrics Society, along with many others. Dr. Pines is author on more than 290 peer-reviewed publications and has six published books. He has contributed to TIME magazine, Slate.com, Emergency Physicians' Monthly, Foreign Policy Magazine and the Wall Street Journal. He earned a bachelor's and a master's degree from University of Pennsylvania; as well as a medical degree and an MBA from

Georgetown University. He completed a residency in emergency medicine at the University of Virginia Health Sciences Center and a fellowship in research at the University of Pennsylvania. He has also completed the Master Teacher Leadership Development Certificate Program at George Washington University School of Education & Human Development.

Emanuel Sferios
Founder, DanceSafe

Emanuel Sferios is the founder of DanceSafe, a national nonprofit offering peer-based drug education and harm reduction services to youth in the electronic music and festival communities. In 2016 he commissioned the first ever laboratory study assessing fentanyl test strips for harm reduction purposes. More recently, he helped develop a new, improved fentanyl test strip with higher specificity to fentanyl and its analogs that does not produce false positives at optimal drug checking concentrations. Today he manages DanceSafe's FTS program, which currently distributes more than 300,000 strips a month to state and municipal public health agencies, hospitals, and syringe exchanges, as well as directly to drug consumers. He also acts as advisor and consultant in drug checking for the immunmoassay test strip industry and the drug checking industry in general.

Marta Sokolowska, Ph.D.
Deputy Center Director for Substance Use and Behavioral Health, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

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 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.

David Strauss, MD, PhD
Director of the Division of Applied Regulatory Science, U.S. Food and Drug Administration

Dr. Strauss received both a B.A. in chemistry and medical degree (M.D.) from Duke University, and a Ph.D. in clinical physiology from Lund University, Sweden. He also completed a postdoctoral fellowship at Johns Hopkins University. He has led regulatory science research since joining FDA in 2010. He has published over 90 peer-reviewed journal articles and book chapters related to assessing the safety and effectiveness of drugs and medical devices and predicting individualized response to therapies. Dr. Strauss

currently serves as FDA's Director of the Division of Applied Regulatory Science, which seeks to move new science into the CDER review process, closing the gap between scientific innovation and product review and improving public health by building and translating knowledge of drug response into science-based, patient-centered regulatory decisions of the highest quality. Dr. Strauss previously served as Senior Advisor for Translational and Experimental Medicine in the Office of Clinical Pharmacology, where he provided strategic, scientific, and operational leadership in several priority areas including early pharmacology studies, biomarker development and evaluation, disease and pharmacologic modeling, induced pluripotent stem cell research and silico modeling.

Justin Strickland, PhD
Assistant Professor, Department of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine

Dr. Strickland is an Assistant Professor in the Department of Psychiatry and Behavioral Sciences at Johns Hopkins University School of Medicine. His research focuses on the use of behavioral economics as a theoretical framework to address issues of public health significance to include addiction and sexual health. This work applies a translational pipeline of preclinical animal research, human laboratory assessment, and clinical trials to evaluate choice and decision-making processes at the intersection of the self (e.g., genetic predisposition, reinforcement history) and setting (e.g., environmental factors, alternative reinforcers).

Mary Sylla, JD, MPH
Director of Overdose Prevention Policy & Strategy, National Harm Reduction Coalition

Mary Sylla, JD, MPH, is the Director of Overdose Prevention Policy & Strategy at the National Harm Reduction Coalition. She oversees the organization's advocacy to increase expand harm reduction services at the federal and state and local level. Prior to joining NHRC Mary was a Senior Staff Attorney at the Drug Policy Alliance.

In recent years she has designed and taught a masters level "Criminal Justice & Public Health" at Touro University of California's School of Public Health and also Peer Health Education classes for and with prisoners in San Quentin State Prison. She is the Founder of the Center for Health Justice, a prisoner HIV advocacy organization in Los Angeles, and was instrumental in expanding prisoner access to condoms in California's jails and prisons. Prior to founding the Center for Health Justice, she worked as a staff attorney at AIDS Project Los Angeles and the ACLU of Southern California. She received her undergraduate degree in Public Policy from Brown University (1989), her law degree from the University of North Carolina School of Law (1995) and her MPH in Epidemiology from UC Berkeley (2004). She is member of the California Bar.

Alexander "Sander" A. Vinks, PharmD, PhD, FCP
Professor, Cincinnati Children's Hospital Medical Center, Department of Pediatrics

Dr. Vinks has been a researcher for more than 37 years and began working at Cincinnati Children's in 2000. His research is in pharmacokinetic-pharmacodynamic (PK/PD) modeling and simulation, systems pharmacology, physiologically based pharmacokinetics (PBPK) and pharmacogenetics/genomics. Dr. Vinks is also interested in applying population and simulation methods to inform pediatric clinical trial design and therapeutic drug management by implementing model-informed precision dosing strategies and clinical decision support tools. He became interested in this research early in my career when he directed a therapeutic drug monitoring and clinical toxicology laboratory and realized that every patient is different in terms of how the body metabolizes drugs and how patients very much differ in their response to medications. His program's goal is to promote the implementation of precision medicine and individualized precision dosing, tailoring doses to individual needs, and work to predict how patients will respond to medications using pharmacogenetics/genomics to select the best drug and corresponding dose.

Nora D. Volkow, MD
Director of the National Institute on Drug Abuse (NIDA), National Institutes of Health

Nora D. Volkow, M.D., is Director of the National Institute on Drug Abuse (NIDA) at the National Institutes of Health. NIDA is the world's largest funder of scientific research on the health aspects of drug use and addiction. Dr. Volkow's work has been instrumental in demonstrating that drug addiction is a brain disorder. As a research psychiatrist, Dr. Volkow pioneered the use of brain imaging to investigate how substance use affects brain functions. In particular, her studies have documented how changes in the dopamine system affect the functions of brain regions involved with reward and self-control in addiction. She has also made important contributions to the neurobiology of obesity, ADHD, and aging.

Much of her professional career was spent at the Department of Energy's Brookhaven National Laboratory in Upton, New York, where she held several leadership positions including Director of Nuclear Medicine, Chairman of the Medical Department, and Associate Laboratory Director for Life Sciences. Dr. Volkow was also a professor in the Department of Psychiatry and Associate Dean of the Medical School at The State University of New York at Stony Brook. She received a Nathan Davis Award for Outstanding Government Service, was a Samuel J. Heyman Service to America Medal (Sammies) finalist and is a member of the National Academy of Sciences and the Association of American Physicians. Dr. Volkow received the International Prize from the French Institute of Health and Medical Research for her pioneering work in brain imaging and addiction science; was awarded the Carnegie Prize in Mind and Brain Sciences from Carnegie Mellon University; and was inducted into the Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD) Hall of Fame.

Erin Winstanley, PhD
Associate Professor, Department of Neuroscience and Behavioral Medicine & Psychiatry
West Virginia University School of Medicine

Dr. Winstanley received her doctoral degree from The Johns Hopkins Bloomberg School of Public Health. She has postdoctoral training in behavioral pharmacology, and she has over 20 years of experience as a behavioral health services researcher. She is the Multiple Principal investigator (MPI) of the Appalachian Node of the NIDA Clinical Trials Network (CTN) and a Site PI for the Tailored Retention and Engagement for Equitable Treatment of OUD and Pain (TREETOP) clinical research center at the University of Pittsburgh (Pitt) which is part of the NIH IMPOWR network. Her current research is focused on reducing the morbidity and mortality associated with the overdose epidemic, as well as the use of technology to improve access and quality of behavioral health services. More specifically, she is investigating cognitive impairments and brain abnormalities that result from opioid-related overdose and problems initiating buprenorphine treatment among individuals using fentanyl.

Eric D. Wish, Ph.D.
Principal Investigator, Emergency Department Drug Surveillance (EDDS) Studies

Dr. Eric Wish received his Ph.D. in psychology from Washington University in St. Louis. He subsequently completed a NIDA post-doctoral fellowship in psychiatric epidemiology in the Department of Psychiatry at the Washington University School of Medicine. Between 1986 and 1990, Dr. Wish served as a Visiting Fellow at the National Institute of Justice in the Department of Justice, where he supervised the development and launching of the Drug Use Forecasting (DUF, later ADAM) program. In 2013, Dr. Wish developed the Community Drug Early Warning System (CDEWS), a new system for detecting emerging drugs by expanded testing of urine specimens obtained from criminal justice drug testing programs. In 2014, Dr. Wish received a 5-year award from NIH/NIDA to establish the Coordinating Center for the National Drug Early Warning System (NDEWS). As part of NDEWS, he oversaw the Drug Outbreak Testing Service (DOTS) pilot study, which collected and analyzed urine specimens from hospitals and treatment facilities. Also, from 2017-2020, he served as Co-PI of the MPowering the State Initiative's Opioid Use Disorders Project. As part of the MPower project, Dr. Wish led development of the Emergency Department Drug Surveillance (EDDS) system to track drug toxicology trends using de-identified electronic health records (EHR) from 7 hospitals in Maryland. In 2021, he received funding from the Office of National Drug Control Policy (ONDCP) to expand the EDDS system to collect EHRs and urine specimens from five hospitals nationally to monitor urine drug trends and identify emerging drugs being used by drug overdose patients.

Moderator

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.