Duke | Robert J. Margolis, MD Center for Health Policy

Developing Novel Therapies for Stimulant Use Disorder

Washington Marriott at Metro Center
775 12th St NW • Washington, DC 20005
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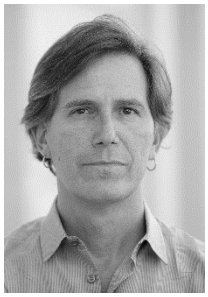
Speaker Biographies

Amelia M. Arria, Ph.D. is a Professor and the Director of the Center on Young Adult Health and Development in the Department of Behavioral and Community Health at the University of Maryland School of Public Health. Her research has focused on the risk and resiliency factors associated with mental health and substance use problems among adolescents and young adults. Her most recent work has clarified the impact of substance use, particularly excessive drinking and marijuana use, on academic achievement. She is the Principal Investigator of the NIDA-funded prospective College Life Study, which annually assessed the behavioral health of 1253 college students through their young adult years. She is the co-leader of the Maryland Collaborative, which provides training and technical assistance to a network of 17 colleges across the state that are committed to aligning their substance use prevention and intervention strategies with scientific evidence. She has authored more than 170 scientific peer-reviewed publications, numerous white papers and book chapters, and is the recipient of several major grant awards from foundations, and state and federal agencies. Much of her work has direct relevance to parents, communities, educational professionals and policy makers. Most relevant to this meeting, she has completed several studies focused on the nonmedical use of prescription stimulants among college students as well as methamphetamine use patterns during pregnancy and associated neurodevelopmental outcomes. She completed her undergraduate degree at Cornell University, a PhD in Epidemiology at the University of Pittsburgh and postdoctoral training in Psychiatric Epidemiology at the Johns Hopkins University Bloomberg School of Public Health.

Caleb Banta-Green is a principal research scientist at the Alcohol & Drug Abuse Institute and an affiliate associate professor in the School of Public Health at the University of Washington. He researches substance use disorder treatment and other interventions, including opioid use disorder and overdose. His research focuses on people who are homeless, utilizing public health services such as syringe exchanges, and/or in the criminal legal system. He has conducted NIDA and foundation funded randomized clinical trials. Currently he is conducting a multi-site implementation research study of a community based medication-first model of opioid disorder treatment with foundation and governmental funding. He oversees a team providing technical assistance and training for health care, addiction treatment, and public health and safety interventions. He is also an epidemiologist and reports drug trends across WA State, has been the Seattle area representative to the National Institute on Drug Abuse's drug epidemiology workgroup since 2001, and partners with state and local agencies on drug epidemiology planning, tracking, and reporting. In addition to a range of traditional drug epidemiology data sources he helped develop and regularly utilizes novel data sources such as statewide syringe services program client surveying and municipal wastewater drug testing. Dr. Banta-Green has an MSW, an MPH, and a Ph.D. in Health Services Research from the School of Public Health, all from the UW. He served as a senior science advisor for the Office of National Drug Control Policy in the Executive Office of the President in 2012. He serves on local, state, and national workgroups and advisory committees related to epidemiology, policy, and interventions for substance-related problems.

Joshua Barocas, MD is an Assistant Professor of Medicine at the Boston University School of Medicine and Infectious Diseases physician at Boston Medical Center. . He received his medical degree from the George Washington University School of Medicine and Public Health. He completed his Internal Medicine residency and was subsequently Chief Resident at the University of Wisconsin Hospitals and Clinics. Dr. Barocas completed a fellowship in Infectious Diseases at Massachusetts General Hospital and Brigham and Women's Hospital in Boston, MA. He leads an an interdisciplinary research program that is specifically aimed at the goal of improving health outcomes for patients with infectious diseases including HIV and HCV, substance use disorders, and other vulnerable populations. His research, which uses clinical epidemiology, health economics, simulation modeling, and cost-effectiveness, informs clinical-decision making and health policy to answer clinically- and policy-relevant questions. He is engaged in research using these innovative methods to help understand the impact of and improve upon policies that affect people who use drugs infected with or at high risk for HIV and viral hepatitis. His research has been funded by NIDA, NIAID, the Providence/Boston Center for AIDS Research (CFAR), the BU-CTSI, and the MGH Executive Committee on Research Fund for Medical Discovery. He currently serves as Co-Director of the Health Economics and Modeling Core for the Massachusetts HEALing Communities Study, an NIH-funded grant to significantly reduce overdose. He has been the recipient of several research awards including the Charles A. King Trust Research Award and the prestigious AAMC Herbert W. Nickens Faculty Fellowship Award, which recognizes a junior faculty member who demonstrates leadership potential in addressing inequity in health care. He has published over 20 peer-reviewed articles and editorials, including in leading journals such as JAMA Internal Medicine, AJPH, Addiction, Clinical Infectious Diseases, and Annals of Internal Medicine. His work has been widely cited in the media, including the Boston Globe, U.S. News and World Report, and NPR.

Kathleen M. Carroll, Ph.D., is the Albert E. Kent Professor of Psychiatry at Yale University School of Medicine. Her work focuses on the development, validation, and dissemination of evidence-based treatments for addiction. She has had 35 years of continuous funding from NIH to support her research, including K05 (Senior Scientist) and MERIT (R37) awards. She has served on the Board of Directors of CPDD (the Committee of Problems on Drug Dependence), the US's longest standing professional association addressing drug use disorders. She also served as President of APA's Division 50 (Addictions) and has been editor of multiple journals, currently as Field Editor for the *Journal of Studies and Alcohol and Drugs*. Dr. Carroll is also Principal Investigator of the Center for Behavioral Therapies Development (NIDA P50 Center), entering its 25th year, and is co-PI, with Dr. Roger Weiss, of the New England Consortium Node of NIDA's Clinical Trial Network since 1999. She was appointed to the National Academy of Medicine's *Committee on Medications to Treat Opioid Use Disorder* in 2018 and has served on several FDA panels reviewing medications to treat Opioid Use Disorder. The author of over 320 peer reviewed publications as well as numerous chapters and books, her major contributions include (1) articulating the Stage Model of behavioral therapies development, (2) developing behavioral interventions to improve adherence and outcome for pharmacotherapies, and (3) establishing the efficacy, durability, and specificity of computer-assisted training in cognitive behavioral therapy (CBT4CBT). Her current projects emphasize implementation of evidence-based treatments for substance use disorders, including opioid use disorder, and the development of technology-based interventions to improve engagement and adherence to buprenorphine treatment.



Dan Ciccarone, MD, MPH is a board certified clinician in Family Medicine and Addiction Medicine. As Professor of Family and Community Medicine at the University of California, San Francisco, Dr. Ciccarone has been principal or co-investigator on numerous NIH/NIDA sponsored research projects. He is an internationally recognized scholar on the medical, public health and public policy dimensions of substance use, risk and consequences. He is currently leading the Heroin in Transition study with its integrated multidisciplinary – ethnographic, economic and statistical modeling – aims to examine the recent rise in heroin use and the expanding diversity of heroin source-forms and illicitly-made synthetic opioids (e.g. fentanyls) and their relationship to sharp increases in illicit opioid-involved mortality and morbidity. He is Associate Editor for the International Journal of Drug Policy and recently edited a special issue on the "triple wave crisis" of opioids, heroin and fentanyl in the US.

Kelly J Clark, MD, MBA is an addiction medicine specialist and psychiatrist who serves as Immediate Past President of the American Society of Addiction Medicine (ASAM) representing over 6,000 addiction physician specialists. She is President of Addiction Crisis Solutions which assists stakeholder groups to transform addiction care into evidence-based, cost-effective systems. Dr. Clark is also a Director of DisposeRx, a simple and inexpensive at-home technological solution to dispose of unused medications in an environmentally friendly manner to make safer communities. Dr. Clark has provided expertise about addiction and needed systems of care to the Presidential Opioid Commission, FDA, SAMHSA, the Pew Trusts, National Safety Council, and National Business Group on Health. Beyond Dr. Clark's clinical work, her unique understanding of the business and economic forces shaping our health system stands upon her experience as Chief Medical Officer for two privately held multi-state treatment organizations, medical director for a community health plan (CDPHP), CVS Caremark, as well as work at a pharmaceutical company (Orexo). Dr. Clark worked on "Opioids and the Workplace: An Employer Toolkit for Supporting Prevention, Treatment, and Recovery" with the Kentuckiana Health Collaborative, a member of the National Alliance of Healthcare Purchaser Coalitions. Currently she is on the Steering Committee of the National Academy of Medicine's Action Collaborative to Counter the US Opioid Crisis as well as the Advisory Committee of the Center for Public Health of the Milken Institute. She is a Distinguished Fellow of both ASAM and the American Psychiatric Association, and is proud to have earned her MBA with Additional Certificate in Health Sector Management from the Fuqua School of Business at Duke University.

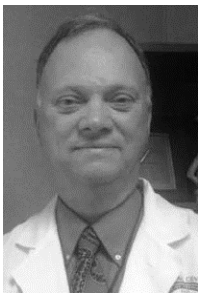
Wilson M. Compton, M.D., M.P.E. is Deputy Director of the National Institute on Drug Abuse (NIDA) of the National Institutes of Health. NIDA supports much of the world's research on health aspects of drug abuse and addiction. Dr. Compton received his undergraduate education at Amherst College and his medical education at Washington University in St. Louis. Over his 25+ year career, Dr. Compton has been an author of more than 200 publications, primarily in the areas of drug abuse epidemiology, including widely cited papers on the opioid crisis; is an invited speaker at multiple high-impact venues, and has received multiple awards. Of note, Dr. Compton received the Senior Scholar Health Services Research Award from the American Psychiatric Association in 2008, the Paul Hoch award from the American Psychopathological Association in 2010, the Food and Drug Administration "Cross-Cutting Award" in 2017, and the U.S. Health and Human Services Secretary's Awards for Meritorious Service in 2013 and Distinguished Service in 2015, 2018 and 2019.

Admiral Brett Giroir, MD is the 16th Assistant Secretary for Health in the U.S. Department of Health and Human Services. He serves as the Secretary's principal public health and science advisor, and in November was appointed Acting FDA Commissioner. He also oversees the Office of the Surgeon General and the U.S. Public Health Service Commissioned Corps. His office leads many critical national initiatives, including an historic new plan to end the HIV epidemic in America, HHS efforts to combat drug overdoses, the National Vaccine Plan, the Physical Activity and Dietary Guidelines for Americans, and a global effort to improve the outcome of people living with Sickle Cell Disease. Previously, Dr. Giroir has served in numerous leadership positions in the federal government and in academic institutions. Most notably, he was the first physician to serve as an office director at the Defense Advanced Research Projects Agency (DARPA). As a pediatric critical care physician, Dr. Giroir cared for critically ill children for 14 years. He continues to bring that hands-on, patient-centered perspective to his work as Assistant Secretary for Health, where his primary goal is leading America to healthier lives.

Jody Green, PhD serves as the Chief Scientific Officer for Inflexxion. Dr. Green provides strategic direction for epidemiologic research design, development and enhancement of public health surveillance networks, and data dissemination activities for postmarket studies of prescription drug misuse and abuse. Dr. Green provides thought leadership in areas of regulatory strategy, study design, and drug safety and has extensive experience related to abuse deterrence, substance abuse and epidemiology studies for prescription medications. Dr. Green is a newly inducted Fellow of the American Academy of Clinical Toxicology and a current member of the Prevention of Overdoses and Treatment Errors in Children Taskforce (PROTECT) of the Centers for Disease Control and Prevention (CDC), an assembly of experts to develop strategies to keep children safe from unintentional medication overdoses. She has over 17 years of experience in drug safety surveillance aimed to advance public health and patient safety, authoring or co-authoring over 60 manuscripts in peer-reviewed journals. Dr. Green received her doctorate in applied statistics and research methods from the University of Northern Colorado in 2000. Prior to joining Inflexxion she was the Director of Research at the Rocky Mountain Poison and Drug Center, where she was the principal investigator on over 40 studies ranging from clinical trials to observational studies, primarily focused on pharmaceutical and consumer product safety. She was an adjunct Assistant Professor of Nursing (Research) at Vanderbilt University School of Nursing (2007-2011) and a Past-President of the Society of Clinical Research Associates (SoCRA; 2014-2015).

Janetta L. Iwanicki, MD is the Interim Director of Research at Rocky Mountain Poison & Drug Safety—Denver Health and Hospital Authority in Denver, Colorado. She is an Assistant Professor of Emergency Medicine at the University of Colorado School of Medicine. Dr. Iwanicki is board-certified by both the American Board of Emergency Medicine and the American Board of Medical Toxicology, and teaches as an attending physician in both fields. Dr. Iwanicki received her undergraduate education at Pomona College in Claremont, California where she was named the Achievement Rewards for College Scientists (ARCS) Nadine and Edward Carson Scholar and was awarded the 15-month Beckman Foundation Beckman Scholar Grant prior to graduating with her bachelor's degree with experimental thesis in Biology. She attended medical school at University of California—San Francisco, and during her training was awarded the year-long Pathways to Careers in Clinical and Translational Research (PACCTR) fellowship prior to earning her degree as Doctor of Medicine with Thesis. She completed her residency in Emergency Medicine at Denver Health, followed by her

fellowship in Medical Toxicology at the Rocky Mountain Poison & Drug Safety. Dr. Iwanicki conducts her clinical research with the RADARS System, focusing on innovative ways to understand the interaction between the treatment of pain and other medical conditions and the benefits and risks associated with stimulants, opioids, and other pharmaceutical and nonpharmaceutical therapies. She has published more than 30 manuscripts and abstracts to better describe the patterns of drug abuse as well as the theoretical constructs vital for understanding these patterns, and has presented at multiple national and international meetings on these topics. She has authored or co-authored eight book chapters in the fields of Medical Toxicology and Emergency Medicine.



Thomas R. Kosten, MD, is the JH Waggoner Chair and Professor of Psychiatry, Pharmacology, Immunology, Pathology and Neuroscience, Director of the Division of Substance Use Addictions, and Emeritus Director of the Dan Duncan Institute for Clinical and Translational Research at Baylor College of Medicine. His other key appointments are Distinguished Professor of Psychiatry at Peking University Medical School and Adjunct Professor of Epidemiology and Behavioral Health at MD Anderson Cancer Center. He is the recent former Vice Chair for Research at Baylor College of Medicine, Professor at Yale University School of Medicine, the founding Vice Chair for Addiction Psychiatry of the American Board of Psychiatry and Neurology, and Past President of both the American Academy of Addiction Psychiatry and the College on Problems of Drug Dependence. He is a Distinguished Life Fellow in the American Psychiatric Association (APA) and a Fellow of the American College of Neuropsychopharmacology (ACNP). He has served as a Congressional Fellow in the US House of Representatives and is a long-standing member of various commissions with the National Academy of Sciences (NAS), the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), and the Department of Defense (DoD) primarily related to veteran health and drug safety and risk management. He is the current Editor for the American Journal on Addictions, and has over 750 publications on pharmacotherapy for addictions supported by over 50 grants from NIH, VA, DoD and various foundations in the USA and China. Over the course of his distinguished career, Dr. Kosten has been ranked by U.S. News and World Report, Castle Connolly, and others, as “Top Doc” in the field of Psychiatry, among the top 10%, of physicians in Addictions Medicine, and in the top 1%, of U.S. physicians nationwide.

Adam Kroetsch is Research Director, Biomedical Innovation and Regulatory Policy, at Duke-Margolis. In this role, he oversees Duke-Margolis’ portfolio of projects aimed at advancing regulatory science, promoting biomedical innovation, and ensuring the availability of safe and effective medical products. In this role, he partners closely with external experts and FDA to carry out this work. Prior to joining Duke-Margolis, Adam served as the deputy director of the FDA’s Office of Program and Strategic Analysis, which serves as an “internal consultancy” for FDA’s Center for Drug Evaluation and Research, providing management consulting, policy analysis, process improvement, and advanced modeling and analytic methods to improve the center’s policy, decision-making, and operations. In this role, Adam managed analytical studies and major initiatives in a range of topics related to pharmaceutical regulation and drug safety, including studies on the impact of FDA’s drug labels on health outcomes and the use of innovative health IT solutions to understand and address the opioid crisis and other critical public health needs.

Frances Rudnick Levin, MD is the Kennedy-Leavy Professor of Psychiatry at Columbia University and the Chief of the Division on Substance Use Disorders at NYSPI/Columbia University. For over 20 years, she has been the Director of the Addiction Psychiatry Fellowship Program at New York Presbyterian Hospital and for the past 14 years, she has been the PI of a T32 NIDA funded Substance Abuse Research Fellowship. Dr. Levin graduated from Cornell University Medical College and completed her psychiatric residency at the New York Hospital-Payne Whitney Clinic. She is Medical Director of the Providers' Clinical Support System- Medication Assisted Treatments (PCSS-MAT), a SAMHSA-supported national training and mentoring initiative focused on addressing the opioid use disorder crisis. Also, she is the Medical Director of a SAMHSA-supported State Targeted Response technical assistance grant to states that received funding to address the national opioid epidemic. She is the principal investigator on several federally funded grants, including a U54 Medications Development grant evaluating novel treatments for opiate and cannabis use disorders, a T32 NIDA funded Substance Abuse Research Fellowship, and a K24 Mid-Career Investigator Award and collaborates on several other grants. Her current research interests include pharmacologic and psychotherapeutic treatment interventions for cocaine and marijuana use disorder, and treatment approaches for adults with substance use disorders and attention-deficit hyperactivity disorder along with other psychiatric illnesses. Dr. Levin has over 200 articles and book chapters on a wide range of topics including treatments of substance use disorders, assessment and treatment of co-occurring psychiatric illnesses and vulnerabilities associated with substance use disorders. She has served on several advisory panels and ad-hoc federal grant review groups and was as a member of the NIDA – Initial Review Group: Training and Career Development Subcommittee for 8 years and served as a member to the NIDA Interventions to Prevent and Treat Addiction (IPTA). She is an editorial board member of three journals, past President of the American Academy of Addiction Psychiatry and past Chair of the APA Council on Addiction Psychiatry.

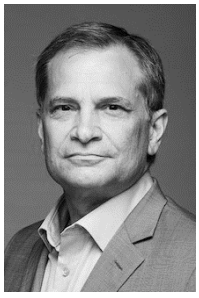
David J. McCann, Ph.D. is Associate Director of the Division of Therapeutics and Medical Consequences (DTMC) within the National Institute on Drug Abuse (NIDA). He received a B.S. in Pharmacy (1981) from the Albany College of Pharmacy and his Ph.D. (1988) from the Department of Pharmacology and Experimental Therapeutics at the State University of New York at Buffalo. He conducted his postdoctoral research 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. In addition, he serves as a consultant to the U.S. Food and Drug Administration related to domestic drug scheduling issues, and he has served the U.S. State Department as a technical expert on drug scheduling issues during meetings of the United Nations Commission on Narcotic Drugs.

Mark McClellan, MD, PhD, is the Robert J. Margolis Professor of Business, Medicine, and Health Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University. With offices in Durham, NC and Washington, DC, the Duke-Margolis Center is a university-wide, interdisciplinary initiative that is nationally and internationally recognized for its research, evaluation, implementation, and educational initiatives to improve health and health policy. The Center integrates Duke's expertise in the social, clinical, and analytical sciences with health care leader and stakeholder engagement to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a physician and an economist who has informed and improved a wide range of strategies and policy reforms to advance health care, including payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and strategies for more effective biomedical innovation. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. With highly distinguished record in public service and academic research, Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These reforms include the Medicare prescription drug benefit, Medicare and Medicaid payment reforms, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. He previously served as a member of the President's Council of Economic Advisers, senior director for health care policy at the White House, and Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA and a member of the National Academy of Medicine (NAM), where he chairs the Leadership Council for Value and Science-Driven Health care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He is also a Senior Advisor on the faculty of the University of Texas Dell Medical School and co-chair of the Accountable Care Learning Collaborative. Dr. McClellan is an independent director on the boards of Johnson & Johnson, Cigna, and Alignment Healthcare. He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.

F. Gerard Moeller received his MD from the University of Texas Health Science Center in Houston. He then transferred to the University of Texas Health Science Center at San Antonio for his internship and residency in psychiatry. Upon completion of his residency, he held a fellowship in clinical psychopharmacology research at the University of California in San Diego. Prior to coming to VCU he was Director of the Center for Neurobehavioral Research on Addictions and Louis A. Faillace Professor at University of Texas - Houston. Currently Dr. Moeller is Professor and Division Chair of Addiction Psychiatry in the Department of Psychiatry. He also holds appointments in the departments of Pharmacology and Toxicology and Neurology. He is Director of Addiction Medicine and Director of the VCU Institute for Drug and Alcohol Studies, as well as Director of the VCU C. Kenneth and Dianne Wright Center for Clinical and Translational Research and Associate Vice President for Clinical Research. With a clinical background in treatment of addictions and related behavioral disorders, Dr. Moeller's research background focuses on impulse control as a key factor in these disorders. This approach is useful for studying other conditions in which impulsivity plays a role, such as traumatic brain injury, attention deficit hyperactivity disorder and binge eating.

Larissa Mooney, MD is a board certified addiction psychiatrist and Associate Clinical Professor of Psychiatry at the University of California, Los Angeles (UCLA). She is the Director of the UCLA Addiction Psychiatry Clinic and Chief of the Greater Los Angeles Veterans Affairs Substance Use Disorders Section, where she supervises psychiatrists in training in the clinical management of addictive and mental health disorders. Dr. Mooney is the Vice President of the American Academy of Addiction Psychiatry (AAAP) and a Fellow of the American Psychiatric Association (APA) and the American Society of Addiction Medicine (ASAM). Dr. Mooney has conducted research at UCLA Integrated Substance Abuse Programs on pharmacological and behavioral treatment interventions for addictive disorders. She is one of two PIs for the Greater Southern California Node of the National Institute on Drug Abuse (NIDA) Clinical Trials Network. She has current NIDA funding to study functional outcomes in cannabis users and treatment interventions for opioid use disorder and stimulant use disorder.

Kenzie L. Preston, Ph.D. is a Senior Investigator and Chief of the Clinical Pharmacology and Therapeutics Research Branch at the National Institute on Drug Abuse Intramural Research Program (NIDA IRP). In her early faculty career at the Johns Hopkins University School of Medicine she conducted human behavioral pharmacology studies to investigate the pharmacology and abuse liability of opioids and cocaine and possible pharmacotherapies for substance dependence. Since 1991 at NIDA IRP she has overseen research in an outpatient substance abuse treatment research program where she conducted a series of clinical trials to document the efficacy of and identify the optimal parameters of contingency management for treatment of cocaine and opioid dependence and evaluate detection of drug in urine and other biological matrices. Most recently Dr. Preston's laboratory has been active in developing and applying mobile technology to substance abuse research and treatment. Hers was the first laboratory to conduct a large-scale study using real-time collection of self-report in the natural environment (Ecological Momentary Assessment; EMA) in people with opioid use disorder and to incorporate EMA collection in randomized relapse prevention trials. To study environmental as well as individual influences on drug use, her team is also collecting real-time location data with GPS along with EMA data. These studies are revealing complex interactions between mood, environmental disorder and drug use.



Kurt Rasmussen, Ph.D. is the Director of the Division of Therapeutics and Medical Consequences at the National Institute on Drug Abuse (NIDA), leading their efforts to promote the development of safe and effective pharmacotherapies, behavioral therapies, and devices to treat addiction. Previously he worked as a senior research scientist in the Neuroscience Division of Eli Lilly & Co., leading efforts to discover novel treatments for psychiatric disorders. He is a research scientist in the field of neuropharmacology and neurotherapeutic drug development with extensive experience in senior scientific and management leadership positions in the pharmaceutical industry and government. Dr. Rasmussen's career spans 30 years of highly innovative scientific research in neuroscience pharmaceutical discovery, from hypothesis generation to clinical candidate evaluation. He is a Fellow of the American College of Neuropsychopharmacology and on the Editorial Board of *Neuropsychopharmacology*. He received his A.B. with honors and distinction from Cornell University, his Ph.D. in neuroscience and psychology from Princeton University, and was a postdoctoral associate in the Department of Psychiatry at the Yale University School of Medicine.

Daniel Raymond has worked in the field of harm reduction for over two and a half decades. Daniel joined Harm Reduction Coalition in 2003 and became Policy Director in 2005. In his current capacity as Harm Reduction Coalition's Deputy Director of Planning and Policy, Daniel oversees the organization's policy, capacity-building, and overdose prevention departments. Daniel works with federal, state and local officials, advocates, and providers to expand critical drug user health interventions, including overdose education and naloxone distribution, syringe access programs, medication-assisted treatment, HIV and hepatitis C care and treatment, and quality health care for people who use drugs. He has served as chair of the Injection Drug Users Health Alliance, the Washington Heights CORNER Project Board of Trustees, and the National Viral Hepatitis Roundtable Steering Committee. Daniel has also served on Governor Cuomo's Heroin and Opioid Task Force, the Food and Drugs Administration's Antiviral Drug Advisory Committee, the American Medical Association Physician Consortium for Performance Improvement Hepatitis C Workgroup, and the AASLD/IDSA Hepatitis C Guidance Panel.

Philip Rutherford is the Director of Operations 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 Director, 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, and Re-entry.

Marta Sokolowska, Ph.D., joined the U.S. Food and Drug Administration in 2018 as Associate Director for Controlled Substances at the Center for Drug Development and Research. She provides strategic leadership in development and implementation of policies related to controlled substances including advising on all matters related to domestic and international drug scheduling. As a recognized expert in drug abuse potential assessment, throughout her career she has focused on facilitating initiatives to improve public health by advancing the science of assessing abuse liability. Dr. Sokolowska earned her doctoral degree in psychology from McMaster University in Canada.

Doug Throckmorton is Deputy Director for Regulatory Programs and shares responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks. Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the FDA in 1997, he conducted basic science research and practiced at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital.

Celia Winchell is the Medical Team Leader for Addiction Products in the Division of Anesthesiology, Addiction Medicine, and Pain Medicine in FDA's Center for Drug Evaluation and Research. Since 1995, she has been responsible for evaluating academic research protocols and commercial drug development programs for medications to treat drug addictions and monitoring post-marketing safety of marketed addiction medications. New medications brought to market during her tenure include, among others, over-the-counter nicotine products, buprenorphine (sublingual, implantable, and injectable depot formulations), depot naltrexone, acamprosate, and varenicline. Dr. Winchell earned her bachelor's degree in Psychology from Harvard College and her medical degree from the University of Virginia School of Medicine. She completed residency in Psychiatry at The Johns Hopkins Hospital.

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