

# **Methadone Treatment for Opioid Use Disorder: Examining Federal Regulations and Laws - A Workshop**

## **Committee**

### **Alan I. Leshner**

#### **Chair**

Alan Leshner, Ph.D., (Chair), is Chief Executive Officer, Emeritus of the American Association for the Advancement of Science and former Executive Publisher of the journal *Science* and the *Science* family of journals. He served as permanent CEO from December 2001 through February 2015, and then as Interim CEO from July-December 2019. Before joining AAAS, Dr. Leshner was Director of the National Institute on Drug Abuse at the National Institutes of Health. He also served as Deputy Director and Acting Director of the National Institute of Mental Health, and in several roles at the National Science Foundation. Before joining the government, Dr. Leshner was Professor of Psychology at Bucknell University, where he taught and conducted research on the relationship between hormones and behavior. Dr. Leshner is an elected fellow of AAAS, the American Academy of Arts and Sciences, the National Academy of Public Administration, and many others. He is a member and served as Vice Chair of the governing Council of the National Academy of Medicine (formerly the Institute of Medicine) of the National Academies of Sciences, Engineering and Medicine. He served two terms on the National Science Board, appointed first by President Bush and then reappointed by President Obama. Dr. Leshner received Ph.D. and M.S. degrees in physiological psychology from Rutgers University and an A.B. in psychology from Franklin and Marshall College. Dr. Leshner has received many honors and awards, including the Walsh McDermott Medal from the National Academy of Medicine and seven honorary Doctor of Science degrees.

## **Gavin Bart**

### **Member**

Gavin Bart, M.D., is Director of the Division of Addiction Medicine at Hennepin Healthcare and Professor of Medicine at the University of Minnesota Medical School. He received his MD from the University of Minnesota and trained in internal medicine at the Hennepin County Medical Center. His PhD is in experimental and clinical pharmacology, also from the University of Minnesota. His areas of expertise include clinical pharmacology and the pharmacological management of opioid use disorders. His current research areas include the population pharmacokinetics of methadone, genetic influences of methadone pharmacology and treatment outcome, and implementation of opioid use disorder in hospital and primary care settings. He is principal investigator of the NorthStar Node of the NIDA National Drug Abuse Treatment Clinical Trials Network and has provided extensive international technical assistance including to the PEPFAR /Substance Abuse and Mental Health Services Administration's capacity building HIV and addiction efforts in Vietnam and South East Asia and the US Bureau of International Narcotics and Law Enforcement Affairs' effort to develop international technology transfer centers for addiction prevention and treatment.

## **Richard J. Bonnie**

### **Member**

Richard Bonnie, L.L.B, is the Harrison Foundation Professor of Medicine and Law and director of the Institute of Law, Psychiatry and Public Policy at the University of Virginia. He has co-authored leading textbooks on criminal law and public health law and has devoted special attention during his career to public policies relating to mental health and substance abuse. His first book, "The Marijuana Conviction: A History of Marijuana Prohibition in the United States" (1974) was republished in 1999 as a "drug policy classic." Bonnie has been involved in public service throughout his career. Among other positions, he has been associate director of the National Commission on Marijuana and Drug Abuse (1971-73) and secretary of the first National Advisory Council on Drug Abuse (1976-80). He recently chaired a Commission on Mental Health Law Reform at the request of the chief justice of Virginia (2006-11) and is currently chairing an Expert Advisory Panel on Mental Health Reform for the Virginia General Assembly. Bonnie was elected to the National Academy of Medicine in 1991 and has chaired more than a dozen studies for the National Academies on subjects ranging from elder mistreatment to underage drinking, including the landmark report, "Ending the Tobacco Problem: A Blueprint for the Nation" (2007). In 2017, he chaired a study on policies needed to address the opioid epidemic in the United States and is now chairing a study on using knowledge about adolescent development to advance the well-being of all adolescents regardless of social background. Bonnie has served as an adviser to the American Psychiatric Association since 1979, received the APA's Isaac Ray Award in 1998 for contributions to forensic psychiatry and special presidential commendations in 2003 and 2016 for service to American psychiatry. He has also served on three MacArthur Foundation research networks, including, most recently, Law and Neuroscience. He is also a consultant to the American Academy of Neurology's Committee on Ethics, Law and Humanities. Bonnie received the University of Virginia's highest honor, the Thomas Jefferson Award, in 2007.

## **Magdalena Cerdá**

### **Member**

Magdalena Cerdá, DrPH, is an Associate Professor and Director of the Center for Opioid Epidemiology and Policy, at the Department of Population Health at NYU Grossman School of Medicine. Her work integrates approaches from social and psychiatric epidemiology to examine how social contexts and drug and health policies shape substance use, violent behavior, and common forms of mental illness. Current funded research focuses on the impact that cannabis laws and opioid policies, as well as emerging sources of social change, such as the COVID-19 pandemic, have on cannabis- and opioid-related harms in the United States and South America. In addition, she is evaluating the potential use of machine learning approaches to forecast overdose hotspots, and the impact of targeting overdose prevention interventions to future hotspots. She has published more than 200 peer-reviewed journal articles, as well as chapters in major textbooks in her field. By conducting work in these areas, she hopes her research can inform evidence-based policies to improve population health.

## **Abby Coulter**

### **Member**

Abby Coulter, is a methadone patient advocate in West Virginia, where she coordinates and spreads awareness about methadone maintenance treatment (MMT), fighting against the stigma that surrounds the treatment, as well as offering individual support to MMT patients. She is the founder and director of the Medication Assisted Treatment Support and Awareness (MATSA) group where she oversees and runs the day-to-day operations of a Facebook Support Group. Ms. Coulter helps lead the Urban Survivors Union's (USU) Methadone Mondays, which is a weekly national call for people who use drugs and methadone patients to come together to talk about methadone reform. As part of the USU Methadone Reform and Advocacy Team, she helped to put together this methadone patients' manifesto.

## **Bridget Dooling**

### **Member**

Bridget Dooling, J.D., is a research professor with the George Washington University Regulatory Studies Center, where she studies federal regulatory law policy. Prior to academia, she was a deputy chief, senior policy analyst, and attorney for the Office of Information and Regulatory Affairs (OIRA) at the U.S. Office of Management and Budget. While at OIRA she reviewed draft regulatory changes related to a variety of domestic policy issues, including substance use and mental health, Medicare, healthcare privacy, pharmaceuticals, rural access to healthcare, and more. She is a senior fellow of the Administrative Conference of the United States and serves on the Council of the American Bar Association's Section of Administrative Law and Regulatory Practice. Professor Dooling has taught courses on regulation, contributes to the Brookings Institute Series on Regulatory Process and Perspective, regularly blogs for the Yale Journal on Regulation's Notice and Comment Blog, and is licensed to practice law in Virginia.

## **Sheri L. Doyle**

### **Member**

Sheri Doyle, MPH, is a manager with Pew's substance use prevention and treatment initiative. In this role, she is an authority on national and state initiatives related to the prevention and treatment of substance use disorders and has a thorough understanding of the evidence surrounding the impact of these programs and models. Additionally, she worked on the project's prevention goals to increase the use of state prescription drug monitoring programs by prescribers, and researched strategies to improve the safety of prescribing methadone as a treatment for chronic pain. Before joining Pew, she worked for the National Association of County and City Health Officials where she provided technical assistance to local health departments on injury and violence prevention. She received a bachelor's degree in public health from the Johns Hopkins University and a master of public health in behavioral sciences and health education from the Rollins School of Public Health at Emory University.

## **Tracie Gardner**

### **Member**

Tracie Gardner, is the Vice President of Policy Advocacy at the Legal Action Center (LAC), where she directs their policy advocacy work, spearheads major initiatives, and fosters strategic partnerships that support LAC's mission. Tracie has worked more than 30 years in the public health, public policy, and not-for-profit fields as a policy advocate, trainer, and lobbyist. She has led advocacy campaigns that achieved substantial increases in funding and landmark policy reforms in the areas of substance use, HIV, alternatives to incarceration and reentry services, and community and correctional health. She is currently a board member of NEXT Distro and Outreach Drug and Alcohol Treatment Services. From 2015 to 2017, Tracie served as the Assistant Secretary of Mental Hygiene for New York State where she oversaw the State's Office of Alcoholism and Substance Abuse Services, Office of Mental Health, Office for People with Developmental Disabilities, the Developmental Disabilities Planning Council, and the Justice Center for the Protection of People with Special Needs. Prior to her appointment by the Cuomo Administration, Tracie was a key member of the Legal Action Center for more than 14 years, serving as LAC's Co-Director of Policy. In this role, she conducted and coordinated LAC's New York State public policy advocacy in the areas of substance use disorders, criminal justice, and HIV and AIDS. Tracie received a BA from Mount Holyoke College.

## **Helena Hansen**

### **Member**

Helena Hansen M.D., Ph.D., is Professor of Psychiatry and Chair of Research Theme in Translational Social Science and Health Equity for UCLA's David Geffen School of Medicine. She has published widely in clinical and social science journals ranging from JAMA and NEJM to Social Science and Medicine and Medical Anthropology, on faith healing of addiction in Puerto Rico, psychiatric disability under welfare reform, opioids and race, ethnic marketing of pharmaceuticals, and structural competency. Her first book, *Addicted to Christ: Remaking Men in Puerto Rican Pentecostal Drug Ministries* was published by University of California Press in 2018, and her second book, *Structural Competency in Medicine and Mental Health: A Case-Based Approach to Treating the Social Determinants of Health*, with co-editor Jonathan Metzl, was published by Springer Press in 2019. Her third book, *Whiteout: How Racial Capitalism Changed the Color of Heroin in America*, is forthcoming from UC Press. She has received major funding from NIDA, the Mellon Foundation, the Robert Wood Johnson Foundation and Open Society Foundation.

## **Van Ingram**

### **Member**

Van Ingram, is the executive director for the Kentucky Office of Drug Control Policy (ODCP). Van joined ODCP in November 2004, shortly after it was created with the mission of coordinating Kentucky's substance abuse efforts in enforcement, treatment and prevention/education. Van served with the Maysville Kentucky police department for more than 23 years, the last six as chief of police. He is a former president of the Kentucky Association of Chiefs of Police, and was named "Kentucky Chief of the Year" in 2001. He is a former recipient of the governor's award for outstanding contribution to law enforcement, as well as the Melvin Shein award for Distinguished Service to Kentucky Law Enforcement. Van is a certified law enforcement instructor and has trained officers across the state on a variety of topics, including community oriented policing, case management, and "Kentucky substance abuse issues" for chiefs, sheriff's and command staff. He is a frequent speaker on a variety of substance abuse issues both in Kentucky and nationally.

## **Matthew Lawrence**

### **Member**

Matthew Lawrence, J.D., is an Associate Professor of law at Emory University School of Law. Mr. Lawrence researches and publishes on health care finance, administrative law, and addictions. He was recognized by the American Society for Law, Medicine, and Ethics as a 2017 Health Law Scholar, and is affiliate faculty at Harvard Law School's Petrie-Flom Center for Health Law Policy, Bioethics, and Biotechnology, where he was previously a fellow. In addition to his teaching and scholarship, Lawrence possesses a wealth of experience in the federal government. He most recently served as a special legal advisor to the US House of Representatives Budget Committee (Majority). Previously, he worked on health care regulatory issues during the Obama and Trump Administrations as a trial attorney in the Department of Justice's Federal Programs Branch and attorney advisor in the Office of Management and Budget's Office of General Counsel in the Executive Office of the President. Mr. Lawrence is a graduate of New York University School of Law and Brown University; and he served as a law clerk to the Honorable Douglas H. Ginsburg on the US Court of Appeals for the DC Circuit.

## **Gail A. Mattox**

### **Member**

Gail Mattox, M.D., DLFAACAP, DLFAPA, currently serves as Professor and Chair of the Department of Psychiatry and Behavioral Sciences at Morehouse School of Medicine. Dr. Mattox received her BS degree with honors from Elmhurst College in Elmhurst, Illinois, a MD degree with honors from Meharry Medical College in Nashville, Tennessee. She completed child and adolescent psychiatry and adult psychiatry training at Northwestern University Feinberg School of Medicine in Chicago, Illinois. Dr. Mattox has been practicing psychiatry for over 30 years. Her clinical work has included a variety of clinical settings and her leadership roles have included serving as Medical Director, and Chief Medical Officer for several large programs providing care to patients with primary psychiatric disorders and co-occurring substance use disorders. She has been instrumental in developing training programs, policies, and procedures to improve quality of care and access to care with a commitment to promoting health equity and addressing behavioral health disparities. Dr. Mattox is a Diplomate of the American Board of Psychiatry and Neurology. She is a Distinguished Life Fellow of the American Academy of Child and Adolescent Psychiatry, and a Distinguished Life Fellow of the American Psychiatric Association. She has received numerous awards for teaching, leadership and service including the Leonard Tow Humanism in Medicine Award. She is a longstanding member of Alpha Omega Alpha National Medical Honor Society.

## **Josiah D. Rich**

### **Member**

Josiah "Jody" Rich, M.D., M.H.P., is a Professor of Medicine and Epidemiology at Brown University, and a practicing infectious disease and addiction specialist providing care to patients at The Miriam Hospital and the Rhode Island Department of Corrections since 1994. He has published over 200 peer-reviewed publications, predominantly in the overlap between infectious diseases, addictions, and incarceration. He is the Director and Co-Founder of The Center for Prisoner Health and Human Rights at The Miriam Hospital and Co-Founder of the nationwide Centers for AIDS Research Collaboration on HIV in Corrections initiative. Dr. Rich has advocated for public health policy changes to improve the health of people with addiction, including improving legal access to sterile syringes and increasing drug treatment for incarcerated and formerly incarcerated populations. He has had continuous NIH research funding for over 2 decades. His primary areas of interest and expertise are in the overlap between infectious diseases and illicit substance use, the treatment and prevention of HIV infection, and the care and prevention of disease in addicted and incarcerated individuals. More recently he has focused on addressing the opioid overdose epidemic. He has testified in congress multiple times and served as an expert advisor to Rhode Island Governor Gina Raimondo's Overdose Prevention and Intervention Task Force since its inception in 2015.

## **Danielle Russell**

### **Member**

Danielle Russell, is currently a doctoral student at Arizona State University, where she hope to expand on past research and continue to study how the criminalization of substances used for personal pleasure has become a key issue and tool for social control, contributing to the ongoing legacy of racialized criminalization and mass incarceration in the U.S. Being personally impacted by many of the harms that affect those of us who use illicit drugs, Ms. Russell is dedicated to working collectively towards dismantling the structural violence and policies that contribute to and impose these harms on PWUD.

## **Kenneth Stoller**

### **Member**

Kenneth Stoller, M.D., FAPA, is an Associate Professor in the Department of Psychiatry and Behavioral Sciences at the Johns Hopkins University School of Medicine, and a well-regarded expert on substance use disorders, including opioid use disorder. He has developed, evaluated and disseminated models of care geared toward multi-morbid populations that are integrative and promote adherence. His most impactful focus has been on collaborative care models, treatment access, program building, health policy, and healthcare utilization/cost. He developed and disseminated a collaborative opioid prescribing (“CoOP”) model which has received high level attention from SAMHSA, ONDCP, and professional societies, and has been instituted by programs and localities nationwide. Dr. Stoller is deeply-engaged with local, state and national associations, oversight entities, and governmental agencies engaged in addressing the opioid epidemic. He directs the Johns Hopkins Hospital’s outpatient substance use disorder treatment program and serves as the Medical Director for Behavioral Health at Johns Hopkins HealthCare, which administers health care services for four health plans.

# Jonathan Watanabe

## Member

Jonathan Watanabe, Ph.D., Pharm.D., M.S., is Associate Dean for Assessment and Quality, and Professor of Clinical Pharmacy at the University of California, Irvine School of Pharmacy & Pharmaceutical Sciences. He is a pharmacist, health economist, and outcomes researcher. Dr. Watanabe examined the impact of addiction disorders, specifically opioid use disorder, on health services utilization including hospitalizations and costs using large, representative validated databases. He has also studied improving access to medications for opioid use disorder and led academic detailing training on MOUD. Dr. Watanabe applies real-world data to develop policy solutions to improve patient care, bolster population-health, enhance access and equity for marginalized populations and reduce medical costs. He is a consultant to the California Health Benefits Review Program of the California State Legislature and served on the Advisory Group on Pain Assessment and Management in Long-Term Care Settings for the Joint Commissions. He was a contributor to the NASEM report Making Medicines Affordable: a National Imperative and served on the committee for the Medications in Single-Dose Vials: Implications of Discarded Drugs report. His research on health implications of non-optimized medication regimens has been cited in multiple successful state legislative efforts to bolster patient-centered care and medication management, and he has testified before the California Senate Health Panel regarding value of comprehensive medication management services to bolster the health and wellness of Californians enrolled in Medicaid. Dr. Watanabe has been involved in national quality metrics development on long-term care and transitions of care with prior service on the Pharmacy Quality Alliance. He has previously served on the American Academy of Neurology Neurotherapies Workgroup on Pharmacoeconomics. Dr. Watanabe was the first recipient of the University of Washington/Allergan Global Health Economics and Outcomes Research Fellowship. He received his BS from the University of Washington, his PharmD from the University of Southern California, and his MS and PhD from the University of Washington Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute. He is past recipient of the University of Washington Distinguished Alumnae in Pharmaceutical Science and Research award. He is a past National Academy of Medicine (NAM) Anniversary Fellow in Pharmacy sponsored by the American Association of Colleges of Pharmacy and the American College of Clinical Pharmacy. He served as a Scholar in the NAM Emerging Leaders in Health and Medicine Program. He is a Board-Certified Geriatric Pharmacist (BCGP) with prior direct-patient care clinical experience at the Medicare-Medicaid Program of All-inclusive Care for the Elderly (PACE) program, assisted living, skilled nursing, and long-term care settings.