

Considerations for Buprenorphine Initiation and Maintenance Care

Wednesday, May 10 from 1 – 4:45 pm ET and Thursday, May 11 from 1 – 4:30 pm ET
Virtual Public Meeting

Speaker Biographies

Barbara Andraka-Christou, PhD, JD

Associate Professor, University of Central Florida



Dr. Barbara "Basia" Andraka-Christou is an Associate Professor in the School of Global Health Management and Informatics, with a Joint Secondary Appointment in the Department of Internal Medicine, at the University of Central Florida (UCF). She is also a licensed attorney in Florida. Her research explores substance use disorder treatment from health services and health policy perspectives. Much of her work focuses on improving access to medications for opioid use disorder, including in problem-solving courts. She leads the UCF Court Health Services & Policies Working Group. Dr. Andraka-Christou has authored more than fifty peer reviewed articles. She is the author of the book *The Opioid Fix: America's Addiction Crisis and the Solution They Don't Want You to Have* (Johns Hopkins University Press, 2020). Dr. Andraka-Christou received her doctoral degree and juris doctorate from Indiana University and completed a postdoctoral research fellowship there.

Pouya Azar, MD, FRCPC, DABAM

Head of Complex Pain and Addiction Service, Vancouver Coastal Health



Dr. Pouya Azar is the Head of the Complex Pain and Addiction Service (CPAS), a consult service under the Department of Psychiatry at Vancouver Coastal Health, British Columbia, Canada, which provides management of pain, mental health disorders, and substance use disorders across all clinical services at Vancouver General Hospital (VGH), University of British Columbia (UBC) Hospital, and GF Strong Rehabilitation Centre. He is also the Addiction Lead at Foundry Vancouver Granville, a provincial clinic for youth and adolescents suffering from addiction and mental illness. In addition, Dr. Azar is a consulting physician for adolescent addiction medicine at BC Children's Hospital, the co-lead of the Addiction Medicine Research and Innovation Program at the British Columbia Centre for Excellence in HIV/AIDS, a pain physician for the VGH Transitional Pain Clinic, a faculty member at the UBC Faculty of Medicine, and the director of the UBC Complex Pain and Addition Postgraduate Fellowship program. Dr. Azar's clinical and translational research focuses on the development and evaluation of novel opioid agonist treatment protocols and medical devices to improve the health outcomes for patients with mental health and substance use disorders.

Robert Baillieu, MD, MPH, FAAFP

**Physician & Senior Advisor, Substance Abuse and Mental Health Services Administration,
Center for Substance Abuse Treatment**



Dr. Robert Baillieu serves as a physician and senior advisor at the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT). In this role Dr. Baillieu has contributed to work on national policies related to the treatment of opioid use disorder and stimulant use disorder, while also contributing to multiple publications available in the SAMHSA Store. He is also involved in departmental evaluation efforts that seek to assess and promote best practices in treatment. Dr. Baillieu graduated with honors from the University of Sydney Medical School in Australia and completed residency training in family medicine at The University of Texas Health Science Center in San Antonio, where he was also chief resident. Prior to this, Dr. Baillieu lived in Australia where he undertook training in adult internal medicine. He is a board-certified family physician and a former Robert L. Phillips, Jr., Health Policy Fellow at the American Academy of Family Physicians' Robert Graham Center and The U.S. Health Resources and Services Administration, Bureau of Primary Care. He holds degrees in medicine, public health, business and modern languages, and has experience in health systems research, policy analysis, community organizing, international business, management, public health, education and medical practice. Dr. Baillieu is also a former assistant professor of clinical family medicine at Georgetown University where he supervised residents and taught classes in policy, advocacy, statistics and clinical medicine. Dr. Baillieu's research activities have focused on the primary care workforce, health IT and the implementation of best practices at the community level. He has presented at national and international meetings, as well as published in international, peer-reviewed journals.

Dionna Berkholder

Peer Coordinator, North Colorado Health Alliance



Dionna Berkholder is a Peer Care Coordinator with the North Colorado Health Alliance. She primarily works with women, and women with children, at inpatient and outpatient supportive services in Northern Colorado. She uses her lived experience, empathy, and expertise with multiple systems to support people as they work to enter treatment and recovery from substances. She guides her members through housing supports, systems engagement, and treatment and recovery coaching. Ms. Berkholder is in recovery from opioid use disorder – and although buprenorphine was not a part of her personal recovery journey, many of her close friends and family members do rely on buprenorphine as part of their recovery. In addition, she has countless members who utilize the medication. She has seen the benefits of MAT services and as a result is an advocate to see this recovery method expand throughout Colorado and across the nation.

Bartholt Bloomfield-Clagett, MD
Medical Officer, US Food and Drug Administration



Dr. Bartholt Bloomfield-Clagett is a Medical Officer in the Division of Anesthesiology, Addiction Medicine, and Pain Medicine in the Office of New Drugs at the FDA. In this capacity, he serves as a clinical reviewer on the Addiction Medicine Team responsible for evaluating clinical trials of new drugs for the treatment of addiction for safety and effectiveness. He received his medical degree from the Perelman School of Medicine at the University of Pennsylvania. Dr. Bloomfield-Clagett completed residency training in psychiatry at New York Presbyterian Hospital – Weill Cornell Medical Center and additional fellowship training at the Experimental Therapeutics & Pathophysiology Branch of the National Institute of Mental Health.

Andrea Bonny, MD
Chief of the Division of Adolescent Medicine, Nationwide Children’s Hospital



Dr. Andrea Bonny is a Professor of Clinical Pediatrics at The Ohio State University School of Medicine and Chief of the Division of Adolescent Medicine at Nationwide Children’s Hospital. Her expertise lies in adolescent reproductive health and addiction. She received her medical degree from the Washington University School of Medicine in St. Louis and then completed Pediatric Residency and Adolescent Medicine Fellowship at Cincinnati Children’s Hospital Medical Center. She has over 10 years of experience providing medication treatment of addiction to adolescents and young adults. She served as an expert clinical consultant to the Ohio Medicaid Opioid Analytic Project which aimed to develop predictive models and data visualization tools to inform opioid medication treatment related decision making for clinicians and state policy makers. She is part of an investigative team funded through the Ohio Department of Education to evaluate the use of passive home monitoring technology to model the risk of relapse among emerging adults with opioid use disorders. In addition, she has collaborated on several epidemiological evaluations of opioid availability, overdose deaths, and receipt of substance abuse treatment in the State of Ohio.

Jeffery Bratberg, PharmD, FAPhA
Clinical Professor, University of Rhode Island



Dr. Jeffrey Bratberg studies the essential and emerging roles community pharmacists play regarding opioid overdose, harm reduction and opioid use disorder treatment as a clinical professor of pharmacy practice at the University of Rhode Island. He advocates for pharmacists’ expanded roles in medication access, public health promotion, and policy change. He is an associate editor of the Journal of the American Pharmacists Association (JAPhA) and is on the Board of Directors of the Association for Multidisciplinary Education and Research in Substance Use and Addiction (AMERSA). He also co-

produces and hosts a weekly public health pharmacy podcast, “The Regimen”, with his pharmacy students.

Gerard Carroll, MD, FAAEM, FAEMS, EMT-P

Associate Professor, Cooper University



Dr. Gerard Carroll is the Program Director for the EMS Fellowship at Cooper University Hospital. He is passionate about utilizing physician field response to translate the bedside, apprenticeship model of medical education into the field. His interests include addiction medicine and the role of urban EMS caring for underserved populations. He graduated from Brandeis University with a bachelor’s degree in History. As an undergraduate, Dr. Carroll became passionate about emergency medical services, and following graduation became certified as a paramedic. He worked for nearly a decade in the New York City 911 system and was recognized for his service on the morning of the 9-11 attacks. He then earned his medical degree from Dartmouth Medical School where he was inducted into the Gold Humanism Honor Society. He completed emergency medicine residency at Temple University Hospital and completed a fellowship in emergency medical services at Cooper University Hospital. He is dual board certified in emergency medicine and emergency medical services. Dr. Carroll thrives on prehospital and disaster medicine and is passionate about resident, fellow, and especially about prehospital provider education. He was integral in the creation of our EMS fellowship and is excited to be the second program director. Dr. Carroll believes in the apprenticeship model of medical education and created Cooper’s prehospital physician response program to bring both physician-level care to patients and to move the bedside teaching model to the prehospital arena. Dr. Carroll loves the practice of academic emergency medicine and emergency medical services, and is not satisfied with the status quo. He believes strongly that EMS is a practice of medicine and as such needs to constantly be refocused on patient outcomes while optimizing its place in the health care system. He is a champion of nontraditional transport models, and helped spearhead the movement of addiction medicine into the field by educating paramedics about opioid use disorder and training them to rescue patients in withdrawal with medication-assisted therapy using buprenorphine. Dr. Carroll loves the varied practice environments of EM and EMS making academic, rural, prehospital, austere disaster deployment, and even cruise ship medicine a part of his regular medical practice.

Dwayne Dean, RCPF, CPRS, RPS

Principal Facilitator, Peer Recovery Training and Support



Dwayne Dean is a Recovery Coach Professional and a Recovery Coach Professional Facilitator through the International Association for Recovery Coach Professionals. Dean is also a Certified Peer Recovery Specialist and a Registered Peer Supervisor through the Maryland Addictions and Behavioral Health Professional Certification Board. He is the founder of Peer Recovery Training and Support Services, LLC, where he is the Principal Facilitator and Lead Recovery Organizational Consultant. As a faculty member of the University of Maryland College Park, Dean is an Interventionist for the Global Mental Health and Addictions Program, where he is currently conducting research through a grant from the National Institute of Health to measure outcomes of having a Peer-delivered behavioral activation model to help improve retention rates of persons receiving medication for opiate use disorder. Dean is the full-time father of a 2-year-old daughter (Monroe), and has almost 10 years of long-term recovery.

Gail D’Onofrio, MD

Emergency Medicine Professor, Yale University



Dr. Gail D’Onofrio is the Albert E. Kent Professor of Emergency Medicine, and Professor of Medicine and Public Health at Yale School of Medicine. She is boarded in emergency medicine and Addiction Medicine. An independent NIH-funded physician-scientist with over two decades of experience designing and implementing clinical trials in the ED setting related to alcohol and drug use, her work (JAMA, 2015) demonstrating that ED-initiated buprenorphine increases engagement in addiction treatment for individuals with OUD, has changed clinical practice. Dr. D’Onofrio has a long track record of mentoring physician scientists in independent research careers. She is the PI of a NIDA K12 establishing the Yale Drug Use, Addiction and HIV Research Scholars (Yale-DAHRS) program, a Mentored Career Development Program with focused training in prevention and treatment of drug use, addiction, and HIV in general medical settings with scholars in multiple medical specialties. Dr. D’Onofrio is the PI of the New England Consortium Node, for the NIDA Clinical Trials Network. Dr. D’Onofrio is a founding Board member of the Board of Addiction Medicine now recognized by ABMS as a Specialty, Sub-specialty under Preventive Medicine. She partners with multiple agencies regionally and nationally to change policies and introduce interventions to combat the opioid crisis.

Jeremy Dubin, DO, FASAM

Assistant Clinical Professor, University of Colorado



Dr. Jeremy Dubin graduated from the Philadelphia College of Osteopathic Medicine (PCOM) in 2002, and completed his Family Medicine Residency in Colorado Springs, CO in 2005. Dr. Dubin has been board certified in Addiction Medicine since 2006 and teaches locally, nationally, and internationally in the field of Addiction Medicine. He is an Assistant Clinical Professor at the University of Colorado School of Medicine in the Department of Family Medicine and Clinical Faculty Adjunct at Rocky Vista College of Osteopathic Medicine (RVCOM). He is a past member of the Opioid Advisory Panel in the Office of Behavioral Health for the state of Colorado. Dr. Dubin is Chief Medical Officer of Front Range Clinic, an official U.S. Ski Team Physician and a past NAUI Scuba Instructor. Dr. Dubin is proud to be behind the over 35 medical providers at Front Range Clinic that challenge stigma and remove barriers daily to provide nonjudgmental, up-to-date medical care. Front Range Clinic offers 'low barrier / high access' MAT treatment at over 60 locations around Colorado, including co-location in homeless shelters, hospitals, counseling centers, syringe access facilities and rural and frontier areas via 4 mobile state-funded MAT units. Dr. Dubin lives in Fort Collins, CO.

Kelly E. Dunn, PhD, MBA

Professor, John Hopkins University



Dr. Kelly Dunn is a Professor in the Behavioral Pharmacology Research Unit within the Department of Psychiatry and Behavioral Sciences in the Johns Hopkins University School of Medicine. Dr. Dunn has worked in the area of opioid use disorder treatment and withdrawal mitigation since 2005 and has served as the Principal Investigator on grants totaling more than \$20 million from the National Institute on Drug Abuse focused primarily on the treatment of opioid use and related comorbidities. Dr. Dunn has also served in positions of leadership in the substance use field, including incoming Editor-in-Chief of the journal *Experimental and Clinical Psychopharmacology (ECP)*, a member of the Board of Directors for the College on the Problems of Drug Dependence, the 2021 President of the American Psychological Association's Division on Psychopharmacology and Substance Use, Co-Editor at the *Journal of Addiction Medicine*, and editor of the forthcoming *Oxford Handbook of Opioids and Opioid Use Disorder*.

Jody Green, PhD, FAACT

Chief Scientific Officer, Uprise Health's Inflexxion



As the Chief Scientific Officer for Uprise Health's Inflexxion, Dr. Green provides strategic direction for drug safety epidemiologic research design, development and enhancement of public health surveillance networks, and data dissemination activities for post market studies of prescription and nonprescription medications. She has also done extensive work partnering with government agencies and industry to combat the opioid crisis, including evaluating the effectiveness of interventions to reduce risk of overdose in adults and pediatrics. Dr. Green is a 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. As an invited expert panelist, she has participated in FDA workshops to address methods for evaluating the effectiveness of abuse deterrent formulations of prescription opioid medications as well as ensuring safe opioid packaging, storage, and disposal. Dr. Green has over 20 years of research experience aimed to advance public health and patient safety, authoring or co-authoring over 85 manuscripts in peer-reviewed journals, including co-authorship of the Annual Report of the National Poison Data System from 2006 to 2010. Dr. Green received her doctorate in applied statistics and research methods from the University of Northern Colorado in 2000, with a minor in psychology. 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 has served as 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).

Eliza Hutchinson, MD

Assistant Professor, University of Michigan



Dr. Eliza Hutchinson is board certified in Family Medicine and Addiction Medicine and currently is an Assistant Professor of Family Medicine at the University of Michigan. She is also Medical Director of MAT services at Packard Health, a federally qualified health center in Ann Arbor, MI. She provides education and support to clinicians across Michigan through work with the Michigan Opioid Collaborative. Prior to living in Ann Arbor, Dr. Hutchinson provided primary and addiction care at a federally qualified health center in Seattle, WA, and served as Clinical Site Director of a low barrier, community-based model for substance use disorder care. Dr. Hutchinson is a passionate advocate for harm reduction, expanding primary care-based addiction treatment, and stigma reduction.

Michelle Lofwall, MD, DFAPA, DFASAM

Professor, University of Kentucky



Dr. Michelle Lofwall, board-certified in psychiatry and addiction medicine, is a Professor in the Departments of Behavioral Science and Psychiatry and the Bell Alcohol and Addictions Endowed Chair at the University of Kentucky (UK). She received her bachelor's degree in Psychology from Northwestern University and her medical and master's degrees from Chicago Medical School. She completed internship, psychiatry residency, and a fellowship in behavioral pharmacology from Johns Hopkins University. Currently, she is the medical director of UK's Robert Straus and First Bridge Clinics, which provide comprehensive opioid use disorder (OUD) treatment within the UK Center on Drug and Alcohol Research. She oversees the Bell Addiction Medicine Scholar Program that aims to grow a highly competent physician faculty in a variety of medical specialties to train medical students, residents and faculty in clinically relevant addiction medicine practice. Her passion is in improving the care of patients with addiction, and her research has included evaluation of novel treatments for opioid use disorder (e.g., buprenorphine implants and depot injections), understanding factors associated with buprenorphine diversion, improving care delivery of complex patients with OUD, and best practices for linking and retaining persons in care for OUD treatment. She helps lead the treatment team for Kentucky's NIH HEALing Communities Study (HCS) and spearheaded the development of the national policy workgroup in the HCS. She was elected as a Distinguished Fellow of American Society of Addiction Medicine (ASAM) and the American Psychiatric Association. She has received numerous teaching and mentoring awards, the Nyswander/Dole (Marie) Award from the American Association for the Treatment of Opioid Dependence and was an expert panel member for SAMHSA's Treatment Improvement Protocol on Medication Treatment for Opioid Use Disorder (TIP 63).

Caitlin Martin, MD, MPH, FACOG, FASAM

Director of OBGYN Addiction Services, Virginia Commonwealth University



Dr. Caitlin Eileen Martin is the Director of OBGYN Addiction Services at Virginia Commonwealth University in Richmond, Virginia. She received her bachelor's degree from the University of North Carolina Chapel Hill followed by degrees in Public Health and Medicine from John Hopkins. She completed her residency in OBGYN at UNC Chapel Hill. As a board-certified physician, in both Obstetrics and Gynecology and Addiction Medicine, she cares for women with substance use disorders through the lifespan. In doing so, she leads the VCU OB MOTIVATE program that provides integrated OBGYN and addiction treatment with wrap-around services to pregnant and parenting people. Lastly as a physician scientist, her research aims to advance the evidence base informing the individualization of addiction treatments by sex, gender, and social determinants of health.

Tom Menighan, MBA, ScD, FAPhA

Founding Partner, Catizone, Luce & Menighan



Dr. Tom Menighan is the founding partner in Catizone, Luce & Menighan, a consulting practice providing guidance in innovative pharmacy practice, operations, advancement of technology, supply chain integrity and regulation. He is the CEO emeritus of the American Pharmacists Association where he served as CEO for over 11 years. He is currently Assistant Dean for Community Engagement for the West Virginia University School of Pharmacy. Dr. Menighan is a board member of the United States Pharmacopeia (USP) and former elected Vice President of the Bureau of International Pharmaceutical Federation (FIP). He is a chairman of the Pharmacy Quality Solutions (PQS), a founding board member in PursueCare and PursueCareRX, companies that support patients in recovery. He also serves on the board of West Virginia Drug Intervention Institute. He received his pharmacy degree from West Virginia University School of Pharmacy and his master's degree in Business Administration from Averett College. He has been awarded honorary doctorate degrees from West Virginia University and the University of Charleston.

Iván Montoya, MD, MPH

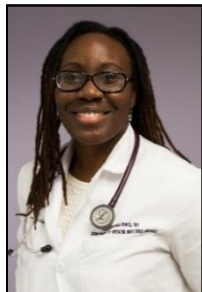
Acting Director, Division of Therapeutics and Medical Consequences, National Institute on Drug Abuse



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 degree in Public Health 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).

Amesika Nyaku, MD, MS

Assistant Professor, Rutgers New Jersey Medical School



Dr. Amesika Nyaku is an Assistant Professor in the Division of Infectious Diseases at Rutgers New Jersey Medical School and a physician-scientist. She provides clinical care for people living with HIV or other infectious diseases and substance use disorders. Her research interests lie at the intersection of HIV and substance use disorders. She focuses on 1) evaluating long-acting therapeutics for HIV and opioid use disorder, 2) the implementation of integrated care models for HIV and substance use disorders to improve health outcomes, and 3) increasing the inclusion and participation of racial/ethnic minorities in clinical trials research. She is also co-director of the Northern New Jersey Medication-Assisted Treatment Center of Excellence that is tasked with assisting the state in expanding access to medication-assisted treatment for opioid use disorder through education, novel service delivery, and community collaboration.

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's degree in Public Health degree from the Johns Hopkins Bloomberg School of Public Health.

Amer Raheemullah, MD

Clinical Associate Professor, Stanford University



Dr. Amer Raheemullah is a Clinical Associate Professor at Stanford University in the Psychiatry and Behavioral Sciences Department. He specializes in the treatment of addiction, has published chapters and peer-reviewed articles in this area, and is director of the Addiction Medicine Consult Service at Stanford Hospital. He is board-certified in Addiction Medicine and Internal medicine and has a special interest in developing novel methods to increase access to addiction treatment, through criminal justice, health care, and tech enabled solutions.

Chad Sabora, MS, JD

Senior Advisor, Faces & Voices of Recovery



Chad Sabora is in long-term recovery from a substance use disorder. Chad has unique lived experience, holding a master's degree in psychology and he is a former prosecuting attorney in addition to being a former drug user. Chad works in many areas involving drug policy, drug use, substance use disorder, treatment and recovery services. He led drug policy reform and other legislative efforts under the umbrella of social justice. He helped write, advocate, and pass numerous drug policy reform laws in Missouri and Washington D.C. Such as Missouri's overdose immunity law, first responder naloxone access, third party naloxone access, and legally removing the criminal justice system from medical decisions in regard to the use of evidence-based medications such as methadone and buprenorphine when someone is involved in the criminal justice system. Chad is embedded in the national dialogue as an expert in harm reduction and drug policy reform; he has served as a correspondent for CNN and MSNBC, he was the focus of an Emmy Award-winning episode of NBC News with Brian Williams, he was awarded the Robert C Randall award by Drug Policy Alliance, he was featured on the front page of the New York Times, he has given TedTalks on drug policy and its historical context and co-authored a research article on the hybrid model recovery community center which he created that recognizes recovery at the point someone engages in safer using practices. Chad co-founded The Missouri Network for Opiate Reform and Recovery and he co-founded Rebel Recovery Florida (both are 501c3 not for profits), he is on the Board of Directors for the Discovery Institute for Addictive Disorders in New Jersey, he does technical assistance with the CDC on syringe service programs, he serves as Vice President of Government and Public Relations at Indiana Center for Recovery and most importantly, he is Senior Advisor for Faces and Voices of Recovery. Chad was also one of the 17 individuals that worked as the stakeholders group in collaboration with SAMHSA and ONDCP to draft the federal literature that will define harm reduction in this country.

Michael Smith, PharmD

Clinical Associate Professor of Pharmacy and Clinical Pharmacist, Michigan Medicine



Michael Smith is a Clinical Associate Professor in the Department of Clinical Pharmacy at the University of Michigan College of Pharmacy and Clinical Pharmacist in Pain and Palliative Care at Michigan Medicine. He is the Residency Program Director for the PGY2 Pain Management and Palliative Care Pharmacy Residency at Michigan Medicine. Dr. Smith received his bachelor's degree in Chemistry and doctoral degree in Pharmacy from the University of Pittsburgh. He completed a pharmacy practice and internal medicine specialty residency at the University of Pittsburgh Medical Center. He is a preceptor of the Pharmacy Residency Programs at Michigan Medicine. He is also a board-certified specialist in pharmacotherapy.

Matthew Strait, MS

Deputy Assistant Administrator, Drug Enforcement Agency



Mr. Matthew J. Strait is a 20-year veteran of the Drug Enforcement Administration (DEA). His contributions to the DEA span several regulatory roles specifically relating to entities authorized to possess controlled substances, currently surpassing 1.92 million nationwide. These roles include activities such as: importation, exportation, manufacture, distribution, prescribing, and dispensing. In June 2020, Mr. Strait was appointed to the role of Deputy Assistant Administrator for the Office of Diversion Control Regulatory.

Marta Sokolowska, PhD

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



Dr. Marta Sokolowska is the Deputy Center Director for Substance Use and Behavioral Health in FDA's Center for Drug Evaluation and Research (CDER). She serves as the center's executive-level leader responsible for advancing FDA's public health response to the non-medical use of substances with abuse potential. With expertise in science-based assessment and management of drug abuse risks, Dr. Sokolowska advises senior FDA officials on shaping scientific and policy interventions and executing strategies pertaining to the use of controlled substances and behavioral health programs. Dr. Sokolowska joined CDER in 2018 as Associate Director for Controlled Substances in the Office of the Center Director. In 2020, she began leading the Controlled Substances Program (CSP), which comprises the Controlled Substance Staff (CSS) and the Controlled Substances Initiatives (CSI) group. CSS provides consultation throughout FDA on evaluation of abuse potential of drugs and advises on all matters related to domestic and international drug scheduling. The strategy group pursues activities and policies to identify, mitigate, and manage emerging issues with controlled substances to minimize risks associated with problematic use while enabling appropriate access to these products for medical use. Dr.

Sokolowska is a recognized expert in drug abuse liability and scheduling strategies. She has facilitated numerous initiatives to improve public health by advancing the science of assessing drug abuse liability. Prior to joining FDA, Dr. Sokolowska held senior clinical and medical leadership roles in the pharmaceutical industry. She earned her doctoral degree in Psychology from McMaster University in Canada.

Jade Waits

Peer Recovery Specialist, Boulder Care



Jade Waits is recognized by the Mental Health and Addiction Certification Board of Oregon as a Certified Recovery Mentor who is currently meeting with patients as a Peer Recovery Specialist with Boulder Care, which specializes in supporting recovery and telehealth treatment for individuals with substance use disorders. As a dedicated advocate of harm reduction practices and outreach efforts for vulnerable populations throughout California and Oregon, she has taken part in various projects including promotional access to prevention medicine, education of safer use strategies, and connecting individuals in rural areas to treatment. She has helped to promote overdose response training to community partners with crisis prevention training in public spaces to support unhoused communities. She has aided with multiple Syringe Exchange programs and Naloxone distribution for various agencies throughout Southern Oregon. She utilizes lived experience in conjunction with academic skills to support patients while working in the field, and simultaneously pursuing a master's degree through Portland State University for Social Work. She has worked as a Case Manager for unaccompanied/McKinney Vento youth and families, has been a residential counselor for Juvenile offenders at a transitional shelter, and has worked as a former Behavioral Interventionist for individuals living with autism in school and home settings. Her overall goal is to continue to support community efforts for equity, advocacy, and innovation, while uplifting any and all oppressed and marginalized populations.

Melissa Weimer, DO, MCR, DFASAM

Associate Professor, Yale University



Dr. Melissa Weimer is a clinician-educator who is board-certified in Internal Medicine and Addiction Medicine. She is an Associate Professor of Medicine and Public Health at Yale School of Medicine and the Medical Director of Yale Addiction Medicine Consult Service. Dr. Weimer has a clinical and research focus on expanding access to treatment for individuals with substance use disorders, particularly in the hospital setting. Dr. Weimer is the chair of the American Society of Addiction Medicine Clinical Practice Guideline Methodology and Oversight Committee.

Nora D. Volkow, MD

Director of the National Institute on Drug Abuse (NIDA), National Institutes of Health



Dr. Nora Volkow 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.

Michelle Winberg

Phlebotomist, Harm Reduction Michigan



Michelle Winberg is the medical clinic lead at Harm Reduction Michigan, a health equity not-for profit, providing services in the mid-western U.S. Ms. Winberg is a Certified Phlebotomy Technician, with 6 years' experience in harm reduction, 11 years' experience employed in medication for opiate use disorder (MOUD) clinical services, and a person in long-term recovery. Most importantly, she is the proud mother of Maddi, 18, and Bronson, 5.

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.