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

Safe Use of Benzodiazepines: Clinical, Regulatory, and Public Health Perspectives

Virtual Meeting
July 12 & 13, 2021

Speaker Biographies

Sumit Agarwal is a physician and health policy researcher at Harvard Medical School and Brigham and Women's Hospital. He has done research on topics including benzodiazepine prescribing, physician burnout, blue-collar workers' ACA insurance gains, and Medicare's new billing codes. He received the Mack Lipkin Senior Associate award for his research on benzodiazepine prescribing patterns and trends, and his work has been published in the New England Journal of Medicine, Journal of the American Medical Association, and Health Affairs as well as featured on CNN and NPR. He sees patients as a primary care physician at the Phyllis Jen Center for Primary Care at Brigham and Women's Hospital.

Kelly J. Clark is a psychiatrist and addiction medicine specialist who has focused her career on issues of evidence informed behavioral health care, addictive disease, and payment reform. Dr. Clark founded Addiction Crisis Solutions to engage stakeholders in transforming addiction care to evidence-based, cost-effective practice. Through her career she has practiced in a wide range of clinical settings, worked as a payer and helped launch a buprenorphine product in the US, and has been Chief Medical Officer for 2 multi-state addiction treatment organizations. She is a member of the Steering Committee of the National Academy of Medicine's Action Collaborative on the US Opioid Epidemic, the Milken Institute Center for Public Health Advisory Group, the AMCP Addiction Treatment Advisory Group ,and is a Past President of the American Society of Addiction Medicine (ASAM).

Wilson M. Compton is Deputy Director of the National Institute on Drug Abuse (NIDA) of the National Institutes of Health, where he has worked since 2002. NIDA supports most of the world's research on health aspects of drug abuse, related to preventing drug abuse, treating addiction and addressing serious health consequences of drug abuse. Dr. Compton received his undergraduate education at Amherst College and medical education, including psychiatry training, at Washington University in St. Louis. Over his career, Dr. Compton has achieved multiple scientific accomplishments. He has authored over 200 publications and often speaks at high-impact venues. He was a member of DSM-5's Revision Task Force and has led, for NIDA, development of the Population Assessment of Tobacco and Health Study, a longitudinal population study, jointly sponsored by NIDA and the U.S. Food and Drug Administration (FDA), with 45,971 baseline participants. Dr. Compton has received multiple awards, including the American Psychiatric Association's 2008 Senior Scholar Health Services Research Award, the American Psychopathological Association's 2010 Paul Hoch Award, FDA awards for collaboration in 2012, 2013 and 2017, and the Health and Human Services Secretary's Awards for Meritorious Service in 2013 and Distinguished Service in 2015, 2018 and 2019.

Barbara Farrell is a pharmacist with the Bruyere Continuing Care Geriatric Day Hospital, and Senior Investigator with the Bruyere Research Institute in Ottawa, Ontario, Canada. She is the lead Canadian researcher for the development of evidence-based deprescribing guidelines and hosts the deprescribing.org website. Dr. Farrell is a co-founder of the Canadian Deprescribing Network, is a member of the Scientific Advisory Board of the United States Deprescribing Research Network, has been a Canadian Pharmacists Association Pharmacist of the Year and is a recent recipient of the CIHR Betty Havens Prize for Knowledge Translation in Aging. In her clinical practice, Barb has worked with hundreds of older people to help them reduce and stop benzodiazepines, has published widely on this experience and most recently contributed a chapter on Rational Deprescribing of Benzodiazepines for the text, Neurology and Psychiatry from the American College of Clinical Pharmacy.

Carla Foster is an Epidemiologist at the New York City Department of Health and Mental Hygiene (NYC DOHMH) in the Bureau of Alcohol and Drug Use, Prevention, Care, and Treatment. Her research focuses on the implementation and evaluation of public health detailing campaigns across New York City with the aim of reducing substance use related mortality. During DOHMH's Incident Command System COIVD-19 emergency activation response she serves as Deputy Director of the Integrated Data Team. Prior to joining the NYC DOHMH, she led development of clinical practice guidelines at the American Urological Association. She obtained dual Bachelor of Arts degrees in Africana Studies and Neuroscience from Wellesley College. Carla also obtained her Master of Public Health Degree in Epidemiology from Columbia University.

Christy Huff is a cardiologist and director of Benzodiazepine Information Coalition, a nonprofit that educates about the adverse effects of prescribed benzodiazepines. Dr. Huff attended medical school at the University of Texas Southwestern where she graduated Alpha Omega Alpha. She completed an internal medicine residency at Washington University in St. Louis and a cardiology fellowship at U.T. Southwestern, with a focus in advanced cardiovascular imaging and noninvasive cardiology. Dr. Huff is a Fellow of the American College of Cardiology, and was a private practice cardiologist in Fort Worth,Texas until 2011, when she became a stay-at-home mom after the birth of her daughter. Dr. Huff experienced benzodiazepine adverse effects and injury firsthand after three weeks of prescribed Xanax use for insomnia in 2015. Over a three-year period, she slowly tapered off benzodiazepines utilizing Valium, and suffered a protracted and disabling withdrawal. Her personal experience led her to realize the serious risks of these medications and the severity of the benzodiazepine withdrawal syndrome, neither of which were emphasized during her medical training. Dr. Huff specifically advocates for better education of physicians regarding the adverse effects of benzodiazepines and how to safely taper patients off these medications. In addition to her work at BIC, she is a member of the Colorado Consortium's Benzodiazepine Action Work Group.

Janetta Iwanicki is the Chief Scientific Officer for Research and Consulting 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 conducts her clinical research with the RADARS® System, and is the PI of an FDA BAA Grant focused on understanding prescription stimulant. Her work focuses on innovative ways to evaluate patterns and trajectories of use of prescription and non-prescription substances, develop novel survey tools and recruitment methodologies, and provide insights into regulatory and policy implications of her findings. She has published more than forty manuscripts and abstracts to better describe the patterns of drug use 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 eight book chapters in the fields of Medical Toxicology and Emergency Medicine.

Kurt Kroenke is Chancellor's Professor of Medicine at Indiana University and a Research Scientist in the Regenstrief Institute. Dr. Kroenke is a past President of the Society of General Internal Medicine from which he received the 2018 Glaser Award for lifetime achievement. He is also a past President of the Association for Clinical Research Training and received the European Association of Psychosomatic Medicine Alison Creed Lifetime Achievement Award in 2015. His research focuses on physical and psychological symptoms in medical patients including pain, depression, and anxiety. He has conducted more than 15 clinical trials funded by the NIH, VA, PCORI, and other sponsors to improve the care of patients with common symptoms. These trials have used collaborative care models as well as telecare interventions. He has also developed the PHQ-9 depression scale, GAD-7 anxiety scale, PEG pain scale, and other brief measures that are widely used in clinical practice and research. He has more than 400 peer-reviewed publications.

Naama Levy-Cooperman has over 15 years of experience in CNS drug development, behavioral and neurocognitive assessment, and critical review and evaluation of abuse liability, including involvement in the design and analysis of over 50 phase I clinical studies. Dr. Levy-Cooperman completed her Doctorate in Neuroscience from the University of Toronto Institute Of Medical Science, where her research focused on brain behavior correlations and neuroimaging in Alzheimer's Disease. Dr. Levy-Cooperman began her career as a research scientist at INC Research where she was responsible for design, critical review and evaluation of abuse potential and phase I clinical studies, review of neurocognitive aspects of clinical trials, expert opinion in behavioral and neurocognitive assessment, and regulatory and legal scientific support. In 2013, Dr. Levy-Cooperman co-founded Altreos Research Partners, Inc., a scientific consulting and writing group focused on abuse liability, CNS drug development and clinical pharmacology. Dr. Levy-Cooperman has presented her research internationally and has a number of peer-reviewed research papers.

Jana McAninch is a Senior Medical Epidemiologist in the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, at FDA. Dr. McAninch has been with FDA for 7 ½ years, first as an epidemiologic reviewer and then, in her current position, providing scientific guidance and leadership to the Nonmedical Use teams in the Division of Epidemiology II. At FDA, Dr. McAninch has led high-profile reviews and drug safety initiatives in the areas of pharmaceutical product nonmedical use and substance use, many of which have led to significant regulatory actions. She has also collaborated extensively across the center and with other federal agencies, academic groups, and other stakeholders to develop and improve data sources and methods for studying nonmedical use of pharmaceuticals and related harms. She has co-authored multiple peer-reviewed papers in this area as well as a new chapter in the 6th edition of the textbook, *Pharmacoepidemiology*, on studying drugs of abuse. Dr. McAninch received her MD from the University of California, San Francisco after completing her BA at Brown University. She also received an MPH from the University of California, Berkeley, and an MS in epidemiology at the University of Maryland Baltimore School of Medicine, where she also served as adjunct faculty. She completed residencies in family medicine and preventive medicine and, before coming to FDA, practiced primary care in underserved populations in the Alaska Native health care system and a community health center. She currently works remotely from Bozeman, Montana, where she lives with her family and two dogs.

Mark McClellan is the Robert J. Margolis, M.D., Professor of Business, Medicine and Policy and Director of the Duke-Margolis Center for Health Policy. A physician-economist focused on advancing quality and value in health care, his COVID-19 response work spans virus containment and testing strategies, resilient care delivery, and accelerating therapeutics and vaccine development. He is a former leader of the Centers for Medicare & Medicaid Services and the U.S. Food and Drug Administration. An independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomIQ, Dr. McClellan co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network and serves as an advisor for Arsenal Capital Partners, Blackstone Life Sciences, and MITRE.

Chinyere Ogbonna received her medical degree from Temple University School of Medicine. She extended her medical school training in order to complete a Masters in Community Health Education from Temple University School of Public Health. She completed a combined family medicine and psychiatry residency at the University of Cincinnati/ The Christ Hospital in Cincinnati, OH. She continued her training with a fellowship in Addiction Medicine at Stanford Hospital & Clinics, where she was actively involved in research and teaching. Dr. Ogbonna is board certified in Family Medicine and Psychiatry, and Addiction Medicine. Dr. Ogbonna is an active speaker on screening, brief intervention, and referral to treatment (SBIRT), with a specific focus on prevention and early intervention among adolescents and young adults. Her clinical focus also includes perinatal addiction, dual diagnoses, chronic pain, and increasing the integration of medicine and psychiatry in primary care. Dr. Ogbonna currently is the Medical Director of Addiction Medicine & Recovery Services (AMRS) at Kaiser Permanente San Jose and Adjunct Faculty at Stanford Health. She continues to teach residents and fellows and collaborates with other medical providers to help improve patient access to addiction services.

Chad J. Reissig is a behavioral pharmacologist with the Controlled Substance Staff (CSS). Dr. Reissig has a decade of public service with FDA and specializes in preclinical and clinical evaluations of abuse liability, addiction, and dependence.

Kerri Schoedel has extensive experience in neuro- and clinical pharmacology, CNS drug development, and the assessment of abuse liability in pre-clinical and clinical studies, including contribution to the design and analysis of over 70 human abuse potential studies. Dr. Schoedel has been involved in over 100 research and review articles, book chapters, and national/international scientific presentations, primarily in the area of abuse liability and CNS drug development. Dr. Schoedel completed her Ph.D. in Pharmacology at the University of Toronto, with a specialization in nicotine pharmacokinetics and addiction. Dr. Schoedel then joined INC Research (formerly Ventana/DecisionLine Clinical Research Corporation and Kendle) in 2004 as a research scientist, was promoted to Scientific Director in 2008 and then Senior Director, Clinical Pharmacology in 2013. In her roles at INC Research Toronto, a CRO that specialized in the assessment of abuse liability, Dr. Schoedel directed the Clinical Pharmacology group, lead strategic planning, and was responsible for study design and support for scientific and clinical projects. Dr. Schoedel has also been involved in the preparation of numerous regulatory submissions, and has interacted extensively with regulatory agencies. As co-founder and director at Altreos Research Partners, Inc., Dr. Schoedel continues to provide scientific and regulatory advice to pharmaceutical and biotech companies.

Marta Sokolowska is the Associate Director for Controlled Substances in FDA's Center for Drug Evaluation and Research (CDER). In this position, she oversees 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.

Marc Stone is the Deputy Director for Safety in the FDA's Division of Psychiatry.

Sangeeta Tandon is a pharmacist member of the Professional Affairs and Stakeholder Engagement staff in the Office of the Center Director. She plays an active role in Safe Use Initiative to support funding research with the goals of reduction of preventable harm. She also leads several engagement activities for the Center and serves as the lead for several task forces that include COVID-19 Task Force, Critical Drugs Core Working Group, Nitrosamine Task Force and Benzodiazepine Task Force. Prior to serving in the Office of the Center Director, she worked in the Office of Surveillance and Epidemiology where she managed, evaluated and modified several opioid risk evaluation and mitigation strategy (REMS) programs and worked closely with other scientific and medical staff across the Agency to identify and understand potential safety signals. Prior to working for the FDA, Sangeeta served as an Operations Manager at The Johns Hopkins Hospital in the Critical Care and Surgery Pharmacy where she optimized workflow efficiency, provided solutions for process improvement and mitigating drug shortages and part of several patient and medication safety efforts.

Douglas 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 medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital. He is a board-certified physician.

Scott Winiecki received his MD degree from the University of Maryland and completed his pediatric training at the Children's Hospital of Philadelphia. After 12 years in private pediatric practice, he joined the U.S. Food and Drug Administration in 2011. In 2012, he received the FDA's "Outstanding New Reviewer" Award for his work on thromboembolism after administration of immune globulin products. In 2014, he received a Public Health Achievement Award for leading the first project at FDA to use Sentinel electronic data combined with medical record review to rapidly refine a safety concern. After 5 ½ years working on biologics, he joined the Center for Drugs in September, 2016. He is currently Director of the Safe Use Initiative, a group whose goal is to reduce preventable harm from medications by collaborating with both public and private groups within the healthcare community.

Steven Wright is a residency-trained family physician for 38 years. Although no longer providing direct medical care to patients he remains active in addiction medicine for 33 years and medical pain management for 17 years. He has a particular interest in benzodiazepines actively involved in the Alliance for Benzodiazepine Best Practices, the Colorado Benzodiazepine Action Workgroup, and The Schreiber Research Group. He has presented continuing medical education on benzodiazepines more than 50 times, and has been involved in several publications on the topic including the book: The Benzodiazepine Crisis: The Ramifications of an Overused Drug Class.

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