Data and Methods for Evaluating the Impact of Opioid Formulations With Properties Designed to Deter Abuse in the Postmarket Setting
Public Workshop – July 10-11, 2017
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Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services

Panelist Biosketches

Jonaki Bose, MSc

Jonaki Bose is the branch chief of the Populations Surveys Branch at the Substance Abuse and Mental Health Services Administration, and is responsible for the National Survey on Drug Use and Health. Prior to that, she worked at the Bureau of Transportation Statistics and the National Center for Education Statistics. Jonaki has a M.Sc. from the Joint Program in Survey Methodology at the University of Maryland.

Edward W Boyer MD PhD

Edward W Boyer MD PhD, an emergency physician, organic chemist, and medical toxicologist, has studied opioid diversion, misuse, and abuse since 1999. From 2002, he served as Chief, Division of Medical Toxicology at the University of Massachusetts Medical School until 2016 when he moved to Brigham and Women's Hospital. Funded by NIH continuously since 2001, his publications in the opioid arena have been published in a number of journals including New England Journal of Medicine and Journal of Medical Toxicology. He lives in eastern Massachusetts where he is a practicing emergency physician and beekeeper.

John T. Brooks, MD

John T. Brooks, MD is presently the Senior Medical Advisor to the Division of HIV/AIDS Prevention, CDC. He has been actively engaged in research to prevent and treat HIV infection since 1994, when he received his medical degree. Dr. Brooks is board eligible in internal medicine and infectious diseases, has a clinical appointment at Emory University, and cares for HIV-infected patients at the Atlanta VA Hospital. He is an editor and contributor to multiple federal guidelines related to the prevention and treatment of HIV and STDs. Dr. Brooks joined CDC in 1998 as an officer in the Epidemic Intelligence Service (EIS or the "disease detectives") assigned to the Foodborne and Diarrheal Diseases Branch. His current research activities focus on the prevention of blood borne pathogen transmission among persons who inject and complications associated with long-term survival with HIV infection.

Daniel Budnitz, MD, MPH, CAPT, USPHS

Dr. Dan Budnitz directs the Medication Safety Program at the U.S. Centers for Disease Control and Prevention (CDC). He leads a collaboration of CDC, FDA and the US Consumer Product Safety Commission to conduct adverse drug event surveillance through the National Electronic Injury Surveillance System. These surveillance data are the basis for the 2014 National Action Plan for Adverse Drug Event Prevention, the PROTECT Initiative, a public-private collaboration to reduce medication overdoses in young children, and over 50 publications on medication

safety, public health surveillance, and injury prevention. Dr. Budnitz joined CDC as an Epidemic Intelligence Service Officer in 2001 after completing a BA in Government from Harvard University, a combined MD-MPH from Emory University, and internal medicine residency at the Hospital of the University of Pennsylvania. Dr. Budnitz is currently a Captain in the US Public Health Service and has practiced as a Board-Certified internist at the Atlanta VA Medical Center and the DeKalb-Grady Neighborhood Health Center.

Theresa Cassidy, MPH

Theresa Cassidy is a Vice President and Principal Scientist at Inflexxion, Inc. responsible for scientific and strategic direction of data analysis and epidemiologic studies. Ms. Cassidy has extensive expertise in areas of post-market surveillance and studies for prescription medications, prescription drug misuse, and abuse deterrence. She has authored several publications and presented at major national and international scientific meetings and conferences on prescription opioid and ADHD medication abuse. Ms. Cassidy holds a master's degree in public health from Yale University School of Medicine and has substantial experience in the public health field. Prior to joining Inflexxion, Ms. Cassidy was a Senior Epidemiologist for the Massachusetts Department of Public Health leading research in health outcomes studies and chronic disease epidemiology including cancer surveillance, birth defects and autoimmune diseases.

Daniel Ciccarone, MD, MPH

Dr. Dan Ciccarone, MD, MPH is a Professor in the Department of Family & Community Medicine at the University of California at San Francisco. Dr. Ciccarone has been principal or co-investigator on numerous NIH sponsored research projects in the areas of public health and HIV/AIDS prevention. His population-based studies, utilizing both quantitative and qualitative methodologies, aim to deepen our understanding of HIV and related disease and risk-taking among socially marginalized groups, e.g., injection drug users. 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 morbidity and mortality. His publications have appeared in JAMA, NEJM, AJPH, IJDP and PLoS Medicine and he is currently Associate Editor for the International Journal of Drug Policy.

Wilson M. Compton, MD, MPE

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 most of the world's research on health aspects of drug abuse and addiction related to preventing drug abuse, treating addiction and addressing serious health consequences of drug abuse, including related HIV/AIDS and other conditions. 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 achieved multiple scientific accomplishments. He is author of more than 150 articles, 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 Health and Human Services Secretary's Awards for Meritorious Service in 2013 and Distinguished Service in 2014, and several awards from the FDA: Leveraging Collaboration Awards in 2012 and 2013 and a Cross-Cutting Award in 2017.

Frederick Conrad, PhD

Frederick Conrad is a Research Professor in the Institute for Social Research and Professor of Psychology at the University of Michigan, where he also directs the Michigan Program in Survey Methodology, a graduate training program. He has been at Michigan since 2002. During this time he also directed the Joint Program in Survey Methodology at the University of Maryland for four years. His research generally involves the application of ideas and methods from cognitive science to survey research methods in order to improve the quality of survey data. Examples include interviewing techniques that promote respondent comprehension; questionnaire pretesting, especially cognitive interviewing; web survey design, particularly involving interactive techniques; mobile data collection, especially text message interviewing; and social media as a possible supplement to survey data. Conrad teaches courses on survey data collection methods and the psychological origins of survey measurement error. He was a Research Psychologist at the Bureau of Labor Statistics for eleven years prior to joining the faculty at Michigan. His PhD is from the University of Chicago. Contact information: fconrad@umich.edu; Institute for Social Research, 426 Thompson Street, University of Michigan, Ann Arbor, MI 40104.

Elizabeth H. Crane, PhD, MPH

Dr. Crane is a social science analyst and leads the Ambulatory Care Services Team in the Division of Surveillance and Data Collection at the Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration (SAMHSA), U. S. Department of Health and Human Services. She received a Ph.D. in Medical Anthropology from the University of California Berkeley/University of California San Francisco Joint Program, and an M.P.H. in Public Health from the University of California, Berkeley. Dr. Crane worked on SAMHSA's Drug Abuse Warning Network in operational and analytic roles beginning in 2000. She is now involved in the development of the SAMHSA Emergency Department Surveillance System, which will use data from NCHS's National Hospital Care Survey to produce national estimates of drug- and mental illness-related ED visits. Dr. Crane has collaborated with federal agencies and national organizations to identify data sources and data collection strategies for tracking drug-related morbidity and to address emerging substance abuse problems. Before joining SAMHSA, she was an Epidemic Intelligence Services officer at the CDC's National Center for Injury Prevention and Control where she was first introduced to the problem of opioid-related mortality. Dr. Crane also participated in the first WHO-CDC STOP Polio campaign in Pakistan.

Nabarun Dasgupta, MPH, PhD

Dr. Nabarun Dasgupta is a quantitative epidemiologist studying the medical and nonmedical use of prescription opioids and heroin. He has worked with diverse groups in public health involved in reducing the adverse consequences of opioid use (e.g., clinical practices, nonprofit organizations, state and local health departments, and the pharmaceutical industry). Dr. Dasgupta is a Senior Scientist at the RADARS System and a researcher at the University of North Carolina in Chapel Hill.

Carol DeFrances, PhD

Carol DeFrances, Ph.D., is Chief of the Ambulatory and Hospital Care Statistic Branch, Division of Health Care Statistics, at the National Center for Health Statistics. She directs a national data collection and research program focused on hospital and ambulatory medical care. She oversee data collection for the National Ambulatory Medical Care Survey (NAMCS), the National Hospital Ambulatory Medical Care Survey (NHAMCS), the National Hospital Care Survey (NHCS), the National Electronic Health Record Survey (NEHRS) and various supplemental surveys. Dr. DeFrances has been heavily involved in transitioning NAMCS and NHCS to electronic data collection utilizing electronic health record (EHR) data. She also has been working closely with the Substance Abuse and Mental Health Services Administration and the Food and Drug Administration to develop algorithms to identify substance-involved emergency department (ED) visits from the NHCS ED data.

Louisa Degenhardt, PhD

Professor Louisa Degenhardt is the University of New South Wales (UNSW) Scientia Professor of Epidemiology and NHMRC Principal Research Fellow at the National Drug and Alcohol Research Centre (NDARC) at UNSW. She was awarded her PhD in 2003, examining the comorbidity of drug use and mental disorders in the Australian population. She has honorary Professorial appointments at University of Melbourne's School of Population and Global Health, Murdoch Children's Research Institute, and University of Washington's Department of Global Health in the School of Public Health. Louisa conducts diverse epidemiological studies including analysis of large-scale community and clinical population surveys, data linkage studies focusing upon people with a history of drug dependence, pharmacoepidemiological studies of pharmaceutical opioid utilisation, post-marketing surveillance of new opioid medications, and cohort studies of young people and of people using opioids. Her work on illicit drug market surveillance, which continues today, is regularly used to inform policy and planning on health and law enforcement responses. Louisa is internationally acknowledged for her research on the epidemiology of illicit drug use, morbidity and mortality. She is regularly sought by researchers, NGOs, and UN agencies to collaborate and provide advice. She is a member of the WHO's Technical Advisory Group on Alcohol and Drug Epidemiology; is on the Core Analytic team for the ongoing Global Burden of Disease study led by IHME at the University of Washington in Seattle. Her data linkage work on opioid dependence, treatment and mortality is used by health and corrective services departments in Australia and internationally to evaluate the benefits and risks of opioid dependence treatment. Her post-marketing surveillance work informed Pharmaceutical Benefits Advisory Committee decisions on listing of opioid medications on the Australian Pharmaceutical Benefits Scheme.

Barry Graubard, PhD

Dr. Barry Graubard is an internationally respected researcher in survey research who has had more than 35 years of experience developing and applying statistical methodology for analyzing complex designed epidemiologic studies and national health surveys. He coauthored a graduate-level text book that is a standard for teaching statistical methods for the analysis of health survey data. He has extensive experience in conducting analyses of nutritional, health behavioral, environmental and biomarker data from epidemiologic studies and surveys such as the National Health and Nutrition Examination Survey, the National Health Interview Survey, and more recently the National Inpatient Survey. Dr. Graubard received a Ph.D. in mathematics from the

University of Maryland in 1991. He began his career as a mathematical statistician at the National Center for Health Statistics in 1977, and has held research positions at the Alcohol Drug Abuse and Mental Health Administration and the National Institute of Child Health and Human Development. Dr. Graubard joined the NCI in 1990, and is senior investigator in Division of Cancer Epidemiology and Genetics, Biostatistics Branch. He received the American Statistical Association and Biometric Society Snedecor Award for Applied Statistical Research in 1990, and he is a Fellow of the American Statistical Association and the American Association for the Advancement of Science.

Jody L. Green, PhD, CCRP

Dr. Jody L. Green is the Director of Research Administration at the Denver Health and Hospital Authority Rocky Mountain Poison and Drug Center in Denver, Colorado, and was an adjunct Assistant Professor of Nursing (Research) at Vanderbilt University School of Nursing from 2007 to 2011. She is the Past-President of the Society of Clinical Research Associates (SoCRA). Dr. Green is a member of the Prevention of Overdoses and Treatment Errors in Children Taskforce (PROTECT) of the Centers for Disease Control and Prevention (CDC) which is an assembly of experts to develop strategies to keep children safe from unintentional medication overdoses. She received her doctorate in applied statistics and research methods from the University of Northern Colorado. Dr. Green has 15 years of experience in drug safety surveillance aimed to advance public health and patient safety. She is responsible for the science and operations of the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System which is an international surveillance network to monitor the abuse, misuse and diversion of prescription drugs. She works closely with the American Association of Poison Control Centers and was a co-author on the published annual report from 2006 through 2010. She has published numerous manuscripts in peer-reviewed journals. Her primary expertise is in developing new data collection systems as well as surveillance methodology and design, specifically for the surveillance of prescription drug abuse, misuse and diversion.

Holly Hedegaard, MD, MSPH

Holly Hedegaard, MD, MSPH is an injury epidemiologist at the CDC/National Center for Health Statistics (NCHS). From 1994-2012, she served as a medical/injury epidemiologist at the Colorado Department of Public Health and Environment, managing the Injury Epidemiology Program, the Colorado Trauma Registry, the Colorado Emergency Medical Services Information System and the Colorado Violent Death Reporting System. Dr. Hedegaard also taught and conducted research as an adjunct faculty in the Department of Preventive Medicine/Biometrics at the Colorado School of Public Health. In May 2012, Dr. Hedegaard joined NCHS, where her focus has been on national trends in injury mortality, including drug overdose deaths and suicide. Dr. Hedegaard has served on several national and international injury surveillance workgroups that developed consensus recommendations for injury surveillance in state health departments, assessed an expanded definition for injury using hospital discharge data systems, and identified strategies to improve surveillance on non-fatal suicide attempts. She serves on the steering committee of the International Collaborative Effort on Injury Statistics and Methods.

Christopher M. Jones, PharmD, MPH

Dr. Christopher M. Jones currently serves as Acting Associate Deputy Assistant Secretary for Science and Data Policy in the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the US Department of Health and Human Services. The Office of Science and Data Policy is the HHS focal point for policy research, analysis, evaluation, and coordination of public health science policy and data policy activities. The Office provides authoritative advice and analytical support to HHS leadership on public health, science, and data policy issues and initiatives. Prior to joining ASPE, Dr. Jones served as senior advisor in the Office of the Commissioner at the US Food and Drug Administration (FDA). Dr. Jones previously led the Centers for Disease Control and Prevention's (CDC) drug abuse and overdose activities where he focused on strategic policy development and implementation, engaging national and state partners, and conducting research to improve policy and clinical practice. During his career, Dr. Jones has served as Senior Public Health Advisor to the White House Office of National Drug Control Policy, led the FDA's Drug Safety and Risk Communication team, and served on the Science Team in the CDC's Strategic National Stockpile. Chris received his Doctor of Pharmacy degree from Mercer University, his Master of Public Health degree from New York Medical College, and his Bachelor of Science degree from Reinhardt College. He is currently completing his Doctorate of Public Health in Heath Policy at The George Washington University Milken Institute School of Public Health. Dr. Jones is a nationally recognized expert on opioid misuse and overdose and has authored more than 50 peer-reviewed publications on the topic.

Erin E. Krebs, MD, MPH

Erin E. Krebs, MD, MPH is a Core Investigator at the Minneapolis Veterans Affairs (VA) Center for Chronic Disease Outcomes Research and Associate Professor of Medicine at the University of Minnesota. She is a general internist with an active primary care practice and also serves as Women's Health Medical Director for the Minneapolis VA Health Care System. Dr. Krebs leads health services and comparative effectiveness research focused on benefits and harms of opioid analgesics and improving chronic pain management in primary care. Her research is funded by VA, PCORI, and NIH.

Peter W. Kreiner, PhD

Peter Kreiner, Ph.D., is a Senior Scientist at the Institute for Behavioral Health at Brandeis University. He is Principal Investigator for the Prescription Drug Monitoring Program Training and Technical Assistance Center (www.pdmpassist.org), and for the Prescription Behavior Surveillance System at Brandeis, a longitudinal multi-state database of prescription drug monitoring program data to serve as an early warning surveillance tool and a tool to help evaluate changes in state policy and regulations. Dr. Kreiner has more than 25 years' experience conducting research and evaluation of substance abuse prevention and treatment systems and programs, at community, state, and regional levels. His research interests include small geographic area measures and models, specifically focused on rates of fatal and non-fatal opioid overdose cases, and measures of appropriate and inappropriate prescribing; and network analysis applied to inter-organizational networks and provider-patient networks related to care coordination.

Vincent Lo Re, MD, MSCE

Vincent Lo Re, M.D., M.S.C.E. is Associate Professor of Medicine (Infectious Diseases) and Epidemiology at the University of Pennsylvania, Senior Scholar in the Penn Center for Clinical Epidemiology and Biostatistics, and Senior Investigator in the Penn Center for Pharmacoepidemiology Research and Training. Dr. Lo Re leads a nationally recognized research program that examines the pharmacoepidemiology of drug-induced liver disease. He has conducted population-based and mechanistic studies that have helped to move the field of drug-induced liver disease, chronic viral hepatitis, and HIV/viral hepatitis coinfection forward in a unique way. Recent research has determined the impact that medications have on acute liver injury and progression of chronic viral hepatitis; assessed adherence and adverse effects of antiviral therapies of chronic hepatitis B and C; evaluated end-stage liver disease and liver cancer events among HIV/hepatitis C-coinfected patients; and examined how chronic viral hepatitis and HIV/viral hepatitis coinfection influence extra-hepatic outcomes, particularly metabolic bone disease. He has particular expertise in evaluating liver-related and other health outcomes within large electronic data sources, such as the Veterans Health Administration, Kaiser Permanente Northern California, US Medicaid, US Medicare, and Sentinel. His research has been funded by the National Institute of Allergy and Infectious Diseases, National Institute of Diabetes and Digestive and Kidney Diseases, National Cancer Institute, Agency for Healthcare Research and Quality, Department of Veterans Affairs, and the US Food and Drug Administration. Additionally, Dr. Lo Re has been a standing member of FDA's Antiviral Drug (now Anti-Infective) Advisory Committee since 2014 and co-chair of the Liver Core of the Veterans Aging Cohort Study since 2009. He has been an Associate Editor of *Pharmacoepidemiology and Drug Safety* since 2009 and will take over as Regional Editor for the Americas in 2018. He maintains an active clinical practice devoted to the care of patients with chronic viral hepatitis, particularly those coinfected with HIV.

F. Leland McClure III, MSci, PhD, F-ABFT

Dr. Leland McClure has served in a wide variety of positions at Quest Diagnostics including Six Sigma Master Black Belt, National Director of Toxicology and LC-MS/MS Operations for Prescription Drug Monitoring and is currently Director, Medical Science Liaison for Corporate Medical Affairs. He is a board certified Fellow of the American Board of Forensic Toxicology and has more than 30 years' experience in clinical and forensic applications of laboratory testing. Dr. McClure also serves as a scientific consultant and laboratory inspector consultant with the federal SAMHSA workplace drug testing program and has served as a subject matter expert member of the laboratory workgroup for the CDC Childhood Lead Poisoning Prevention Program and the AMA CPT coding committee Quantitative Drug Testing Workgroup. In his home state of Missouri, Dr. McClure has also served three gubernatorial appointments for the Childhood Lead Poisoning advisory committee.

Richard Miech, PhD, MPH

Richard Miech, Ph.D., MPH is Principal Investigator of *Monitoring the Future*, which annually surveys a nationally-representative sample of 40,000+ adolescents in schools, as well as an additional sample of 10,000+ high school graduates age 18-55. He is a Research Professor at the Institute for Social Research in the University of Michigan. He received his Ph.D. in Sociology at the University of North Carolina Chapel Hill, his MPH from Johns Hopkins University, and a B.A. in Sociology from Stanford University. His research focuses on trends in substance use

over time and the associated determinants that shape these trends. He is particularly interested in the rapid identification of types and methods of substance use that are newly emerging, as well as documenting drug use that is falling out of favor.

Scott P. Novak, PhD

Scott Novak, PhD. is the Director of Substance Abuse Research at Battelle Memorial Institute. He holds research interests in the causes, correlates, and consequences of prescription drug abuse, with a focus on the clinical and public policy implications. Dr. Novak's expertise is in novel statistical and methodological approaches to the analysis of epidemiological and clinical data for post-marketing surveillance. He is the principal investigator on several NIH grants, federal contracts, and commercial projects on the topics of prescription drug diversion and tampering. He has a current project funded by the National Institute on Drug Abuse (NIDA) to understand the public health impact of state and local prescription drug access laws on prescription pain reliever abuse and heroin initiation. Dr. Novak was the principal investigator of the EU-Meds Study, the first nationally representative survey on prescription drug abuse in the European Union. The study examined the prevalence and characteristics of prescription abusers in 5 European Union Countries (Denmark, Germany, Great Britain, Spain, Sweden). In addition Dr. Novak was also involved in evaluating several innovative programs for the prevention and treatment of opioid abuse in high risk populations, such as the Centers for Disease Control and Prevention (CDC) Prescription Drug Overdose for States Program, a sixty-million dollar program targeting risk reduction and prescription drug overdose at the state and local level.

Jennifer D. Parker, PhD

Jennifer Parker is the Special Assistant to the Director in the Division of Research and Methodology and the Senior Statistician in the Division of Health and Nutrition Examination Surveys at the National Center for Health Statistics. She has over 20 years of experience with national survey data and vital statistics for measuring health outcomes and risk factors. Dr. Parker’s research area has included record linkage, combining geographic information with national health data, and measuring health disparities.

Elizabeth J. Scharman, BS, PharmD, DABAT, BCPS, FAACT

Elizabeth J. Scharman, BS, Pharm.D., DABAT, BCPS, FAACT has been the Director of the West Virginia Poison Center (WVPC) and a full-time faculty member with the West Virginia University (WVU) School of Pharmacy since July 1992. Dr. Scharman works out of the WVU Robert C. Byrd Health Sciences Center Charleston Division. She received tenure in 1998 and became a full Professor within the Department of Clinical Pharmacy in July 2003. Dr. Scharman received a B.S. in Pharmacy (1986) from Butler University and a Pharm.D. (1991) from Virginia Commonwealth University (Medical College of Virginia) then completed a Clinical Toxicology Fellowship (1992) at the Pittsburgh Poison Center affiliated with the University of Pittsburgh. She became a Diplomate of the American Board of Applied Toxicology (ABAT) in 1992 and a Board Certified Pharmacotherapy Specialist in 1995. Dr. Scharman has held numerous elected positions on boards of national organizations including the American Academy of Clinical Toxicology (AACT), the American Board of Applied Toxicology (in which she also served as President from 2004 to 2006), and the American Association of Poison Control Centers. She currently serves as a member and/or Chair of multiple of national committees; many of which

are working to advance the accuracy and rigor of toxicosurveillance databases. In 2014, Dr. Scharman was appointed to the editorial board of the journal, Clinical Toxicology (Phila); she has been Chair of the Toxicology and Poison Control Editorial Panel for the journal, Annals of Pharmacotherapy, since 2003. Dr. Scharman teaches the clinical toxicology, disaster planning, and substance abuse classes for the WVU School of Pharmacy in addition to content area related to adverse drug reactions. She also provides continuing education presentations for physicians, nurses, and pharmacists throughout WV on topics related to clinical toxicology and drugs of abuse. Dr. Scharman has multiple peer reviewed publications in the field of clinical toxicology and evidence-based practice.

Sidney H. Schnoll, MD, PhD

Sidney H. Schnoll, M.D., Ph.D. is an internationally recognized expert in addiction and pain management. Sid was a member of the team that developed the Tramadol Independent Steering Committee (ISC), and he was the principal investigator on the health care professional surveillance project to determine rates of abuse of tramadol among health professionals. Sid also developed the RADARS® System to study the abuse and diversion of prescription opioids, which was cited by the FDA as a model risk management program. He was Professor of Internal Medicine and Psychiatry and Chairman of the Division of Substance Abuse Medicine with adjunct appointments in Pharmacology and Toxicology and Psychology at the Medical College of Virginia, Virginia Commonwealth University and Voluntary Professor of Behavioral Science, University of Kentucky. Sid has served on numerous committees and boards, including the FDA's Drug Abuse Advisory Committee (DAAC), NIH study sections, National Board of Medical Examiners test development committees, and was a board member of the College on Problems of Drug Dependence (CPDD). He has received numerous awards including listings in The Best Doctors in America and is a Fellow of CPDD and the American Society of Addiction Medicine. With over thirty years in academic medicine, Sid has published over 150 research papers, book chapters and educational materials. His areas of research include both addiction and pain management with special emphasis on perinatal addiction and prescription drug abuse.

Abigail Shoben, PhD

Abigail Shoben, Ph.D. is an Associate Professor in the Division of Biostatistics within the College of Public Health at The Ohio State University. Her research interests include clinical trial design, analysis, and ethics. She is particularly interested in the advantages and challenges of correlated data within clinical trials, such as longitudinal studies and cluster randomized trials. For the FDA, she has been a member of the Anesthetic and Analgesic Drug Products Advisory Committee since 2015, and has participated in 10 advisory committees related to opioid products or issues to date.

George Jay Unick, PhD, MSW

Dr. Unick has over 20 years of experience working with injection drug using populations in both a clinical and research capacity. His recent work is focused on understanding how the changing supply and use of opiates affects the health of opiate using populations. Dr. Unick is widely published in the field and has been funded by two National Institute of Drug Abuse grants focused on understanding the health consequences of changes in the heroin market.

Almut Winterstein, RpH, PHD, FISPE

Almut Winterstein received her pharmacy degree from Friedrich Wilhelm University in Bonn, Germany and her PhD in Pharmacoepidemiology from the Charité Humboldt University in Berlin, Germany. She holds the position of Professor and Chair in the Department of Pharmaceutical Outcomes and Policy at the College of Pharmacy, and an affiliate appointment in the Department of Epidemiology at the Colleges of Medicine and Public Health and Health Professions, both at the University of Florida. In 2017, she was named the Dr. Robert and Barbara Crisafi Chair in recognition of her research on evaluating drug safety and effectiveness in real-world populations and on devising ways to improve medication use. Dr. Winterstein's research interests have centered on the post-marketing evaluation of drugs in pediatrics and perinatal care, infectious disease and psychiatry and the evaluation and improvement of quality surrounding medication use using real-world data. She has contributed this expertise to the Federal Interagency Task Force on Preventable Adverse Drug Events, which has prioritized opioids in its action plan. Dr. Winterstein chairs the Food and Drug Administration's Drug Safety and Risk Management Advisory Committee, which has addressed a broad range of questions involving the risk-benefit of opioids. Recognizing her contributions in pharmacoepidemiology, Dr. Winterstein was inducted as a fellow of the International Society of Pharmacoepidemiology in 2013.