

Packaging, Storage, and Disposal Options to Enhance Opioid Safety
Exploring the Path Forward
Public Workshop—December 11-12, 2017
Docket No. FDA-2017-N-5897
Center for Drug Evaluation and Research
Food and Drug Administration
Department of Health and Human Services

Panelists Biosketches

Brian Bateman, MD, MSc

Dr. Brian Bateman holds appointments as the Chief of the Division of Obstetric Anesthesia in the Department of Anesthesiology, Perioperative and Pain Medicine at Brigham and Women's Hospital and as a researcher in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine. He is also an Associate Professor of Anaesthesia at Harvard Medical School. His research interests focus on pharmacoepidemiology in pregnancy and the epidemiology of pregnancy related complications. He has published extensively on the use of opioids during pregnancy and its consequences, the safety of cardiovascular medications in pregnancy, predictors of severe maternal morbidity and mortality, and medication safety in the perioperative period.

Walter Berghahn, BS

Mr. Berghahn, having spent the last 21 years focused solely on pharmaceutical packaging, has been involved in numerous industry work groups addressing gaps in packaging safety and supply chain security. His work with the Healthcare Compliance Packaging Council has allowed him to collaborate with industry participants from manufacturers through distributors and pharmacy on improving pharmaceutical packaging safety. He has authored dozens of articles on the topic for print and e-media as well as presenting on the area of improved pharmaceutical safety several times a year at industry conferences. Most recently he helped organize and launch several graduate classes at Rutgers University on the topic of pharmaceutical packaging and the regulatory requirements that are ingrained in the process of bringing them to market.

Laura Bix, PhD

Dr. Laura Bix is the Associate Director at the School of Packaging at Michigan State University and an Adjunct Associate Professor at Clemson University. Her work focuses on quantifying the interface between people and packaging with the ultimate goal of improving health outcomes. Her unique vein of inquiry was recognized in 2008 by Medical Devices and Diagnostics Industry magazine, when she was named one of the 100 most notable people in the medical device industry. Since 2009, she has served on expert panels convened by the US Centers for Disease

Control and Prevention (CDC) as part of their medication safety programs. From 2012-2014, Dr. Bix served on a national panel formed by the Gerontological Society of America (GSA) and the Consumer Healthcare Products Association (CHPA) that examined behaviors related to medication use in older adults. Her approach to multi-disciplinary endeavors and the value that she places on unique collaborations were honored with the Phi Kappa Phi Excellence in Interdisciplinary Scholarship Award (MSU Chapter) and more recently, her leadership skills were recognized when she was appointed as a 2015-2016 MSU fellow for the CIC Academic Leadership Program. Work from her group has been published or cited by numerous publications, including: The Proceedings of the National Academy of Sciences of the US, PLoS One, Consumer Reports and Men's Health.

Hayden Bosworth, PhD

Dr. Hayden Bosworth is a health services researcher and Professor of Population Health Sciences, Medicine, Psychiatry, and Nursing at Duke University Medical Center as well as the Associate Chair of Education for the Department of Population Health Sciences. He is also the Associate Director of the Center for Health Service Research in Primary Care Center of Innovation (COIN) at the Durham VAMC. Dr. Bosworth is an Adjunct Professor in the Department of Health Policy and Administration in the School of Public Policy at the University of North Carolina at Chapel Hill. His research interests comprise three overarching areas of research: 1) clinical research that provides knowledge for improving patients' treatment adherence and self-management in chronic care; 2) translation research to improve access to quality of care; and 3) eliminate health care disparities. His expertise is in patient-centered, multidisciplinary self-management programs for adults with chronic disease. Dr. Bosworth is the recipient of an AHA EIA and the VA Undersecretary Award for Outstanding Achievement in Health Services Research. He has led over 30 trials and participated in another 50 resulting in over 300 peer-reviewed publications and four books. This work has been implemented in multiple health care systems.

Daniel Budnitz, MD, MPH

Dr. Daniel 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.

Elizabeth Whalley Buono, BSN, RN, MBA, JD

Dr. Liz Whalley Buono brings over 25 years of life science experience in legal, regulatory, operational and executive roles in drug, device, tobacco, clinical research and healthcare packaging companies. After careers in clinical nursing and big pharma, she obtained a JD in Health Law and Economics and practiced Food & Drug, Fraud & Abuse, Insurance and Privacy law at Wiley, Rein LLP in DC. Transitioning in-house to Altria Client Services, Dr. Whalley Buono managed the legal, regulatory and ethics considerations associated with tobacco harm reduction clinical research and new product development. At WestRock, she focuses her business and legal acumen into a dual law and executive role with jurisdiction over global healthcare regulatory and legal support for the company's healthcare innovation work. She has been integral in creating an innovative manufacturer to retail supply chain model for Walmart, permitting introduction of the first US \$5.00 generic drug program and the first retail-branded adherence program. Additionally, she worked with CVS to pilot hardware and software designed to dispense personalized co-mingled co-packaged daily medication. Dr. Whalley Buono's consulting practice is focused on healthcare innovation and new product development. She holds a JD in Health Law and Economics from the George Mason University as well as an MBA from St. John's University and a BSN/RN from Boston College School of Nursing.

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 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. fentanyl) 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. He is Associate Editor for the International Journal of Drug Policy and recently edited an IJDP special issue on the “triple wave crisis” of opioids, heroin and fentanyl in the US.

Elizabeth Cox, MD, PhD

Dr. Elizabeth Cox is an Associate Professor in the Department of Pediatrics, Division of General Pediatrics and Adolescent Medicine at the University of Wisconsin-Madison (UW). She completed her pediatrics residency and PhD in Population Health Sciences, with a focus in Health Services Research, at University of Wisconsin-Madison. She currently serves as Director of the UW Program of Research on Outcomes for Kids (PROKids) and sees patients at the University Station Pediatric Clinic. Dr. Cox leads a research program focused on improving children’s health outcomes by developing, implementing, and evaluating system-level interventions, especially for children who are chronically ill. The innovation in her research often arises from the engagement of children, their families, and other stakeholders in the design, delivery, evaluation, and dissemination of interventions to improve pediatric healthcare. Her research has been funded through multiple awards from a variety of sources, including AHRQ, NIH, and the Patient-Centered Outcomes Research Institute (PCORI). She has also served on PCORI’s Improving Healthcare Systems Advisory panel. Her current projects include primary data collection to support analysis of the validity and clinical utility of pediatric PROMIS measures in three populations of chronically ill children and a multi-site trial of a family-centered intervention to improve outcomes for youth with type 1 diabetes.

Penney Cowan

Penney Cowan is the founder and CEO of the American Chronic Pain Association. Over the past 37 years, Ms. Cowan has been an outspoken advocate and consumer representative for pain issues, contributed to numerous books, videos and Websites, and consulted on the development of several pain management programs. Ms. Cowan is a recognized speaker advocating a multi-disciplinary approach to pain management. Currently she serves on the Board of the American Chronic Pain Association and International Alliance of Patient Organizations.

Thomas Emmendorfer, PharmD

Dr. Thomas Emmendorfer has served as VA’s Deputy Chief Consultant for Pharmacy Benefits Management (PBM) Services since July 2013. As Deputy Chief Consultant, Dr. Emmendorfer provides leadership in national programs on various aspects of pharmacy practice policy. Prior to his current assignment, Dr. Emmendorfer served as the Assistant Chief Consultant for the Pharmacy Benefits Management Services in Hines, IL where his responsibilities included formulary management and drug therapy policy development. He has over 20 years of service with the Department of Veterans Affairs in a variety of VA Pharmacy positions. Dr. Emmendorfer received a B.S. in Pharmacy and his Doctor of Pharmacy from Ferris State

University in 1998 and 2000, respectively. He completed his general pharmacy practice residency at Spectrum Health, Grand Rapids, Michigan in 2001.

Paul Gileno

Paul Gileno is a strong force in the chronic pain awareness movement. With his team, he crafts programs and events that educate, support and inspire the community, volunteers and loved ones. His own experience informs his work—he strives to help others live with meaning and purpose in spite of pain. Paul is on the Advisory Board for PainPathways magazine. In 2014, he was the recipient of the Unsung Hero Award for his stellar work in pain policy initiatives. In 2015, Paul received the “Educator of the Year Award” from the American Society of Pain Educators (ASPE).

Jody Lynn Green, PhD

Dr. Jody L. Green is the newly appointed Chief Scientific Officer at Inflexxion located in Waltham MA. Prior to her current role she was 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 over 15 years of experience in drug safety surveillance aimed to advance public health and patient safety. She has published numerous manuscripts in peer-reviewed journals. Her primary expertise is in developing and operationalizing new data collection systems as well as surveillance methodology and design, specifically for the surveillance of prescription drug abuse, misuse and diversion.

Christopher M. Jones, PharmD, MPH

Dr. Christopher M. Jones 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, and data policy activities, and 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. Dr. Jones has authored more than 50 peer-reviewed publications on the topic of drug abuse and overdose.

Jeff Kelman, MD, MMSc

Dr. Jeffrey Kelman is the Chief Medical Officer for the Center for Medicare within the Centers for Medicare & Medicaid Services (CMS). He has held this position for 6 years and was previously Chief Medical Officer for the Centers for Beneficiary Choices in CMS. He also served as Senior Medical Advisor to the Congressional Budget Office (CBO) before moving to Department of HHS. His responsibilities include oversight of the Part D drug benefit and the Part C Medicare Advantage program. He is also co-Director of the emPower resiliency project working with the Assistant Secretary for Planning and Response. Dr. Kelman received his MD from Harvard Medical School, and his clinical training at the Peter Bent Brigham Hospital and the National Institutes of Health.

John Mendelson, MD

Dr. John Mendelson is an Internist, Clinical Pharmacologist and Entrepreneur. His lab has studied the human pharmacology of commonly abused drugs such as MDMA, MDA, Salvinorin A, cocaine and methamphetamine. He performed many of the abuse liability and pharmacokinetic studies of buprenorphine-naloxone combinations. More recently he founded a Ria Health, a telemedicine digital health solution for alcohol use disorder. He is clinically active with a private practice and has served as a Medical Director for a large opiate treatment program.

Richard Miech, PhD, MPH

Dr. Richard Miech 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.

Sharon Morgan, MSN, RN, NP-C

Sharon A. Morgan is an advanced practice registered nurse (APRN) currently working as Senior Policy Advisor at the American Nurses Association (ANA), the premier organization representing the interests of the nation's 3.6 million registered nurses. Ms. Morgan is the resident expert on issues surrounding the opioid epidemic and was a key developer of ANA's 2016 issue brief addressing the growing drug overdose problem. She has over 24 years of clinical nursing experience in diverse practice settings such as critical care, hospice and palliative care,

integrative health, as well as experience working with underserved populations in Guatemala. Prior to a career in nursing, Sharon was a Military Intelligence Officer and Geopolitical Analyst.

Ashesh Patel, MD, FACP

Dr. Ashesh D. Patel is currently in solo private practice with a focus in primary care. He received his MD from the University of Cincinnati College of Medicine and completed his Internal Medicine Residency at the George Washington University School of Medicine, which is where he is currently an Associate Clinical Professor of Medicine. Dr. Patel currently serves as Governor of the DC chapter of the American College of Physicians as well as being a member of the Internal Medicine Board Exam Committee of the American Board of Internal Medicine.

Anuradha Rao-Patel, MD

As a medical director for Blue Cross and Blue Shield of North Carolina, Dr. Rao-Patel is responsible for the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, prescription drugs, and facilities under the provisions of the applicable health benefits plan. In addition to her role in utilization management at Blue Cross, Dr. Rao-Patel is leading an internal opioid workgroup where she is collaboratively working with other key stakeholders to identify solutions and best practices on the treatment of opioid use disorder, raise awareness and education on addiction, and focus on effective care coordination for member focused care delivery. Dr. Rao-Patel is originally from Louisiana where she attended medical school at Louisiana State University and completed her internship in internal medicine. She then went on to complete her residency in Physical Medicine and Rehabilitation at Sinai Hospital in Baltimore, Maryland. Prior to joining Blue Cross Blue Shield of North Carolina, she was in private practice doing chronic pain management and addiction management. She continues to be clinically active and see patients on a part-time basis in addition to her primary role at the Plan.

Elizabeth J. Scharman, PharmD

EDr. Elizabeth J. Scharman, 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.

Chris Smith, JD

Chris Smith is Director of Federal Public Policy for NACDS. In that capacity, he works on various supply chain issues, including implementation of the DSCSA, drug importation, management of pharmaceutical hazardous waste, and drug disposal. He also works on Medicaid drug reimbursement issues, 340B drug issues, anti-discrimination provisions under the ACA, and the impact of the ACA and possible future health care reform on chain pharmacies. Previously, Chris was a health law professor at Widener University School of Law, as well as Director of Public Policy for NCPA. He holds a LLM from American University Washington College of Law, a JD from Vanderbilt Law School, and a BA from the University of Richmond.

Cecelia Spitznas, PhD

Dr. Cecelia Spitznas the Senior Science Policy Advisor in the Director's Office of the Office of National Drug Control Policy (ONDCP), a component of the Executive Office of the President. She provides policy analysis and scientific advice to the ONDCP Director and Chief of Staff on special matters of concern to ONDCP. She is the agency's lead subject matter expert on opioid addiction and prescription opioid misuse policy implementation including pain management, disposal, storage, prescriber education, regulation, treatment, diversion, enforcement. She and helps to develop policy and legislative responses to problems of national scope, particularly on prescription opioids, heroin and fentanyl. From 2000-2012, Dr. Spitznas was a program official at the National Institutes of Health's National Institute on Drug Abuse (NIDA) where her research portfolio concerned developing and testing screening and treatments for people with substance use disorders including pregnant women and provider training. In 2010 she co-led a meeting for National Institute of Health leaders, DOD and VA to address substance use in military, veterans and their families which led to several funding opportunity announcements and a research program funded by VA, NIDA and NIAAA. She represents the ONDCP Director on the Interagency Task Force on Military and Veterans Mental Health

Robert Twillman, PhD

Dr. Bob Twillman is the Executive Director of the Academy of Integrative Pain Management (formerly the American Academy of Pain Management). In that capacity, Dr. Twillman is

responsible for guiding the organization in its efforts to promote an integrative approach to managing pain. He formerly served the Academy for four years as its Director of Policy and Advocacy. Dr. Twillman received his Ph.D. in Clinical Psychology at the University of California in Los Angeles, and maintains a volunteer faculty appointment as Clinical Associate Professor of Psychiatry and Behavioral Sciences at the University of Kansas School of Medicine in Kansas City, KS. Prior to working for the Academy, Dr. Twillman was a full-time faculty member at the University of Kansas Medical Center, where he founded and directed the inpatient pain management program and was a co-founder of the hospital's Palliative Care Team. Dr. Twillman also served for many years as Chair of the Prescription Monitoring Program Advisory Committee for the Kansas Board of Pharmacy.

Sharon L. Walsh, PhD

Dr. Sharon Walsh is a Professor of Behavioral Science, Psychiatry, Pharmacology and Pharmaceutical Sciences in the Colleges of Medicine and Pharmacy at the University of Kentucky. She is the Director of the Center on Drug and Alcohol Research. She earned her Ph.D. from Rutgers University in Behavioral Neuroscience and, after postdoctoral training she joined the faculty at Johns Hopkins University School of Medicine where she remained for 13 years before leaving at the rank of Professor. Her clinical research focuses on pharmacological and behavioral issues in opioid abuse and dependence, including studies on the pharmacodynamic and pharmacokinetic characteristics of opioid dependence pharmacotherapies (i.e., buprenorphine, methadone, LAAM) and more recently on widely used opioid analgesics (i.e., oxycodone, hydrocodone, tramadol and morphine). She lectures nationally and internationally on opioid abuse, dependence and its treatment. More broadly, she has conducted studies in cocaine, nicotine and marijuana dependence and contributed to clinical practice guidelines and board specialty requirements in addiction medicine. She has published over 120 manuscripts and book chapters. Her honors include receiving the Presidential Early Career Award for Scientists and Engineers from President William Clinton, the Joseph Cochin Young Investigator Award, the Betty Ford Award, serving as President of the College on Problems of Drug Dependence, the Provost's Distinguished Service Professorship and the Marion W. Fischman Lectureship award. She has served on review and advisory boards for the National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, the Veteran's Administration, National Institutes of Health, the American Society for Addiction Medicine, served an expert reviewer for the World Health Organization, and presently serves as a Special Government appointee to the Food and Drug Administration.

Kevin Webb, MBA

Kevin Webb is Director of Government Affairs & Advocacy at Mallinckrodt Pharmaceuticals. Kevin is instrumental in executing upon the company's commitment to address opioid misuse and expand access to substance abuse treatment. Mr. Webb manages key strategic partnerships and engages external stakeholders, including Federal and State legislators/policymakers, professional societies, patient advocacy groups, law enforcement and community-based organizations to advance patient health and safety needs through

collaboration. With a proven track record of bringing together strategically aligned stakeholders and third party organizations, while advancing unique and innovative solutions, Kevin has been instrumental in positioning Mallinckrodt Pharmaceuticals as a leader in addressing the nation's opioid epidemic. Mr. Webb holds a bachelor's degree in behavioral science from St. Louis University and a master's degree in business administration (MBA) from the University of Illinois.