

Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes--Exploring the Path Forward for Assessment

Public Workshop

December 11, 2020

Docket No. FDA-2020-N-1561

Center for Drug Evaluation and Research

Food and Drug Administration

Department of Health and Human Services

Panelist Biosketches

G. Caleb Alexander, MD, MS

Dr. Alexander is a Professor of Epidemiology and Medicine at the Johns Hopkins Bloomberg School of Public Health, where he serves as founding co-Director of the Center for Drug Safety and Effectiveness and Principal Investigator of the Johns Hopkins Center of Excellence in Regulatory Science and Innovation. He is a practicing primary care physician, internationally renowned pharmacoepidemiologist and the author of over 325 scientific articles examining prescription drug utilization, safety and effectiveness. Many of these investigations have used primary and secondary data to characterize the epidemiology of prescription opioid use in the United States as well as to evaluate the effect of federal and state regulatory and payment policies on opioid prescribing, dispensing and utilization. He has extensive experience disseminating these findings to professional and lay audiences and has testified in front of both the U.S. House of Representatives and the U.S. Senate regarding his team's work. He is also one of three editors of a widely cited monograph produced by the Johns Hopkins Bloomberg School of Public Health that has provided comprehensive and concrete, evidence-based recommendations for addressing the epidemic. Dr. Alexander received his B.A. cum laude from the University of Pennsylvania, an MD from Case Western Reserve University, and a Master of Science from the University of Chicago.

Daren Anderson, MD

Dr. Daren Anderson is VP/Chief Quality Officer for Community Health Center, Inc., (CHCI) based in Middletown, CT, and Director of its Weitzman Institute. CHCI is at large, statewide Federally Qualified Health Center. The Weitzman Institute is a research and innovations center dedicated to improving primary care for underserved populations. Dr. Anderson leads a diverse team of innovators, health services researchers, educators, and quality improvement specialists working together to design new models to transform primary care for the underserved. Under his leadership, Weitzman has grown from a small, Connecticut-based institute to a national organization working with health centers, payers, and funders, across the US. Weitzman researchers are engaged in studies focused on issues such as health equity, telehealth, chronic disease management and pain management in primary care. Dr. Anderson's research in eConsults is the basis of a new model for using eConsults in primary which led to the creation of Community eConsult Network, a national eConsult provider now used by practices in 15 states and internationally. Dr. Anderson obtained his undergraduate degree at Harvard College and his MD from Columbia University. He

completed his residency training in internal medicine at Yale-New Haven Hospital and is a board certified general internist.

William C. Becker, MD

Dr. Becker is a general internist additionally trained in addiction medicine who is Medical Director of the Opioid Reassessment Clinic at VA Connecticut and co-chairs Yale School of Medicine's Pain Curriculum Committee. Dr. Becker's VA, NIH, FDA and PCORI-funded clinical research uses observational and experimental methods to examine and improve the quality of chronic pain treatment in primary care, particularly at the interface between high impact chronic pain and substance use disorders. Increasingly, his work focuses on de-implementing high-dose, long-term opioid therapy and improving patient's access to non-pharmacologic pain treatments.

Ronald M. Cervero, PhD

Ronald M. Cervero is Deputy Director and professor in the Center for Health Professions Education at the Uniformed Services University of the Health Sciences. Dr. Cervero has provided intellectual and organizational leadership for the field of health professions education over the span of his career, with special emphasis on continuing professional development. He serves on the Executive Editorial Board for the *Journal of Continuing Education in the Health Professions* and has provided leadership for the National Academy of Medicine's Global Forum on Innovation in Health Professions Education. Among his professional honors, Dr. Cervero was awarded the 2018 Dave Davis Research in Continuing Medical Education Award by the Society for Academic Continuing Medical Education. Before coming to USUHS in 2016, he served in a variety of executive leadership roles at the University of Georgia and was extensively involved in health professions education, including being the founding director of the Institute for Evidence-Based Health Professions Education, the co-PI for Georgia's Public Health Training Center, and the educational consultant for eight years at the Augusta University-UGA Medical Partnership to strengthen the medical school's teaching and educational research projects.

Kari Cruz, MPH

Kari Cruz, MPH, is a lead health scientist for the Program Evaluation Team in the Prevention Program and Evaluation Branch in the Division of Overdose Prevention at the Centers for Disease Control and Prevention. At CDC Ms. Cruz leads evaluation of CDC funded jurisdictions on their overdose prevention initiatives. Ms. Cruz received her master's in public health from Emory University.

James Floyd, MD, MS

Dr. Floyd is a physician and epidemiologist with experience conducting multi-disciplinary research on etiologic factors for cardiovascular diseases and adverse drug effects. Much of his prior research, funded by NIH, PCORI, and FDA, has been conducted in healthcare systems with electronic health data and NIH-funded prospective cohort studies. Dr. Floyd has also served as an *ad hoc* member of several FDA Advisory Committee meetings on opioid therapies and drug safety topics.

Martin Garcia-Bunuel, MD

Dr. Garcia-Bunuel a primary care physician. His core area of interest and professional activity centers around the implementation of system-based practices that are informed by the convergence of data analytics with day to day clinical practice. Dr. Garcia-Bunuel is a lead participant in the Opioid Safety Initiative at my medical center and continue to work with a multidisciplinary team to better understand the impact of opioid prescribing patterns on primary care, specialty care and behavioral health programs.

Don Goldman, MD

As Chief Scientific Officer, Emeritus at the Institute for Healthcare Improvement, Dr. Goldman focuses on deepening the credibility of improvement and by forging relationships with key scientific, academic, and health services research organizations. He has experience across the translational research continuum (bench science, epidemiology, clinical trials, & implementation research). He has participated in the development of numerous quality measures, especially in pediatrics and infection prevention. He ensures the rigor and dissemination of IHI's results-oriented work. Dr. Goldman explores new ways to teach, bringing promising innovations to in-person and distance-learning. He is lead faculty for a IHI/HarvardX MOOC on Practical Improvement Science. He is Co-director for the Harvard-Wide Pediatric HSR Fellowship Program he founded (funded since 1994 via NRSA T32 Training Grants). He leads a Harvard College General Education course that explores how global infectious diseases lead to social injustice. He advocates for integration of improvement science and IT/technology to accelerate progress towards equity and population health. He has served as Chair of the AHRQ NAC and the Board of AcademyHealth, and he is Vice-Chair of the Advisory Committee of the Institute for Medicaid Innovation. He is Professor of Pediatrics, Harvard Medical School and Professor of Epidemiology, Harvard T.H. Chan School of Public Health.

Lisa Howley, PhD

Lisa Howley is an Educational Psychologist who has spent 25 years in the field of medical education supporting learners and faculty, conducting research, and developing curricula. She joined the Association of American Medical Colleges (AAMC) in 2016 to advance the continuum of medical education, support experiential learning, and curricular transformation across its member institutions and their clinical partners. In this role, she leads a national educational initiative to combat the opioid epidemic. Prior to joining the AAMC, she spent eight years as the Associate DIO and AVP of Medical Education and Physician Development for Carolinas HealthCare System in North Carolina, one of the largest independent academic medical centers in the U.S. In that role, she led a number of medical education initiatives across the professional development continuum, including graduate medical education accreditation, as well as physician leadership development for the large integrated healthcare system. She concurrently served as Associate Professor at the University of North Carolina School of Medicine, where she led curriculum and faculty development. She also held a faculty appointment in educational research at UNC-Charlotte where she taught social science research methods, led and collaborated on numerous studies of effective education. From 1996 to 2001, she was a member of the medical education faculty at the University of Virginia School of Medicine where she designed and led performance based clinical assessments and simulation-enhanced curricula. She received her Bachelor's degree in Psychology from the University of

Central Florida, and both her Master of Education and Ph.D. in Educational Psychology from the University of Virginia.

Joanna G. Katzman, MD, MSPH

Joanna Katzman, MD, MSPH, is a neurologist and Professor at the University of New Mexico (UNM). She is the Director of the UNM Pain Center and Director of Project ECHO's Chronic Pain, Substance Use and Public Health programs. In 2008, Dr. Katzman created ECHO Pain and Opioid Management, which has been replicated by the Department of Defense, the Veterans Affairs, the Indian Health Service and over 145 medical centers in six countries. Dr. Katzman's clinical research focuses on the public health benefits of take-home naloxone. Currently, she is working with the CDC to train Public Health Service commissioned corps officers with an Opioid Rapid Response ECHO, and with the IHS regarding a Substance Use Disorder and Chronic Pain ECHO and a Mental Health and Resiliency ECHO. Dr. Katzman is a member of the New Mexico Governor's Council for Pain and Opioid Misuse. She has served on two Institute of Medicine (IOM) Committees related to the Gulf War and Health.

Marc Laroche, MD, MPH

Marc Laroche is an Assistant Professor of Medicine at the Boston University School of Medicine and a clinician investigator at the in the Section of General Internal Medicine and Grayken Center for Addiction at Boston Medical Center. Dr. Laroche's clinical and research interests focus on the safety of opioid prescribing and the recognition and treatment of opioid use disorders. As a health services researcher, he aims to leverage insights from large data sources and translate the findings into interventions that improve the quality and value of health care delivered. He is a buprenorphine-waivered physician with an active outpatient general medicine and addiction practice and also attends on the inpatient general medicine service at Boston Medical Center. Dr. Laroche received a BSE from Duke University, an MD from the University of Pittsburgh School of Medicine, and an MPH from the Harvard University School of Public Health. He completed his residency in internal medicine at Johns Hopkins Bayview and a fellowship in general medicine at Harvard Medical School's Department of Population Medicine.

Jan Losby, PhD, MSW

Jan L. Losby, PhD, MSW is the Branch Chief for the Health Systems and Research Branch in the Division of Overdose Prevention at the Centers for Disease Control and Prevention. Dr. Losby is responsible for evaluating and advancing the implementation of CDC's *Guideline for Prescribing Opioids for Chronic Pain*, conducting applied health systems research, and building scientific evidence to support state, community, and tribal efforts to address the opioid overdose epidemic. In addition, Dr. Losby works with healthcare systems on quality improvement, electronic clinical decision support tools, linkage to care, and data system integration with electronic health records.

Graham McMahon, MD, MMSc

Graham McMahon, MD, MMSc, is the President and Chief Executive Officer of the Accreditation Council for Continuing Medical Education (ACCME). The ACCME sets standards for high-quality continuing medical education (CME) that improves physician competence and

performance and contribute to healthcare improvement for patients and their communities. As President and CEO, Dr. McMahon leads efforts to strengthen the role of accredited CME as a strategic resource to public health initiatives on the national and international level. Dr. McMahon serves as an endocrinologist in practice in Chicago and an Adjunct Professor of Medicine and Medical Education at Northwestern University.

Elaine H. Morrato, DrPH, MPH

Elaine Morrato, DrPH MPH CPH is professor and founding dean for the Parkinson School of Health Sciences and Public Health, Loyola University Chicago. Trained in epidemiology and board-certified in public health, her work focuses on accelerating the translation of evidence into practice with a particular focus on drug safety. Her pharmaceutical industry experience developing and commercializing new drugs and indications informs her implementation science research and practice. She remains active in the NIH Clinical & Translational Sciences Award (CSTA) program where she directs Loyola's collaboration with the University of Chicago-Rush Institute for Translational Medicine and the dissemination of clinical informatics platforms and national expansion of the Innovation-Corps (I-Corps)TM training program for business model development. She regularly advises the Food and Drug Administration on issues of risk communication and management and completed a visiting professorship with the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research. She currently chairs the Benefit-Risk Assessment, Communication and Evaluation Special Interest Group for the International Society for Pharmacoepidemiology.

Jesse Roach, MD

Jesse Roach, MD, is a Medical Officer and Nephrologist at the Centers for Medicare and Medicaid Services (CMS) in the Center for Clinical Standards and Quality. He is currently the CMS Acting Chief Medical Officer for Quality Measurement. He received his medical degree from the Medical University of South Carolina, where he also completed a residency in Internal Medicine and Pediatrics. Dr. Roach completed fellowships in Adult and Pediatric Nephrology at the University of Michigan. Dr. Roach previously served on the faculty at the University of Wisconsin- Madison as an adult and pediatric nephrologist, engaging in health policy research focusing on access to care and disparity issues. Before coming to CMS, Dr. Roach served as a Medical Officer for the Food and Drug Administration as a drug reviewer in the Center for Drug Evaluation and Research.

Friedhelm Sandbrink, MD

Dr. Friedhelm Sandbrink is the National Program Director for Pain Management, Opioid Safety and Prescription Drug Monitoring Programs in the Veterans Health Administration. He joined the Department of Veterans Affairs in 2001 and since then has been leading the comprehensive interdisciplinary Pain Management Program at the Washington VA Medical Center. He became the National Program Director in September 2018. He is board certified in Neurology, Clinical Neurophysiology and Pain Medicine. He is Clinical Associate Professor in Neurology at the Uniformed Services University in Bethesda, MD and Assistant Clinical Professor of Neurology at George Washington University in Washington DC.

David A. Thomas, PhD

Dr. Dave Thomas began his research career at the National Institute on Dental and Craniofacial Research conducting research on the impact of opioids on pain and pruritus. In 1995, Dr. Thomas joined the National Institute on Drug Abuse (NIDA) where he managed much of NIDA's pain and opioid research. He is also a founding member of the National Institutes of Health (NIH) Pain Consortium and established the NIH Pain Consortium Centers of Excellence in Pain Education. In 2019, Dr. Thomas was awarded the Emma and Jon Bonica Public Service Award. In 2019, he joined the NIH Office of Research on Women's Health as the Senior Advisor to the Director.

Alec M. Walker, MD, DrPH

Alexander Walker is a Principal of the firm World Health Information Science Consultants. His research encompasses the safety, efficacy and utilization of drugs, devices, vaccines and medical procedures, as well as health effects of chemicals used in the workplace and statistical methods in epidemiology. He is a former Chair of the Department of Epidemiology at the Harvard T.H. Chan School of Public Health. He has served a statistical consultant for the *New England Journal of Medicine* and a Contributing Editor of *The Lancet*. Walker received AB (Biochemistry), MD, MPH and DrPH (Epidemiology) degrees from Harvard. He has written or contributed to over 300 peer-reviewed articles.

Julie L. White, MS, CHCP

Julie White, MS, CHCP is the Director of Continuing Medical Education at Boston University School of Medicine (BUSM CME). Boston University School of Medicine is accredited with Commendation by the Accreditation Council for Continuing Medical Education and with Distinction by the American Nurses Credentialing Center. Julie has been with BUSM CME since 1995, and has extensive experience in adult education, educational design, and program development and management. She was the recipient of the Distinguished Service in Continuing Medical Education at the Society for Academic Continuing Medical Education in 2019.

The BUSM CME team is known nationally for their *SCOPE of Pain* program, providing education to healthcare clinicians on safer opioid prescribing, and their work in quality improvement. The *SCOPE* team has published and presented nationally on their research related to the *SCOPE* program. The quality improvement team works closely with BUSM's affiliated hospital Boston Medical Center and community health centers, contributing to practice improvements and scholarship in this area.

Almut G. Winterstein, RPh, PhD, FISPE

Almut Winterstein is Professor and Chair in the Department of Pharmaceutical Outcomes and Policy at the College of Pharmacy, the founding Director of the Center for Drug Evaluation and Safety, and affiliate professor in epidemiology at the University of Florida. She received her pharmacy degree from Friedrich Wilhelm University in Bonn, Germany and her PhD in Pharmacoepidemiology from Humboldt University in Berlin. In 2017, she was named the Dr. Robert and Barbara Crisafi Chair for Medication Safety in recognition of her research on drug safety and on devising ways to improve medication use.

Since joining the University of Florida in 2000, Winterstein has served as principal investigator on more than 25 extramurally funded grants and contracts and published more than 400 manuscripts and conference abstracts. Her 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. As expert in drug safety, she has chaired the Food and Drug Administration's Drug Safety and Risk Management Advisory Committee from 2012-2018, a time period that involved many regulatory decisions on prescription opioids. Recognizing her contributions in pharmacoepidemiology, Dr. Winterstein was inducted as a fellow of the International Society of Pharmacoepidemiology in 2013 and served as president of the society from 2019-2020. Before she became department chair in 2016, Dr. Winterstein served as graduate program director in her department. She has chaired more than two dozen PhD committees and was awarded the UF-wide Dissertation Advisor/Mentoring award for her excellence in graduate training.