Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Public Virtual Scientific Workshop
Morphine Milligram Equivalents: Current Applications and Knowledge Gaps, Research Opportunities, and Future Directions
June 7-8, 2021

Participants'
Biography and Disclosures

Biography's

Shanna Babalonis, PhD
Dr. Babalonis is an Assistant Professor in the Center on Drug and Alcohol Research and the College of Medicine at the University of Kentucky. Her research focuses on the abuse potential, therapeutic effects and safety profile of opioids, cannabinoids, and their combination.

Jeffrey J. Bettinger, PharmD
Dr. Bettinger is a Pain Management Pharmacist Specialist with Saratoga Hospital Medical Group in Saratoga, NY, as well as the Senior Strategy Consultant and Therapeutics Associate for Remitigate, LLC. He earned his PharmD from Albany College of Pharmacy and Health Sciences in 2017 with a concentration in nephrology. Following his doctoral training, he completed a PGY1 general practice residency at the Stratton VA Medical Center in Albany, NY. Immediately following his general practice residency, he trained with Drs. Jeff Fudin and Erica Wegrzyn and completed a PGY2 Pain and Palliative Care residency at the same institution. His current position with Saratoga Hospital Medical Group involves him working alongside the Director of Pain Management, Director of Sports Medicine, and all Primary Care Providers allowing for a service to provide safe, appropriate, and optimum pharmacologic and non-pharmacologic pain management to chronic pain patients, especially those on high dose opioids.

Grace Chai, PharmD
Dr. Chai serves as the Associate Director for Special Initiatives for the Office of Surveillance and Epidemiology (OSE) in CDER, FDA. In this role, she serves as a senior scientific expert leading OSE's activities on public health concerns related to the distribution and utilization of FDA regulated products. She serves as OSE's principal liaison on distribution and utilization data with the Center, Agency, Department, and other Federal agencies, for activities including but not limited to drug abuse and misuse, and more recently activities related to drug supply/ shortages.

Since joining FDA in 2009, Dr. Chai has worked in various roles within OSE/CDER, as a reviewer, team leader, and as the Deputy Director for Drug Utilization for the Division of Epidemiology II. She also proudly served for many years as a Commissioned Officer in the United States Public Health Service. Prior to joining FDA, she practiced as a clinical pharmacist in a variety of inpatient and outpatient healthcare settings. She received her Doctor of Pharmacy

degree from the University of Maryland, School of Pharmacy and is in the process of completing the Master of Public Health program at the University of South Florida.

Brooke Chidgey, MD
Division Chief of Pain Management at The University of North Carolina at Chapel Hill

Sandra Comer, PhD
Dr. Comer is Professor of Neurobiology in the Department of Psychiatry at Columbia University and Research Scientist VI at the New York State Psychiatric Institute. Following PhD studies at the University of Michigan and post-doctoral research at the University of Minnesota, Dr. Comer joined Columbia University, where her research focus has been on the development and testing of novel approaches to the treatment of opioid use disorders. She is Director of the Opioid Laboratories in the Division on Substance Use Disorders and runs a very active research program devoted to examining various aspects of the abuse liability of opioids.

Penney Cowan
In 1980, Ms. Cowan founded and is CEO of the American Chronic Pain Association (ACPA) and recognized speaker advocating a multi-disciplinary approach to pain management. She has been an outspoken advocate and consumer representative for pain issues, contributed to numerous books, videos and Websites, consulted on the development of several pain management programs, issues and received numerous awards from organizations, such as the Institute for Public Service, American Pain Society, and American Academy of Pain Medicine. She is also co-founder of the World Patients Alliance and serves at secretary.

Francesca Cunningham, BS Pharmacy, PharmD
Dr. Cunningham is the Director of the Center for Medication Safety, National Center for Patient Safety (NCPS) and Program Director of Outcomes Assessment at the Department of Veterans Affairs (VA) Pharmacy Benefits Management Services (PBM).

Nabarun Dasgupta, MPH, PhD
Dr. Dasgupta is a scientist at the Opioid Data Lab (OpioidData.org), a multi-disciplinary collaboration between The University of North Carolina, University of Kentucky, and University of Florida. He has been using MME constructs in epidemiology studies for 15 years. His research team includes patients with chronic pain and people who use drugs.

Thomas Emmendorfer, PharmD
Dr. Emmendorfer has served as the Department of Veterans Affairs Deputy Chief Consultant for Pharmacy Benefits Management since July 2013. As Deputy Chief Consultant, he serves in a leadership role for national programs

Perry G. Fine, MD
Dr. Fine is Professor of Anesthesiology at the University of Utah in Salt Lake City. He has been on the faculty within the School of Medicine as a clinician, educator, and researcher since 1985. He serves as Chair of the Utah Department of Health Cannabis Medical Review Board and as an advisor to Ananda Scientific, Inc., involved in developing proof-of-concept clinical trials of cannabidiol for several potential indications.

Jeffrey Fudin, PharmD, FCCP, FASHP, FFSMB
Dr. Fudin is a past Diplomate to the Academy of Integrative Pain Management and widely published author/editor with over 300 peer reviewed articles in various medical, pharmacy, and nursing journals worldwide. He has participated in developing practice guidelines for use of opioids in chronic noncancer pain and participated in national (US Health and Human Services) and international guideline development for various pain types.

David J. McCann, PhD
Dr. McCann is Associate Director of the Division of Therapeutics and Medical Consequences within the National Institute on Drug Abuse. He received a B.S. in Pharmacy (1981) from the Albany College of Pharmacy and his Ph.D. (1988) from the Department of Pharmacology and Experimental Therapeutics at the State University of New York at Buffalo

Mary Lynn McPherson, PharmD, MA, MDE, BCPS
Dr. McPherson is a Professor at the University of Maryland School of Pharmacy, and Executive Director of the Online Master of Science and Graduate Certificate Program in Palliative Care at University of Maryland, Baltimore. Dr. McPherson has practiced in pain management and palliative care her entire career. She is the author of the book, *Demystifying Opioid Conversion Calculations: A Guide for Effective Dosing*.

R. Daniel Mellon, PhD
Dr. Mellon is currently the Deputy Director for the Division of Pharmacology/Toxicology for Neuroscience in the Office of New Drugs and has been the Pharmacology/Toxicology Supervisor supporting the Division of Anesthesiology, Addiction Medicine, and Pain Medicine since August of 2003. He has worked on opioids in one form or another since 1993 when he started his graduate studies to obtain his PhD in pharmacology from Georgetown University, where he specifically researched the effects of central opioid receptors on the immune system.

Tamra Meyer, PhD, MPH
Dr. Meyer currently leads the Nonmedical Use Team #1 in the Division of Epidemiology, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Her team is responsible for evaluating nonmedical use and related outcomes involving opioids in the postmarket setting. Dr. Meyer has served at FDA for seven years as both an epidemiology reviewer and team lead across several therapeutic areas with the last five years focused on nonmedical use of FDA-regulated products. She previously served as a civilian epidemiologist with the Army Pharmacovigilance Center where she conducted drug safety studies using the Military Health System electronic healthcare data. Prior to her work in pharmacoepidemiology, Dr. Meyer studied genetic and cancer epidemiology while earning an MPH and PhD at University of Texas School of Public Health, and later as a postdoctoral fellow at the National Cancer Institute.

Maria Luisa Molinari, MD
Dr. Molinari is a medical doctor graduated from the University of Genoa (Italy) specialised in geriatric medicine with clinical experience first in Italy and the United Kingdom. Prior to joining UK's Medicine and Healthcare Products Regulatory Agency (MHRA), she worked in a UK

Contract Research Organization (CRO) specialised in early phase studies. In 2007 Dr. Molinari joined the UKs MHRA where she has worked with products for the central nervous system, anesthetics, gastrointestinal and pain. In 2019 she obtained a Diploma in Drug Development Science from King's College London.

Jennifer Nadel, MD
Dr. Nadel is an emergency medicine physician. Prior to joining the FDA in 2016, she worked in community emergency departments in the Washington, DC area. She is currently a medical reviewer in the Division of Anesthesiology, Addiction Medicine, and Pain Medicine.

Mary Therese O'Donnell, MD, MPH
Dr. O'Donnell is a Pulmonary Critical Care specialist who has a special interest in Hospice and Palliative Care. Prior to joining the FDA in 2017 she was the Associate Chief Medical Officer, Director of Hospitalist Medicine and Palliative Care at a hospital in Washington, DC. She is currently a medical reviewer in the Division of Anesthesiology, Addiction Medicine and Pain Medicine.

Nicola Parkinson, PhD
Nicola joined the MHRA in December 2000 after a career in academia. Nicola gained a PhD in Clinical Pharmacology at Imperial College London, moving through various scientific research positions in London and Cambridge, ending as a research fellow at University College London. Nicola now monitors the safety of human medicines in her current regulatory and pharmacovigilance role at the Medicines and Healthcare products Regulatory Agency in the UK to ensure that the benefits of a medicine outweigh the risks. Nicola has led on a number of safety reviews, concerning a diverse range of medicines, including addiction and dependence to opioids with experts and representatives across healthcare professions and the public, and international regulators.

Justin Pittaway-Hay, PhD
Justin Pittaway-Hay is a Senior Pharmacokinetics assessor at the United Kingdom's Medicine and Healthcare Products Regulatory Agency (MHRA). Prior to joining the MHRA, he worked in clinical drug development for 15 years. Dr Pittaway-Hay was conferred his PhD in Medicine (Pharmacology), with a thesis investigating opioid-induced hyperalgesia, from the University of Adelaide, Australia

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

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.

Judy Staffa, PhD. RPh
Dr. Staffa is the Associate Director for Public Health Initiatives at FDA, Center for Drug Evaluation and Research (CDER), Office of Surveillance and Epidemiology (OSE), where she is responsible for setting strategic direction for complex, multidisciplinary reviews related to opioid abuse – from a planning, scientific, and policy point of view. Prior to this role, Judy was the Director, Division of Epidemiology II, directing the regulatory review and research work of epidemiologists in CDER. She has spent her FDA career serving in various roles as the office has evolved over the years. While in the role of the Associate Director for Regulatory Research she assisted in building OSE's epidemiologic research program, and prior to that she was an epidemiology reviewer and a drug utilization analyst team leader. Before joining FDA in 1999, Judy was a researcher at The Degge Group for ten years, conducting numerous pharmacoepidemiologic studies using both administrative claims data and electronic medical records data to investigate drug safety issues. Judy is a registered pharmacist who received her bachelor's degree in pharmacy from the University of Connecticut. She practiced community pharmacy prior to receiving her training in public health. She holds a master's degree in behavioral sciences from the Harvard School of Public Health, and a doctoral degree in epidemiology from the Johns Hopkins Bloomberg School of Public Health.

Donna A. Volpe, PhD
In the Division of Applied Regulatory Science (DARS), Dr. Volpe is a principal investigator in the drug metabolism, transporter, and drug-drug interaction group. She has been involved in a number of studies including in vitro drug metabolism, P-gp efflux and permeability assays in Caco-2 cells, binding affinities of opioid drugs, and cell models of drug uptake transporters. Dr. Volpe also provides scientific expertise to reviewers as a member of DARS multi-disciplinary teams on pharmacology and toxicity topics.

David A. White, PhD
Dr. White is the Director of National Institute on Drug Abuse's Addiction Treatment Discovery Program within the Division of Therapeutics and Medical Consequences. He received his B.A. in Biology and Foreign Languages (1994) from the Albany College of Pharmacy and his Ph.D. (1988) from the Department of Pharmacology and Experimental Therapeutics at the State University of New York at Buffalo.

Corinne Woods, RPh, MPH
Corinne Woods is one of the team leads on the Drug Utilization team, within the Office of Surveillance and Epidemiology in CDER. She earned a pharmacy degree from the University of North Carolina Chapel Hill in 1995. She practiced pharmacy for 15 years before earning a Master of Public Health in Epidemiology from San Diego State University.

Kun Zhang, PhD
Kun Zhang, Ph.D., Health Scientist, Division of Overdose Prevention (DOP), National Center for Injury Prevention and Control, Center for Drug Evaluation and Prevention (CDC.) Dr. Zhang has served as Health Scientist at DOP since 2015. His research focus on using large national dispensing data and claims data to study prescribing patterns of opioids, benzodiazepines, naloxone, and buprenorphine for MOUD. He leads DOP's efforts using simulation modeling to understand disease trajectory of opioid use disorder and effectiveness of interventions. He also provides technical assistance around prescribing measures, Prescription Drug Monitoring Program (PDMP) data, etc. to DOP funded State overdose prevention programs (OD2A).

Disclosures

Shanna Babalonis, PhD
No conflicts of interest to report

Jeffrey J. Bettinger, PharmD
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Grace Chai, PharmD
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Brooke Chidgey, MD
No financial conflicts to disclose

Sandra Comer, PhD
Within the past 3 years, I have received research funding and/or study medications from Alkermes, BioXcel, Corbus, GoMedical (NIDA grant), Intra-cellular Therapies (NIDA grant), Lyndra (NIDA grant), and Janssen. I have also consulted for Alkermes, Charleston Labs, Clinilabs, Collegium, Epiodyne, Mallinckrodt, Nektar, Opiant, Osmotica, Otsuka, and SunPharma

Penney Cowan
No disclosures to report

Francesca Cunningham, BS Pharmacy, PharmD
Disclosures: None

Nabarun Dasgupta, MPH, PhD
Dr. Dasgupta is a contractor to the US Food and Drug Administration and the RADARS System of Denver Health and Hospitals Authority.

Thomas Emmendorfer, PharmD
Disclosures: None

Perry G. Fine, MD
Serves as Chair of the Utah Department of Health Cannabis Medical Review Board and as an advisor to Ananda Scientific, Inc., involved in developing proof-of-concept clinical trials of cannabidiol for several potential indications. Neither provides financial compensation.

Jeffrey Fudin, PharmD, FCCP, FASHP, FFSMB
Abbott Laboratories Speaking, non-speakers' bureau, AcelRx Pharmaceuticals Acute perioperative pain (speakers bureau, consulting, advisory boards), BioDelivery Sciences International Collaborative publications, consulting, advisory boards, Firstox Laboratories Micro serum testing for substances of abuse (consulting), GlaxoSmithKline (GSK)Collaborative non-paid poster presentations), Hisamitsu America Inc Advisory Board, Hikma Pharmaceuticals Advisory Board, Scilex Pharmaceuticals Collaborative non-paid publications, Salix Pharmaceuticals Speakers' bureau, consultant, advisory boards, Torrent Pharmaceuticals Lecture, non-speakers' bureau. KemPharm (Advisory Board). Collegium Pharmaceutical (Studio recording)

David J. McCann, PhD
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Mary Lynn McPherson, PharmD, MA, MDE, BCPS
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