Naloxone Access: Answering Questions

Virtual Public Workshop

March 29, 2022

Speaker Biographies

Opening Remarks

Patrizia Cavazzoni, MD

Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Dr. Patrizia Cavazzoni is the Director at the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). Dr. Cavazzoni received her medical degree at McGill University and completed a residency in Psychiatry and a fellowship in mood disorders at the University of Ottawa. She subsequently joined the faculty of medicine at the University of Ottawa as an assistant professor, where she was engaged in clinical work, teaching, and research on genetic predictors of mood disorders, authoring numerous peer-reviewed scientific publications. Following this, Dr. Cavazzoni worked in the pharmaceutical industry for several years, and held senior leadership positions in clinical development, regulatory affairs and safety surveillance. Dr. Cavazzoni is certified by the American Board of Neurology and Psychiatry, a Fellow of the Canadian Royal College of Physician and Surgeons, a member of the Canadian College of Neuropsychopharmacology and recipient of the American College of Psychiatrists' Laughlin Fellowship.

Panelists

Jeffrey Bratberg, PharmD

Clinical Professor, College of Pharmacy, The Rhode Island University

Dr. Jef Bratberg studies the essential roles community pharmacists play regarding opioid overdose, harm reduction and opioid use disorders as a clinical professor of pharmacy practice at the University of Rhode Island. He works with student pharmacists to advocate for pharmacist's expanded roles in medication access, public health promotion, and policy change in his role at the Rhode Island Department of Health. He is an associate editor of the Journal of the American Pharmacists Association (JAPhA), and is secretary of the Association for Multidisciplinary Education and Research in Substance use and Addiction.

Josh Bolin

Associate Executive Director for Federal Affairs and Strategy, National Association of Boards of Pharmacy

Josh Bolin serves as the Associate Executive Director for Federal Affairs and Strategy for the National Association of Boards of Pharmacy (NABP). Since joining NABP in 2005, Josh has worked on development of PMP InterConnect, multiple pharmacy accreditation and inspection programs, including accreditation programs for durable medical equipment and specialty pharmacy, and inspection programs for the prescription drug supply chain, sterile and nonsterile compounding and nuclear pharmacy. In his federal affairs capacity, Josh also worked on proposals related to the COVID-19 pandemic, licensing, and expanding access to medication assisted treatment (MAT). Josh is currently working with NABP member boards of pharmacy on uniform processes and tools with respect to the Drug Supply Chain Security Act.

Nabarun Dasgupta, PhD, MPH

Senior Scientist, Injury Prevention Research Center Innovation Fellow, Gillings School of Global Public Health

Dr. Nabarun Dasgupta is a pioneer in community-based naloxone access. He co-founded Project Lazarus, a groundbreaking Appalachian overdose prevention program. He is the Board Chair of the Remedy Alliance/For The People, a national non-profit ensuring affordable naloxone reaches harm reduction programs. He has served as an advisor to US FDA, CDC, and the World Health Organization on opioid epidemiology. His team's work can be found at OpioidData.org.

Bobby Mukkamala, MD

Chair, Board of Trustees, American Medical Association

Dr. Bobby Mukkamala, a board-certified otolaryngologist-head and neck surgeon, is the Chair of the American Medical Association (AMA) Board of Trustees and Chair of the AMA Substance Use and Pain Care Task Force. A graduate of the University of Michigan Medical School, he is in solo, private practice in Flint, Michigan, and serves as immediate past president of the Michigan State Medical Society Board of Directors. Dr. Mukkamala was elected to the AMA Board of Trustees in 2017 and previously served as a member and chair of the AMA Council on Science and Public Health. He is also a member of the board of the Foundation for Flint, an organization that is working to increase access to high-quality early education for children—a proven strategy for helping children who have been exposed to lead.

Marta Sokolowska, PhD
Associate Director for Controlled Substances, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Dr. Marta Sokolowska is the Associate Director for Controlled Substances in FDA's Center for Drug Evaluation and Research (CDER). In this position, she oversees the Controlled Substances Program (CSP), which comprises the Controlled Substance Staff (CSS) and the Controlled Substances Initiatives (CSI) group. CSS provides consultation throughout FDA on evaluation of abuse potential of drugs and advises on all matters related to domestic and international drug scheduling. The strategy group pursues activities and policies to identify, mitigate, and manage emerging issues with controlled substances to minimize risks associated with problematic use while enabling appropriate access to these products for medical use. Dr. Sokolowska is a recognized expert in drug abuse liability and scheduling strategies. She has facilitated numerous initiatives to improve public health by advancing the science of assessing drug abuse liability. Prior to joining FDA, Dr. Sokolowska held senior clinical and medical leadership roles in the pharmaceutical industry. She earned her doctoral degree in psychology from McMaster University in Canada.

Moderator

Susan C. Winckler, RPh, Esq.
Chief Executive Officer, Reagan-Udall Foundation for the FDA

Susan C. Winckler, is CEO of the Reagan-Udall Foundation for the FDA, the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post, she served as President of Leavitt Partners Solutions, a healthcare strategy firm founded by Gov. Michael O. Leavitt, former Secretary of the U.S. Department of Health and Human Services. Winckler directly advised C-suite executives of a wide range of organizations on public policy and regulation, business strategy, investments, and other major business matters. As Chief of Staff for the U.S. Food and Drug Administration (2007-2009), she managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association in a series of positions of increasing responsibility.