

## **Margolis-FDA Convening: Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Crisis**

*Virtual Public Meeting*

October 13, 2021 | 1:00 – 5:00 p.m. ET

October 14, 2021 | 1:00 – 4:05 p.m. ET

### **Speaker Biographies**



**Doris Auth** joined the FDA in January 2011 as a Risk Management Analyst in the Division of Risk Management and was the team leader of the REMS Assessment team from 2012-2016 before becoming the Associate Director of DRM, and Division Director in 2020. Prior to joining the FDA, Doris worked as a clinical pharmacist in California, Hawaii, Washington D.C. and Virginia in both hospitals and long-term care. Her last position before joining the agency was as a research pharmacist where she oversaw primarily studies of antibiotics and psychiatric drugs. Doris has a Bachelor of Science in Pharmacy from the University of Pittsburgh and a Doctor of Pharmacy from the University of Maryland and completed a pharmacy residency at the National Institutes of Health Clinical Center. Doris' contributions to DRM include the development of the 2019 Draft Guidance on REMS assessments, the 2019 REMS assessment MAPP, serving as the Scientific Lead for the 2016 ER/LA Opioid Analgesic REMS and the 2018 Transmucosal immediate-release REMS joint advisory committee meetings, and as co-lead for the 2017 public meeting on mandatory prescriber education for opioid prescribers. Doris also supported the Center Director in 2019 at a House Energy and Commerce Committee Opioids briefing. Doris also presented on the US experience with REMS at the 2019 International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE) Plenary Session alongside international colleagues.



**Theresa M. Campo** is the Vice President of Education and Accreditation for the American Association of Nurse Practitioners. Previously, she was Chair of Emergency Medical Services, Director of the Emergency Nurse Practitioner Postmaster Certificate track and Associate Clinical Professor in the College of Nursing and Health Professions at Drexel University. She is board-certified as a family nurse practitioner and emergency nurse practitioner. Dr. Campo received a Doctor of Nursing Practice from Case Western Reserve University in Cleveland, Ohio and earned a Master of Science in Nursing, Family Nurse Practitioner, from Widener University in Chester Pennsylvania. She has over 30 years of experience in emergency medicine, including pre-hospital, emergency department/quick care and trauma. Theresa was a founding board member of the American Academy of Emergency Nurse Practitioners, a national organization, and has served as the inaugural chair of the education committee, editor of the quarterly newsletter, and co-lead of the academic and fellowship special interest group. She has served as vice chair of the American Nurses Credentialing Center content expert panel for Emergency Nurse Practitioner certification and was the first ENP-BC in New Jersey. Dr. Campo

was awarded the American Association of Nurse Practitioners State Award for Excellence in 2011 and was inducted into the Fellows of the American Association of Nurse Practitioners in 2015 and the American Academy of Nursing in 2017.



**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.



**Kathy Chappell** is the Senior Vice President of Accreditation, Certification, Measurement, the Institute for Credentialing Research and Quality Management, and APRN Initiatives at the American Nurses Credentialing Center. She is responsible for certification of individual registered nurses (RNs) and advanced practice registered nurses (APRNs); and development of board certification examinations. She is responsible for the accreditation of organizations that provide continuing nursing education and interprofessional continuing education; and for accreditation of residency and fellowship programs for RNs and APRNs. She directs the Institute for Credentialing Research, analyzing outcomes related to credentialing, and the quality management department.

She also leads the APRN Initiatives department. She holds a baccalaureate in nursing with distinction from the University of Virginia, a master of science in advanced clinical nursing, and a doctorate in nursing from George Mason University. She is a Fellow in the American Academy of Nursing and a Distinguished Scholar & Fellow in the National Academies of Practice.



**Wilson M. Compton**, is Deputy Director of the National Institute on Drug Abuse (NIDA) of the National Institutes of Health, where he has worked since 2002. NIDA supports most of the world's research on health aspects of drug abuse, related to preventing drug abuse, treating addiction and addressing serious health consequences of drug abuse. Dr. Compton received his undergraduate education at Amherst College and medical education, including psychiatry training, at Washington University in St. Louis. Over his career, Dr. Compton

has achieved multiple scientific accomplishments. He has authored over 200 publications and often speaks at high-impact venues. He was a member of DSM-5's Revision Task Force and has led, for NIDA,

development of the Population Assessment of Tobacco and Health Study, a longitudinal population study, jointly sponsored by NIDA and the U.S. Food and Drug Administration (FDA), with 45,971 baseline participants. Dr. Compton has received multiple awards, including the American Psychiatric Association's 2008 Senior Scholar Health Services Research Award, the American Psychopathological Association's 2010 Paul Hoch Award, FDA awards for collaboration in 2012, 2013 and 2017, and the Health and Human Services Secretary's Awards for Meritorious Service in 2013 and Distinguished Service in 2015, 2018 and 2019.



**Penney Cowan** founded and was CEO (retired) of the American Chronic Pain Association (ACPA) and is the co-founder of the World Patients Alliance. Ms. Cowan is a 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. She has 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.



**Blake Fagan** is a family physician at the Mountain Area Health Education Center (MAHEC) in Asheville and a Professor in the Department of Family Medicine at the University of North Carolina at Chapel Hill. He is co-director of the Office-Based Opioid Treatment services provided at MAHEC's Family Health Center and trains healthcare providers and medical residency programs across the state in medication-assisted treatment, safe pain management, and safe opioid prescribing practices. Dr. Fagan completed his undergraduate education at the University of Missouri–Columbia, medical school at Vanderbilt University School of Medicine, and his family medicine residency at MAHEC in Asheville. In 2019, Dr. Fagan served as the clinical consultant for the opioid crisis at the CDC Foundation

in North Carolina. He is board certified in Addiction Medicine by the American Board of Preventive medicine.



**David A. Fiellin** is a Professor of Medicine, Emergency Medicine and Public Health at Yale where he Directs the Yale Program in Addiction Medicine. An internist, board certified in Addiction Medicine, his work is focused on integrating treatment for unhealthy substance use in general medical settings including office-based practice, primary care, emergency departments, hospitals and HIV specialty settings. He has served on expert panels for the White House Office of National Drug Control Policy, the Substance Abuse and Mental Health Services Administration, the World Health Organization and directed the Connecticut Opioid REsponse (CORE) strategic planning initiative at the request of the

governor. He has received awards from the American Association for the Treatment of Opioid Dependence, the American Society of Addiction Medicine, AMERSA, and the Hazelden Betty Ford Foundation. He is Co-Editor of the American Society of Addiction Medicine's textbook, *Principles of Addiction Medicine*, 4<sup>th</sup>, 5<sup>th</sup> and 6<sup>th</sup> Editions, and serves on the Editorial Boards of 4 addiction specialty

journals. He has served on the Board of Directors of the College on Problems of Drug Dependence and as Co-Chair of the Substance Abuse Interest Group at the Society of General Internal Medicine.



**Adriane Fugh-Berman** is a Professor of Pharmacology and Physiology with a joint appointment in the Department of Family Medicine at Georgetown University Medical Center (GUMC). Dr. Fugh-Berman co-directs Georgetown's M.S. program in Health and the Public Interest and directs PharmedOut, a GUMC research and education project that promotes rational prescribing, exposes the effect of pharmaceutical marketing on prescribing practices and has had a profound impact on

prescribers' perceptions of the adverse consequences of industry marketing. Dr. Fugh-Berman has authored many key articles in peer-reviewed literature on the area of industry influence on medicine, including the first studies in the medical literature about how the pharmaceutical industry influences surgeons, pharmacists, basic scientists, and individual patients. Dr. Fugh-Berman has created dozens of pharma-free CME activities, lectures internationally and has appeared on 20/20, Nightline, the 1A, the Diane Rehm show, and every major television network. Previously, Dr. Fugh-Berman was a medical officer in the Contraception and Reproductive Health Branch of the National Institute for Child Health and Human Development, within NIH. She has also worked with the nonprofit Reproductive Toxicology Center and edited an award-winning CME newsletter on women's health. Dr. Fugh-Berman graduated from Georgetown University School of Medicine and completed a family medicine internship in the Residency Program in Social Medicine at Montefiore Hospital in the Bronx.



**Stefan Kertesz** is a Professor of Medicine at the University of Alabama at Birmingham and an attending physician at the Birmingham, Alabama VA Health Care System. He has a 25-year history of delivering primary care to persons who have experienced homelessness and addiction, and an 18-year history of VA- and NIH-funded research on care for vulnerable populations. Dr. Kertesz has published on opioids since 2008. After 2016, he began writing about adverse effects of policy

changes for patients with severe chronic pain who were subject to prescription opioid reductions. His work contributed to policy modifications by the Centers for the Medicare and Medicaid Services, and statements from the US Food and Drug Administration, the Centers for Disease Control and Prevention, Human Rights Watch and other organizations. Dr. Kertesz serves on the Science & Policy Advisory Council of the National Pain Advocacy Center, a nonprofit that accepts no industry funding.



**Erin E. Krebs**, is a health services researcher, chief of general internal medicine at the Minneapolis Veterans Affairs (VA) Health Care System, and professor of medicine at the University of Minnesota Medical School. Her professional goal is to improve the management of chronic pain in primary care. She conducts research that is informed by her practice as a primary care physician and funded by VA, the Patient-Centered Outcomes Research Institute, and the National Institutes of Health. Her current studies focus on opioid tapering outcomes and care of patients prescribed opioids for chronic pain.





**Graham McMahon**, 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 improve 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. In

addition to his role at the ACCME, Dr. McMahon serves as an endocrinologist in practice at Howard Brown Health in Chicago and an Adjunct Professor of Medicine and Medical Education at Northwestern University.



**Mary Lynn McPherson**, is Professor and Executive Director, Advanced Post-Graduate Education in Palliative Care in the Department of Pharmacy Practice and Science at the University of Maryland School of Pharmacy in Baltimore. In addition to a PharmD degree, Dr. McPherson has a master's degree in Instructional Systems Development, and a Masters in Distance Education and e-Learning. Dr. McPherson has

maintained a practice in both hospice (local and national) and ambulatory care her entire career. She is the Executive Program Director of the Online Doctor of Philosophy, Master of Science and Graduate Certificate Program in Palliative Care at the University of Maryland, Baltimore. Dr. McPherson is particularly interested in the safe and effective use of medications in patients with a life-limiting illness, ranging from drug selection, deprescribing, and risk mitigation. Dr. McPherson developed one of the first and few palliative care pharmacy residencies in the U.S. Dr. McPherson has won numerous awards for teaching, and her innovative practice in end of life care. She has published numerous articles, chapters, and four books including the second edition of the best-selling "Demystifying Opioid Conversion Calculations: A Guide for Effective Dosing."



**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.



**Kate Nicholson** is the President and founder of the National Pain Advocacy Center (NPAC), a non-profit advocacy organization that takes no industry funding and advocates to advance the health and human rights of people in pain. NPAC is a coalition of scientists, clinicians, health policy experts and people with lived experience of pain. Kate Nicholson is a civil rights attorney and a nationally-recognized expert on the Americans with Disabilities Act (ADA). She served in the U.S. Department of Justice for 18 years, where she litigated and managed cases, coordinated federal disability policy, and

drafted the current ADA regulations. Kate developed intractable pain after a surgical mishap left her unable to sit or stand and severely limited in walking for many years. She gave the TEDx talk, [What We Lose When We Undertreat Pain](#), and speaks widely at universities and conferences and to medical groups. She was an appointed member of the Opioid Workgroup of the Centers for Disease Control and Prevention and a 2019-20 Mayday Pain & Society Fellow. Kate also serves on task forces and working groups of aligned civil rights, disability rights, women's health, and drug policy organizations. Kate was a Senior Fellow at Dartmouth College and is a graduate of Harvard Law School.



**Daniel Pace** is Chief Strategy Officer and Vice President of Education and Research at the American Academy of PAs. As Chief Strategy Officer, Daniel collaborates with the AAPA Board of Directors, Chief Staff Officers and other volunteer leaders to develop and implement AAPA's multiyear strategic plan. As Vice President of Education and Research, Daniel leads the teams responsible for Learning Central – the continuing professional development home for PAs, JAAPA – the peer-reviewed clinical journal of AAPA, the AAPA Category 1 CME credit system and developing solutions that facilitate practice improvement, certification maintenance, and career development. Daniel is passionate about

helping PAs and the healthcare team improve patient outcomes through continuing professional development and by ensuring that a variety of internal and external stakeholders have access to reports, publications, and resources to better understand the PA profession.



**Elyse Powell** is the State Opioid Coordinator for NCDHHS. In this role, Dr. Powell leads NC DHHS' response to the opioid epidemic, leading coordination across harm reduction, treatment, prevention, and policy strategies to best improve outcomes for North Carolinians. During COVID-19, she has led the business intelligence unit of DHHS' COVID19 response, which included overseeing the launch of the COVID19 data dashboard and a statewide vaccine Site Locator and eligibility screener. She holds her Ph.D from the Gilling's School of Global Public Health at UNC, and her B.A. in Psychology and Neuroscience from Princeton University. When she can, Dr. Powell spends time enjoying NC's outdoors biking, camping, and rock climbing.



**Anuradha Rao-Patel** attended medical school at Louisiana State University in New Orleans and completed her internship in Internal Medicine at Earl K. Long Hospital in Baton Rouge. She then completed her residency in Physical Medicine and Rehabilitation at Sinai Hospital in Baltimore, Maryland. She is a physician member of the North Carolina Medical Board appointed in November 2020 by Governor Roy Cooper.



**Lisa Robin** is the Federation of State Medical Boards' (FSMB) Chief Advocacy Officer and oversees the FSMB's Washington, D.C., office. During her long tenure at the FSMB, she has been active in policy analysis, development and promulgation on issues including license portability, telemedicine, pain and addiction policy, scope of practice, professional conduct and ethics, and Internet prescribing. She represents the position of state medical boards to Congress and the Administration and supports individual boards in achieving their state legislative agendas. In her current position, she oversees the FSMB's education services, federal and state legislative and policy services, and public affairs. She

also provides support to the FSMB Foundation and its grant programs. Ms. Robin earned her bachelor's and master's degrees from Texas Christian University in Fort Worth, Texas.



**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 National Program Director for Pain Management in September 2018 and is now the Executive Director for the Pain Management, Opioid Safety and Prescription Drug Monitoring Program (PMOP) in the Veterans Health Administration. He is board certified in Neurology, Clinical Neurophysiology and Pain Medicine. He is a 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.



**Kristine Schmit** is a medical epidemiologist with the Clinical Practice Team in CDC's Division of Overdose Prevention. Kristine is board certified in both Family Medicine and Preventive Medicine. She attended medical school at Duke University and completed her Family Medicine residency at the University of California at San Diego. After finishing residency, she practiced for two and a half years at a Federally Qualified Health Center in Washington, DC before returning to North Carolina to complete her Preventive Medicine Residency at the

University of North Carolina at Chapel Hill. Subsequently, she split her time practicing at a rural clinic in Henderson, North Carolina and conducting primary care research with the Duke Primary Care Research Consortium. Kristine completed an EIS Fellowship at CDC with the Division of TB Elimination from 2015-

2017 and then transitioned to a full-time position as a medical epidemiologist within the same Division where she served for nearly three years before transitioning to her current position with the Division of Overdose Prevention.



**Steve Singer** oversees development of programs and resources to support the ACCME system of accredited CME providers, ACCME-recognized state accreditors, and accreditation volunteers, including the annual ACCME Meeting and ACCME's online learning portal, *ACCME Academy*. Dr. Singer also oversees the educational support for *Joint Accreditation for Interprofessional Continuing Education*, a collaborative initiative founded by ACCME, American Nurses Credentialing Center (ANCC), and Accreditation Council for Pharmacy Education (ACPE). Dr. Singer's liaison responsibilities for the ACCME include the National Academy of

Medicine's Action Collaboratives on Clinician Well-Being and Resilience and Countering the U.S. Opioid Epidemic, the Agency for Healthcare Research and Quality (AHRQ) evidence-based Care Transformation Support (ACTS) initiative, and other partnerships to elevate the role of continuing education as a strategic asset for healthcare change. Dr. Singer received his doctorate in neuropharmacology from the Stritch School of Medicine.



**David Tauben** is Emeritus Clinical Professor in the Departments of Medicine and Anesthesia & Pain Medicine, and recently retired Chief of the UW Division of Pain Medicine, board certified in both Internal Medicine and Pain Medicine, and has practiced as Primary Care physician for 30 years and Pain Medicine expert for over 25 years. Dr. Tauben is also UW Director of Medical Student Education in Pain Medicine and leads UW TelePain, an innovative tele-video-conferencing program delivering pain and addiction management educational consultative support to Pacific Northwest primary care providers. He has been principal investigator for the UW's NIH Pain Consortium Center of Excellence for Pain Education, a member of the NIH National Pain Strategy task force on Pain Education, and a founding and

continuing member of the State of Washington Agency Medical Directors panel of clinician experts developing opioid prescription guidelines for chronic pain. He earned his BA in Philosophy at Yale University, Medical Degree at Tufts University, and completed his Residency training at the University of Washington.



**Corinne Woods** is a Team Lead on the Drug Utilization Team in the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research at FDA. Ms. Woods has been with FDA for five years and has presented at public Advisory Committee Meetings and an FDA-led public workshop. She has contributed to several high-profile FDA reviews and peer-reviewed articles. Prior to joining FDA, she held research positions and practiced pharmacy in retail, home-health, long-term care, and hospital pharmacies, gaining a keen understanding of the movement of pharmaceutical products within the U.S. health care system. Ms. Woods received her Bachelors of Pharmacy from the University of North Carolina,



Chapel Hill in 1995 and completed her Masters in Public Health, Epidemiology at San Diego State University in 2011. She currently lives in Maryland with her family and sundry pets.

### **Duke-Margolis Moderators**



**Marianne Hamilton Lopez** is the Senior Research Director of Biomedical Innovation, an adjunct associate professor, and core faculty at the Duke-Margolis Center for Health Policy in Washington, DC. She leads the strategic design and direction of the Center's Biomedical Innovation portfolio, with a focus on medical products development and regulation, real world evidence, infectious disease preparedness, and payment, pricing, and coverage of drugs and medical devices. She also oversees the Value for Medical Products Consortium and partners with Duke University faculty, scholars, and external health experts to advance this work. Prior to joining Duke-Margolis, Dr. Hamilton Lopez was a senior program officer with the National Academy of Medicine's Leadership Consortium for a

Value & Science-Driven Health System and led the Consortium's Science and Technology portfolio and Clinical Effectiveness Research Innovation and the Digital Learning Collaboratives. She was a Senior Manager at AcademyHealth; a Public Health Community Advisor for the United States Cochrane Center; and the Federal Women's Program Manager and American Indian/Alaska Native Employment.



**Mark McClellan** is the Robert J. Margolis, M.D., Professor of Business, Medicine and Policy and Director of the Duke-Margolis Center for Health Policy. A physician-economist focused on advancing quality and value in health care, his COVID-19 response work spans virus containment and testing strategies, resilient care delivery, and accelerating therapeutics and vaccine development. Dr. McClellan is a former leader of the Centers for Medicare & Medicaid Services and the U.S. Food and Drug Administration. An independent director on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and PrognomiQ, Dr. McClellan co-chairs the Guiding Committee for the Health Care Payment Learning and Action Network and serves as an advisor for Arsenal Capital Partners, Blackstone

Life Sciences, and MITRE.