Duke | Robert J. Margolis, MD Center *for* Health Policy

Exploring Packaging, Storage, and Disposal Solutions to Enhance Opioid Safety

Duke-Margolis Center for Health Policy Conference Center • Washington, DC
June 1, 2017

Speaker Biographies

Onur Babat, PhD is a Research Assistant in Industrial and Systems Engineering Department of Lehigh University. His research interests and expertise are primarily in financial optimization and financial engineering areas. Throughout his academic career, he had a number of interdisciplinary research collaborations with the companies and institutions including Air Products and Chemicals, Inc., Lehigh Valley Health Network, and the FDA. Previously, Dr. Babat served as the president of the Institute for Operations Research and the Management Sciences (INFORMS) Student Chapter and the Turkish Student Club at Lehigh University. Dr. Babat recently received a PhD in operations research and financial engineering from Lehigh University. He also obtained an MEng. degree in management science and engineering from Lehigh University and a BS degree in industrial engineering from TOBB University of Economics and Technology (TURKEY). Dr. Babat will be joining the Quantitative Advisory Services practice at Ernst & Young company in New York, NY as a Senior Financial Consultant in August 2017.

Walter Berghahn is the Executive Director for the Healthcare Compliance Packaging Council, a non-profit trade organization promoting improved patient safety and health outcomes through better pharmaceutical packaging. Started in 1990 the associations mission has grown to include promoting packaging that benefits product protection (stability) and supply chain safety in addition to the primary goal of improving patient outcomes through improved adherence to regimen. Mr. Berghahn also serves as an Adjunct Professor for Pharmaceutical Packaging at Rutgers University, College of Engineering in the Packaging School. Working with industry colleagues Mr. Berghahn has begun creating several graduate level courses focused on pharmaceutical packaging with the goal of building out the curriculum to better serve the specific needs of this market segment. Mr. Berghahn also works as the Vice-President of Operations and Business Development for Pester USA, a 130 year old German machinery manufacturer focused on secondary packaging in the pharmaceutical and personal care industries. The work with Pester dovetails with the HCPC as supply chain safety has become a key concern for both as the industry attempts to comply with the Drug Supply Chain Security Act signed by President Obama in 2013. Mr. Berghahn has a Bachelors of Science Degree in Packaging from Rutgers University College of Engineering and currently has over 30 years' experience in the packaging industry.

Laura Bix, PhD is a Professor and the Associate Director of the School of Packaging at Michigan State University and also holds an Adjunct status at Clemson University. She specializes in healthcare packaging at MSU, where she has been recognized with an Excellence in Teaching Award (2007). The mission of her research team, the Packaging HUB, is to improve health through packaging. Dr. Bix has served as the US expert to ISO/TC 122 WG9, a guideline aimed at creating inclusionary packaging, and as the Vice-Chair of ASTM Committee D10.32, the Committee on Consumer, Pharmaceutical and Medical Packaging (2004-2008). In 2008 she was named one of the Medical Device Industry's most notable people by *Medical Device and Diagnostic Industry* magazine. She was named to the PROTECT and PROTECT Rx Panels in 2012; two committees tasked by the US CDC to reduce unintentional poisoning of children under five. She also served a panel jointly appointed by the Gerontological Society of America (GSA) and the Consumer Healthcare Products Association (CHPA) which examined behaviors related to medication use by older adults. Her approach to multi-disciplinary endeavors and the value that she places unique collaborations were honored in 2014 with the Phi Kappa Phi Excellence in Interdisciplinary Scholarship Award, and, more recently, her leadership skills were recognized when she was appointed as an academic fellow of the CIC's Academic Leadership Program. Work from her group has been published in numerous peer-reviewed outlets, including the *PLoS One* and *The Proceedings of the National Academy of Sciences of the US.*

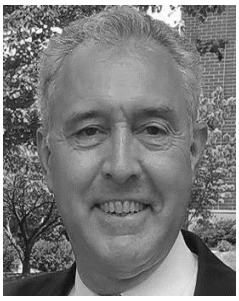
Hayden Bosworth, PhD is a health services researcher and a Professor of Medicine, Psychiatry, and Nursing at Duke University Medical Center and Adjunct Professor in Health Policy and Administration at the School of Public Health at the University of North Carolina at Chapel Hill. He is involved with the development of the new Department of Population Health Sciences at Duke University. 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. Dr. Bosworth was the recipient of an American Heart Association established investigator award, the 2013 VA Undersecretary Award for Outstanding Achievement in Health Services Research (The annual award is the highest honor for VA health services researchers), and a VA Senior Career Scientist Award. In terms of medication safety and packaging, Dr. Bosworth recently conducted a RCT testing blister packaging to improve medication adherence. He has led over 30 trials and participated in another 50 resulting in over 280 peer reviewed publications and four books. This work has been or is being implemented in multiple arenas including Pharma patient support programs, Medicaid of North Carolina, The United Kingdom National Health System Direct, Kaiser Health care system, and the Veterans Affairs.

Dan Budnitz, MD, MPH directs the Medication Safety Program at the U.S. Centers for Disease Control and Prevention (CDC). He has authored over 50 publications on medication safety, public health surveillance, and injury prevention, work which became the basis for the 2014 National Action Plan for Adverse Drug Event Prevention. Dr. Budnitz also launched a public-private partnership, the PROTECT Initiative, to reduce medication overdoses in children. This collaboration has led to voluntary development and implementation of innovative child-resistant packaging, development and endorsement of dosing and e-prescribing standards, and a public education campaign UpAndAway.org to promote safe medication use and storage. Dr. Budnitz joined CDC as an Epidemic Intelligence Service Officer with CDC's Injury Center in 2001 where he co-led injury response efforts to the terrorist attack on the World Trade Center and early investigations identifying increasing deaths from prescription opioids before starting the Medication Safety Program in the Division of Healthcare Quality Promotion in 2005. He received a BA in Government from Harvard University, a combined MD-MPH from Emory University and completed 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.

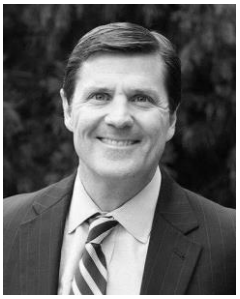
Robert M. Califf, MD, MACC is Donald F. Fortin, MD Professor of Cardiology at Duke University School of Medicine. He was the Commissioner of Food and Drugs in 2016-2017 and Deputy Commissioner for Medical Products and Tobacco from February 2015 until his appointment as Commissioner in February 2016. Prior to joining the FDA, Dr. Califf was a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,200 publications in the peer-reviewed literature. Dr. Califf is a Member of the National Academy of Medicine (formerly known as the Institute of Medicine (IOM)) in 2016, one of the highest honors in the fields of health and medicine. Dr. Califf has served on numerous IOM committees, and he has served as a member of the FDA Cardiorenal Advisory Panel and FDA Science Board's Subcommittee on Science and Technology. Dr. Califf has also served on the Board of Scientific Counselors for the National Library of Medicine, as well as on advisory committees for the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Environmental Health Sciences and the Council of the National Institute on Aging. He has led major initiatives aimed at improving methods and infrastructure for clinical research, including the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by the FDA and Duke. He also served as the principal investigator for Duke's Clinical and Translational Science Award and the NIH Health Care Systems Research Collaboratory coordinating center and co-PI of the Patient Centered Outcomes Research Institute Network. Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco and a fellowship in cardiology at Duke.

Melinda Campopiano, MD is senior medical adviser for the Center for Substance Abuse Treatment which is part of the Substance Abuse and Mental Health Services Administration. Her activities have included development of SAMHSA's Opioid Overdose Prevention Toolkit, Brief Guides on Medication for the Treatment of Alcohol Use Disorder and the Clinical Use of Extended-Release Injectable Naltrexone in the treatment of Opioid Use Disorder, and the recent Advisory: Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder. She served as chairperson for the Treatment and Recovery Committee of the National Heroin Taskforce in 2015.Originally from Iowa Dr. Campopiano is a graduate of the University of Pittsburgh School of Medicine. She is board certified in Family Medicine and Addiction Medicine. She provided primary care and buprenorphine services in her solo practice in Pittsburgh and was medical director of Western Psychiatric Institute and Clinic's Opioid Addiction Treatment Program prior to coming to SAMHSA.

Gregory Daniel, PhD, MPH is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform. Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA and Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc). Dr. Daniel's research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoeconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes form the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.



William "Bill" Davies, Colonel, United States Army (retired) served 26 years as an Army Pharmacist, retiring as the Director Pharmacy Operations for the Department of Defense (DoD). Following three years with a larger consulting firm he returned to DoD and currently serves as the Integrated Utilization Branch Chief for the Pharmacy Operations Division at the Defense Health Agency. While on active duty, Mr. Davies, also served as the Army Pharmacy Systems Consultant, and the DoD Program Manager for the Pharmacy Data Transaction Service which aggregates DoD prescription transactions from TRICARE retail network pharmacies, the TRICARE mail order pharmacy, and military facility pharmacies worldwide with real time drug utilization review processing and patient profiling. Mr. Davies has extensive experience in pharmacy operations, medical information systems, and policy development for the DoD TRICARE Program, military medical facilities, and commercial managed care organizations. Mr. Davies received an MS in institutional pharmacy from the University of Maryland, Baltimore, an MA in computer resource management from Webster University, and his BS in Pharmacy from University of Louisiana, Monroe.



Jon Easter joined the UNC Eshelman School of Pharmacy in January 2016 as a Professor of the Practice and Director, Center for Medication Optimization through Practice and Policy (CMOPP). CMOPP creates impactful real-world research, generates evidence, disseminates best practices, and advances education to integrate medication optimization into value-based care delivery and payment models. Previously, Jon spent 20 years at GlaxoSmithKline (GSK), where he primarily worked in the health policy arena. He led a team that facilitated the adoption of evidence based quality measures and drove care delivery improvements through better coordination and medication management. Jon championed North Carolina First in Health, a self-insured patient-centered medical home project. He co-authored a prescriptive analytics pilot through a collaboration with Community Care of North Carolina (CCNC) that aimed to improve patient care through better medication management. He was also directly involved with replication of the Asheville Project, a recognized model for care coordination to improve patient outcomes for chronic disease. Jon has a B.S. in Pharmacy from the University of Georgia and is a registered pharmacist.

Thomas Emmendorfer, PharmD 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 including the VA's Opioid Safety Initiative. 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 Pharmacy Practice Residency at Spectrum Health, Grand Rapids, Michigan in 2001.

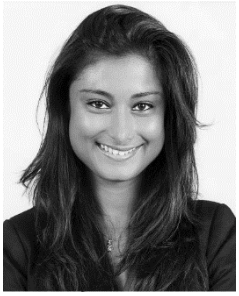
Matt Ervin, MS is the founder and CEO of MedicaSafe, a company developing technologies that improve medication therapy management for high-stakes treatments. Matt is also the Founder and President of Plum Voice, a leader in cloud technology for communications with a special focus on IVR and speech dialogs. Previously Matt worked as an investment analyst and was co-manager of both the Baron Opportunity Fund (BIOPX) and Baron Growth Fund (BGRFX). Matt's educational background includes a B.A. in physics from Harvard University and M.S. in Applied Sciences from Harvard University.

Michael Fraser, MPH is the Senior Manager of Data Services at the American Association of Poison Control Centers (AAPCC). Mr. Fraser leads all components of The National Poison Data System (NPDS), a national database collating over 30 years of poison data from poison centers across the nation. Mr. Fraser's responsibilities include working with the nation's 55 poison centers, and various industry and government entities, to provide oversight and management of poison data. At the AAPCC, Mr. Fraser reinforces data quality standards by performing thorough quality assurance and quality check's for requested data, and ensures that all clients' data needs are met. Mr. Fraser's public health background spans across various sectors (federal government, non-profit, academic), focus areas (health policy, environmental health, communicable diseases), and target populations (men, ethnic/ cultural populations, adolescents). Mr. Fraser received his Master of Public Health from Morehouse School of Medicine with a concentration in Health Policy and Management, and a Bachelor of Science in Health Science from Howard University.

Paul Gileno A powerful voice in the pain community and beyond, Paul Gileno is the founder and president of the U.S. Pain Foundation. Gileno, a chef by training, started the organization in 2006 after a work injury led to several severe pain conditions and forced him to close his thriving catering business. Since then, Gileno has grown U.S. Pain into the leading chronic pain advocacy organization in the nation, with more than 90,000 members across the country. The overarching mission of the group is to connect, inform, empower, and advocate for the 100 million American living with some form of constant pain. Toward that goal, U.S. Pain offers dozens of support and educational programs, including its flagship program, the INvisible Project, which highlights patient stories. In honor of his efforts, Gileno has received several awards, including Unsung Hero Award from Grünenthal USA in 2014, the Pain Educator of the Year Award from the American Society of Pain Educators in 2015, and a Presidential Commendation from the American Academy of Pain Medicine in 2017. He also sits on multiple pain-related advisory boards and task forces. Gileno resides in New York with his wife and two sons, and in his spare time, loves to cook for family and friends.

Christopher M. Jones, PharmD, MPH currently 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 policy and data policy activities. The Office 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. During his career, Dr. Jones has served as Senior Public Health Advisor to the White House Office of National Drug Control Policy, led the FDA's Drug Safety and Risk Communication team, and served on the Science Team in the CDC's Strategic National Stockpile. Chris received his Doctor of Pharmacy degree from Mercer University, his Master of Public Health degree from New York Medical College, and his Bachelor of Science degree from Reinhardt College. He is currently completing his Doctorate of Public Health in Heath Policy at The George Washington University. Dr. Jones is a nationally recognized expert on opioid misuse and overdose and has authored more than 50 peer-reviewed publications on the topic.

Stella Kim, PharmD, JD is a Public Health and Regulatory Research Fellow at the Food and Drug Administration in the Office of Public Health Strategy and Analysis. She is a recent graduate of both the University of Maryland's School of Pharmacy (2016) and Francis King Carey Law School (2016). To pursue her goal of working at the intersection of science and law, she joined the FDA to learn about designing methodologies and quantitative analysis techniques to evaluate current laws and policies that affect public health. Her current projects include: utilizing the American Association Poison Control Center database to evaluate adverse events associated with different categories of dietary supplements; analyzing opioid-related public health issues, such as naloxone accessibility, medication-assisted therapy accessibility, and continuing education requirements for practitioners; and examining agency transparency issues.



Shruti Kulkarni, Esq is outside counsel to the Center for Lawful Access and Abuse Deterrence (CLAAD). Ms. Kulkarni offers policy insight on the prevention of diversion, misuse, and abuse of controlled prescription medications and treatment of substance use disorders. In this capacity, she proposes and analyzes policies and legislation; drafts legislative language, testimony, white papers, and scholarly articles; and educates state and federal legislators and policy makers. Ms. Kulkarni has over 10 years of experience in the health care industry, including government affairs and sales positions in the pharmaceutical industry. She previously completed a legal internship at the FDA's Office of Policy in the Office of the Commissioner. Ms. Kulkarni is also an associate attorney at DCBA Law & Policy, a Washington, DC law firm that focuses on health care law and policy. Ms. Kulkarni obtained her Juris Doctor degree from George Mason University School of Law. She received her bachelor's degree *magna cum laude* from Saint Joseph's University.

Nathan Langley is Co-Founder and Vice President of Business Development at Gatekeeper Innovation, Inc. Gatekeeper has developed and patented the first locking cap for existing prescription bottles to reduce prescription drug abuse, a growing epidemic in America. Gatekeeper's patented locking cap has been recognized with many awards including Top Five Technology to Reduce Prescription Drug Abuse by the Center for Lawful Access and Abuse Deterrence. Mr. Langley is also a part of the National Pain Care Forum and the Abuse Deterrent Coalition, which collectively develop initiatives and drive legislation for improving pain care and reducing prescription drug abuse in the U.S. He is a thought leader and sought after public speaker on the topic of prescription drug abuse. Mr. Langley has a Bachelors of Science in Business Administration with a concentration in Entrepreneurship from California State University Sacramento. He was also recognized by the Sacramento Business Journal as a 2016 "Top 40 under 40" honoree.

Bernadette Loftus, MD has served as Associate Executive Director of the Mid-Atlantic Permanente Medical Group since it legally affiliated with The Permanente Medical Group (TPMG) of Northern California in 2008. In this role, Dr. Loftus is responsible for the health care of over 710,000 Kaiser Permanente members in Maryland, Virginia and the District of Columbia. A longtime health care executive with a deep understanding of the complexities of managing an integrated health care delivery model, Dr. Loftus uses innovative approaches to improve the value of care provided, driving to award-winning quality and patient satisfaction levels, while improving the affordability of care. For the second year in a row, Kaiser Permanente of the Mid-Atlantic States achieved a 5.0 out of 5.0 rating for its commercial plans in NCQA's 2016–2017 national health insurance plan ratings, which makes KPMAS one of the thirteen in the nation – out of over 500 to be rated – to earn a 5 out of 5 rating for commercial line of business. For the eighth consecutive year, J.D. Power and Associates ranks Kaiser Permanente of the Mid-Atlantic States highest in member satisfaction in the Mid-Atlantic Region. Board-certified in Otolaryngology/Head and Neck Surgery, Dr. Loftus received her medical degree from Case Western Reserve University School of Medicine, Cleveland (with honors); did preliminary general surgery residency at Albert Einstein Medical Center, Philadelphia; and completed her Otolaryngology/Head and Neck Surgery residency at Columbia University, where she was also appointed Chief Resident in Head and Neck Surgery.

Kevin Nicholson, RPh, JD is Vice President of Public Policy and Regulatory Affairs for the National Association of Chain Drug Stores (NACDS). In this role, he is responsible for the strategic direction of the Association's public policy and regulatory affairs activities. Nicholson oversees activities and staff in providing legislative and regulatory policy analysis in federal and state healthcare issues. He and his team provide expertise to lobbyists and other Association staff, as well as chain members. He has over 30 years' experience in the pharmacy industry, including six years as a practicing community pharmacist.

Doug Throckmorton, MD As Deputy Director for Regulatory Programs, Dr. Throckmorton shares the responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks. Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital.

Kevin Webb, MBA is Director of Government Affairs & Advocacy at Mallinckrodt Pharmaceuticals, an independent global specialty pharmaceutical company with U.S. headquarters located in St. Louis, MO. Kevin is instrumental in executing upon the company's commitment to address opioid misuse, abuse and diversion. Kevin manages key strategic partnerships and engages external stakeholders, including legislators/policymakers, professional societies, patient advocacy groups, law enforcement and community-based organizations to advance patient health and safety needs through collaboration. He successfully brought together strategically aligned stakeholders and third party organizations to achieve a shared objective of ensuring patient access to addiction treatment and appropriate pain management, including alternatives to opioids. And within the company's Specialty Generics division, Kevin is responsible for advancing initiatives that promote new drug formulations, removing barriers to access and focus on patient care. With more than 20 years of experience in the healthcare industry, Kevin has been with Mallinckrodt for the past 10 years with experience in marketing management and advocacy and government affairs. Prior to Mallinckrodt, Kevin spent 10 years with Sanofi Pasteur in a variety of sales management and marketing management roles and four years with Memorial Health System in Springfield, IL, as a Marketing and Planning Manager. Kevin 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. His volunteer leadership experience includes both within his church and scouting organizations. Kevin currently resides in the St. Louis area with his wife of 23 years and their three children.

Elizabeth "Liz" Whalley Buono, **BSN, RN, MBA, JD** 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 successful careers in clinical nursing and big pharma, Liz 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, Liz managed the legal and health ethics considerations associated with tobacco harm reduction clinical research and new product development. As V.P., Global Quality, Regulatory and External Affairs at WestRock, Liz focused 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. At Westrock, Liz was 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. Liz's consulting practice is focused on healthcare innovation and new product development where she can utilize her skills in Regulatory & Compliance Analysis, Novel Technology Navigation, and Differential Disease Management. Liz 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.

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