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

Assessing the Public Health Impact of Prescription Drug Postmarketing Safety Labeling Changes

The Duke-Margolis Center for Health Policy • Washington, DC
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Biographies

W. David Bradford, PhD, is the Busbee Chair in Public Policy in the Department of Public Administration and Policy at the University of Georgia. Prior to joining UGA, he was the Director and founder of the Center for Health Economic and Policy Studies at the Medical University of South Carolina (MUSC) and has been a visiting faculty member at Yale Medical School and a tenured faculty member in the Department of Economics at the University of New Hampshire. Dr. Bradford has over 90 publications, and has significant experience with funded research, serving or having served as Principal Investigator on 21 extramurally funded research grants. Dr. Bradford is an associate editor for the journal Health Economics and is on the oversight boards for both the American Health Economics Conference and the Southeastern Health Economics Study Group. Dr. Bradford has three main areas of active research. First, he studies the U.S. pharmaceutical industry. This includes NIH- and AHRQ-funded research on the impact of direct to consumer advertising for prescription pharmaceuticals, the impact of various information sources on pharmaceutical use, and the effectiveness of FDA post-marketing surveillance in light of competing information availability. Dr. Bradford also studies the role of off-label prescribing of drugs on the dynamic functioning of pharmaceutical markets. Second, he studies the impact of cannabis laws and opioid control laws on health outcomes and risky behaviors. Finally, Dr. Bradford conducts research on the role of time and risk preferences on health care related decisions.

Becky Briesacher, PhD, is an Associate Professor in the Department of Pharmacy and Health Systems Sciences at Northeastern University. She is a health services researcher with nationally-recognized expertise in drug policy and medication use in older adults. Dr. Briesacher is currently studying the long-term impacts of the Medicare Part D prescription drug program and the off-label prescribing of atypical antipsychotic drugs in nursing homes. Her research has received funding from NIH, AHRQ, Centers for Medicare and Medicaid Services, The Robert Wood Johnson Foundation, The Commonwealth Fund, The Henry J. Kaiser Family Foundation, and AARP. She has published over 90 peer-reviewed articles in such journals as *JAMA, Annals of Internal Medicine*, and *Journal of General Internal Medicine.* Dr. Briesacher has a bachelor's degree from the University of California, Berkeley, a master's degree from Williams College, and a doctorate from the University of Maryland.

Gerald J. Dal Pan, MD, MHS, became the Director of the Office of Surveillance and Epidemiology (known then as the Office of Drug Safety) in November 2005. Before that, he was the Director of the Division of Surveillance, Research, and Communication Support in CDER's Office of Drug Safety, a position he held since December 2003. He received his medical degree from Columbia University, and his Master's degree in clinical epidemiology from Johns Hopkins University. He trained in internal medicine at the Hospital of the University of Pennsylvania, and in neurology at Johns Hopkins Hospital. Dr. Dal Pan is board certified in internal medicine and neurology. He was an instructor in the Neurology Department at Johns Hopkins. He next worked for Guilford Pharmaceuticals in Baltimore, and then for HHI Clinical Research and Statistical Services in Hunt Valley, MD. He joined FDA in July 2000 as a medical officer in the Division of Anesthetic, Critical Care, and Addiction Drug Products.

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.

Bruce A. Donzanti has a PhD in pharmacology/neuroscience with almost 30 years experience in the pharma/biotech industry. After serving in the US Army Medical Service Corp, he entered academia where he performed pre-clinical research on mechanisms of neuronal degeneration and neurotoxicology and lectured in pharmacology to both graduate and medical students. He continued his preclinical neuropharmacology and toxicology research in industry before moving over to clinical development and eventually Medical Affairs. Bruce has held various positions in drug safety including Head of Drug Safety at Genentech, Inc. before transitioning into a new role at Genentech/Roche as Senior Group Director of Global Pharmacovigilance Innovation Policy in Global Regulatory Affairs. In this role, Bruce focuses on current challenges in pharmacovigilance (e.g., predictive drug safety, quality of safety data sources, etc.) by interacting with health authorities, various non-governmental organizations and consortia, as well as industry colleagues. Previously, Bruce was the Chair of the Biotechnology Industry Organization (BIO) Post-Approval Committee that seeks to address current challenges in pharmacovigilance.

Stacie B. Dusetzina, PhD, is an associate professor in the Department of Health Policy and a Vanderbilt-Ingram associate professor of cancer research at Vanderbilt University Medical Center. She is a population health scientist and pharmacoepidemologist specializing in large data informatics and has authored or co-authored over 85 peer reviewed applied studies using Medicaid, Medicare, and commercial insurance claims data. Dr. Dusetzina's work focuses on measuring and evaluating population-level use and costs of medications in the United States. She has also contributed to the evidence base for the role of drug safety warnings on patient utilization of medications through publication of a systematic review on the topic (published in 2012) and authoring or co-authoring over a dozen papers evaluating changes in prescription drug utilization, including studies focused on the changes in medication use as a result of FDA advisories.

Chester "Bernie" Good, MD, MPH, is an internist from Pittsburgh, Pennsylvania. In December 2017 he joined the UPMC Health Plan as the Senior Medical Director for the Center for Value Based Pharmacy Initiatives, after serving as the Chairperson for the Medical Advisory Panel for Pharmacy Benefits Management for the Department of Veterans Affairs from 1999-2017. Dr. Good is also a Professor of Medicine and Pharmacy at the University of Pittsburgh, and previously served as a board member for the FDA Drug Safety Board (2005-2018) and was a member of the Therapeutic Information and Formulary Support Expert Committee for the US Pharmacopeia from 2013-2015. He is widely published in the areas of formulary management, drug safety, conflicts of interest, and health disparities. Dr. Good is proud of his 3 grown children, 4 small grandchildren, and 3 chickens.

Mwango Kashoki, MD, MPH, is the Associate Director for Safety in the Office of New Drugs (OND), in the Center for Drug Evaluation and Research (CDER) at FDA. Dr. Kashoki's responsibilities include assisting in the development and ensuring OND's implementation of the policies and procedures related to CDER's various safety initiatives, including the Safety First and Sentinel Initiatives. She also leads OND's implementation of FDA's new authorities to require safety labeling changes, postmarketing investigations, and risk evaluation and mitigation strategies, as provided under the FDA Amendments Act of 2007 (FDAAA). Dr. Kashoki joined OND in 2002 as a primary medical officer in the former Division of Anesthetic, Critical Care and Addiction Drug Products, and then served as a clinical team leader in that division for several years. As a team leader, she supervised primary medical officers in reviewing investigational and new drug applications, as well as in providing guidance to individual researchers and pharmaceutical companies regarding addiction and analgesic drug development programs. Prior to her current position, Dr. Kashoki served as Associate Director for Special Projects in the former Division of Anesthesia, Analgesia and Rheumatology Products, leading the development and conduct of research projects under FDA's Critical Path Initiative and in collaboration with external groups. Dr. Kashoki is board certified in Preventive Medicine and Public Health. She received her M.D. from the Johns Hopkins School of Medicine, and her M.P.H. degree from Columbia University.

Julie Lawrence oversees the Patient Care Program's safety and serious illness work focused on health system redesign and model programs. Before joining the foundation, Julie spent eight years at Stanford Healthcare, most recently as a design fellow at the Clinical Excellence Research Center (CERC), where she researched and developed a new model of cancer care delivery that improves quality and patient experience while dramatically reducing unnecessary healthcare spending. As the director of cancer patient experience at Stanford, Julie used Lean performance improvement and Design Thinking innovations to improve care for patients. For her work as the director of operations for Stanford's Cyberknife program, she was recognized by the FDA for outstanding contribution in promoting patient safety with medical devices. Julie served as Stanford's representative to the National Comprehensive Cancer Network's Best Practice Committee and Board Member of the National CyberKnife Coalition addressing issues of advocacy and reimbursement parity for emerging cancer treatments. Prior to Stanford, Julie held positions at the University of California, San Francisco as director of strategic planning, and as managing director of the Angara Group consultancy. In the 1990s, she worked for the International Finance Corporation in the former Soviet Union, advising government officials and entrepreneurs on economic transition. Julie received a B.S. in Russian from Georgetown University, an M.A. in International studies from the Lauder Institute at the University of Pennsylvania and an M.B.A. from the Wharton School at the University of Pennsylvania.

Carol Linden, PhD, is the Director, Office of Regulatory Science and Innovation at U.S. Food and Drug Administration. She oversees a broad array of both intramural and extramural programs focused on bringing understanding of the latest in scientific and technological advances to the process of regulating products that support the health of the American public. Prior to assuming this position, Dr. Linden was the Principal Deputy Director of the Office of the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Her duties included oversight of advanced development and acquisition programs for Project BioShield medical countermeasures for CBRN threats as well as pandemic influenza vaccines, drugs, diagnostics and infrastructure. In 2009, Dr. Linden co-chaired with the Department of Defense the Working Group on Strengthening the Biosecurity of the United States, which was mandated by an Executive Order, and produced a report with recommendations submitted to the White House. Dr. Linden obtained her bachelor's degree in biology from Bryn Mawr College, and a Ph.D. from the University of California Los Angeles in molecular biology. She conducted postdoctoral research at the California Institute of Technology and University of Maryland prior to joining the research staff at the U.S. Army Medical Research Institute of Infectious Diseases, where she subsequently served as the Chief, Research Plans and Programs.

Mark McClellan, MD, PhD, is the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Duke-Margolis Center for Health Policy at Duke University with offices at Duke and in Washington DC. The new Center will support and conduct research, evaluation, implementation, and educational activities to improve health policy and health, through collaboration across Duke University and Health System, and through partnerships between the public and private sectors. It integrates the social, clinical, and analytical sciences to integrate technical expertise and practical capabilities to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a

doctor and an economist, and his work has addressed a wide range of strategies and policy reforms to improve health care, including such areas as payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and more effective drug and device innovation. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. He also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, Medicare and Medicaid payment reforms, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA, is a member of the National Academy of Medicine and chairs the Academy's Leadership Council for Value and Science-Driven Health care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He has also previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and as Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.

Mary K. Olson, Ph.D, is an Associate Professor of Economics at Tulane and is the director of the Murphy Institute's Health Policy Program. Professor Olson's teaching and research interests include health economics, the political economy of health policy, regulation, and the study of bureaucracy. She is an expert on Food and Drug Administration (FDA) regulation. Her research uses conceptual and empirical tools from economics and institutional knowledge from political economy and medicine to investigate the causes and consequences of pharmaceutical regulation. She has published articles that examine new-drug approval policies, FDA enforcement strategies, FDA advisory committees, the effects of prescription drug user fees on the FDA, the effects of increased drug review speed on the safety of new medicines, the risks associated with novel and less novel drugs, and the consequences of eliminating the U.S. drug lag on drug safety. Her current research examines how firm innovation strategies were affected by the FDA's pediatric exclusivity policy and how new clinical information in drug labels affects physician prescribing to children. Dr. Olson has received grant awards from the National Science Foundation, the Agency for Healthcare Research and Quality, and the Smith Richardson Foundation. She also served as a member of the Institute of Medicine Committee that assessed the U.S. drug safety system. Prior to coming to Tulane, Dr. Olson was an Associate Professor of Health Policy and Administration at Yale University and an Assistant Professor of Economics at Washington University. Dr. Olson received a Ph.D. in Political Economics from Stanford University.

Liz Richardson, MsC, is a Managing Associate at the Duke-Robert J. Margolis Center for Health Policy, where she manages and oversees a portfolio of projects related to biomedical innovation, FDA regulatory policy, and value-based payment for medical products. Prior to joining the Center, she worked as a Research Associate at the Brookings Institution and the Urban Institute, focusing on pharmaceutical policy, care delivery reform, and health care payment-related topics. She has a Master's degree in Global Health and Public Policy from the University of Edinburgh.

Matthew Rosenberg, MSPPM, is a member of the Economics Staff within the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). In this role, he serves as an economic consultant and policy analyst for CDER Senior Leadership, helping to evaluate the external impacts of FDA regulation on market structure and public health. He holds a Master's degree in Public Policy and Management from Carnegie Mellon University, and a Bachelor's degree in Mathematics and Economics from Rensselaer Polytechnic Institute.

Joseph S. Ross, MD, MHS, is an Associate Professor of Medicine (General Medicine) and of Public Health (Health Policy and Management) at the Yale School of Medicine, a member of the Center for Outcomes Research and Evaluation at Yale-New Haven Health System, and Co-Director of the National Clinician Scholars Program at Yale. His expertise includes performance measure development and understanding the translation of clinical research into practice, using health policy research methods to examine the use and delivery of higher quality care and to better understand issues related to pharmaceutical and medical device regulation, evidence development, postmarket surveillance, and clinical adoption. Dr. Ross co-directs the Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI) and the Yale Open Data Access (YODA) Project. He has published more than 300 articles in peer-reviewed biomedical journals and is currently an Associate Editor at JAMA Internal Medicine.

Patrick Ryan, PhD, is Senior Director of Epidemiology and the Head of Epidemiology Analytics at Janssen Research and Development, where he is leading efforts to develop and apply analysis methods to better understand the real-world effects of medical products. He is currently a collaborator in Observational Health Data Sciences and Informatics (OHDSI), a multi-stakeholder, interdisciplinary collaborative to create open-source solutions that bring out the value of observational health data through large-scale analytics. He served as a principal investigator of the Observational Medical Outcomes Partnership (OMOP), a public-private partnership chaired by the Food and Drug Administration, where he led methodological research to assess the appropriate use of observational health care data to identify and evaluate drug safety issues. Patrick received his undergraduate degrees in Computer Science and Operations Research at Cornell University, his Master of Engineering in Operations Research and Industrial Engineering at Cornell, and his PhD in Pharmaceutical Outcomes and Policy from University of North Carolina at Chapel Hill. Patrick has worked in various positions within the pharmaceutical industry at Pfizer and GlaxoSmithKline, and also in academia at the University of Arizona Arthritis Center.

Lisa M. Schwartz, MD, MS, is a general internist, Professor of Medicine and Community & Family Medicine and co-Director of the Center for Medicine and the Media at the Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth (Lebanon, NH, USA). Together with Dr. Steven Woloshin, her research addresses the excessive fear and hope created by exaggerations, and selective reporting in medical journals, advertising, and the health news. She has worked to improve communication of medical evidence to physicians, journalists, policy makers and the public. She is a co-author of 2 books: *Know Your Chances* and *Overdiagnosed*, her essays have appeared in the New York Times, Washington Post and Los Angeles Times and she is a founding-organizer of the international *Preventing Overdiagnosis* meeting sponsored by BMJ, Dartmouth, Consumers Union and Oxford and Bond Universities.

Ann Marie Trentacosti is the Medical Lead for the Labeling Development Team (LDT) in the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). As the LDT medical lead, Dr. Trentacosti participates in CDER labeling policy initiatives to promote consistency in and improve labeling practices, assists in the development and review of the prescribing information, provides oversight of labeling quality, develops labeling resources, and provides labeling review training.

Steven Woloshin, MD, MS, is a general internist, Professor of Medicine and Community & Family Medicine and co-Director of the Center for Medicine and the Media at the Dartmouth Institute for Health Policy and Clinical Practice, Geisel School of Medicine at Dartmouth (Lebanon, NH, USA). Together with Dr. Lisa Schwarz, his research addresses the excessive fear and hope created by exaggerations, and selective reporting in medical journals, advertising, and the health news. He has worked to improve communication of medical evidence to physicians, journalists, policy makers and the public. He is a co-author of 2 books: *Know Your Chances* and *Overdiagnosed* and his essays have appeared in the New York Times, Washington Post and Los Angeles Times and he is a founding-organizer of the international *Preventing Overdiagnosis* meeting sponsored by BMJ, Dartmouth, Consumers Union and Oxford and Bond Universities.