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

Understanding How the Public Perceives and Values Pharmaceutical Quality

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Speaker Biographies

Cindy Buhse

Cindy Buhse, Ph.D., Director, Office of Surveillance (OS), OPQ, joined FDA in 2001 as Deputy Director, Division of Pharmaceutical Analysis in OTR. She was promoted to Division Director in June 2004 and served as Director of the Office of Testing and Research since June 2013. Dr. Buhse received a B.A. in Chemistry from Grinnell College and a Ph.D. in Physical Chemistry from the University of California, Berkeley under the direction of John H. Clark and George C. Pimentel. Before joining FDA, Dr. Buhse worked in multiple management positions in Production, Validation and Analytical Services at Sigma Aldrich Corporation and as a Senior Research Scientist for Rohm and Haas Company.

Patrizia Cavazzoni

Patrizia Cavazzoni, M.D., is the Deputy Director for Operations at FDA's Center for Drug Evaluation and Research (CDER). In this position, Dr. Cavazzoni provides strategic leadership related to regulatory and scientific programs. 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, and she is 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.

Adam Fisher

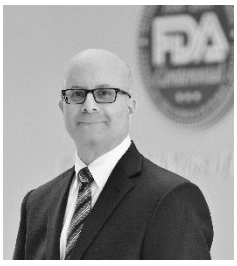
Adam Fisher, Ph.D. serves as the Associate Director of Communications (Acting) in the Immediate Office of the Office of Pharmaceutical Quality in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. Prior to serving in this role, he was on OPQ's Science and Research Staff as an Acting Team Lead focused on complex drug substances and complex manufacturing processes. He joined the FDA in 2014 as a chemical engineer with expertise in the synthesis of biomolecules. Dr. Fisher's past work focused on the microbial production of proteins and glycoproteins for a variety of applications. His Ph.D. dissertation concentrated on the use of the secretion pathways of bacteria to perform protein engineering. There he received the Austin O. Hooey Award for Research Excellence. Prior to the FDA, Dr.

Fisher was the co-founder and Chief Science Officer of a startup company focused on microbial technologies for the production of glycoproteins. There he served as the Principal Investigator on several million dollars of research grants. Dr. Fisher is the inventor of four patented technologies and the author of over thirty scientific publications and book chapters. He earned his B.S. degree at the University of Maryland College Park (Chemical Engineering) and his Ph.D. at Cornell University (Chemical & Biomolecular Engineering).

Michael Ganio

Michael Ganio Pharm.D., M.S., BCPS, FASHP joined the staff at ASHP as Director of Pharmacy Practice and Quality in January of 2018. As a member of the Center on Medication Safety and Quality team, his responsibilities span the practice of pharmacy and include drug shortages, pharmaceutical quality, sterile and non-sterile drug compounding practices, hazardous drug handling, and the ASHP Standardize 4 Safety initiative. Dr. Ganio earned his Pharm.D. from the Rutgers University Ernest Mario School of Pharmacy and his Master's degree in Health-System Pharmacy Administration from The Ohio State University College of Pharmacy. He completed a PGY1 Pharmacy Practice residency at The Ohio State University Wexner Medical Center. Dr. Ganio is a Board Certified Pharmacotherapy Specialist (BCPS) and is a Certified Professional in Healthcare Information and Management Systems (CPHIMS). Dr. Ganio has over 18 years of hospital and health-system experience. His previous job roles have included clinical pharmacy practice, pharmacy informatics and technology, and operations management of outpatient oncology infusion pharmacies. He has extensive knowledge of pharmacy informatics and automation, medication billing and reimbursement, sterile compounding, and outpatient infusion and ambulatory care models.

Michael Kopcha



Michael Kopcha, Ph.D., R.Ph., Director, Office of Pharmaceutical Quality (OPQ), is a leader in the development of innovative solutions to resolve scientific, manufacturing, and commercialization issues worldwide – and in standardizing and harmonizing global processes. With more than 25 years of pharmaceutical industry experience, his areas of expertise include formulation and process development, process validation, technology transfer, off-shoring/outsourcing, and change management. Dr. Kopcha recently served as vice president, and global research and development franchise head, for cough, cold, and respiratory products at Novartis Consumer Health, Inc. in New Jersey. He joined Novartis in 2008 as the global head for pharmaceutical and analytical development, later serving as global head for new technologies and product innovation, and vice president and global head for global product development. Dr. Kopcha earned his doctorate and master's degrees in pharmaceutical science, and a bachelor's degree in pharmacy, from Rutgers University in New Brunswick, New Jersey. He served as an adjunct assistant professor in the Department of Pharmaceutics, Ernest Mario School of Pharmacy at Rutgers.

Keagan Lenihan

Keagan Lenihan became the Chief of Staff of FDA in June of 2019, and oversees the daily management of the Agency and leads the Agency's activities on major initiatives. She provides strategic direction to senior leadership to advance FDA's policy priorities, including efforts to promote medical product innovation, pursue a comprehensive plan for tobacco regulation, improve drug competition, fight the opioids crisis, and strengthen our food safety system. Mrs. Lenihan works closely with the leadership of all FDA product centers and field operations to support their implementation of Agency policies. She also serves as the Commissioner's direct liaison to other executive Agencies and organizations and engages across government on critical public health initiatives. In addition, she plays a key role in legislative engagement, communications, and stakeholder outreach. Prior to her role as Chief of Staff, Mrs. Lenihan served as the Associate Commissioner for Strategic Initiatives and External Affairs within the Office of the Commissioner at the U.S Food and Drug Administration (FDA) where she focused on priority projects across the agency, Department of Health and Human Services (HHS), Executive Offices of the President (EOP) and entire U.S. Government. In this role, she advanced our work in opioids, drug shortages and other strategic initiatives as well as advanced the FDA's communication portfolio through stakeholder engagement and assisting with collaborations with Federal partners. She also managed media affairs, internal communications, FDA Voices, the agency's website and the work underway to enhance our web presence. Prior to her time at FDA, Mrs. Lenihan served as the Senior Counselor to the Secretary of HHS where she focused on drug pricing reform initiatives, reduction in patient and provider regulatory burden, price transparency and patient empowerment, The Office of Health Reform, and assisting with the Center for Medicare and Medicaid Services (CMS) portfolio. Prior to entering the Administration, Mrs. Lenihan was in the private sector for five years as an executive with McKesson Specialty Health managing federal government relations. She spent nearly a decade on Capitol Hill working for three Members of Congress in key leadership positions as well as the House Rules Committee staff. Mrs. Lenihan received her degree from the University of Colorado, Boulder; and resides with her family in Virginia.

Mark McClellan

Mark McClellan, MD, PhD, is the Robert J. Margolis Professor of Business, Medicine, and Health Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University. With offices in Durham, NC and Washington, DC, the Duke-Margolis Center is a university-wide, interdisciplinary initiative that is nationally and internationally recognized for its research, evaluation, implementation, and educational initiatives to improve health and health policy. The Center integrates Duke's expertise in the social, clinical, and analytical sciences with health care leaders and stakeholder engagement to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a physician and an economist who has informed and improved a wide range of strategies and policy reforms to advance health care, including payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and strategies for more effective biomedical 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. With highly distinguished record in public service and academic research, Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food

and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These reforms 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. He previously served as a member of the President's Council of Economic Advisers, senior director for health care policy at the White House, and Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA and a member of the National Academy of Medicine (NAM), where he chairs the 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 is also a Senior Advisor on the faculty of the University of Texas Dell Medical School and co-chair of the Accountable Care Learning Collaborative. Dr. McClellan is an independent director on the boards of Johnson & Johnson, Cigna, and Alignment Healthcare. 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.

Martin VanTrieste

Martin VanTrieste is the CEO of Civica Rx who was recently named a "Champion of Change" on The Medicine Maker's Power List for his role in leading Civica, a new, nonprofit enterprise created to stabilize the supply of essential generic medications. Martin brings over 36 years in the industry, with comprehensive experience in biopharmaceutical manufacturing, quality systems and related government regulations in the US and around the world. He was the former chief quality officer at Amgen. Prior to joining Amgen, Mr. VanTrieste was with Bayer Healthcare's Biological Products Division as vice president of worldwide quality and Abbott Laboratories as the vice president of quality assurance for the Hospital Products Division. Mr. VanTrieste is the founder of Rx-360, an international nonprofit organization that enhances patient safety by increasing security and quality in the biopharmaceutical supply chain. He has also served as the Chairman and Board Member of the Parenteral Drug Association (PDA) Board of Directors. The PDA has 10,000 members and its mission is to advance pharmaceutical/biopharmaceutical manufacturing science and regulation so members can better serve patients. PharmaVoice has named Mr. VanTrieste one of the 100 most inspiring people in the pharmaceutical industry, calling him "a man with a mission." The Medicine Maker has previously named him one of the most influential people in the world of drug development and manufacture saying he "is known throughout industry as a change agent and influencer for his work on advancing pharmaceutical manufacturing, quality and helping to ensure a more reliable supply of high-quality medicines." He was honored in 2013 by Parenteral Drug Association (PDA), naming an annual award the Martin VanTrieste Pharmaceutical Science Award. He has delivered numerous presentations and authored articles on pharmaceutical quality and the security and robustness of supply chain. Mr. VanTrieste earned a Pharmacy degree in 1983 from Temple University School of Pharmacy.

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