

## Understanding How the Public Perceives and Values Pharmaceutical Quality

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### Speaker Biographies

#### Ashley Boam



Ashley Boam, Director, Office of Policy for Pharmaceutical Quality (OPPQ), OPQ, spent nearly 20 years in the Office of Device Evaluation in FDA's Center for Devices and Radiological Health (CDRH), with oversight of clinical trials of and marketing applications for coronary drug-eluting stents, cardiac occluders to correct congenital heart defects, and other interventional devices. She was also involved in the initial development and renewal of the Medical Devices User Fee and Modernization Act. Most recently, as acting deputy director of OPS, Ms. Boam focused on regulatory and policy issues related to pharmaceutical quality assessment. She remains involved in policy issues related to drug-device combination products. Ms. Boam received a master's degree in biomedical engineering from the University of

Alabama at Birmingham and a bachelor's degree in biomedical engineering from Tulane University in New Orleans.

#### 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.

#### Jan Burkett



Jan Burkett, R.Ph, MBA, is Chief Drug Sourcing Officer at Express Scripts. Jan is a pharmacist with diverse experience in pharmacy benefit management, pharma negotiation and contracting, and joint venture strategy. Jan is responsible for Express Scripts' strategic drug sourcing functions. In this role, she leads a team that supports the day-to-day and long-term strategy of Express Scripts' \$40 billion drug spend. An extension of Express Scripts' sourcing strategy, Jan is the president of two joint venture group purchasing organizations, Econdisc and ValoremRx. Jan manages staff located overseas as well as in the United States. In addition to her procurement

responsibilities, Jan leads Strategic Pharmaceutical Investment (SPI), an affiliate of the Company. One of the affiliate's main goal is drug supply, quality and risk management. Jan joined Express Scripts in 1993. During her 26 years with the Company, she has held many roles in areas such as PBM account

management, clinical product management, prior authorization operations, electronic prescribing, national formulary development and maintenance, and Specialty Pharma account management. Jan serves on the Board of Memory Care Home Solutions and is a member of the Advisory Board of the Boeing Center for Supply Chain Innovation at Washington University. She served five years on the Missouri State Board of Pharmacy including the position of President.

### 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.

### Joe Graedon



Joe Graedon is a pharmacologist who has dedicated his career to making drug information understandable to consumers. His best-selling book, *The People's Pharmacy*, was published in 1976 and led to a syndicated newspaper column, syndicated public radio show and web site. In 2006, Long Island University awarded him an honorary doctorate as "one of the country's leading drug experts for the consumer." Joe was elected to the rank of AAAS Fellow for "exceptional contribution to the communication of the rational use of pharmaceutical products and an understanding of health issues to the public" in 2005. Joe earned his MS in pharmacology from University of Michigan. He served as a consultant to the Federal Trade Commission on OTC drug issues from 1978 to 1983 and was on the Advisory Board for the Drug Studies Unit at UCSF from 1983 to 1989. He has been an adjunct assistant professor, Division of Pharmacy Practice and Experiential Education, UNC Eshelman School of Pharmacy at Chapel Hill since 1986. Joe served as a member of the Board of Visitors, UNC Eshelman School of Pharmacy, from 1989 to 2014. He served on the Patient Safety and Clinical Quality Committee of the Duke University Health System (DUHS) Board of Directors from 2003-2011. Joe started providing health commentaries to NPR in 1977. *The People's Pharmacy* weekly talk and interview show began in 1981. It won a Silver Award from the Corporation for Public Broadcasting in 1992. It is syndicated to hundreds of radio stations on public radio.

## Paula Gurz



Paula Gurz is the Sr. Director Pharmacy Contracting, Generics and Biosimilars at Premier. In this position Paula is responsible for the management of all negotiation and contracting activities surrounding the Generic contracted portfolio including PremierProRx® program. Additionally, Paula is responsible for all contracting activities as it relates to biosimilars. She has nearly 30 years of experience in the generic pharmaceutical industry working with Sandoz, Dr. Reddy's Laboratories and Bedford Laboratories. During that time she functioned in various Pricing & Contracting or Marketing roles including Director Pricing & Contracts, and Sr. Director Rx Marketing. Paula has extensive experience developing pricing strategies, negotiating pricing and contracts, marketing product portfolios, new product launches and product portfolio selection. Paula completed her undergraduate work at Daemen College receiving a BS in Marketing and graduate work at Canisius College in Buffalo New York with an MBA in Management. Paula resides in Lake Wylie, SC.

## Dan Kistner



Dan Kistner, Pharm.D., is Group Senior Vice President of Pharmacy at Vizient. As Group Senior Vice President, Dan oversees pharmacy contract analytics, a dedicated pharmacy field team, contracting, and clinical solutions while setting the strategic direction to ensure that members maximize value by utilizing the industry's leading GPO pharmacy program. Before joining Vizient, Dan held various positions at MedAssets. In his most recent role at MedAssets, Dan served as the General Manager where he led the pharmacy group by using customer insight and data to drive value for clients and the pharmacy program. Dan began his pharmacy career at Express Scripts as a client account executive where he managed formularies and clinical analytics for large managed care plans. Dan has a diverse background in the pharmaceutical industry with experience in retail, hospital, specialty, pharmacy benefits management, supply chain management, and mail order. Regardless of the pharmacy environment, one concept has rung true through Dan's career: understanding and being able to manipulate "Big Data" as the key to building calculated savings opportunities in a healthcare industry that is dominated by expense increases. Dan is a native of St. Louis, Missouri and earned his Doctor of Pharmacy from the St. Louis College of Pharmacy in St. Louis, Missouri.

## 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/outourcing, 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.

## Steven Kozlowski



Steven Kozlowski, M.D., Director, Office of Biotechnology Products (OBP), OPQ, joined the Division of Monoclonal Antibodies in 1993, becoming involved in all phases of the regulatory process as a reviewer, from pre-IND product development through inspections, licensing, and post approval supplements. Dr. Kozlowski and his staff are responsible for the quality review of therapeutic proteins at CDER. OBP also provides expertise on immunologic responses to therapeutic proteins and performs mission related research. Before joining FDA, he worked as a staff fellow in the Molecular Biology Section of the Laboratory of Immunology, National Institutes of Allergy and Infectious Diseases, NIH. Dr. Kozlowski received a medical degree from Northwestern University and trained in pediatrics at the University of Illinois.

## Harry Lever



Harry M. Lever, MD is staff physician at the Cleveland Clinic and Medical Director of the Hypertrophic Cardiomyopathy Clinic. The Clinic has one of the largest populations of patients with hypertrophic cardiomyopathy in the country. Dr. Lever graduated from The University of Pittsburgh School of Medicine. He completed his house staff training at Montefiore Hospital in Pittsburgh, PA. He finished his cardiology fellowship at The University of Rochester in Rochester NY. Dr. Lever has co-authored 91 papers in cardiology with the majority of them pertaining to hypertrophic cardiomyopathy. He has developed a deep interest in drug quality and safety. Dr. Lever was the subject of a chapter in Katherine Eban's book, *Bottle of Lies*. He was coined the "Sheriff" of generic drugs in an article published by Medscape and recognized among The Best Physicians of 2019.

## David Light



David is a biotech entrepreneur and scientist with over 10 years of broad experience in the field. A graduate of Yale University, David studied molecular biology and has worked in a variety of scientific and business roles at start-ups like Synthetic Genomics, Ion Torrent, and Valisure. At Ion Torrent, David developed key technologies that directly led to the semiconductor DNA sequencing company's \$725M acquisition and ran its flagship technology programs through development and global commercialization. David is the Founder and CEO of Valisure, an online pharmacy that is attached to an analytical laboratory where all medications are chemically validated before being dispensed to consumers, and helped found, fund, and invent the core technology. David is named inventor on numerous patents, published in journals including *Nature* and cover of *Electrophoresis*, has been invited to submit testimony at congressional hearings as well as speak at the U.S. Capitol Building on the introduction of critical bills regarding medication safety and quality. David has been quoted in numerous publications including *Bloomberg*, *The New York Times*, *The Wall Street Journal*, *The Washington Post* and on the *CBS Evening News*. He also sits on the boards of non-profits supporting criminal justice reform and bolstering the local community and is very passionate about entrepreneurship and improving public health.



## Steven Loborec



Steven M. Loborec, PharmD, MS, MPH, BCPS is an Assistant Director of Pharmacy with responsibility over finance, supply chain, and 340B. He received his Doctor of Pharmacy degree from Purdue University and completed the two year Health-System Pharmacy Administration residency at OSUWMC. After residency, Steven completed an additional year of fellowship training focusing on pharmacy finance while completing his Master of Public Health degree and serving as a Student Trustee on The Ohio State University Board of Trustees. His research focuses on the impact of cost and quality of medication management for hospitalized patients. Steven serves as the course director for PHR 8250: Pharmaceutical Supply Chain Principles for Health System Pharmacy at The Ohio State University College of Pharmacy, and actively participates in residency training. He enjoys the residency recruitment process and precepts residents on the longitudinal pharmacy supply chain rotation, the finance/budgeting rotation, and the 340B elective. In his free time, Steven enjoys exercising and exploring the restaurant scene in Columbus with his wife.

## 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 leader 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.

### **Douglas Throckmorton**



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. He is a board-certified physician.

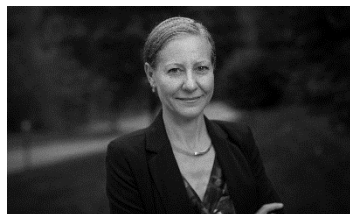
### **John Whyte**



Dr. John Whyte is a popular physician and writer who has been communicating to the public about health issues for nearly two decades. He is currently the Chief Medical Officer, WebMD. In this role, Dr. Whyte leads efforts to develop and expand strategic partnerships that create meaningful change around important and timely public health issues. Prior to WebMD, Dr. Whyte served as the Director of Professional Affairs and Stakeholder Engagement at the Center for Drugs Evaluation and Research at the U.S. Food and Drug Administration. Dr. Whyte worked with health care professionals, patients, and patient advocates, providing them with a focal point for advocacy, enhanced two-way communication, and collaboration, assisting them in navigating the FDA on issues concerning drug development, review,

and drug safety. He also developed numerous initiatives to address diversity in clinical trials. Prior to this, Dr. Whyte worked for nearly a decade as the Chief Medical Expert and Vice President, Health and Medical Education at Discovery Channel, the leading non-fiction television network. In this role, Dr. Whyte developed, designed and delivered educational programming that appealed to both a medical and lay audience. This included television shows as well as online content that won over 50 awards including numerous Tellys, CINE Golden Eagle, and Freddies. Dr. Whyte is a board-certified internist and continues to see patients. He completed an internal medicine residency at Duke University Medical Center as well as earned a Masters of Public Health (MPH) in Health Policy and Management at Harvard University School of Public Health. Prior to arriving in Washington, Dr. Whyte was a health services research fellow at Stanford and attending physician in the Department of Medicine. He has written extensively in the medical and lay press, including two best-selling books, "Is This Normal: The Essential Guide to Middle Age and Beyond" and "AARP New American Diet: Lose Weight, Live Longer."

## Marta Wosińska



Marta E. Wosińska, PhD, is the Deputy Director, Policy at the Duke-Margolis Center for Health Policy and Consulting Professor at the Fuqua School of Business. Widely recognized as an expert on health policy, economics, and regulation, Dr. Wosińska leads the Center's Washington, DC office. Dr. Wosińska's experience spans both academia as well as the executive and legislative branches of the federal government. In 2019, Dr. Wosińska served as an economic advisor to the U.S. Senate Finance Committee, providing drug market analysis and expert guidance for the Committee's bipartisan investigative and legislative work on drug pricing. Dr. Wosińska also served as Chief Healthcare Economist in the Office of Inspector General (OIG) at the US Department of Health and Human Services. Before then, Dr. Wosińska headed the Economics Staff at FDA's Center for Drug Evaluation Research. Before entering public service, Dr. Wosińska was an Assistant Professor of Marketing at the Harvard Business School and a visiting Assistant Professor at the Columbia Business School. Dr. Wosińska received her PhD in economics from University of California at Berkeley and a bachelor's degree from Arizona State University.

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