

Expert Workshop: Communicating Findings from Active Medical Product Surveillance

Participant Biographies



Rachel E. Behrman, MD, MPH is the director of the Office of Medical Policy in the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA). She is responsible for developing, coordinating, and implementing medical policy programs and strategic initiatives, including those focused on clinical trial modernization, policy issues related to human subject protection, and good clinical practices. Dr. Behrman began her career with the FDA in the Division of Antiviral Drug Products and has served in numerous positions, most recently as associated commissioner for Clinical Programs and director of the Office of Clinical Programs. Dr. Behrman is a board-certified internist and infectious disease subspecialist. She received her MD from Mt. Sinai School of Medicine, her MPH from The Johns Hopkins School of Hygiene and Public Health, and her BA in mathematics from Washington University.



Marc Boutin, JD is the executive vice president and chief operating officer of the National Health Council, an organization that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Mr. Boutin has been actively involved in health advocacy, policy, and legislation throughout his career. He currently serves on the Advisory Board, Council for American Medical Innovation; Advisory Board, Coalition Against Major Diseases; and Advisory Board, Partnership to Fight Chronic Disease. He is a member of the Agency for Healthcare Research and Quality's Effective Healthcare Program Stakeholder Group and the eHealth Initiative Leadership Council, and a panel expert for the National Institutes of Health-funded grant on Protecting Privacy in Health Research.



Robert M. Califf, MD is the vice chancellor for clinical research, director of the Duke Translational Medicine Institute (DTMI), and professor of medicine in the division of cardiology at the Duke University Medical Center. Dr. Califf leads a large, multifaceted organization focused on the transformation of how discoveries are translated into improved medical care. Prior to his role at DTMI, he was the founding director of the Duke Clinical Research Institute, a premier academic research organization. He is the editor-in-chief of *American Heart Journal*, the oldest cardiovascular specialty journal. As director of DTMI, funded in part by a National Institutes of Health Clinical and Translational Science Award (CTSA), Dr. Califf's contribution includes service as the first co-chair of the Principal Investigators Steering Committee of the CTSA. He has served on the Cardiorenal Advisory Panel of the Food and Drug Administration (FDA) and the Pharmaceutical Roundtable of the Institute of Medicine (IOM). He is currently a member of the IOM Forum in Drug Discovery, Development, and Translation and sits on a subcommittee of the Science Board of the FDA. During his tenure as a founding director of the Coordinating Center for the Centers for Education & Research on Therapeutics, a public-private partnership among the Agency for Healthcare Research and Quality, the FDA, academia, the medical-products industry, and consumer groups, he focused on research and education to advance and optimize the use of medical products. He currently serves as the co-chair of the Clinical Trials Transformation Initiative, a public-private partnership focused on improving the clinical trials system, and as the chair of the Clinical Research Forum, an organization of academic health and science system leaders focused on enhancing the effectiveness of the clinical research enterprise.



Patrizia Cavazzoni, MD is the senior vice president for Worldwide Safety Strategy at Pfizer, where she leads the company's safety surveillance, risk management, and epidemiology programs. Dr. Cavazzoni is the former head of Global Pharmacovigilance and Epidemiology at Sanofi-Aventis, and previously held various positions within the clinical development and safety organizations at Eli Lilly. Dr. Cavazzoni earned her medical degree from McGill University. She served as a medical officer in the Canadian Armed Forces and subsequently completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa, becoming a recipient of the American College of Psychiatrists' Laughlin Fellowship. Prior to joining the pharmaceutical industry, she was an assistant professor of medicine at the University of Ottawa, where she was actively engaged in clinical work, teaching, and research of genetic predictors of mood disorders, authoring numerous peer-reviewed manuscripts. She is certified by the American Board of Neurology and Psychiatry and a fellow of the Canadian Royal College of Physician and Surgeons.



David Ceryak, JD is assistant general counsel for Human Medicines Regulation for Eli Lilly and Company. In this role, Mr. Ceryak heads the group that provides legal counsel on drug and device law, including matters related to clinical development, registration, labeling, Hatch-Waxman, biosimilars, GMPs/manufacturing, diagnostics, and drug safety. In addition, he has worked for three years within Lilly's Medical division as the head of Global Quality and, prior to joining Lilly, practiced law with the Indianapolis firm Baker & Daniels. Mr. Ceryak is a frequent speaker on matters of drug law, having chaired sessions on 505(b)(2) drug applications, REMS, and legal liability for drug safety. He also has served as a subcommittee member on the Secretary of the U.S. Department of Health and Human Services' Advisory Commission on Human Research Protections and as chair of the U.S. Food and Drug Administration's Focus Group of the Pharmaceutical Research and Manufacturers of America.

Gregory Curfman, MD is the executive editor of the *New England Journal of Medicine (NEJM)*, a position that he has held for 10 years. Prior to becoming executive editor, Dr. Curfman was deputy editor of NEJM for 15 years. He graduated from Princeton University and Harvard Medical School, and he is a board-certified internist and cardiologist. He is a fellow of the American College of Cardiology and of the American Heart Association. He has had numerous responsibilities at NEJM, but one of his current roles is to provide editorial oversight for the Perspective section of NEJM, which has published numerous articles on the U.S. health care system and health care reform. Together with his editorial colleagues, he has moderated a national dialogue on health care within NEJM.



Heidi Garwood, JD has served as in-house counsel of Humana, with primary legal responsibility for all Humana business in Florida and Puerto Rico since 1999. In her capacity as senior legal counsel, Ms. Garwood manages the vast majority of legal, regulatory, and contractual issues affecting Humana's operations in Florida and Puerto Rico. She also has primary responsibility over legal issues relating to research and HIPAA privacy. Prior to joining Humana, Ms. Garwood served for two and a half years as the director of governmental relations for the Florida Association of HMOs (now known as Florida Association of Health Plans), managing and helping to set the HMO industry's legislative agenda. From 1994 through 1997, Ms. Garwood was senior attorney with the Agency for Health Care Administration, advising the Agency on a wide variety of Medicaid and HMO issues and representing the Agency in a number of cases involving Medicaid fraud and abuse. A 1991 graduate of Florida State University College of Law, Ms. Garwood began her health care law career as an intern of the House Health Care Committee. Upon graduation, she joined the statewide law firm, Carlton Fields, where she was an associate for three years.



Jean A. Krause serves as the executive vice president and chief executive officer for the American College of Physicians (ACP) Foundation. The ACP Foundation was incorporated in 1999 to improve the health and welfare of patients and society through initiatives that provide patients with the information they need to understand and manage their health. Since 2001, the ACP Foundation has concentrated their efforts on health communication with an emphasis on health literacy. The health communication initiative focuses on an individual's capacity to obtain, process, and understand basic health information and services, and shapes the Foundation's effort to improve patient health literacy. On behalf of an organization that is a national leader in developing patient-focused health

information, Ms. Krause serves on the Institute of Medicine's Roundtable on Health Literacy Planning Committee, the Joint Commission's Public Policy Roundtable, the Association of Clinicians for the Underserved (ACU), U.S. Pharmacopeia – National Coordinating Council for Medication Error Reporting and Prevention, and the National Consumers League Medication Adherence Committee. Ms. Krause received her BA in English from Boston University, with additional postgraduate work at the University of Pennsylvania in Philadelphia and the University of Colorado in Greeley, Colo. Ms. Krause has received numerous awards through the years focusing on finance, human resources, and management.



Christine Laine, MD, MPH is editor of *Annals of Internal Medicine*. She is a practicing physician, board-certified in internal medicine, and a member of the faculty in the Division of Internal Medicine at Jefferson Medical College in Philadelphia. Dr. Laine first joined *Annals of Internal Medicine* in June 1995 as an associate editor, became a deputy editor in 1998, and then senior deputy editor in 2001. In July 2009, Dr. Laine became the youngest editor of the journal and a senior vice president at the American College of Physicians. Dr. Laine graduated from Hamilton College in Clinton, NY with a double major in biology and writing, received her medical degree from the State University of New York at Stony Brook, and completed residency training in internal medicine at The New York Hospital

(Cornell University). While a fellow in general internal medicine and clinical epidemiology at Beth Israel Hospital in Boston, MA, Dr. Laine earned her master of public health degree with a concentration in quantitative methods and clinical epidemiology at Harvard University. Dr. Laine holds leadership positions in the International Committee of Medical Journal Editors, the Council of Science Editors, and the Ethics committee of the World Association of Medical Editors. She has been instrumental in the development of editorial policy about issues such as authorship, conflicts of interest in medical research, and data sharing.

Michael McCaughan is a founding member of Prevision Policy LLC and an editor with *The RPM Report*, a leading publication focusing on the intersection between biopharmaceutical regulation, policy and business. Previously, Mr. McCaughan was editor-in-chief of Elsevier Business Intelligence's Biopharma Group, the leading publisher of news and information services for the pharmaceutical industry, including *The Pink Sheet*, *IN VIVO*, *The RPM Report*, *PharmAsia News*, and *The IN VIVO Blog*. Mr. McCaughan speaks frequently on regulatory and policy developments affecting the biopharmaceutical industry. Mr. McCaughan joined "The Pink Sheet" in 1990 as a business reporter. He became assistant managing editor in 1993, managing editor in 1995, and editor-in-chief in 1996. He oversees an editorial staff of 35, and helped launch affiliated publications and on-line services, including *Pharmaceutical Approvals Monthly*, *FDA Advisory Committee.com*, "The Pink Sheet" On The Web, "The Pink Sheet" DAILY and *The RPM Report*. Mr. McCaughan is a summa cum laude graduate of Yale University. Prevision Policy LLC provides health care policy analysis to advance the mutual understanding among policymakers, business executives, and the investment community in the belief that a deeper understanding of policy leads to better business, and a deeper understanding of business leads to better policy.



Mark McClellan, MD, PhD is director of the Engelberg Center for Health Care Reform and Leonard D. Schaeffer Chair in Health Policy Studies at the Brookings Institution. At the Center, his work focuses on promoting high-quality, innovative and affordable health care. A doctor and economist by training, 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 Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan chairs the FDA's Reagan-Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He 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 was an associate professor of economics and medicine at Stanford University.



Thomas E. Menighan, MBA is the executive vice president and chief executive officer of the American Pharmacists Association, assuming this position in July 2009. Mr. Menighan received his Bachelor of Science in Pharmacy in 1974 from West Virginia University School of Pharmacy and a Masters in Business Administration in 1990 from Averett College. In May 2010, he was awarded an honorary Doctor of Science degree by the University of Charleston. Mr. Menighan is also a fellow of the American Pharmacists Association (APhA). Prior to rejoining APhA, Mr. Menighan was president of SynTegra Solutions Inc., in Germantown, MD. The company provides supply chain and chargeback auditing and consulting in risk management, 340B Systems, anti-counterfeiting, and the technology of medication information. Mr. Menighan founded SymRx, Inc., and developed CornerDrugstore.com®. Throughout his career, Mr. Menighan has served volunteer roles within the profession of pharmacy, including president of APhA from 2001 to 2002 and a member of the APhA Board of Trustees between 1995 and 2003. Other professional experiences include management of the PharMark Corporation, creator of RationalMed®, and licensed systems for states to conduct Drug Utilization Review for millions of state Medicaid enrollees. Mr. Menighan also founded and was a 20-year Medicine Shoppe owner in Huntington, WV, and is a partner in Pharmacy Associates, Inc., a multi-state specialty pharmacy that today serves patients in much of the United States.



Richard Platt, MD, MSc is a professor and chair of the Department of Population Medicine at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is principal investigator of the Food and Drug Administration's (FDA) Mini-Sentinel program and of contracts with FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to conduct post-marketing studies of drugs' and biologics' safety and effectiveness. He chaired the FDA's Drug Safety and Risk Management Advisory Committee, and is a member of the Association of American Medical Colleges' Advisory Panel on Research and the Institute of Medicine Roundtable on Evidence-Based Medicine. Dr. Platt was co-chair of the Board of Scientific Counselors of the Centers for Disease Control and Prevention's (CDC) Center for Infectious Diseases. Additionally, he has chaired the National Institutes of Health study section, Epidemiology and Disease Control 2, and the CDC Office of Health Care Partnerships steering committee. Dr. Platt is also principal investigator of a CDC Center of Excellence in Public Health Informatics, the Agency for Healthcare Research and Quality (AHRQ) HMO Research Network Center for Education and Research in Therapeutics, the AHRQ HMO Research Network DEcIDE Center, the CDC Eastern Massachusetts Prevention Epicenter, and FDA contracts to conduct post-marketing studies of drugs' and biologics' safety and effectiveness.



Joshua M. Sharfstein, MD was appointed by President Obama to be the Principal Deputy Commissioner, Food and Drugs, in March 2009. From December 2005 to March 2009, Dr. Sharfstein was the commissioner of health for the City of Baltimore, Maryland. In this position, he led efforts to expand literacy efforts in pediatric primary care, facilitate the transition to Medicare Part D for disabled adults, engage college students in public health activities, increase influenza vaccination of health care workers, and expand access to effective treatment for opioid addiction. Under his leadership, the Baltimore Health Department and its affiliated agencies have won multiple national awards for innovative programs, and in 2008, Dr. Sharfstein was named Public Official of the Year by *Governing Magazine*. From July 2001 to December 2005, Dr. Sharfstein served as minority professional staff of the Government Reform Committee of the U.S. House of Representatives for Congressman Henry A. Waxman. Dr. Sharfstein is a 1991 graduate of Harvard College, a 1996 graduate of Harvard Medical School, a 1999 graduate of the combined residency program in pediatrics at Boston Children's Hospital and Boston Medical Center, and a 2001 graduate of the fellowship in general pediatrics at the Boston University School of Medicine.

Brian Sweet, MBA is responsible for overseeing all clinical pharmacy services for WellPoint, Inc., a 33-million member health benefits company located in Indianapolis, Ind. Mr. Sweet is involved with WellPoint's clinical product development, aligning strategic partnerships with pharmacy-based organizations, and oversees pharmacy programs for WellPoint nationally. Mr. Sweet also serves as president for the Academy of Managed Care Pharmacy. Prior to joining WellPoint, he had experience in a staff model HMO, an IPA HMO, and the PBM industry. He received his Masters of Business Administration from the State University of New York at Buffalo School of Management in May 1994, and his Bachelor of Science in Pharmacy from the State University of New York at Buffalo School of Pharmacy in May 1988. Mr. Sweet has also authored formulary and clinical pharmacy intervention program successes in various managed care settings.



Stanley B. Watson, JD, MA has been the director of Kaiser Foundation Research Institute since February 2006. In that position, he is the authorized organizational official for federal research funding and is the institutional official for Kaiser Permanente's Federalwide Assurance regarding human subjects protection. Mr. Watson joined Kaiser Permanente in 1993, in the National Legal Department of Kaiser Foundation Hospitals/Health Plan, Inc. His practice focused on health and hospital issues including patient treatment issues, bioethics issues relating to human subject experimentation and research integrity, and regulation of emergency department treatment delivery. Prior to joining Kaiser Permanente, Mr. Watson was a consultant with the Bioethics Consultation Group, Inc., of Berkeley, CA, where he trained and consulted with hospital ethics committees. Prior to receiving his MA in ethics, he was a partner with Wilson, Sonsini, Goodrich & Rosati of Palo Alto, CA, where he practiced litigation. He received his JD from Harvard Law School in 1972 and his MA in ethics from the Pacific School of Religion in Berkeley, CA, in 1990.



Bill Vaughan worked for various members of the Ways and Means Committee of the U.S. House of Representatives since 1965. He retired in 2001 as staff director for the Minority on the Subcommittee on Health. He worked as a lobbyist for Families USA from 2003 to 2005, and has been senior health policy analyst with Consumers Union, the independent, non-profit publisher of *Consumer Reports*, from February 2005-2008 and from February 2009 until present.



Julie A. Zawisza, MA (Zah-Veesah) is the director of the Center for Drug Evaluation and Research's Office of Communications at the U.S. Food and Drug Administration (FDA) and has also served as FDA's acting and assistant commissioner for Public Affairs. Prior to joining FDA in 2000, Ms. Zawisza had established over 15 years of private sector and other government experience, including positions with the University of Michigan Medical Center, VA Medical Center – Ann Arbor, the National Institutes of Health, and the George Washington University Medical Center. She was also associate vice president for Regulatory Affairs with AdvaMed, the medical device trade association, and director of public relations for the American Association for Clinical Chemistry. Additionally, Ms. Zawisza has served as a public relations consultant for Porter Novelli. She holds a bachelor's degree from the University of Michigan and a Master of Arts in Science, Technology, and Public Policy from The George Washington University. In 2009, she completed a certificate course in Public Health at Georgetown University.

Deborah A. Zarin, MD is the director of ClinicalTrials.gov at the Lister Hill National Center for Biomedical Communications in the National Library of Medicine. Dr. Zarin oversees the development and operation of a clinical trials registry and results database. Dr. Zarin is also involved in the implementation of Title 8 of The Food and Drug Administration Amendments Act. Previous positions held by Dr. Zarin include director of the Technology Assessment program at the Agency for Healthcare Research and Quality, and the director of the Practice Guidelines program at the American Psychiatric Association. In these positions, Dr. Zarin conducted systematic reviews and related analyses in order to develop clinical and policy recommendations. Dr. Zarin's academic interests are in the area of evidence-based clinical and policy decision-making and the analysis and reporting of clinical trials. She is the author of over 70 peer-reviewed articles. Dr. Zarin graduated from Stanford University and received her doctorate in medicine from Harvard Medical School. She completed a clinical decision-making fellowship, and is board certified in general psychiatry, as well as in child and adolescent psychiatry.