ENGELBERG CENTER for Health Care Reform at BROOKINGS

Fourth Annual Sentinel Initiative Public Workshop
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Biographies

Elliott M. Levy, MD is senior vice-president in Global Pharmacovigilance and Epidemiology at Bristol-Myers Squibb (BMS). He is responsible for safety reporting, signal detection and evaluation, and risk management. Over the course of his career Elliott has had a broad range of experiences in clinical research and held a variety of scientific and operational leadership roles. Prior to assuming his current responsibilities, he was vice-president for Global Development Operations and Biometric Sciences at BMS, responsible for all aspects of clinical trial execution, including protocol development, study start-up and recruitment, data collection, cleaning, analysis, and reporting, and vendor and resource management. He has also served as head of clinical research in Immunology, led clinical development projects in cardiovascular and metabolic disease, and led the scientific evaluation of licensing candidates across all therapeutic areas. He is a graduate of Yale College and Medical School, where he also trained in internal medicine and nephrology. Before joining BMS he was a member of the renal division at Brigham and Women's Hospital in Boston, where he was an investigator in federally-sponsored outcomes research, as well as industry-sponsored clinical trials

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 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, 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.

Rhonda Medows, MD, FAAFP is executive vice president and chief medical officer for UnitedHealthcare Quality Management & Performance. Dr. Medows has led quality improvements across all medicare, commercial and medicaid health plans for UnitedHealthcare's 33 million members nationwide. Dr. Medows serves on the National Quality Forum and **National Committee for Quality Assurance** advisory boards transforming the national quality agenda. Before joining UnitedHealthcare in April 2010, Dr. Medows served as Georgia's State Health Officer and Commissioner for the Georgia Department of Community Health. As head of this $12 billion agency, Dr. Medows oversaw Medicaid, State Children's Health Insurance Program (SCHIP), the State Employee Benefit Plan, and Public Health. Prior to this position, Dr. Medows was Secretary of the Agency for Health Care

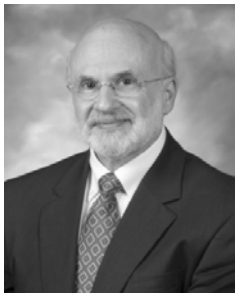
Administration - Florida's $14 billion state agency responsible for the Medicaid and SCHIP programs, health facility regulation, managed care quality, health information exchange, and public policy development. Between her appointments in Florida and Georgia, Dr. Medows was the Centers for Medicare & Medicaid Services Region 4 Chief Medical Officer. Dr. Medows practiced medicine at Mayo Clinic Jacksonville, providing comprehensive outpatient, inpatient and nursing home care for families. She received her undergraduate degree from Cornell University, her medical degree from the Morehouse School of Medicine and completed a Family Medicine residency at the University Hospital at Stony Brook. Dr. Medows is Board Certified in Family Medicine and is a Fellow of the American Academy of Family Physicians.

Richard Platt, MD, MSc is a professor and chair of the Department of Population Medicine at Harvard Medical School and executive director of the Harvard Pilgrim Health Care Institute. He is principal investigator of the U.S. Food and Drug Administration (FDA) Mini-Sentinel program, of contracts with FDA's Center for Drugs Evaluation and Research and Center for Biologics Evaluation and Research to conduct post-marketing studies of drugs' and biologics' safety and effectiveness. He chaired the FDA's Drug Safety and Risk Management Advisory Committee, is a member of the Association of American Medical Colleges' Advisory Panel on Research and the Institute of Medicine Roundtable on Value & Science-Driven Health Care. 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 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 HMO Research Network DEcIDE Center, and a CDC Prevention Epicenter.

John Santa, MD, MPH is the director of the Consumer Reports Health Ratings Center. The Ratings Center focuses on explicit approaches evaluating and comparing health services, products and practitioners. Dr. Santa was the administrator of the Office of Oregon Health Policy and Research from 2000 to 2003. He helped organize and implement an evidence-based approach to prescription drug purchasing that eventually came to be known as the Drug Effectiveness Review Project. He has worked in leadership positions for hospitals, physician groups and health insurers. Dr. Santa has taught in multiple environments including medical school, residency training and graduate courses in Public Health. Dr. Santa received his bachelor's degree from Stanford University in 1972, his MD from Tufts University in 1976 and MPH from Portland State University in 2005. He has practiced primary care internal medicine in several settings, most recently at the Portland, Oregon Veterans Affairs Medical Center.

Rachel Sherman, MD, MPH is the associate director for Medical Policy in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA), where she is responsible for developing, coordinating, and implementing the Center's medical policy programs and strategic initiatives. She oversees the regulation of prescription drug promotion and advertising; provides leadership and scientific advice in clinical trial implementation and policy issues related to human subject protection; and is leading the implementation of the Agency's Sentinel Initiative and the development of FDA biosimilars policy. Since 1998, she has held a series of senior management positions, including deputy office director for the Office of Drug Evaluation I, deputy office director of the Office of Medical Policy in CDER, and associate commissioner for Clinical Programs. She also spent five years managing the development and

implementation of FDA's Critical Path Initiative. Dr. Sherman is a board certified internist and infectious disease subspecialist. She received her BA in mathematics from Washington University, her MD from Mt. Sinai School of Medicine, and her MPH from The Johns Hopkins School of Hygiene and Public Health.



Stephen P. Spielberg, MD is deputy commissioner for Medical Products and Tobacco of the U.S. Food and Drug Administration (FDA). He received an AB in Biology from Princeton University, an MD and PhD in Pharmacology from the University of Chicago, completed a pediatric internship and residency at Children's Hospital in Boston, and a post-doctoral fellowship in human biochemical genetics at the National Institute of Child Health and Human Development. He then joined the faculty of Johns Hopkins University School of Medicine as assistant professor of Pediatrics and Pharmacology, then moving to the University of Toronto Hospital for Sick Children he was professor of Pediatrics and Pharmacology, director of the Division of Clinical Pharmacology and Toxicology, and director of the Centre for Drug Safety Research. After 15 years in academic medicine, he moved to Merck Research Laboratories as executive director, Exploratory Biochemical Toxicology and of Clinical and Regulatory Development, and subsequently to Johnson & Johnson from 1997 to 2003 to become vice president for Pediatric Drug Development. He chaired the Pediatric Task Force for Pharmaceutical Research and Manufacturers of America (PhRMA), represented the pharmaceutical industry on the FDA Pediatric Advisory Subcommittee and on pediatric legislative initiatives in the U.S. and EU, and was the rapporteur for the Pediatric Institute of Child Health (ICH) Initiative (ICH E-11) to harmonize pediatric drug development regulations among Europe, Japan, and the U.S. He then returned to academic medicine as dean of Dartmouth Medical School and vice president for Health Affairs at Dartmouth College from 2003-2007. From 2007-September 2011, he was the Marion Merrell Dow Chair in Pediatric Pharmacogenomics and director of the Center for Personalized Medicine and Therapeutic Innovation at Children's Mercy Hospital, Kansas City, MO. He also served as principal investigator for the Institute for Pediatric Innovation, a non-profit organization focused on developing improved medicines and devices to meet the therapeutic needs of sick children. Dr. Spielberg has served as associate editor of *Drug Metabolism and Disposition*, and on the editorial boards of multiple pediatric and pharmacology journals. He served on the Board of Directors of the Foundation for the National Institutes of Health, the Science Board Advisory Committee for the FDA, the Executive Board of Observational Medical Outcomes Partnership which includes the Foundation for the National Institutes of Health, PhRMA and FDA, and was president of the American Society for Clinical Pharmacology and Therapeutics in 2006. His research interests include: mechanisms of idiosyncratic adverse drug reactions, human pharmacogenetics and personalized medicine, and pediatric clinical pharmacology; he has published over 130 papers in these areas. He is the recipient of the Rawls-Palmer Award and Lectureship from the American Society of Clinical Pharmacology and Therapeutics (1992), the first recipient of the Werner Kalow Award in Pharmacogenetics and Drug Safety (1995), the Williams B. Abrams Lectureship from the FDA and American Society Clinical Pharmacology Therapeutics (2001), Award in Excellence in Clinical Pharmacology, PhRMA Foundation (2007), the Distinguished Service Award from the University of Chicago, Pritzker School of Medicine (2008), presented the FDA Chief Scientist's Distinguished Lecture (2009), and received the Sumner J. Yaffe Lifetime Achievement Award in Pediatric Pharmacology and Therapeutics from the Pediatric Pharmacy Advocacy Group (2009).

Ed Staffa, R Ph is a writer/editor for the Office of Communications (OCOMM) in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). Ed is a communications liaison for a variety of CDER's activities including special communications projects, media briefings, safety communications, journal articles, and daily media monitoring. He is also OCOMM's lead for a variety of CDER initiatives including innovation, biosimilars, and Sentinel. A pharmacist by training and past community pharmacy practitioner, Ed has also served as vice president of Pharmacy Practice and Communications for the National Association of Chain Drug Stores (NACDS) and vice president of Pharmacy for the Mirixa Corporation. In his role at NACDS, Ed wrote and edited newsletters, white papers, and press releases, organized industry initiatives, covered federal and state legislative issues affecting community pharmacy, and served as the association's liaison with FDA, other trade associations, and professional organizations. In his role with Mirixa, Ed worked on advancing community pharmacy practice via the development of web-based patient care services.

Robert Temple, MD is deputy center director for Clinical Science of the Center for Drug Evaluation and Research (CDER) and Acting Director of the Office of Drug Evaluation I (ODE-I) at the U.S. Food and Drug Administration (FDA). Dr. Temple received his medical degree from the New York University School of Medicine in 1967. In 1972 he joined CDER as a review medical officer in the Division of Metabolic and Endocrine Drug Products. He later moved into the position of director of the Division of Cardio-Renal Drug Products. In his current position, Dr. Temple oversees ODE-1 which is responsible for the regulation of cardio-renal, neuropharmacologic, and psychopharmacologic drug products. Dr. Temple has a long-standing interest in the design and conduct of clinical trials and has written extensively on this subject, especially on choice of control group in clinical trials, evaluation of active control trials, trials to evaluate dose-response, and trials using "enrichment" designs. He also has a long-standing interest in hepatotoxicity of drugs, having participated in the first detailed FDA-National Institutes of Health outside discussion of the subject in 1978.

Myrl Weinberg, FASAE, CAE is president of the National Health Council, the only organization of its kind that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Her extensive career has focused on health care delivery, medical research, long-term care, and related issues that affect people with chronic conditions. Ms. Weinberg has testified repeatedly before Congress and federal regulatory bodies and is a frequent speaker on the patient perspective in health policy. Ms. Weinberg has a long history of board and committee service. She is currently a member of the Institute of Medicine (IOM) Value Incentives Learning Collaborative; the Robert Wood Johnson Foundation's Aligning Forces for Quality Program National Advisory Committee; and the Better Business Bureau (BBB) Wise Giving Alliance Board of Directors, among other boards and commissions. She was also instrumental in the creation and operations of the International Alliance of Patients' Organization (IAPO), where she served as Chair of the Governing Board.