Participant Biographies

Barbara Alving, MD, MACP is the director of the National Center for Research Resources (NCRR), which funds the development of new technologies for basic and clinical research, supports training for researchers in the biomedical sciences, develops preclinical models, and provides health and biomedical education for the public. Dr. Alving received her MD cum laude from Georgetown University School of Medicine in Washington, DC. After an internship in internal medicine at Georgetown University Hospital, she completed a residency in internal medicine and a fellowship in hematology at the Johns Hopkins University Hospital in Baltimore, MD. Dr. Alving then became a research investigator in the Division of Blood and Blood Products at the Food and Drug Administration (FDA) on the NIH campus. In 1980, she joined the department of Hematology and Vascular Biology at the Walter Reed Army Institute of Research and became chief of the department in 1992. She left the Army at the rank of colonel in 1996 to become the director of the Medical Oncology/Hematology Section at the Washington Hospital Center in Washington, DC. In 1999, she joined the National Heart, Lung, and Blood Institute (NHLBI), serving as the director of the extramural Division of Blood Diseases and Resources until becoming the deputy director of the Institute in September 2001. From September 2003 until February 1, 2005, she served as the acting director of the NHLBI. From October 2002 until January 2006, she served as the director of the Women's Health Initiative, which is funded through the NHLBI. In March 2005 she became the acting director of NCRR and was named its director in April 2007. Dr. Alving is a professor of medicine at the Uniformed Services University of the Health Sciences in Bethesda, a Master in the American College of Physicians, a former member of the Subcommittee on Hematology of the American Board of Internal Medicine, and a previous member of the FDA Blood Products Advisory Committee.

Peter Arlett, MD earned his degree in medicine from University College London (UCL) in 1991 and specialized in hospital medicine. In 1994, he became a Member of the Royal College of Physicians (MRCP) of London. Dr. Arlett became a member of the faculty of Pharmaceutical Medicine (MFPM) of the Royal College of Physicians of London in 2002, and in 2004 he also became honorary senior lecturer in the Department of Medicine at UCL. Later, he became a fellow of the faculty of Pharmaceutical Medicine (FFPM) of the Royal College of Physicians of London. After his basic training in medicine, he worked as a hospital physician in Oxford and at the Hammersmith Hospital (Imperial College). He was appointed UK delegate to the European Committee for Human Medicinal Products (CHMP) in 2001. In 2003, Dr. Arlett joined the Pharmaceuticals Unit, DG Enterprise and Industry of the European Commission as Principal Administrator where his responsibilities included: international relations, pharmacovigilance (including lead responsibility for the revision to legislation), implementation of new pharmaceutical legislation, and medicines for children. Dr. Arlett joined the European Medicines Agency in September 2008.

Rachel E. Behrman, MD, MPH is the associate director for medical policy in 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.

Kenneth H. Buetow, PhD is the associate director of Bioinformatics and Information Technology and director of the Center for Biomedical Informatics and Information Technology at the National Cancer Institute (NCI). In his current role as associate director, he initiated and oversees the caBIG® (cancer Biomedical Informatics Grid) program. caBIG® has pioneered the infrastructure and a portfolio of tools that enable organizations and individual researchers to securely share biomedical data, and its capabilities serve as a demonstration of the connectivity required for Personalized Medicine. Dr. Buetow also serves as the director of the NCI Center for Bioinformatics and Information Technology (CBIIT), which is responsible for maximizing the interoperability and integration of NCI research. He is also the chief of the Laboratory of Population Genetics, where his group applies genomics to increase our understanding of the genetics of complex phenotypes. In addition to serving on the governing and advisory boards for numerous government organizations, academic institutions, and scientific and medical societies, Dr. Buetow has published more than 160 scientific papers.

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 (DCRI), 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 an NIH Clinical and Translational Science Award, 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 (CERTS), 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.

Kin-Wei Arnold Chan, MD, ScD is a pharmacoepidemiologist at i3 Drug Safety. His research has focused on drug, device and vaccine safety, utilization, and efficacy – in particular, studying them through large, linked automated health care databases. At i3, Dr. Chan directs i3Aperio, an active drug safety surveillance system based on large linked automated health care data sources. Prior to joining i3, he was an associate professor in the Harvard School of Public Health, Department of Epidemiology. In addition, Dr. Chan also has extensive experience in development of automated database for public health research in Asia. Dr. Chan was elected fellow of the International Society of Pharmacoepidemiology in 2003. More than 90 of his articles have been published in peer-reviewed journals and books. He is a co-editor of the textbook *Pharmacoepidemiology and Therapeutic Risk Management*, which was published by Harvey Whitney Books in February 2008.

COL Trinka Coster, MD is the director of the Pharmacovigilance Center in the United States Army Office of the Surgeon General. At the Center, her work focuses on providing military leadership with timely and actionable drug safety surveillance information. COL Coster is an internist and clinical pharmacologist by training. Her assignments in the military have included directing a clinical trials unit at the U.S. Army Institute of Infectious Diseases that conducted Phase 1 and Phase 2 clinical trials, overseeing product development of combat casualty care military products, and most recently developing the newly established

Army's Pharmacovigilance Center. She is also actively involved in new initiatives that are exploring methods to develop decision supports systems for her Pharmacovigilance Center, using Structured Product Label information and using semantic web technology.

Stan Crosley, JD is the co-director of the Indiana University (IU) Center for Strategic Health Information Provisioning (C-SHIP), a health information strategy and management center created through IU's schools of Law, Medicine, and Informatics. Mr. Crosley's work at C-SHIP is dedicated to addressing the sociological issues surrounding health information utilization – such as privacy, ethics, liability, and education – that will enable the critical flow of health information to improve patient health outcomes and safety, improve multi-path communications and education of patients and practitioners, and maximize the potential for the development of new and improved therapies. He is also a principal in Privacy and Information Management Services and Crosley Law Offices, LLC. Mr. Crosley is the former chief privacy officer for Eli Lilly Company, where he initiated Lilly's global privacy program in 1998. He also co-founded and served as chair of the International Pharmaceutical Privacy Consortium and was a member of the Institute of Medicine Medical Research and Privacy Committee. He serves on the boards of the Indiana Health Informatics Technology, Inc., the International Association Privacy Professionals, and The Privacy Projects. Mr. Crosley also serves on the board of the Shepherd Community Center, dedicated to breaking the cycle of poverty for families on Indianapolis' east side.

Francesca Cunningham, PharmD is director of the Center for Medication Safety PSCI and program director of outcomes assessment at the Department of Veterans Affairs (VA) National Center for Patient Safety and Pharmacy Benefits Management Services (PBM). Dr. Cunningham was the driving force behind the successful effort of PBM to establish reliable methods for merging the VA's prescription database with other large VA-related databases in order to evaluate the safe and appropriate use of medications in the veteran population. Her focus has been on assessing new agents where safety data is lacking and older drugs when a newly emerging danger requires evaluation. She also designed the VAMedSAFE and PBM Drug Safety Quality Improvement programs. Under her direction, the programs have become a major tool in the evaluation of drug safety in the VA and its role in the formulary decision process. Since joining the VA, Dr. Cunningham has focused her research efforts in the area of drug safety. Dr. Cunningham's group has worked independently and with other researchers to perform several drug safety and pharmacoepidemiologic studies. She sits on several internal and external boards and committees that focus on patient safety with an emphasis on pharmacovigilance, including the newly formed federal group for the FDA's Sentinel Initiative.

Rick Kuntz, MD, MSc is senior vice president of Strategy and Scientific Operations at Medtronic, Inc. In this role, which he assumed in August 2009, Dr. Kuntz oversees the company's global regulatory affairs, health policy and reimbursement; clinical research activities; ventures and new therapies; strategy and innovation; corporate development; and acquisitions, integrations, and divestitures functions. He joined Medtronic in October 2005, as senior vice president and president of Medtronic Neuromodulation, which encompasses the company's products and therapies used in the treatment of chronic pain, movement disorders, spasticity, overactive bladder and urinary retention, benign prostatic hyperplasia, and gastro paresis. Dr. Kuntz brings to Medtronic a broad background and expertise in many different areas of health care. Prior to Medtronic, he was the founder and chief scientific officer of the Harvard Clinical Research Institute, a university-based contract research organization which coordinates National Institutes of Health and industry clinical trials with the Food and Drug Administration. Dr. Kuntz also served as associate professor of Medicine at Harvard Medical School, chief of the Division of Clinical Biometrics, and an interventional cardiologist in the division of cardiovascular diseases at the Brigham and Women's Hospital in Boston, MA.

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.

Briggs Morrison, MD is senior vice president and leader of the Primary Care Medicines Development Group. He was formerly senior vice president in the Global Research & Development Division of Pfizer Inc. and led all clinical development (Phase I to III) activities for Pfizer, overseeing all the Development Therapeutic Areas as well as Clinical Operations. Prior to joining Pfizer, Dr. Briggs held various positions of increasing responsibility in Clinical Development at Merck & Co., Inc. He received a BS in biology from Georgetown University in 1981 and earned his MD from the University of Connecticut in 1985. He completed his internship and residency in Internal Medicine in 1988 at the Massachusetts General Hospital, completed his fellowship in Medical Oncology in 1991 at the Dana Farber Cancer Institute, and completed a post-doctoral fellowship in molecular oncology in 1994 at the Harvard Medical School/Howard Hughes Medical Institute under the guidance of Dr. Philip Leder.

J. Marc Overhage, MD, PhD is president and chief executive officer of the Indiana Health Information Exchange, director of Medical Informatics at the Regenstrief Institute, Inc., and a professor of medicine at the Indiana University School of Medicine. He has spent more than 25 years developing and implementing scientific and clinical systems and evaluating their value. He helped create the Indiana Network for Patient Care, an electronic patient record containing data from many sources including laboratories, pharmacies, and hospitals in central Indiana. It currently connects nearly all acute care hospitals in central Indiana and includes inpatient and outpatient encounter data, laboratory results, immunization data, and other selected data. In his work, he has played a significant regional and national leadership role in advancing the policy, standards, financing, and implementation of health information exchange. Dr. Overhage also is an expert in clinical decision support including inpatient and outpatient computerized physician order entry and the underlying knowledge bases to support them. He is a fellow of the American College of Medical Informatics and the American College of Physicians.

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.

Judy Racoosin, MD, MPH is Sentinel Initiative scientific lead at the Food and Drug Administration (FDA). There, she leads efforts to develop the data infrastructure and scientific methodologies needed to enable FDA to conduct active surveillance in automated health care data sources such as administrative claims databases and electronic health record systems. Dr. Racoosin has worked at the FDA on pre- and post-market safety issues and safety policy for more than 13 years. Previously, she was the senior safety policy advisor in the Center for Drugs Evaluation and Research's (CDER) Office of the Center Director. She was also a reviewer and team leader on the safety team in CDER's Divisions of Neurology Products and Psychiatry Products for nine years. Dr. Racoosin graduated magna cum laude from the University of Maryland School of Medicine and completed a residency in internal medicine at the University of Chicago Hospitals. Following her residency, she earned an MPH from the University of Illinois at Chicago School of Public Health. She is also board-certified in clinical pharmacology.

Chesley Richards MD, MPH, FACP is the acting director, Office of Prevention through Healthcare (OPTH) in the Office of the Director, Centers for Disease Control and Prevention (CDC). OPTH, a new office at CDC, works to build and enhance strategic collaboration between public health and health care sector stakeholders to improve the use of preventive services, and to enhance the quality and safety of health care. Previously, Dr. Richards served as the deputy director, Division of Healthcare Quality Promotion in the National Center for Infectious Diseases at CDC. Dr. Richards is a board-certified internist and geriatrician and holds an appointment as clinical associate professor of medicine in the Division of Geriatric Medicine and Gerontology at Emory University. Dr. Richards earned his MD from the Medical University of South Carolina, an MPH in health policy and administration from University of North Carolina at Chapel Hill, and is a graduate of the Epidemic Intelligence Service (EIS) at CDC and the Program on Clinical Effectiveness at Harvard School of Public Health. Dr. Richards's interests include patient safety, health care quality, and preventive services, especially among older adults. Dr. Richards is reviewer for several professional and scientific journals, and is an author on more than 50 peer-reviewed journal articles and book chapters.

Harry Seifert, MD, MSCE is director and head of the North America Safety Evaluation and Risk Management group at GlaxoSmithKline (GSK) Biologicals. He completed a residency in anesthesiology at the University of Connecticut and spent several years in academic practice before completing a fellowship in pharmacoepidemiology and obtaining a master's degree in clinical epidemiology at the University of Pennsylvania School of Medicine. Dr. Seifert has had positions of increasing responsibility since joining GSK, and has extensive experience in drug and vaccine safety, pharmacovigilance, pharmacoepidemiology, and risk management. He currently leads GSK's worldwide safety monitoring and risk management for seasonal and pandemic influenza vaccines, Neisseria vaccines, and several vaccines undergoing clinical development. Dr. Seifert is also an associate editor for *Pharmacoepidemiology and Drug Safety*, serves on the CIOMS Vaccine Pharmacovigilance Working Group, and is an adjunct assistant professor in the Department of Anesthesiology and Critical Care at the Children's Hospital of Philadelphia. His research interests include vaccine pharmacovigilance and pediatric cardiac surgery outcomes.

Navjot Singh, PhD, MBA is a partner in McKinsey's Pharmaceuticals and Medicals practice and Public Sector Practice. He is a leader in the R&D sub-practice and a leader of their work with regulatory agencies. He has more than nine years of experience at McKinsey and more than six years at GE. He works across Pharmaceuticals, Contract Research Organizations, Private Equity Clients, and Government Agencies. Dr. Singh received a PhD in chemical engineering from the University of Minnesota, and an MBA from Rensselaer Polytechnic Institute. He holds a bachelor's degree in chemical engineering from the Indian Institute of Technology. He is a co-author of more than a dozen peer-reviewed articles and external presentations on pharmaceutical R&D. He is trained in Six Sigma and Lean. Dr. Singh is also a co-inventor on more than 15 patents and has published in reputed journals such as *In Vivo* and *Nature Drug Discovery*.

Jean R. Slutsky, PA, MSPH has directed the Center for Outcomes and Evidence (COE), Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services, since June 2003. Prior to her appointment, she served as acting director of the Center for Practice and Technology Assessment at AHRQ. Most recently, Ms. Slutsky has implemented a comparative effectiveness research program that includes evidence synthesis, evidence generation, and evidence translation and implementation. The Effective Health Care Program is authorized under Section 1013 of the Medicare Modernization Act. Ms. Slutsky oversees the Evidence-based Practice Center program; Technology Assessment Program; extramural and intramural research portfolios concerning translating research into practice, outcomes and effectiveness research, including pharmaceutical outcomes, and cost-effectiveness analyses; and the National Guideline, Quality Measures, and QualityTools Clearinghouses. She is a member of the editorial board of *Implementation Science*. Prior to serving as acting director of the Center for Practice and Technology Assessment, Ms. Slutsky, served as project director of the U.S. Preventive Services Task Force, an internationally recognized panel of experts who make evidence-based recommendations on clinical preventive services.

Paul Stang, PhD is senior director of epidemiology at Johnson & Johnson, as well as co-principal investigator for the Foundation for the National Institutes of Health's Observational Medical Outcomes Partnership (OMOP), a public-private partnership whose aim is to engage in a program of study to objectively assess the performance, value, and impact of observational data and methods in monitoring the safety and benefit of medications. Dr. Stang has held a number of positions over the past 20 years in epidemiology and pharmacoepidemiology. Previously, Dr. Stang was a vice president at Cerner Corporation, which he joined after co-founding and serving as the chief scientific officer of Galt Associates, a health care consulting and informatics start-up that was acquired by Cerner. He previously served in positions at other health care companies, universities, and academic medical centers including the State University of New York-Stony Brook and the University of North Carolina at Chapel Hill. He holds adjunct faculty appointments at a number of institutions and is an elected fellow of the International Society for Pharmacoepidemiology. Dr. Stang has published widely in epidemiology, health outcomes, productivity, and communications including a recent book, *Health and Work Productivity: Making the Business Case for Quality Healthcare* with University of Chicago Press.

Miriam Sturkenboom, PhD, MSC is a professor in analysis of observational data at the departments of Medical Informatics and Epidemiology of the Erasmus University Medical Center in the Netherlands. She is a pharmacist who received her PhD with honors in pharmacoepidemiology and MSC in epidemiology from the Harvard School of Public Health. She worked with the Boston Collaborative Drug Surveillance Database in the United States, the National Research Council in Italy, and Erasmus University, and teaches pharmacoepidemiology in several countries. Under her guidance, the Integrated Primary Care Information (IPCI) medical record database has become a well-known and valuable data source for epidemiological research. Her current research interest is to study drug and vaccine safety in large populations through the creation of national and international networks of databases and novel tools from biomedical sciences for effectively analyzing such linked databases. Dr. Sturkenboom is project coordinator of several EC-funded studies on drug safety signal

detection and safety testing (SOS, ARITMO, EU-ADR) and manages workpackages in several other EC-funded studies dealing with distributed data models in the area of vaccine safety (VAESCO) and drug use in children (TEDDY, GRIP and ARPEC). She is chair of the database resources working group and elected member of the Steering Committee of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance that is coordinated by the European Medicines Evaluation Agency. She is immediate past president of the International Society of Pharmacoepidemiology, co-chair of International Society for Pharmacoepidemiology's task force on common data models, and is a scientific advisor of various regulatory agencies, companies, and institutions.

Alec Walker, MD, DrPH is a principal at World Health Information Science Consultants, LLC (WHISCON), and adjunct professor of Epidemiology at Harvard School of Public Health. At Harvard, he was formerly a professor and chair of the Department of Epidemiology. At WHISCON, he oversees research strategy. Dr. Walker's work encompasses the safety of drugs, devices, vaccines, and medical procedures. Recent studies include post-marketing safety studies for recently approved drugs, natural history of disease studies to provide context for Phase III clinical trials, studies of the impact of drug labeling and warnings on prescribing behavior, and determinants of drug uptake and discontinuation. Additional areas of research and expertise include health effects of chemicals used in the workplace and statistical methods in epidemiology. Dr. Walker is on the editorial board of *Pharmacoepidemiology and Drug Safety* and is on the board of directors of the International Society for Pharmacoepidemiology, which he also served as president in 1995-1996. He was a statistical consultant for the *New England Journal of Medicine*.

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.

Myrl Weinberg, MA has served as president of the National Health Council (NHC) since 1996. The NHC 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. Ms. Weinberg's extensive career has focused on health care delivery, medical research, long-term care, and related issues that affect people with chronic conditions. She has testified repeatedly before Congress and federal regulatory bodies and is a frequent speaker on the patient perspective in health policy. Ms. Weinberg currently serves on the U.S. Department of Health and Human Services National Advisory Council for Healthcare Research and Quality and the National Library of Medicine Board of Regents' Working Group on Clinical Trials. She is immediate past chair of the International Alliance of Patients' Organization Governing Board.

Marcus Wilson, PhD is president of HealthCore, a wholly owned subsidiary of WellPoint, Inc. HealthCore utilizes the vast real world research environment provided by WellPoint's national reach and local depth to provide research services focused on clinical effectiveness, health economics, and safety evaluation of various health care interventions. The results of the studies offer clarity that empowers a broad array of health care decision-makers to act with precision to improve quality, safety, and affordability. In addition to his leadership position with HealthCore, he also serves as co-chair of eHealth Initiative's Workgroup on Using Health IT for Research on Comparative Effectiveness and Outcomes, and on a number of relevant WellPoint committees including the Strategy & Innovations Council, the Information Management Steering Committee, the Public Policy Steering Committee, and the Enterprise Regulatory Council. He is a past member of the board of directors of the International Society for Pharmacoeconomics & Outcomes Research and is a reviewer for multiple journals. His publications, including book chapters, span various clinical, safety, and health outcomes topics.

Janet Woodcock, MD is the director, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA). Dr. Woodcock held various leadership positions within the FDA's Commissioner's office, including deputy commissioner and chief medical officer, deputy commissioner for operations, and chief operating officer and director, Critical Path Programs. Previously, Dr. Woodcock served as director of CDER from 1994-2005. She also held other positions at FDA including director, Office of Therapeutics Research and Review and acting deputy director, Center for Biologics Evaluation and Research. A prominent FDA scientist and executive, Dr. Woodcock has received numerous awards, including a Presidential Rank Meritorious Executive Award, the American Medical Association's Nathan Davis Award, and Special Citations from FDA Commissioners. Dr. Woodcock received her MD from Northwestern Medical School, completed further training, and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.