ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

FDA Sentinel Initiative Strategic Review
Brookings Institution • Washington, DC
September 26 – 27, 2011

Biographies

Josh Benner, PharmD, ScD is a managing director at the Engelberg Center for Health Care Reform and a fellow in the Economic Studies program at Brookings, where his work focuses on improving the safety, effectiveness and value of health care interventions. He directs a portfolio of activities related to the infrastructure and methods for developing better evidence, including medical product safety surveillance, comparative effectiveness research, and clinical research and development. Prior to joining Brookings, Dr. Benner was senior principal in health economics and outcomes research at IMS Health, where he led studies on the utilization and value of medicines, including prospective trials, retrospective studies in administrative and medical records databases, patient surveys, and economic modeling. Dr. Benner completed an AHRQ post-doctoral fellowship 4 in health services research at the Division of pharmacoepidemiology & Pharmacoeconomics, Brigham and Women's Hospital. He holds a doctor of pharmacy degree from Drake University and a doctor of science in health policy and management from the Harvard University School of Public Health.

Jeffrey S. Brown, PhD is an assistant professor in the Department of Population Medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is research director of the Therapeutics Research and Infectious Disease program at DPM and Director of Scientific Operations for the FDA's Mini-Sentinel project. Dr. Brown is a health services researcher with expertise in pharmacoepidemiology and drug safety, with primary research activities involving the development of new methodologies and techniques to facilitate drug and vaccine safety surveillance using automated healthcare claims and encounter data. This includes application of new sequential analytic and data mining methodologies using observational data as well as new methods and approaches for facilitating multi-institutional research using such data. His research portfolio also holds work in health policy, health economics, outcomes research. Dr. Brown holds a Master's degree in Economics from Tufts University and a PhD in Social Policy from Brandeis University. Jeff is a 7-time national champion and 3-time world champion in Ultimate Frisbee.

K. Arnold Chan, MD, ScD is a pharmacoepidemiologist at OptumInsight Life Sciences. His research has focused on drug, device and vaccine safety, utilization, and efficacy – in particular, studying these topics through large, linked automated health care databases. At OptumInsight, Dr. Chan leads teams of scientists to conduct post-marketing safety studies of pharmaceutical agents and vaccines. He directs Aperio, an active drug safety surveillance system based on large automated health care datasets. Prior to joining OptumInsight, he was an associate professor in the Harvard School of Public Health, Department of Epidemiology. In addition, Dr. Chan has extensive experience in development and utilization of automated healthcare databases for public health research in Asia. Dr. Chan was elected Fellow of the International Society of

Pharmacoepidemiology in 2003. More than 100 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.

Francesca Cunningham, PharmD is director of the Center for Medication Safety 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 federal group for the FDA's Sentinel Initiative.

Rich Elmore, MA is the Office of the National Coordinator for Health Information Technology's (ONC) leader for Query Health, an ONC-sponsored initiative to establish standards and services for distributed population queries of electronic health records. He is on a leave of absence from health care technology provider Allscripts, where as vice president of Strategic Initiatives, he managed exploration and execution of acquisitions and strategic partnerships and prior to that he ran the Allscripts Provider Analytics business. He had a long career at IDX where he ran the Flowcast Hospital business and prior to that was vice president of Product Development for IDX Flowcast. Mr. Elmore is the Communications Workgroup leader for the ONC's Direct Project. He was a charter member of the Interoperability Workgroup for the Certification Commission for Healthcare Information Technology. Mr. Elmore has degrees from Dartmouth College (BA) and New School University (MA Economics). He is on the Board of Directors for Patient Engagement Systems, a chronic disease technology company, and serves as Vice Chair on the Board of Directors for the King Street Center serving impoverished youth and their families in Burlington Vermont.

Brian J. Kelly, MD, MBA, MS is the head of Informatics and Strategic Alignment at Aetna. Dr. Kelly leads the Informatics and Strategic Alignment team of approximately 160 people who work with the chief medical officer and Aetna's clinical teams to define and measure the quality and affordability of healthcare. He also develops strategies to build market-leading business and system capabilities that allow Aetna to deliver on its strategy of helping members improve their health by accessing cost effective, high quality care. Dr. Kelly joined Aetna in 2008 as the national medical director for National Accounts, where he provided clinical support for sales and retention efforts and helped lead the development of the Benefit, Engagement and Network Strategy (BEN) program. A former Navy neurologist and intensive care medicine specialist, Dr. Kelly retired from the Navy in 2003 and spent five years at Accenture consulting for a large number of health plans, hospitals, and governments with a primary focus on using information technology to improve health care. He has worked on care management initiatives with a variety of health plans and led Accenture's global electronic health record practice.

David Knutson, MS recently joined the U.S. Department of Health and Human Services as a senior analyst in the Health Financing Policy Division of the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Prior positions include senior research fellow at the University of Minnesota - Division of Health Policy and Management. His duties included research, teaching, and the development of the Center for Care Organization Research and Development. Previous positions include director of Health Systems Studies at the Park Nicollet Institute, director of provider contracting for two HMOs, director of Emergency Medical Services (EMS) and long-term care regional planning, and executive director of hospital and community-based mental health programs. Mr. Knutson conducts research and development projects related to risk adjustment; performance-based purchasing; insurance markets; and organizational issues associated with chronic illness management. He has served on the Society of Actuaries Risk Adjustment Project Oversight Group. From 2002-2006 he served on the Centers for Medicare & Medicaid Services (CMS) National Advisory Panel on Medicare Education. Since 2006, he has served on the Efficiency Measurement Advisory Panel and consultant for the National Committee on Quality Assurance (NCQA). He led the State of Minnesota's Technical Expert Panel on provider performance e-reporting using the state's all-payer claims data base. Most recently, he served on the Minnesota State Health Insurance Exchange Workgroup. His projects that have been funded by the Robert Wood Johnson Foundation (RWJ), RWJ-Program for Changes in Healthcare Financing and Organization (HCFO), the Society of Actuaries, the Centers for Medicare & Medicaid Services (CMS), the Agency for HealthCare Research and Quality (AHRQ), state Medicaid programs, the Center for Health Care Strategies (CHCS), and the health care systems of the United Kingdom (UK), Sweden, and Germany. Mr. Knutson has a BA in biology and an MS in health economics.

Ronald Lee Krall, MD is an associate fellow at the University of Pennsylvania Center for Bioethics, and former senior vice president and chief medical officer for GlaxoSmithKline (retired). He is a member of the executive board of the Observational Medical Outcomes Partnership, as well as the Institute of Medicine Forum for Drug Discovery, Development, and Translation. With over 25 years in the pharmaceutical industry, Dr. Krall has worked for Lorex Pharmaceuticals, Abbott Laboratories, Zeneca/AstraZeneca, and GlaxoSmithKline, holding a variety of positions responsible for drug development and safety of medicines. He has overseen the development of more than 20 medicines, including Ambien, Hytrin for benign prostatic hypertrophy, Depakote for migraine and bipolar disorder, Nolvadex, Arimidex and Faslodex for breast cancer, Seroquel, Accolate, Diprivan, Iressa, Tykerb, and Entereg. Dr. Krall received his MD from the University of Pittsburgh, completed his training in neurology and a fellowship in clinical pharmacology at the University of Rochester, and holds a bachelor's degree in mathematics from Swarthmore College.

Ralph I. Horwitz, MD, MACP is senior vice president for Clinical Evaluation Sciences and senior advisor to the chairman of Research and Development at GlaxoSmithKline, and Harold H. Hines, Jr. Professor Emeritus at Yale University. In his role at GSK, Dr. Horwitz is responsible for developing improved approaches to evaluating the long-term benefit and risks associated with GSK medicines. To accomplish this goal, he is leading the design of randomized trials and rigorous observational studies of medicines after they are approved for use in clinical practice. He trained in internal medicine at institutions (Royal Victoria Hospital of McGill University and the Massachusetts General Hospital) where science and clinical medicine were connected effortlessly. Unexpected experiences as a resident unleashed a deep interest in clinical research training which he pursued as a fellow in the Robert Wood Johnson Clinical Scholars Program at Yale under the direction of Alvan R. Feinstein. He joined the Yale faculty in 1978 and remained there for 25 years as co-director of the program and later as chair of the Department of Medicine. Before joining GSK, Dr. Horwitz was chair of Medicine at Stanford and dean of Case Western Reserve Medical School. He is an elected member of the Institute of Medicine of the National Academy of Sciences; the American Society for Clinical Investigation; the American Epidemiological Society; and the Association of American Physicians (he was

President in 2010). He served on the American Board of Internal Medicine and was Chairman in 2003. He is a master of the American College of Physicians.

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.

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, FDAAdvisoryCommittee.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.

Patrick Miller, MPH, research associate professor, NH Institute for Health Policy and Practice, University of New Hampshire, and Co-Founder, All-Payer Claims Database Council (APCD), has more than 20 years of health care experience working in the private, public, non-profit, and academic healthcare sectors. His work with the APCD Council involves technical assistance to states, development of standards, claims analysis projects, and working with policy makers. He has been co-author on papers regarding APCDs for The Commonwealth Fund and AcademyHealth's State Coverage Initiatives. Patrick's areas of expertise beyond all-payer claims databases include health information technology, health information exchange, privacy and security, operations, public health, and Medicaid policy. He served as member of the National Governor's Association's State Alliance for e-Health Privacy and Security Task Force in 2008, and served in 2008 and 2009 as New Hampshire's Project Director for the Federally funded Healthcare Information Security and Privacy Collaborative (HISPC). He is a current member of New Hampshire's HIE Advisory Group. He has delivered conference presentations on e-Health issues to the National Governors Association, Centers for Medicaid and Medicare Services, National Association for Health Data Organizations, provider groups, and other organizations. He is both a board member for the National Association of Health Data Organizations and the New Hampshire Fiscal Policy Institute, and he founded the NH Purchasers Group on Health. He holds both a B.S. in Health Management and Policy and a M.P.H. from the University of New Hampshire.

Briggs W. Morrison, MD is senior vice president and Head of Medical Excellence at Pfizer Inc., overseeing Clinical Development, Regulatory Strategy and Safety Strategy for all human biopharmaceuticals. He was formerly leader of the Primary Care Medicines Development Group at Pfizer, and prior to that he 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. Morrison 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.

Garry Neil, MD is corporate vice president, Corporate Office of Science and Technology (COSAT) at Johnson & Johnson World Headquarters in New Brunswick, NJ. In this role, Dr. Neil leads a team that catalyzes sustained growth for Johnson & Johnson by identifying and launching emerging technologies that underpin the creation of future businesses. Dr. Neil has broad experience in science, medicine and pharmaceutical development. He has held a number of senior positions within J&J, most recently group president, Johnson & Johnson Pharmaceutical Research and Development. Under his leadership a number of important new medicines for the treatment of cancer, anemia, infections, central nervous system and psychiatric disorders, pain, and genitourinary and gastrointestinal diseases, gained initial or new and/or expanded indication approvals.

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 U.S. 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 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 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 DEcIDE Center, and the CDC Translational Research Prevention Epicenter.

Melissa Robb, RN joined the Center for Drug Evaluation and Research's (CDER), Office of Medical Policy, U.S. Food and Drug Administration (FDA) in 2009. She is the Project Director for the Agency's Sentinel Initiative. The Initiative's goal is to create a national, integrated, electronic system for monitoring medical product safety, augmenting the Agency's current postmarket surveillance capabilities. In 2002, CDR Robb began her career with the Agency as a Project Manager in FDA's Division of Cardiovascular and Renal Products within CDER. She has also worked as a Senior Program Management Officer in the Office of Critical Path Programs within the Office of the Commissioner. Prior to joining the FDA and the United States Public Health Service Commissioned Corps, CDR Robb was active duty in the United States Air Force and served at Andrews Air Force base in Maryland. She is a registered nurse and received her degree at Purdue University's School of Nursing in 1997. She has also received a Regulatory Affairs Certification from the University of California, San Diego and a Certification in Patient and Product Safety from the University of Southern California.

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 VA.

Nancy C. Santanello, MD, MS, is vice president and head of epidemiology at Merck Research Laboratories, Merck & Co. Inc. Dr. Santanello has been a physician epidemiologist in the Department of Epidemiology since 1991. Her areas of research interest include: the development and validation of outcome measures for use in clinical trials, study design, adherence to therapy, satisfaction with and preference for therapy, comparative safety and effectiveness study design and methods, drug and vaccine safety and pharmacoepidemiology. Dr. Santanello has published over 60 peer-reviewed manuscripts. She has been invited to speak on outcome research measurement, drug and vaccine safety, and signal detection and evaluation issues at national and international meetings, including the Institute of Medicine, International Society of Quality of Life, International Society of Pharmacoepidemiology (ISPE) and the Agency for Healthcare Research Quality Centers for Education & Research on Therapeutics. Dr. Santanello is the current president of ISPE. Prior to joining Merck, Dr. Santanello was a medical officer with the National Heart, Lung, and Blood Institute (NHLBI) Prevention and Demonstration Research Branch of the Division of Epidemiology and Clinical Applications (1987-1991).

Joe Selby, MD, MPH, was named as the first executive director of the Patient-Centered Outcomes Research Institute in May 2011 and assumed this position in July 2011. Prior to that, Dr. Selby served as the director of the Division of Research (DOR) at Kaiser Permanente since 1998. The DOR is Kaiser Permanente Northern California's externally funded research shop. It is comprised of approximately 50 MD and PH.D. investigators who conduct a wide range of epidemiological and health services research, and has an annual budget of more than $90 million. Dr. Selby is a family physician, clinical epidemiologist and health services researcher. His personal scientific interests and contributions have included drug safety research, observational evaluations and randomized quality improvement studies in diabetes mellitus and other chronic illnesses; studies of the efficacy of colon cancer screening; studies of variation in coronary angiography and revascularization following myocardial infarction; and of the effects of cost-sharing in the emergency department and for prescription medications. He has served on AHRQ's Healthcare Quality and Effectiveness Research Study Section, as co-chair of the Technical Expert Panel to the NCQA for diabetes quality measurement, and on the Data Safety Monitoring Board of the National Lung Cancer Screening Trial. In 2009, he was elected to the Institute of Medicine.

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.

Ellen V. Sigal, PhD, is chairperson and founder of Friends of Cancer Research (Friends), a cancer research think tank and advocacy organization based in Washington, DC. Dr. Sigal is vice chair of the inaugural board of directors of the Reagan-Udall Foundation, a partnership designed to modernize medical product development, accelerate innovation, and enhance product safety in collaboration with the U.S. Food and Drug Administration. She serves on the Board of the Foundation for the National Institutes of Health where she chairs its Public-Private Partnerships Committee. In 2010, Dr. Sigal was appointed to a six year term on the Board of Governors of the Patient Centered Outcomes Research Institute (PCORI) as a representative of patients and health consumers. She also holds leadership positions with a broad range of cancer advocacy, public policy organizations, and academic health centers including: the American Association for Cancer Research Foundation Board; Research!America Board; M. D. Anderson Cancer Center External Advisory Board, the Duke University Cancer Center Board of Overseers, and The Sidney Kimmel Comprehensive Cancer Center Advisory Council.

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.

Sean Tunis, MD, MSc is the founder and director of the Center for Medical Technology Policy (CMTP) in Baltimore, Maryland. CMTP's main objective is to improve the quality, relevance and efficiency of clinical research by providing a neutral forum for collaboration among experts, stakeholders and decision makers. Dr. Tunis was a member of the Institute of Medicine Committee on Initial National Priorities for Comparative Effectiveness Research. He advises a wide range of domestic and international public and private health care organizations on issues of comparative effectiveness, evidence based medicine, clinical research, reimbursement and health technology policy. Through September of 2005, Dr. Tunis was the chief medical officer at the Centers for Medicare and Medicaid Services, where he had lead responsibility for clinical policy for the Medicare and Medicaid programs. Previously he served as the director of the Health Program at the Congressional Office of Technology Assessment and as a health policy advisor to the U.S. Senate, where he worked on pharmaceutical and device policy issues. Dr. Tunis trained at the University of California in Los Angeles and the University of Maryland in Internal Medicine and Emergency Medicine, and holds adjunct faculty positions at the Center for Health Policy at Stanford University, the Department of Internal Medicine at the Johns Hopkins School of Medicine, and the Department of Surgery at the University of California at San Francisco.

Alexander M. 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 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 has served as a statistical consultant for the New England Journal of Medicine and a contributing Editor for The Lancet.

Marcus Wilson, PharmD 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), U.S. 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.