Brookings Active Surveillance Implementation Council Meeting #2

Participant Biographies

Dennis A. Ausiello, MD is the Jackson Professor of Clinical Medicine at Harvard Medical School, chief of medicine at Massachusetts General Hospital, and chief scientific officer of Partners Healthcare. He received his undergraduate degree from Harvard College and his medical degree from the University of Pennsylvania. He has made a substantial contribution to knowledge of epithelial biology in the areas of membrane protein trafficking, ion channel regulation, and signal transduction. He has published numerous articles, book chapters, and textbooks and currently serves as the co-editor of *Cecil's Textbook of Medicine,* now in its 23rd edition. A nationally recognized leader in academic medicine, Dr. Ausiello was elected to the Institute of Medicine of the National Academy of Science in 1999 and the American Academy of Arts and Sciences in 2003. He has written for *The New York Times*, *The Wall Street Journal*, and *Boston Globe* on health subjects, including human genetics, clinical trials, and the relationship between the academy and industry.

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.

Kim A. Caldwell, RPh is the director of Competitive Health Analytics (CHA). Mr. Caldwell leads an outcomes research group focusing on key health care questions in collaboration with private, public, and internal research partners. Primarily using the extensive Humana database, CHA engages in extensive work relating to comparative effectiveness research, post-marketing surveillance, return-on-investment queries, and numerous scenario-based health care studies. Additionally, he leads the Humana Pharmacy Solutions Public Policy staff. Mr. Caldwell joined Humana in April 2008. During 2004-2005, Mr. Caldwell served the Centers for Medicare & Medicaid Services (CMS) as division director – Clinical and Economic Performance in the Center for Beneficiary Choices (CBC). As one of two outside, non-government directors asked to join the Medicare Drug Benefit Group, Mr. Caldwell helped lead the development and implementation of Part D – the Medicare prescription drug benefit that began on January 1, 2006. His career has included positions such as privacy officer and vice president for one of the early e-Prescribing companies, vice president – Clinical Operations for a national pharmacy benefit manager (PBM), pharmacy director for national managed care organizations, manager of Outpatient Pharmacy Services in a regional hospital system, owner/pharmacist of an independent pharmacy, and he has a lengthy service in long-term care consulting and chain pharmacy operations. He served as a member of the Texas Health Care System Integrity Partnership, on the Policy Committee for the National Alliance for Health Information Technology, and as a board member for the Center for Improving Medication Management. Mr. Caldwell was recently appointed to the Agency for Healthcare Research and Quality's (AHRQ) CER Pharmacy Workgroup.

Louis I. Hochheiser, MD joined Humana in March of 2006 and was recently appointed to the position as chief medical leader. He provides oversight for the technology assessment process, policy Implementation, molecular diagnostic strategy, and the medical directors who conduct reviews and provide medical leadership within Humana's markets. He is responsible for supervising the clinical components of Humana's objective to providing guidance for its members and providers in order to support the information and knowledge necessary to make appropriate choices about health care needs. Prior to joining Humana, Dr. Hochheiser led medical management of the TRICARE program in the Mid-Atlantic Region. His background includes 17 years as chairperson of Family Medicine, first at Brown University and then the University of Vermont, where he holds the position of professor emeritus.

Karen Ignagni is president and chief executive officer of America's Health Insurance Plans (AHIP), where she is the voice of health insurance plans, representing members that provide health care, long-term care, dental, and disability benefits to more than 200 million Americans. Ms. Ignagni joined the organization as its chief executive in 1993. From there she led two mergers with other organizations to form AHIP in 2003, making the company the leading voice for the health plan community in America. Ms. Ignagni has won many accolades for her leadership. *The New York Times* wrote, "In a city teaming with health care lobbyists, Ms. Ignagni is widely considered one of the most effective. She blends a detailed knowledge of health policy with an intuitive feel for politics." *Fortune* described the political program Ms. Ignagni spearheaded as "worthy of a presidential election bid." Ms. Ignagni regularly testifies before Congress on key federal legislation. In recent years, she has appeared before Senate and House committees on matters ranging from health insurance plans' role in homeland security to Medicare reform to patient protection issues and access to health care coverage. Prior to 1993, Ms. Ignagni directed the AFL-CIO's Department of Employee Benefits. In the 1980s, she was a professional staff member on the U.S. Senate Labor and Human Resources Committee, preceded by work at the Committee for National Health Insurance and the U.S. Department of Health and Human Services.

Xavier Kurz, MD, PhD, MSc graduated in 1982 as a medical doctor at the University of Liege, Belgium. He specialized in tropical medicine and worked for several years in public health projects in Africa and Asia. He obtained an MSc (1991) and a PhD (1997) in Epidemiology and Biostatistics at McGill University, Montreal, Canada. He joined the Department of Pharmacology of the University of Liege, where he developed and conducted pharmacoepidemiological and pharmacoeconomic studies on vascular disorders and dementia. In 1995, he joined the Belgian Centre for Pharmacovigilance (Ministry of Health) as a scientific expert. He joined the Pharmacovigilance and Risk Management Sector of the European Medicines Agency (EMA) in September 2005. As signal detection scientific advisor and project leader, he has coordinated the EMA activities for the benefit-risk monitoring of Influenza A/H1N1 pandemic vaccines in Europe. On behalf of EMA, he also coordinates the PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium) project, a public-private partnership of 29 participants, carried-out within the framework of the Innovative Medicines Initiative of the European Commission.

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.

Amol Navathe, MD, PhD is medical officer and senior program manager, Comparative Effectiveness Portfolio, for the Office of the Secretary, U.S. Department of Health and Human Services (HHS). At HHS, he coordinates the Comparative Effectiveness Research (CER) program including managing the implementation of funds through the Office of the Assistant Secretary of Planning and Evaluation. Dr. Navathe leads the data infrastructure initiatives within the CER portfolio and spearheads an effort to increase coordination of these activities within the federal government as well as with states and the private sector. He brings a diverse background to this position with training as a medical doctor, economist and health services researcher, and engineer. His past experience includes serving as a visiting fellow at the Council of Economic Advisers in The White House, serving health care clients as a consultant with McKinsey & Company, and numerous technical and research consulting roles. He holds an MD from the School of Medicine and PhD in health economics from The Wharton School at the University of Pennsylvania, and a BS in electrical engineering and economic systems from Stanford University.

Samuel Nussbaum, MD is executive vice president, clinical health policy and chief medical officer for WellPoint, Inc. He oversees corporate medical policy, clinical pharmacy programs, and programs in clinical excellence. His principal responsibilities include: serving as chief spokesperson and policy advocate on medical issues, guiding the corporate vision regarding quality of care and its measurements, leading efforts to assess clinical quality performance and safety, and developing a strategy to foster further collaboration with physicians, hospitals, and national organizations to strengthen and improve patient care. Dr. Nussbaum also has responsibility for HealthCore, WellPoint's clinical outcomes research subsidiary. Dr. Nussbaum has served as president of the Disease Management Association of America, chairman of the National Committee for Quality Health Care, chair of America's Health Insurance Plan's (AHIP) Chief Medical Officer Leadership Council and as a member of the AHIP Board, and currently serves on the National Quality Forum Board and on the Secretary of Health and Human Services' Advisory Committee on Genetics, Health, and Society. He received the 2004 Physician Executive Award of Excellence from the American College of Physician Executives and *Modern Physician* magazine. Dr. Nussbaum is professor of clinical medicine at Washington University School of Medicine and serves as adjunct professor at the Olin School of Business, Washington University. He served as executive vice president, Medical Affairs and System Integration, of the BJC Health Care, where he led integrated clinical services across the health system and served as President of its medical group. Dr. Nussbaum earned his medical degree from Mount Sinai School of Medicine. He trained in internal medicine at Stanford University Medical Center and Massachusetts General Hospital and in endocrinology and metabolism at Harvard and Massachusetts General Hospital, where he directed the Endocrine Clinical Group.

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 the Sentinel Initiative scientific lead at the U.S. Food and Drug Administration (FDA). In that role, she leads efforts to develop the 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 14 years. Previously, she was the senior safety policy advisor in the Center for Drug 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.

Andrew Slavitt, MBA is chief executive officer of Ingenix, one of the world's leading health information, technology, and consulting companies. Ingenix helps clients improve quality, reduce costs, and make the health care more system work better for everyone. With over 10,000 team members in 40 countries worldwide, Ingenix delivers business solutions to 250,000 clients, including physicians, hospitals and health systems, commercial health plans, employers, government agencies, and organizations who develop cures, including pharma, biotech, and medical device companies. Mr. Slavitt was named chief executive officer of Ingenix in 2006. Prior to joining Ingenix in 2005 as chief operating officer, he served as chief executive officer of the consumer solutions business of UnitedHealth Group. He was responsible for leading consumer-driven health care, consumer portal development, and other initiatives to serve consumers and the uninsured. Previously, Mr. Slavitt was founder and chief executive officer of HealthAllies, one of the first consumer health care benefits companies focusing on the un-and under-insured, which was acquired by UnitedHealth Group in 2003. Prior to founding HealthAllies, Mr. Slavitt served as chief operating officer and director of Paula Financial, an employee benefits insurance company and one of the largest benefits distributors in the United States. He also worked as a strategy consultant with McKinsey & Company and as an investment banker with Goldman Sachs. Mr. Slavitt is a graduate of the Wharton School and The College of Arts & Sciences at the University of Pennsylvania, and received his MBA from the Harvard Business School. In addition, he is a director and health policy chair for The Hope Street Group, a non-profit public policy organization based in Washington, DC, and is a board member of the Council for Affordable Quality Healthcare. He also serves on the boards of Capella Education and the Guthrie Theater in Minneapolis.

Jean R. Slutsky, PA, MSPH has directed the Center for Outcomes and Evidence, 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.

Reed V. Tuckson, MD, FACP is executive vice president and chief of Medical Affairs at UnitedHealth Group. He leads the company's 19,000 clinical experts of many disciplines and is responsible for working with all of the company's business units to improve the quality and efficiency of health services. Dr. Tuckson is a graduate of Howard University, Georgetown University School of Medicine, and the Hospital of the University of Pennsylvania's General Internal Medicine Residency and Fellowship Programs. Formerly, Dr. Tuckson served as senior vice president for the American Medical Association; president of the Charles R. Drew University of Medicine and Science; senior vice president for Programs of the March of Dimes Birth Defects Foundation; and commissioner of Public Health for the District of Columbia. Dr. Tuckson is an active member of the prestigious Institute of Medicine of the National Academy of Sciences and was recently appointed to the National Institute of Health's Advisory Committee to the Director, and the U.S. Department of Health and Human Services' Health Information Technology (IT) Policy Committee-Enrollment Workgroup. He is past chair of the Secretary of Health and Human Services' Advisory Committee on Genetics, Health, and Society. Dr. Tuckson currently serves on the board of directors for the National Hispanic Medical Association; the Alliance for Health Reform; the American Telemedicine Association; the National Patient Advocate Foundation, and the Arnold P. Gold Foundation. Additionally, he serves on several boards within his local community of Minneapolis, including Big Brothers Big Sisters of the Greater Twin Cities and Minnesota Public Radio.

Philip S. Wang, MD, DrPH is the deputy director of the National Institute of Mental Health (NIMH). Prior to joining NIMH, he served on the faculty at Harvard Medical School where his research focused on effectiveness trials, pharmacoepidemiology, pharmacoeconomics, and health services research. He completed his undergraduate, medical school, psychiatry residency, and doctoral training in epidemiology, all at Harvard University. Dr. Wang has served as a voting member on the U.S. Food and Drug Administration's (FDA) Psychopharmacologic Drugs Advisory Committee, the FDA Neurological Devices Panel, and the FDA Endocrinologic and Metabolic Drugs Advisory Committee. He also served on the NIMH Services Research and Clinical Epidemiology Study Section. He was chair of the World Health Organization's World Mental Health Survey Services Research Work Group. He is a member of the American Psychiatric Association's (APA) DSM-V Task Force and has consulted on several APA Work Groups to develop evidence-based treatment guidelines. Dr. Wang is an author of approximately 160 scientific publications.

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.

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.