Brookings Active Surveillance Implementation Council Meeting #3

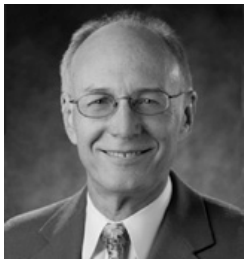
Participant Biographies

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.

Donald O. Beers, JD serves as associate chief counsel for drugs in the Office of Chief Counsel of the Food and Drug Administration (FDA). Previously, he was a partner in Arnold & Porter, as well as counsel to McCutchen, Doyle, Brown & Enersen. He also served in the FDA's Office of Chief Counsel from 1975 to 1985, spending most of his time as a litigator for the agency, and clerked for a District Judge in the Southern District of New York. The 7th edition of his book, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*, which focuses on issues raised by the 1984 Drug Price Competition and Patent Term Restoration Act and related legislation, was published in 2008, before he returned to government service. Mr. Beers received a bachelor's degree from Dartmouth College and his JD from Columbia Law School.

Josh Benner, PharmD, ScD is a research 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

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.



James W. Buehler, MD is the director of the Public Health Surveillance Program Office (PHSPO) at the Centers for Disease Control and Prevention (CDC). From 1981-2002, Dr. Buehler served as a medical epidemiologist in the U.S. Public Health Service (PHS) at CDC, where he worked in a range of areas, including general field epidemiology, maternal and child health, HIV/AIDS prevention, and, for a short period in 2001, anthrax. At the time of his retirement from PHS in 2002, he was the associate director for Science of CDC's National Center for HIV, STD, & TB Prevention. His work in public health surveillance has spanned analysis, methods development, system design and management, participation in program management and policy development, support for community-based planning, and assurance of ethical practice. In 2002, he joined the faculty of the Epidemiology Department at the Rollins School of Public Health at Emory University, where his work focused on the role of epidemiology in public health preparedness and response programs and on the emerging field of public health systems research. In 2009, he returned to CDC to contribute to surveillance for H1N1 influenza, and since 2010, he has served as the director of PHSPO.

Kenneth H. Buetow, PhD is the associate director of bioinformatics and information technology and the director of the Center for Biomedical Informatics and Information Technology at the National Cancer Institute (NCI). Dr. Buetow's multi-disciplinary scientific career has focused for more than 20 years on understanding the role of genetics in complex human diseases such as cancer, and on applying sophisticated informatics technologies to solve major biomedical challenges. In his current role of National Cancer Institute associate director responsible for Bioinformatics and Information Technology, he initiated and oversees the caBIG® (Cancer Biomedical Informatics Grid) program, a groundbreaking initiative built to connect the entire cancer community in a "World Wide Web" of biomedical research. 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 director of the NCI Center for Bioinformatics and Information Technology (NCI CBIIT), which is responsible for maximizing the interoperability and integration of NCI research. He is also the chief of the Laboratory of Population Genetics (LPG), 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. His recent honors and awards include the Editor's Choice Award from Bio-IT World (2008), the Federal 100 Award (2005), the NIH Award of Merit (2004), and the NCI Director's Gold Star Award (2004). Dr. Buetow received a BA in biology from Indiana University in 1980 and a PhD in human genetics from the University of Pittsburgh in 1985.

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

K. Arnold Chan, MD, ScD is a pharmacoepidemiologist at Ingenix Life Sciences. 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 Ingenix, Dr. Chan leads a team 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 linked automated health care data sources. Prior to joining Ingenix, 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 health care database 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.

COL Trinka Coster, MD is 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 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.

Gregory W. Daniel, PhD, MPH, RPh is vice president, government & academic research at HealthCore. Dr. Daniel has extensive experience leading large health outcomes, comparative effectiveness, and epidemiologic research focusing on economic, effectiveness, and safety evaluations of health care technologies and interventions, guideline adherence and patterns of care. His research projects have used health insurance claims data integrated with electronic laboratory results, electronic hospital data, paper-based and electronic medical record data. In addition to serving as a co-investigator on several large federally-funded grants, Dr. Daniel is currently the principal investigator (PI) for HealthCore on several large multi-year research agreements with the Food and Drug Administration (FDA), including evaluation of vaccine and biologic product safety with the Center for Biologics Evaluation & Research (CBER) and leveraging large data environments and research expertise to evaluate near real-time risk associated with prescription drug use with the Center for Drug Evaluation and Research/Office of Surveillance and Epidemiology (CDER/OSE). Further, Dr. Daniel is the PI for HealthCore's involvement in the FDA Sentinel Initiative (Mini-Sentinel), a pilot project designed to inform and facilitate development of a fully operational active surveillance system, the Sentinel System, for monitoring the safety of FDA-regulated medical products. Dr. Daniel is a licensed pharmacist and holds a PhD in Pharmaceutical Economics, Policy, and Outcomes Research from the University of Arizona, an MPH specializing in biostatistics as well as an MS in Pharmaceutical Administration from The Ohio State University.

Richard Elmore, MA manages exploration and execution of strategic partnerships and acquisitions as vice president, strategic initiatives for health care technology provider Allscripts. Mr. Elmore has been with Allscripts for three years, where prior to his current assignment, he ran the provider analytics business. He had a long career at IDX Systems where he was vice president of product development for IDX Flowcast and then ran the IDX Flowcast Hospital business. Mr. Elmore is the communications workgroup leader for the ONC's Direct Project. He is editor of *Healthcare Technology News*. 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 a patient engagement 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.

Howard Hutchinson, MD, FACC is the chief medical officer for AstraZeneca. In this role, he is responsible for the overall benefit/risk assessment of AstraZeneca products and for the medical oversight of the organization's early and late stage portfolio. Dr. Hutchinson joined Zeneca in 1995 and was responsible for marketed products in the cardiovascular, respiratory, and anti-infective therapy areas. Following the merger with Astra, he was appointed medical leader of the cardiovascular therapy area and was responsible for all U.S. cardiovascular and metabolism development programs. Dr. Hutchinson served in this role until appointed vice president of clinical research in April 2003 where he would oversee the activities of physicians and medical communications personnel for Phase II to IV Clinical Development. In January 2005, he was promoted to vice president of the clinical cardiovascular therapy area and in March 2006 was appointed clinical vice president for the combined cardiovascular/gastrointestinal therapy area. In November 2006, Dr. Hutchinson was appointed chief medical officer. Dr. Hutchinson graduated *summa cum laude* with a degree in chemistry from Drexel University in 1983, and graduated *cum laude* from the Thomas Jefferson University Medical School in 1987. He remained at Jefferson for his internal medicine and cardiovascular fellowship training and received board certifications in internal medicine and cardiovascular disease. After completing his fellowship in 1993, he was awarded a Bugher Foundation Award to study molecular cardiology at the Stanford University School of Medicine. During this time, he also received an Investigator Award from the American Federation of Clinical Research. His research centered on the study of the effects of natriuretic peptide and renin-angiotensin systems on vascular smooth muscle cell growth during normal physiologic development and following vascular injury. Dr. Hutchinson is a fellow of the American College of Cardiology, a member of the PhRMA Science and Regulatory Committee, on the board of directors for the PhRMA Foundation and an adjunct clinical associate professor of medicine at Thomas Jefferson University Hospital. He is also a member of professional societies including the American Heart Association, American College of Cardiology, and the American Academy of Pharmaceutical Physicians. In addition to receiving numerous honors and awards, Dr. Hutchinson has over 30 peer-reviewed journal articles as well as numerous abstracts and book chapters.

S. Lawrence Kocot, JD, LLM, MPA serves as a visiting fellow in the Economic Studies program and deputy director of the Engelberg Center for Health Care Reform at Brookings. Mr. Kocot is also senior counsel at SNR Denton LLP. Mr. Kocot was interim president and CEO and currently serves on the Board of Directors of the Partnership for a Healthier America. Previously, he was senior advisor to the Administrator of the Centers for Medicare & Medicaid Services at the U.S. Department of Health and Human Services. In this capacity, he was involved in a wide range of health care policy issues and operations related to Medicare and Medicaid. Mr. Kocot is former chairman and currently a member of Virginia's Commonwealth Health Research Board; he was appointed by Virginia Governor Mark R. Warner and reappointed by Virginia Governor Tim Kaine. Prior to his government service, he spent nearly a decade at the National Association of Chain Drug Stores, where he was senior vice president and general counsel. Mr. Kocot received his BA and MPA degrees from the University of Massachusetts at Amherst. He earned his JD and LLM degrees at the Georgetown University Law Center.

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.

Jean A. Krause serves as the executive vice president and chief executive officer for the American College of Physicians (ACP) Foundation. The ACP Foundation was incorporated in 1999 to improve the health and welfare of patients and society through initiatives that provide patients with the information they need to understand and manage their health. Since 2001, the ACP Foundation has concentrated their efforts on health communication with an emphasis on health literacy. The health communication initiative focuses on an individual's capacity to obtain, process, and understand basic health information and services, and shapes the Foundation's effort to improve patient health literacy. On behalf of an organization that is a national leader in developing patient-focused health information, Ms. Krause serves on the Institute of Medicine's Roundtable on Health Literacy Planning Committee, the Joint Commission's Public Policy Roundtable, the Association of Clinicians for the Underserved (ACU), U.S. Pharmacopeia – National Coordinating Council for Medication Error Reporting and Prevention, and the National Consumers League Medication Adherence Committee. Ms. Krause received her BA in English from Boston University, with additional postgraduate work at the University of Pennsylvania in Philadelphia and the University of Colorado. Ms. Krause has received numerous awards through the years focusing on finance, human resources, and management.

Richard 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 (HCRI), a university-based contract research organization which coordinates National Institutes of Health (NIH) and industry clinical trials with the United States Food and Drug Administration (FDA). 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.

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 Dr. Levy 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 Bristol-Myers Squibb he was a member of the renal division at Brigham and Women's Hospital in Boston, where he was an investigator in federally-sponsored outcomes research, as well as industry-sponsored clinical trials.

Mark McClellan, MD, PhD is director of the Engelberg Center for Health Care Reform and Leonard D. Schaeffer Chair in Health Policy Studies at the Brookings Institution. At the Center, his work focuses on promoting high-quality, innovative and affordable health care. A doctor and economist by training, he also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (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 at Pfizer. 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.

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 (J&J) by identifying and launching emerging technologies that underpin the creation of future businesses. He 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 Center for Education and Research in Therapeutics, the AHRQ HMO Research Network DEcIDE Center, and the CDC Translational Research Prevention Epicenter.

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.

Jane Reese-Coulbourne, MS, ChE is the executive director of the Reagan-Udall Foundation for the U.S. Food and Drug Administration (FDA). Created by Congress, the Foundation supports the mission of the FDA by identifying, funding, and supporting public private partnerships and projects that will provide the highest caliber science and technology, to enhance the safety and effectiveness of FDA regulated products. Ms. Reese-Coulbourne's background includes experience in patient advocacy, industry and government. As an employee of the Procter & Gamble Company for more than 10 years, she worked in production operations, chemical engineering, government regulation, new technology and product/brand start-ups. Later working with other Fortune 500 companies, she consulted in strategic planning, reengineering/restructuring, new technology

plans and start-ups, and total quality management in unionized manufacturing and utility operations. Her diagnosis of breast cancer led to her interest in health research and patient advocacy, serving as executive vice president of the National Breast Cancer Coalition, and then as a consultant to the director of the National Cancer Institute (NIH), as well as to leaders in not-for-profit advocacy organizations, foundations, and biotechnology /pharmaceutical companies. Projects have included strategic planning, branding, organizational turnarounds, and philanthropic planning as well as community and patient advocacy involvement in clinical trial initiatives, company-patient advocacy strategy and pre-approval drug initiatives such as expanded access programs. Ms. Reese-Coulbourne holds a BS in Chemistry from the University of Mary Washington and an MS in Chemical Engineering from the University of Virginia.

Melissa Robb joined the Center for Drug Evaluation and Research's (CDER), Office of Medical Policy 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.

Michael Rosenblatt, MD is executive vice president and chief medical officer of Merck & Co., Inc. He is the first person to serve in this role for Merck. Previously he served as dean of Tufts University School of Medicine. Prior to that, he held the appointment of George R. Minot professor of medicine at Harvard Medical School. He served as the president of Beth Israel Deaconess Medical Center (BIDMC) from 1999-2001. Previously, he was the Harvard faculty dean and senior vice president for Academic Programs at BIDMC. Prior to that, he served as director of the Harvard-MIT Division of Health Sciences and Technology, during which time he led a medical education organization for MD, PhD, and MD-PhD training jointly sponsored by Harvard and MIT. Earlier, he was senior vice president for research at Merck Research Laboratories where he co-led the worldwide development team for alendronate (FOSAMAX), Merck's bisphosphonate for osteoporosis and bone disorders. He is the recipient of the Fuller Albright award for his work on parathyroid hormone, the Vincent du Vigneaud award in peptide chemistry and biology, and the Chairman's Award from Merck. His research was in the field of hormone-receptor interactions, osteoporosis, and breast cancer metastasis to bone. He has been an active participant in the biotechnology industry, serving on the board of directors and scientific advisory boards of several biotech companies. He was a scientific founder of ProScript, the company that discovered bortezomib (Velcade), now Millennium Pharmaceutical's drug for multiple myeloma and other malignancies. He was a member of the Board of Scientific Counselors of the National Institute of Diabetes and Digestive and Kidney Diseases of the NIH. He has been elected to the American Society of Clinical Investigation, the Association of American Physicians, to Fellowship in the American Association for the Advancement of Science and the American College of Physicians, and the presidency of the American Society of Bone and Mineral Research. He has testified before a Senate hearing on U.S. biomedical research priorities in 1997, and in 2011 as a consultant to the U.S. President's Council of Advisors on Science and Technology. From 1981 to 1984, he served as chief of the endocrine unit at Massachusetts General Hospital. He received his undergraduate degree *summa cum laude* from Columbia and his MD *magna cum laude* from Harvard. His internship, residency, and endocrinology training were all at the Massachusetts General Hospital.

Thomas Scarnecchia, MSc is an accomplished life-science technology leader with significant experience as a senior executive, company officer, and technologist within the biopharmaceutical industry. Mr. Scarnecchia is CTO at Digital Aurora, a management consulting firm focused on information technology strategy and initiative management in the life science industry. He serves as executive director of the Observational Medical Outcomes Partnership, a public-private partnership for the FNIH. Prior to Digital Aurora, he was the vice president of corporate informatics at Millennium Pharmaceuticals. He provided overall strategy and leadership for Millennium's R&D Informatics organization including computational sciences and knowledge management. Mr. Scarnecchia was previously a member of the management board at R.W. Johnson Pharmaceutical Research Institute, a Johnson & Johnson Company. There he held various senior leadership positions including vice president of information management and technology. His life-sciences experience includes leadership roles at Janssen Research Foundation and Lederle Laboratories. He holds a master of science degree in computer science and a bachelor of science degree in biology, both from Pace University.

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.

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.

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 work packages 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.

John M. Taylor III, Esq. is the acting principal deputy commissioner and the counselor to the Commissioner in the Office of the Commissioner at the Food and Drug Administration (FDA) where he renders advice to the Commissioner on policy development, interpretation, and integration that cuts across program lines. He also provides leadership in advocating for and advancing the Commissioner's priorities for the development and management of emergency and crisis management policies and programs for FDA. In addition, he provides strategic oversight of FDA's participation in internal and external counter-terrorism and emergency exercises, and oversees the coordination of the Agency's evaluation of emergency and crisis situations. Mr. Taylor received his law degree in 1991 from the College of William and Mary. He started his career with the Food and Drug Administration in 1991. From 1991 to 1996, he worked in the Office of the Chief Counsel (OCC). In OCC he was responsible for all phases of criminal and civil litigation, involving violations of the Federal Food, Drug, and Cosmetic Act, and other federal laws. From 1992 to 1994, he also served as a Special Assistant United States Attorney as part of the Department of Justice's Generic Drug and Data Integrity Task Forces. He then moved to the Office of the Commissioner and became the Senior Advisor for Regulatory Policy. In the spring of 1999, he served as a Special Assistant to the Associate Commissioner for Regulatory Affairs. From April 2000 through July 2000, he served as the Acting Director of the Office of Compliance in the Center for Drug Evaluation and Research. From August 2000 through September 2002, Mr. Taylor served as the Director of the Office of Enforcement, before accepting the position of Associate Commissioner for Regulatory Affairs (ACRA). In this position, Mr. Taylor directed the Office of Regulatory Affairs' headquarters and field operations. Mr. Taylor served as ACRA from 2002 to 2005. In 2007, Mr. Taylor joined the Biotechnology

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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*.

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

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.