Sentinel Initiative Public Workshop

Participant Biographies

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.

Margaret Hamburg, MD is Commissioner of Food and Drugs, confirmed on May 18, 2009, by a unanimous Senate vote. The second woman to be nominated for the position, Dr. Hamburg is exceptionally qualified to serve with her training and experience as a medical doctor, scientist, and public health executive. Previously, Dr. Hamburg served as senior scientist as well as vice president for biological programs at the Nuclear Threat Initiative, a foundation dedicated to reducing the threat to public safety from nuclear, chemical, and biological weapons. In that position, she advocated broad reforms in public health infrastructure and policy – from local health departments to the national agency – in order to meet the dangers of modern bioterrorism as well as the threats of naturally occurring infectious diseases such as pandemic flu. Dr. Hamburg also served as assistant secretary for policy and evaluation at the U.S. Department of Health & Human Services, assistant director of the National Institute of Allergy and Infectious Diseases, and commissioner of the New York City Department of Health and Mental Hygiene. She was elected to membership in the Institute of Medicine in 1994. Dr. Hamburg graduated from Harvard Medical School, and completed her residency in internal medicine at what is now New York Presbyterian Hospital-Weill Cornell Medical Center, one of the top ten hospitals in the nation.

Kristen B. Rosati, JD is a partner in the law firm of Coppersmith Gordon Schermer & Brockelman PLC. Her practice concentrates in clinical research, electronic health records, health information privacy and security, and consent issues. Much of her work is at the intersection of these areas, including data sharing in collaborative research, the creation of data warehouses and tissue banks for research, and "secondary" uses of health information. Ms. Rosati chaired the legal work for the Adoption of Standard Policies Collaborative, part of the Health Information Privacy and Security Collaboration (HISPC) funded by the Office of the National Coordinator for Health Information Technology. She is outside general counsel to eHealth Initiative (eHI) and the Foundation for eHealth Initiative, nonprofit affiliated organizations at the cutting edge of health information exchange and health information technology policy. On behalf of eHI, Ms. Rosati has been involved in assisting with the creation of the FDA's Sentinel Initiative.

Jeffrey S. Brown, PhD is a lecturer in the department of population medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is also director of the HMO Research Network Center for Education and Research in Therapeutics (CERT) Data Coordinating Center housed at DPM, as well as research director of the Therapeutics Research and Infectious Disease program. 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 health care 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, and outcomes research. Dr. Brown holds a master's degree in economics from Tufts University and a PhD in social policy from Brandeis University. He is a seven-time national champion and three-time world champion in Ultimate Frisbee, and the men's ultimate frisbee coach at Tufts University.

Jennifer Nelson, PhD is an associate investigator and head of the Biostatistics Unit at Group Health Research Institute (GHRI). She also has an affiliate faculty appointment in the Department of Biostatistics at the University of Washington. During the past six years, Dr. Nelson's work has focused on GHRI's immunization safety and effectiveness research program, where she has provided statistical leadership within the national CDC-sponsored Vaccine Safety Datalink (VSD) project. As chair of the VSD's Methodology Committee, she promotes and leads multi-site research collaboration on active vaccine safety surveillance methods and practice. She also successfully led a recent contract evaluating signal detection methods for use in the Sentinel Initiative to improve post-licensure medical product safety surveillance. Dr. Nelson is looking forward to continuing this work as co-chair of the Methods Core for the recently established mini-Sentinel Coordinating Center.

Janet Woodcock, MD is director of the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA). Before becoming director, Dr. Woodcock held various leadership positions within the FDA Commissioner's office, including deputy commissioner and chief operating officer, deputy commissioner and chief medical officer, and director of Critical Path Programs. Dr. Woodcock also served as director of the Center for Drug Evaluation and Research at FDA from 1994 to 2005. 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 six Special Citations from FDA Commissioners.

Patrick Ryan, ME is a manager in statistical and quantitative sciences at GlaxoSmithKline Research and Development, where he has led several efforts to develop and apply exploratory analysis methods to better understand the effects of medicines. He also currently serves as the co-investigator of the Observational Medical Outcomes Partnership (OMOP), a public-private partnership managed by the Foundation for the National Institutes of Health and chaired by the Food and Drug Administration. As part of this effort, he is conducting methodological research to assess the appropriate use of observational health care data to identify and evaluate drug safety issues.

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 a member of the Association of American Medical Colleges' Advisory Panel on Research, the Food and Drug Administration's (FDA) Drug Safety and Risk Management Advisory Committee, and the Institute of Medicine Roundtable on Evidence-Based Medicine. He has also chaired the executive committee of the HMO Research Network, and 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 principal investigator of the FDA's mini-Sentinel program, the CDC-sponsored Center of Excellence in Public Health Informatics, the Agency for Healthcare Research and Quality (AHRQ)-sponsored HMO Research Network Center for Education and Research in Therapeutics, an AHRQ-sponsored HMO Research Network DEcIDE Center, the CDC-sponsored Eastern Massachusetts Prevention Epicenter, and an FDA contract to conduct post-marketing studies of drugs' safety and effectiveness. He is also co-principal investigator of a modeling infectious disease agent study, as well as the CDC-sponsored Harvard Pilgrim/Harvard Vanguard Medical Associates Vaccine Safety Datalink program.

Josh Benner, PharmD, ScD is a research director at the Engelberg Center for Health Care Reform 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.

Verne Rinker, JD, MPH serves as a health information privacy specialist with the Office for Civil Rights (OCR) at the U.S. Department of Health & Human Services (HHS), where he leads enforcement efforts for the Patient Safety and Quality Improvement Act of 2005. He serves as the primary contact for emergency preparedness and HIV/AIDS health information privacy issues and as a member of the health information privacy team that enforces the HIPAA Privacy and Security Rules. Prior to working for OCR, Mr. Rinker served in the Medicare Contractor Management Group in the Centers for Medicare & Medicaid Services (CMS). Verne began his career in late 1999 as a Presidential Management Intern with CMS. Through the intern program, he served in the HHS Office of the General Counsel and at the Office of Management and Budget. Mr. Rinker received a JD from the University of Houston Law School and an MPH from the University of North Carolina at Chapel Hill School of Public Health. He received a BS in biochemistry and a BA in science, technology, and public policy from North Carolina State University.

Jeffrey C. Torres, JD is a partner in the Chicago Office of Lathrop & Gage LLP as well as vice president and general counsel of Qual-Rx, Inc., a service-disabled veteran-owned health information techology business. He provides counsel to government contractors on matters involving the Federal Acquisition Regulations and other regulatory overlays particularly as they intersect with new technology. Mr. Torres has also advised and represented clients on a wide range of privacy issues both in the United States and internationally, including data security and regulatory compliance; employee privacy; Web site and online privacy issues; industry-specific privacy issues facing sectors such as financial services and health care; and international data protection.

Deven McGraw, JD, LLM, MPH is director of the Health Privacy Project at the Center for Democracy and Technology (CDT), where she focuses on developing and promoting public policies that ensure individual privacy as personal health information is shared electronically. Prior to joining CDT, Ms. McGraw was the chief operating officer of the National Partnership for Women & Families, providing strategic direction and oversight for all of the organization's core program areas. Ms. McGraw also was an associate in the public policy group at Patton Boggs, LLP and in the health care group at Ropes & Gray. Previously, she served as deputy legal counsel to the Governor of Massachusetts and taught in the Federal Legislation Clinic at the Georgetown University Law Center.

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 JD from Columbia Law School.

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.

Arthur L. Holden, MBA is chairman and founder of the Pharmaceutical Biomedical Research Consortium, Ltd. (PBRC), as well as chairman, chief executive officer, and founder of the Serious Adverse Event Consortium, Ltd. PBRC is a 501(c)(3) that serves to advance the field of medicine through the development and implementation of high-quality "pre-competitive" biomedical research consortia across the pharmaceutical industry and academia. Currently, a major international effort is underway, focusing on the pharmacogenetics of serious adverse drug reactions with the Serious Adverse Event Consortium. Previously, Mr. Holden was senior vice president of corporate and market development at Illumina, as well as founder, chairman, and chief executive officer of First Genetic Trust. He served as chairman and CEO of the SNP Consortium Ltd., a nonprofit entity dedicated to creating a high-quality, high-density single nucleotide polymorphism (SNP) map of the human genome. He earned his MBA with honors in 1981 from Northwestern's J.L. Kellogg Graduate School of Management, and is a 1977 graduate of Union College with a bachelor's degree in science, magna cum laude.

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

Judy Racoosin, MD, MPH is the scientific lead for the Sentinel Initiative for the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). There, she leads efforts to develop the data infrastructure and scientific methodologies needed to enable FDA to conduct active surveillance in automated health care data sources such as administrative claims databases and electronic health record systems. Dr. Racoosin has worked at the FDA on pre- and post-market safety issues and safety policy for more than 13 years. Previously, she was the senior safety policy advisor in CDER's Office of the Center Director. She was also a member of 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.

Carolyn Clancy, MD is director of the Agency for Healthcare Research and Quality (AHRQ). Prior to her appointment, Dr. Clancy served as the agency's acting director and was previously director of AHRQ's Center for Outcomes and Effectiveness Research. Dr. Clancy holds an academic appointment at George Washington University School of Medicine and serves as senior associate editor for *Health Services Research*. She is a member of the Institute of Medicine and was elected a Master of the American College of Physicians in 2004. Dr. Clancy, who is a general internist and health services researcher, is a graduate of Boston College and the University of Massachusetts Medical School. Her major research interests include health care quality and patient safety, and reducing health care disparities.

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 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.

Rachel E. Behrman, MD, MPH is acting associate director for 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.