Sentinel Initiative Public Workshop
Participant Biographies

Rachel Behrman, MD, MPH is the associate director for Medical Policy and director of the Office of 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. Behrman 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.

David Blumenthal, MD, MPP serves as the national coordinator for Health Information Technology under President Barack Obama. In this role he is charged with building an interoperable, private, and secure nationwide health information system and supporting the widespread, meaningful use of health IT. Dr. Blumenthal received his undergraduate, medical, and public policy degrees from Harvard University and completed his residency in internal medicine at Massachusetts General Hospital. Prior to his appointment to the administration, Dr. Blumenthal was a practicing primary care physician; director, Institute for Health Policy; and the Samuel O. Thier Professor of Medicine and Professor of Health Policy at the Massachusetts General Hospital/Partners HealthCare System and Harvard Medical School. Dr. Blumenthal is a renowned health services researcher and national authority on health IT adoption. With his colleagues from Harvard Medical School, he authored the seminal studies on the adoption and use of health IT in the United States. He is the author of over 200 scholarly publications, including most recently, "Heart of Power: Health and Politics in the Oval Office," which tells the history of U.S. Presidents' involvement in health reform, from FDR through George W. Bush. A member of the Institute of Medicine and a former board member and national correspondent for the *New England Journal of Medicine*, Dr. Blumenthal has held several leadership positions in medicine, government, and academia including senior vice president at Boston's Brigham and Women's Hospital; executive director of the Center for Health Policy and Management and lecturer on Public Policy at the Kennedy School of Government; and as a professional staff member on Senator Edward Kennedy's Senate Subcommittee on Health and Scientific Research. He was the founding chairman of AcademyHealth and served previously on the boards of the University of Chicago Health System and of the University of Pennsylvania Health System. He is recipient of the Distinguished Investigator Award from AcademyHealth, and a Doctor of Humane Letters from Rush University.

Lesley Curtis, PhD is associate professor of medicine in the Duke University School of Medicine and works primarily in the Center for Clinical and Genetic Economics. A health services researcher by training, Dr. Curtis oversees a portfolio of projects that use observational data to address questions related to clinical and comparative effectiveness, pharmacoepidemiology, health care delivery, and epidemiological trends. Dr. Curtis has considerable experience analyzing Medicare claims data, large clinical registries, and prescription drug data, and has led the linkage of large clinical registries with longitudinal Medicare claims data. She is a co-investigator for the AHRQ-sponsored Cardiovascular Center for Education and Research on Therapeutics (CERTS), the director of the Duke DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) center, and co-leads the Data Core for FDA's Mini-Sentinel program.

Bruce Fireman, MA is a biostatistician and research scientist at the Division of Research, Kaiser Permanente Northern California. His research interests include assessment of the effectiveness and safety of vaccines and drugs, and the costs and outcomes of health care delivery systems. He works with population-based data, comparing the effectiveness of alternative treatments and alternative ways of delivering healthcare. He has evaluated disease management programs, Web-based care and primary care teams. He has collaborated with Kaiser Permanente clinicians and administrators in efforts to improve health services.

Brian Gallagher, RPh, JD serves as senior vice president of Government Affairs at the American Pharmacists Association (APhA). Prior to joining APhA, he was Rite Aid's vice president for Regulatory Compliance. Mr. Gallagher graduated from West Virginia University School of Pharmacy in 1981 and Wake Forest University School of Law in 1984. He previously served as vice president of Risk Management and Governance for NDCHealth and General Counsel for TechRx, Inc. For three years he was director of Pharmacy Regulatory Affairs for the National Association of Chain Drug Stores. He served in the West Virginia Legislature for eight years in a variety of leadership positions where, among other legislation, he authored the West Virginia Pharmacy Practice Act. Mr. Gallagher is also an adjunct assistant professor at West Virginia University School of Pharmacy teaching pharmacy law. He spent 11 years as general counsel for West Virginia University Hospitals and practiced hospital, chain and independent pharmacy.

Sherry Glied, PhD, MA was sworn-in as the assistant secretary for Planning and Evaluation at the U.S. Department of Health and Human Services on July 1, 2010. Previously, Dr. Glied was department chair and professor in the Department of Health Policy and Management of Columbia University's Mailman School of Public Health. In 1992–1993, she served as a senior economist for health care and labor market policy on the President's Council of Economic Advisers under Presidents Bush and Clinton, and participated in the Clinton Health Care Task Force. She has been elected to the Institute of Medicine of the National Academy of Sciences and to the Board of AcademyHealth. She was a member of the Congressional Budget Office's Panel of Health Advisers. Dr. Glied's principal areas of research are in health policy reform and mental health care policy. Her book on health care reform, *Chronic Condition*, was published by Harvard University Press in January 1998. Her latest book, with Richard Frank, is *Better But Not Well: Mental Health Policy in the U.S. since 1950*, which was published by The Johns Hopkins University Press in 2006. Dr. Glied holds a BA in economics from Yale University, an MA in economics from the University of Toronto, and a PhD in economics from Harvard University.

J. Leonard Lichtenfeld, MD, MACP is deputy chief medical officer for the American Cancer Society. Among his responsibilities is directing the Society's Cancer Control Science Department. This group of internationally-recognized experts focuses on the prevention and early detection of cancer, as well as emerging science and trends in cancer. The department is responsible for producing the Society's widely recognized guidelines for the prevention and early detection of cancer, including the role of nutrition and physical activity. In addition, Dr. Lichtenfeld oversees the Society's cancer control programs in health disparities, global health, and the preventive health partnership with the American Heart Association and the American Diabetes Association. Dr. Lichtenfeld is recognized as a resource both within and outside the Society for his expertise in oncology and medical affairs. He serves as a liaison for the Society with many professional and public organizations, and is a frequent spokesperson on behalf of the Society on a variety of cancer related subjects. A board-certified medical oncologist and internist who was a practicing physician for over 19 years, Dr. Lichtenfeld has long been active in medical affairs on a local, state, and national level. He is active in several state and national medical organization and advisory committees. He is a member of the Relative Value Update Committee (RUC) of the American Medical Association, which works with the Centers for Medicare & Medicaid Services to update the Medicare physician fee schedule (RBRVS). He has a long-standing interest in legislative and regulatory issues, quality medical care, and the role of health information technology in health care delivery. Dr. Lichtenfeld

is a graduate of the University of Pennsylvania and Hahnemann Medical College (now Drexel University College of Medicine) in Philadelphia. His postgraduate training was at Temple University Hospital in Philadelphia, Johns Hopkins University School of Medicine and the National Cancer Institute in Baltimore. He is a member of Alpha Omega Alpha, the national honor medical society. Dr. Lichtenfeld has received several awards in recognition of his efforts on behalf of his colleagues and his professional activities. He has been designated a Master of the American College of Physicians in acknowledgement of his contributions to internal medicine. Dr. Lichtenfeld is married, and resides in Atlanta and Thomasville, Georgia.

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.

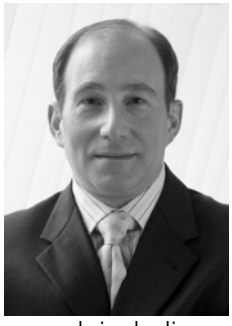
Samuel Nussbaum, MD is executive vice president, clinical health policy and chief medical officer for WellPoint, Inc. He oversees corporate medical policy, clinical pharmacy programs, and programs in clinical excellence. His principal responsibilities include serving as chief spokesperson and policy 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 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 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.

Kristen Rosati, JD is a partner in the law firm of Coppersmith 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" use of health information. She has been listed in Best Lawyers in America for health care since 2007. Ms. Rosati is a member of the American Health Lawyers Association (AHLA) Board of Directors, serves as Secretary on its Executive Committee, and chairs its Professional Resources Committee. She has also chaired the AHLA Quality Council and AHLA's Health Information and Technology Practice Group. Ms. Rosati is assisting with the creation of the FDA Sentinel Initiative, an effort to create a national electronic distributed network to monitor medical product safety. She is serving on the Privacy Panel for the "Mini-Sentinel Coordinating Center" at Harvard Pilgrim, is on the Brookings Active Surveillance Implementation Council (BASIC), and served on the planning committee for "Legal Issues in Active Medical Product Surveillance" conference sponsored by the Engelberg Center for Health Care Reform at the Brookings Institution. Ms. Rosati is working with Battelle Memorial Institute's Technology Partnership Practice in the Arizona Translational Resource Network (AzTransNet), an effort by the Arizona Biomedical Research Commission to build clinical and translational research capacity in Arizona. AzTransNet is working to serve the needs of research sites across Arizona's biomedical community, including developing a "virtual" tissue bank, creating educational and compliance resources and assisting in the creation of collaborative IRB resources. On behalf of the Arizona Hospital and Healthcare Association, she developed a Clinical Research Policies Handbook. Ms. Rosati chairs the Legal Committee for Arizona Health-e Connection and the Health Information Network of Arizona, Arizona's e-health initiatives, and was a member of the National Governor's Association State Alliance for e-Health, Health Information Protection Task Force. She 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, non-profit affiliated organizations at the cutting edge of health information exchange and health information technology policy. Ms. Rosati is a member of the Advisory Board for the Arizona State University (ASU) Biomedical Informatics Department and was a founding Executive Committee member of the ASU Center for Health Care Innovation and Clinical Trials. She is also an adjunct professor of law and frequent guest lecturer at ASU. Ms. Rosati lectures nationally on clinical research, electronic health records, and HIPAA and has written numerous articles and book chapters on these issues. Ms. Rosati received her BA, with high honors, and her JD, *cum laude*, from the University of Michigan.



Daniel Troy, JD joined GlaxoSmithKline as senior vice president and general counsel in September 2008. Mr. Troy was previously a partner of the Life Sciences Practice & Appellate Litigation Group at Sidley Austin LLP where he regularly represented pharmaceutical and biotechnology companies before the U.S. Food and Drug Administration (FDA) and other federal government agencies. He was chief counsel of FDA from 2001 until 2004. In that capacity, he reviewed and approved major regulations and important guidances issued during that time, and oversaw the agency's litigation. Before serving as FDA's chief counsel, he was a partner at Wiley, Rein and Fielding, a Washington, DC law firm specializing in constitutional and administrative law issues. Mr. Troy has argued more than a score of cases to federal and state courts of appeal, including a successful appearance before the U.S. Supreme Court. He was also an associate scholar at the American Enterprise Institute, writing *Retroactive Legislation* (AEI Press 1998). He has also published articles in *Commentary, The Wall Street Journal, the Weekly Standard, the Washington Times, National Review, Legal Times*, and others. Mr. Troy is a contributor to the *Cato Supreme Court Review* and the *Heritage Guide to the Constitution.* His writing on commercial speech, which includes his article "Advertising: Not Low Value Speech" in the *Yale Journal of Regulation* has been cited by the California Supreme Court, as well as justices of the U.S. Supreme Court. From 1987-1989 he served in the Office of Legal Counsel of the U.S. Department of Justice as an attorney-advisor. From 1983-1984 Mr. Troy clerked for D.C. Circuit Judge Robert Bork. He has served as a lecturer-in-law at his alma mater where he was a Book Review Editor of the *Law Review*, a Harlan Fiske Stone Scholar, and a James Kent Scholar. He has served on numerous committees and was the chairman of the American Bar Association's Section of Administrative Law and Regulatory Policy from 2006-2007. Previous to that, he was an adjunct scholar at the American Enterprise Institute in Washington, DC. He was recently named one of Washington's Best Lawyers in food and drug and in administrative law. Mr. Troy received his undergraduate degree from Cornell University's School of Industrial and Labor Relations and his law degree from Columbia Law School.

Reed 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.

Myrl Weinberg, MA has served as president of the National Health Council (NHC) since 1996. The NHC brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Ms. Weinberg's extensive career has focused on health care delivery, medical research, long-term care, and related issues that affect people with chronic conditions. She has testified repeatedly before Congress and federal regulatory bodies and is a frequent speaker on the patient perspective in health policy. Ms. Weinberg currently serves on the Coalition Against Major Diseases Coordinating Committee and The Center for Information and Study on Clinical Research Participation Board of Advisors. She is a former chair of the International Alliance of Patients' Organization Governing Board.

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.

Diana Zuckerman, PhD is the president of the National Research Center for Women & Families, a nonprofit research and education organization that works to improve policies and programs that affect the health of adults and children. She is a frequently quoted expert on health and health policy, especially FDA issues. She worked with Members of Congress and their staff to strengthen patient safeguards in FDAAA and has testified about medical products and FDA policies several dozen times before Congress, FDA Advisory Committees, and the FDA Science Board. After starting her career as a faculty member at Vassar and Yale and a researcher at Harvard, Dr. Zuckerman worked as a Congressional staffer on health policy issues in the U.S. House of Representatives and Senate. She then served as a senior policy advisor in the Clinton White House. She has been president of the National Research Center for Women & Families since 1999, and a fellow at the University of Pennsylvania Center for Bioethics for several years. She serves on the Board of Directors of the Reagan-Udall Foundation and the Alliance for a Stronger FDA. She is the author of five books, several book chapters, and dozens of articles in academic journals and national newspapers.