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.

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.

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 FDA's Mini-Sentinel program, and of contracts with FDA's Center for Drugs 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.

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.

Judy Racoosin, MD, MPH is Sentinel Initiative scientific lead 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 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 B. Rosati, JD is 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" 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.

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.

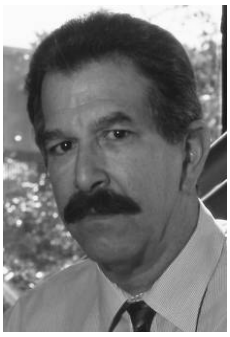
Joy Pritts, JD joined the Office of the National Coordinator for Health Information Technology (ONC) in February 2010 as chief privacy officer. Ms. Pritts provides critical advice to the Secretary and the National Coordinator in developing and implementing ONC's HITECH privacy and security programs. Prior to joining ONC, Ms. Pritts was on the faculty at Georgetown University where she held a joint appointment as a senior scholar with the O'Neill Institute for National and Global Health Law and as a research associate professor with the Health Policy Institute. Her work has focused on the critical issues surrounding the privacy of health information and patient access to medical records at both the federal and state levels. She has written extensively on such topics as the HIPAA Privacy Rule, federal alcohol and substance abuse confidentiality laws, and the confidentiality of health information in research. She has worked closely with national consumer organizations and federal policymakers on ensuring the protection of health information. Ms. Pritts has most recently participated in a number of federal HIT initiatives including serving on the Technical Advisory Panel for the multi-state Health Information Security and Privacy Collaborative (HISPC) and as a board member of the National Governors Association's State Alliance for e-Health. Ms. Pritts holds a law degree from Case Western Reserve University School of Law, and a Bachelor of Arts degree from Oberlin College.

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.

Barbara Evans, PhD, JD, MS, LLM is a member of the health law faculty and co-director of the Health Law & Policy Institute and Center on Biotechnology & Law at the University of Houston Law Center. Her research interests include governance, privacy, and financing issues with large health information networks and tissue repositories; regulatory and judicial uses of evidence from large-scale observational studies; and legal barriers to clinical translation of pharmacogenomics. Earlier in her career, she was a partner in the international regulatory practice of a large New York law firm and subsequently advised clients on U.S. privacy, research, and medical device regulatory matters. Prior to joining the University of Houston Law Center, she was a research professor of medicine and director of the program in Pharmacogenomics, Ethics, and Public Policy at the Indiana University School of Medicine/Center for Bioethics. She holds an electrical engineering degree from the University of Texas at Austin; MS and PhD degrees from Stanford University; a JD from Yale Law School; an LLM in Health Law, and she completed a post-doctoral Fellowship in Clinical Ethics at the M.D. Anderson Cancer Center.

Jerry Menikoff, MD, JD is director of the federal Office for Human Research Protections, which leads the Department of Health and Human Services' efforts to ensure the responsible conduct of research involving human subjects. He is a former director of the Office of Human Subjects Research at the National Institutes of Health (NIH), where he was responsible for the oversight of NIH's human research protection program. Prior to joining the NIH, he was associate professor of law, ethics and medicine at the University of Kansas (KU), and was director of KU's Institute for Bioethics, Law and Public Policy. has been a faculty fellow at the MacLean Center for Clinical Medical Ethics at the University of Chicago, and at the Center for Ethics and the Professions at Harvard University. He also

has been on the faculty of the University of Chicago School of Law and other law schools. He is the author of the textbook *Law and Bioethics: An Introduction* (Georgetown University Press, 2001), and *What the Doctor Didn't Say: The Hidden Truth about Medical Research* (Oxford University Press, 2006).



Kenneth W. Goodman, PhD, FACMI is founder and director of the University of Miami Bioethics Program and its Pan-American Bioethics Initiative and co-director of the university's Ethics Programs, including its Business Ethics Program. The Ethics Programs have recently been designated a World Health Organization Collaborating Center in Ethics and Global Health Policy, one of six in the world and the only one in the United States. Dr. Goodman is a professor of medicine at the University of Miami with appointments in the Department of Philosophy, Department of Epidemiology and Public Health, Department of Electrical and Computer Engineering, School of Nursing and Health Studies and Department of Anesthesiology. He chairs the Ethics Committee of the American Medical Informatics Association, for which organization he co-founded the Ethical, Legal, and Social Issues Working Group. He is a Fellow of the American College of Medical Informatics, the only philosopher or ethicist to be elected. His research has emphasized issues in health information technology, including bioinformatics, or the use of computers, in genetics, and in epidemiology and public health. Current funded work includes a National Institutes of Health/Fogarty International Center grant to help expand research ethics education around the Americas. He recently led a Robert Wood Johnson Foundation-funded project to identify and address ethical issues in the use of electronic personal health records.

Laura Youngblood, MPH, CIP is a health scientist in the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) at the Centers for Disease Control and Prevention (CDC). An expert in human subjects research regulations, Ms. Youngblood serves as the National Center authority for determining the applicability of research regulations and IRB liaison. Ms. Youngblood has served as an Institutional Review Board (IRB) member since 2005, and is currently the vice-chair of one of CDC's 5 Atlanta-based IRBs. Trained as an epidemiologist, Ms. Youngblood began her career as a researcher in CDC's Division of Viral and Rickettsial Diseases. Before assuming her current position in 2007, she worked as an IRB Administrator in CDC's Human Research Protection Office and as a Health Scientist in CDC's Division of Parasitic Diseases.

Kate Cook, JD is a regulatory counsel in the Office of the Center Director at the Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research. She has also worked in the Office of the Center Director at FDA's Center for Devices and Radiological Health, and was an associate chief counsel for 14 years in FDA's Office of Chief Counsel. At FDA, Ms. Cook has worked on regulations, guidances, and other matters related to the regulation of biological products, combination products, and medical devices, with a particular focus on issues related to clinical trials and human subject protection.

Stanley B. Watson, JD, MA has been the director of Kaiser Foundation Research Institute since February 2006. In that position, he is the authorized organizational official for federal research funding and is the institutional official for Kaiser Permanente's Federalwide Assurance regarding human subjects protection. Mr. Watson joined Kaiser Permanente in 1993, in the National Legal Department of Kaiser Foundation Hospitals/Health Plan, Inc. His practice focused on health and hospital issues including patient treatment issues, bioethics, issues relating to human subject experimentation and research integrity, and regulation of emergency department treatment delivery. Prior to joining Kaiser Permanente, Mr. Watson was a consultant with the Bioethics Consultation Group, Inc., of Berkeley, California, 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, California, 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, California, in 1990.

Heidi Garwood, JD has served as in-house counsel of Humana since 1999, with primary legal responsibility for all Humana business in Florida and Puerto Rico. In her capacity as senior legal counsel, Ms. Garwood manages the vast majority of legal, regulatory and contractual issues affecting Humana's operations in Florida and Puerto Rico. She also has primary responsibility over legal issues relating to research and HIPAA privacy. Prior to joining Humana, Ms. Garwood served for two and a half years as the director of governmental relations for the Florida Association of HMOs (now known as Florida Association of Health Plans), managing and helping to set the HMO industry's legislative agenda. From 1994 through 1997, she was senior attorney with the Agency for Health Care Administration, advising the agency on a wide variety of Medicaid and HMO issues and representing the Agency in a number of cases involving Medicaid fraud and abuse. Ms. Garwood began her health care law career as an intern of the House Health Care Committee. Upon graduation, she joined the statewide law firm, Carlton Fields, where she was an associate for three years.

Daniel E. 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. He was also chief counsel of the Food and Drug Administration (FDA) from 2001 to 2004. Before serving as FDA's chief counsel, he was a partner at Wiley, Rein and Fielding, 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 been published in *Commentary*, the *Wall Street Journal*, the *Weekly Standard*, the *Washington Times*, *National Review*, *Legal Times*, and others. 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 was the chairman of the American Bar Association's Section of Administrative Law and Regulatory Policy from 2006-2007. Mr. Troy 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.