Biographies

Jeff Allen, PhD serves as the executive director of Friends of Cancer Research (Friends), a cancer research think tank based in the Washington, D.C. area. Working with the entire cancer research and advocacy community, Friends pioneers innovative public-private partnerships, organizes critical policy forums, educates the public, and brings together key stakeholders to overcome the barriers standing between patients and the most promising cancer treatments. Prior to joining Friends, Dr. Allen was an endocrinology fellow in the Laboratory of Clinical Investigation of the National Center for Complementary and Alternative Medicine at the National Institutes of Health. His background in cancer research focused upon molecular changes associated with cancer formation as well as treatments to prevent cancer progression. Dr. Allen has been published in numerous policy and medical journals. Dr. Allen serves on C-Change's Chemoprevention Advisory Committee, Patent Law Advisory Subcommittee and the Clinical Trials and Biomarker Workgroup. Allen is also a member of the National Health Council FDA Issue Team, serves on the Global Access Project of the National Patient Advocacy Foundation, and was recently named to the National Cancer Institute Director's Consumer Liaison Group federal advisory committee. Jeff is also a thought leader is Comparative Effectiveness Research and recently served as the organizing author of a 2009 report, "Improving Medical Decisions Through Comparative Effectiveness Research: Cancer as a Case Study" co-authored by a 25 member academic committee. Dr. Allen received his PhD in cell and molecular biology from Georgetown University, and holds a Bachelors of Science in Biology (cum laude) from Bowling Green State University.

Naomi Aronson, PhD is the executive director of the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Dr. Aronson has overseen TEC's development as a nationally recognized technology assessment program and an Evidence-based Practice Center of the Agency for Healthcare Research and Quality (AHRQ). She has directed over 300 technology assessments and 15 evidence reports for AHRQ. Dr. Aronson is a member of the Methodology Committee of the Patient-Centered Outcomes Research Institute. She represented the private sector on a U.S. Agency for International Development Team providing technical assistance to the Hungarian government on building evidence-based medicine capacity in the national health insurance system. She was a member of the 2007 Ontario Health Technology Assessment Evaluation Review Team. Dr. Aronson is a member of the Institute of Medicine Forum on Drug Discovery Translation and Development, the Institute of Medicine Genomics Roundtable, the Steering Committee of the Chicago-Area DEcIDE Research Center, the National Business Group on Health Committee on Evidence-Based Benefit Design, and a review committee co-chair for the International Society for Pharmacoeconomics and Outcomes Research 14th Annual International Meeting. Previously, Dr. Aronson was a member of the Northwestern University faculty, specializing in the sociology of science and medicine. She also was a post-doctoral fellow in the Science, Technology and Society Program at the Massachusetts Institute of Technology and received research awards from the National Science Foundation and the American Council of Learned Societies. Dr. Aronson's academic research focused on how the organization of scientific specialties in biomedical and clinical research affects the process of scientific discovery.

Donald Berry, PhD is a professor in the Department of Biostatistics of the University of Texas MD Anderson Cancer Center. He was founding Chair of this department in 1999. Dr. Berry received his PhD in statistics from Yale University, and previously served on the faculty at the University of Minnesota and at Duke University. He has held endowed faculty positions at Duke University and MD Anderson. Since 1990 he has served as a faculty statistician on the Breast Cancer Committee of the Cancer and Leukemia Group B (CALGB), a national oncology group. In this role he has designed and supervised the conduct of many large U.S. intergroup trials in breast cancer. Through Berry Consultants, LLC he has designed many innovative clinical trials for pharmaceutical and medical device companies and for federally funded collaborations in a variety of diseases. He is well known as a developer of Bayesian adaptive designs that efficiently use information that accrues over the course of the trial. These trials minimize sample size while increasing the likelihood of detecting drug activity. Under his direction the Department of Biostatistics at MD Anderson designed over 300 clinical trials that take a Bayesian approach. He is co-developer (with Giovanni Parmigiani) of BRCAPRO, a widely used program that provides individuals' probabilities of carrying mutations of breast/ovarian cancer susceptibility genes BRCA1 and BRCA2. Dr. Berry is the author of several books on biostatistics and over 300 published articles, including first-authored articles in the New England Journal of Medicine, the Journal of the American Medical Association, and Nature. Dr. Berry has been the principal investigator for numerous research grants from the National Institutes of Health and the National Science Foundation. He is a fellow of the American Statistical Association and of the Institute of Mathematical Statistics.

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 U.S. 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.

Gregory W. Daniel, PhD, MPH, RPh is a fellow in Economic Studies and managing director for Evidence Development and Innovation in the Engelberg Center for Health Care Reform at the Brookings Institution. In this position, Dr. Daniel oversees and provides strategic direction regarding the Center's evidence development and biomedical innovation portfolio, including medical product safety surveillance, regulatory science and U.S. Food and Drug Administration policy issues, comparative effectiveness research, and other biomedical innovation policies. Dr. Daniel was previously Vice President, Government and Academic Research and HealthCore (subsidiary of WellPoint,

Inc) where he led a division responsible for providing research services in the areas of pharmacoepidemiology, drug, vaccine, and biologic safety evaluations, comparative effectiveness research, and health economics and outcomes research. His research has utilized electronic health insurance claims data integrated with clinical data including laboratory results, electronic hospital data, and paper-based and electronic medical record data, and registries. Dr. Daniel is a registered pharmacist and holds a PhD in Pharmaceutical Economics, Policy, and Outcomes Research with a minor in Epidemiology from the University of Arizona, an MPH specializing in biostatistics, an MS in Pharmaceutical Administration, and a BS in Pharmacy, all from The Ohio State University.

James C. Greenwood is president and chief executive officer of the Biotechnology Industry Organization in Washington, D.C., which represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. Mr. Greenwood represented Pennsylvania's Eighth District in the U.S. House of Representatives from January 1993 through January 2005. A senior member of the Energy and Commerce Committee, he was widely viewed as a leader on health care and the environment. From 2001 to 2004, Mr. Greenwood served as Chairman of the Energy and Commerce Committee Subcommittee on Oversight and Investigation with oversight authority over issues in the full Committee's vast jurisdiction. He led hard-hitting investigations into corporate governance at Enron, Global Crossing and WorldCom; terrorist threats to our nation's infrastructure; and waste and fraud in federal government agencies. Prior to his election to Congress, Mr. Greenwood served six years in the Pennsylvania General Assembly (1981-86) and six years in the Pennsylvania Senate (1987-1992). Mr. Greenwood graduated from Dickinson College in 1973 with a BA in Sociology. From 1977 until 1980, he worked as a caseworker with abused and neglected children at the Bucks County Children and Youth Social Service Agency.

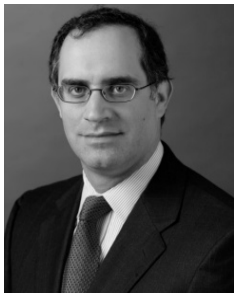
Margo Heath-Chiozzi, MD is vice president, Global Regulatory Sciences - Global Virology Strategy at Bristol-Myers Squibb (BMS). Dr. Heath-Chiozzi has been responsible for guiding the development and execution of global regulatory strategy for products in the HIV, HCV and oncology areas for the past eight years. Prior to joining BMS, Margo worked at Abbott in several medical and management roles including participation in the development programs for ritonavir and Kaletra. She also served as Abbott's first medical director for pharmacognetics for three years. Prior to Abbott, Dr. Heath-Chiozzi was a clinical investigator in HIV medicine and held academic appointments at Harvard and the University of Hawaii. Dr. Heath-Chiozzi received her BS and MD from the University of Utah; did her Internal Medicine residency training at Duke; and completed an Infectious Diseases fellowship at the Harvard affiliated hospitals in Boston. She has authored more than 50 articles, book chapters and scientific abstracts.

Kathleen M. Hewitt, MSN, RN is associate vice president for the National Cardiovascular Data Registry (NCDR™) of the American College of Cardiology. In this, role Ms. Hewitt is responsible for the management and operation of a broad range of data registries for measuring and improving quality patient care throughout the nation. Under Ms. Hewitt's leadership, the NCDR™ has grown into an unprecedented gold standard quality measurement program and research infrastructure that over 2,500 hospitals and healthcare system participate.

Louis B. Jacques, MD joined the Centers for Medicare & Medicaid Services (CMS) in 2003 and has been director of the Coverage and Analysis Group (CAG) since October 2009. The CAG group reviews evidence and develops Medicare national coverage policy. From 2004 through 2009 he was Director of the Division of Items and Devices within CAG. Prior to his arrival at CMS, Dr. Jacques was the Associate Dean for Curriculum at Georgetown University School of Medicine, where he

retains a faculty appointment. He served on a number of university committees including the Executive Faculty, Committee on Admissions and the Institutional Review Board. He previously worked in the Palliative Care program at Georgetown's Lombardi Cancer Center where he covered the gynecologic oncology service and he made home visits as a volunteer physician for a rural hospice on the Maryland Eastern Shore.

Russell Katz, MD joined the U.S. Food and Drug Administration as a medical officer in 1983, where he is currently the Director of the Division of Neurology Products (previously called the Division of Neuropharmacological Drug Products). He has lectured extensively on various aspects of neurologic drug development as well as written numerous articles on the same issues. He received his BA in mathematics from Queens College in New York City and his medical degree from Albert Einstein College of Medicine in New York City, and completed his residency in Neurology in 1982 at the Einstein affiliated hospitals in New York.



Jonathan S. Leff, MBA is based in New York and joined Warburg Pincus in 1996. He is a member of the firm's Healthcare Group and leads the firm's investment efforts in biotechnology and pharmaceuticals. Prior to joining Warburg Pincus, he was a consultant at Oliver, Wyman & Co. Mr. Leff received an AB in government from Harvard University and an MBA from the Stanford University Graduate School of Business. Mr. Leff is a director of Allos Therapeutics, InterMune, Protox Therapeutics, ReSearch Pharmaceutical Services Inc., Rib-X Pharmaceuticals and Talon Therapeutics. He also is a director of the Spinal Muscular Atrophy Foundation and a member of the Executive Committee of the Board of Visitors of Columbia University Medical Center. In addition, Mr. Leff is a member of the boards of directors of the National Venture Capital Association and the Emerging Companies Section of the Biotechnology Industry Organization.

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 U.S. 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.

Jeffrey S. Murray, MD, MPH is deputy director for the Division of Antiviral Products (DAVP) in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). He has worked in the Division in various capacities for 19 years. At DAVP, Dr. Murray has reviewed and approved applications for numerous HIV drugs, influenza drugs, and applications for hepatitis B and C products. He has co-authored FDA guidance documents in HIV drug development, development of HIV drugs for the President's Emergency Plan for AIDS Relief and the development of drugs for the treatment of Influenza and Chronic Hepatitis C. Dr Murray received his MD from

The Ohio State University, in Columbus, and his MPH in Epidemiology and Biostatistics from George Washington University in Washington, D.C. He completed his internship, residency and chief residency in Internal Medicine at Riverside Methodist Hospitals in Columbus, followed by a fellowship in Infectious Diseases (1990-1992) at the University of Cincinnati Medical Center in Cincinnati, Ohio. Dr Murray is board certified in Internal Medicine and Infectious Diseases.

Garry Neil, MD is corporate vice president, Corporate Office of Science and Technology at Johnson & Johnson World Headquarters in New Brunswick, NJ. In this role, Dr. Neil leads a team that catalyzes sustained growth for Johnson & Johnson by identifying and launching emerging technologies that underpin the creation of future businesses. Dr. Neil has broad experience in science, medicine and pharmaceutical development. He has held a number of senior positions within Johnson & Johnson, 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.

Daniel Perry is the president and chief executive officer of the not-for-profit Alliance for Aging Research in Washington, D.C. Founded in 1986, the Alliance is a leading U.S. citizen advocacy organization for promoting a broad agenda of medical and scientific research to improve the health and independence of older people. Mr. Perry's background spans a wide range of health policy, governmental, political and journalistic experience. Mr. Perry held staff positions for more than a dozen years on Capitol Hill in Washington, D.C. He has been a key advisor on aging and medical research policies to democratic and republican legislators and presidents. He has led a number of large and politically potent coalitions advancing research in aging, Alzheimer's disease and for embryonic stem cell research. He is an advisor to the Institute on Aging of the University of Pennsylvania Medical School, a member of the New York Academy of Sciences, and a member of the National Advisory Council on Aging – having been appointed in 2010 by Health and Human Services Secretary Kathleen Sebelius. As a journalist he was the recipient of many awards and citations, including a nomination for the Pulitzer Prize.

Richard Platt, MD, MSc is a professor and chair of the Department of Population Medicine at Harvard Medical School and executive director of the Harvard Pilgrim Health Care Institute. He is principal investigator of the U.S. Food and Drug Administration (FDA) Mini-Sentinel program, of contracts with FDA's Center for Drugs Evaluation and Research and Center for Biologics Evaluation and Research to conduct post-marketing studies of drugs' and biologics' safety and effectiveness. He chaired the FDA's Drug Safety and Risk Management Advisory Committee, 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 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 HMO Research Network DEcIDE Center, and a CDC Prevention Epicenter.

Peter Saltonstall has been the president and chief executive officer of National Organization for Rare Diseases (NORD) since 2008. In the past three years, he has forged new relationships between the patient community and Congress, U.S. Food and Drug Administration (FDA), National Institutes of Health and Social Security Administration, along with drug/device companies and the medical/academic and investment communities. His efforts to build collaborations with all stakeholders stems from his view that advances for the patient community can be achieved best through joint efforts. Under Mr. Saltonstall's leadership, NORD also has updated and expanded its Patient Assistance Programs, which include assistance to patients in need of medications that they cannot afford. In addition, he has initiated steps to globalize the rare disease patient community and to facilitate research into new therapies and assure access by patients. Before joining NORD, Mr. Saltonstall had more than 30 years of healthcare experience in both for-profit and not-for-profit environments. He held senior positions with a number of major academic medical centers and organizations, including Harvard's Brigham and Women's Hospital, Tufts-New England Medical Center and St. Elizabeth's Medical Center of Boston. He also helped launch Harvard Risk Management Foundation's startup venture, Risk Management Strategies, and the University of Pittsburgh Medical Center's private equity arm, Strategic Business Initiatives. In addition, Mr. Saltonstall was the co-founder and chief executive officer of SafeCare Systems, LLC, which developed one of the country's first patient safety management systems. He played an active role on Capitol Hill in the development of the *Patient Safety Act of 2005*, which dramatically improved the reporting of events that adversely affect patients. Mr. Saltonstall serves on the Humana Cares Advisory Board, the FDA Cellular, Tissue & Gene Therapies Advisory Committee, and the Child Neurology Foundation Board of Directors.

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.

Ellen V. Sigal, PhD is chairperson and founder of Friends of Cancer Research (Friends), a cancer research think tank and advocacy organization based in Washington, D.C. Dr. Sigal is vice chair of the inaugural board of directors of the Reagan-Udall Foundation, a partnership designed to modernize medical product development, accelerate innovation, and enhance product safety in collaboration with the U.S. Food and Drug Administration. She serves on the Board of the Foundation for the National Institutes of Health where she chairs its Public-Private Partnerships Committee. In 2010, Dr. Sigal was appointed to a six year term on the Board of Governors of the Patient Centered Outcomes Research Institute as a representative of patients and health consumers. She also holds leadership positions with a broad range of cancer advocacy, public policy organizations, and academic health centers including: the American Association for Cancer Research Foundation Board; Research America Board; MD Anderson Cancer Center External Advisory Board, the Duke

University Cancer Center Board of Overseers, and The Sidney Kimmel Comprehensive Cancer Center Advisory Council.

Brian Solow, MD, FAAFP is chief medical officer at OptumRx, a segment of UnitedHealth Group. OptumRx provides innovative pharmacy benefit management services and products to employer groups, union trusts, commercial, Medicare and other governmental health plans. Dr. Solow's primary responsibility is the coordination of clinical activities related to the development, enhancement and implementation of clinical programs that support formulary management for OptumRx clients. Dr. Solow has also served as a member of national pharmacy and therapeutics committees for leading managed care organizations and pharmacy benefit management firms. He is a member of the Board of Trustees of the National P&T Society, and the National Council on Patient Information and Education. Additionally, he is a member of the American College of Physician Executives, the FDA Advisory Panel and the U.S. Pharmacopeial Medicare Model Guidelines Expert Panel. Dr. Solow holds an active appointment as Clinical Professor at the University of California, San Francisco, School of Pharmacy and an appointment at the University of Southern California, School of Pharmacy. Prior to joining the clinical team at OptumRx, Dr. Solow was an active member of a physician owned medical group, maintaining a full-time practice while simultaneously holding various management roles within the group.

Janet Woodcock, MD is director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). Dr. Woodcock held various leadership positions within the Office of the Commissioner, FDA, 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 the CDER from1994-2005. She also held other positions at FDA including director of the office of Therapeutics Research and Review, and acting deputy director at the 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.