Biographies

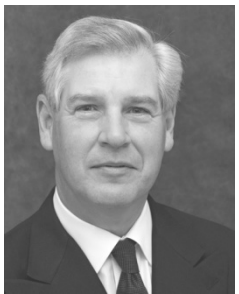
Jeff Allen, PhD, is the executive director of Friends of Cancer Research, a think tank and advocacy organization based in Washington, D.C. Friends is the country's leading voice in advocating for policies and proposing and promoting real solutions that will get treatments to patients in the safest and quickest way possible. Friends develops new, groundbreaking partnerships, creates a more open dialogue among both public and private sectors and tears down the barriers that stand in the way of conquering cancer. As Executive Director of Friends, Dr. Allen has the privilege to also serve on a variety of influential committees, boards, and advisory councils, including: board member, the Alliance for a Stronger FDA; technical expert panel member, Chemotherapy Infusion Quality Measures Group, Center for Medicare and Medicaid Services; strategic team member, U.S. Food and Drug Administration Entrepreneurs in Residence Program; Director's Consumer Liaison Group, National Cancer Institute; and as a governance board member of the Multi-Payer Claims Database Initiative of Health and Human Services. Prior to joining Friends, Dr. Allen was an endocrinology fellow at the National Institutes of Health.

Margaret Anderson, MA, is the executive director of FasterCures/The Center for Accelerating Medical Solutions, a Milken Institute center that works to speed up the timeline for new medicines to go from discovery to patients. She is a founding board member and past-president of the Alliance for a Stronger FDA, co-chairs the eHealth Initiative's Council on Data and Research, and is a member of the National Center for Advancing Translational Sciences Advisory Council, the Cures Acceleration Network Review Board, the National Health Council Board of Directors, United for Medical Research Steering Committee, and the Institute of Medicine's Forum on Drug Discovery, Development and Translation. Previously, Ms. Anderson was the deputy director and a team leader in the Center on AIDS & Community Health at the Academy for Educational Development, where she led public health projects; program director at the Society for Women's Health Research; health science analyst at the American Public Health Association, where she managed a programmatic portfolio on HIV/AIDS and other sexually transmitted diseases, infectious diseases, women's health, and public health infrastructure issues; and analyst and project director at the Congressional Office of Technology Assessment in the Biological Applications Program, where she studied societal and business implications of genetic testing. Ms. Anderson holds a bachelor's degree from the University of Maryland and a master's degree in science, technology, and public policy from George Washington University.

Cheryl Bettigole, MD, MPH, is a family physician and the chief medical officer of Complete Care Health Network, a group of community health centers serving southern New Jersey. She is also the president of the National Physicians Alliance (NPA), a multi-specialty group of physicians that works to improve health and well-being, and to ensure equitable, affordable, high quality health care for all people. Prior to her current position, Dr. Bettigole worked for the Philadelphia Department of Public Health where she served as clinical director of a city clinic from 2006-2011. While with the health department in Philadelphia, she worked to improve services for patients of limited English proficiency and to implement chronic disease management programs. She is a *magna cum laude* graduate of Jefferson Medical College, completed her residency in family medicine at Thomas Jefferson University Hospital, and completed her Masters in Public Health at Johns Hopkins Bloomberg School of Public Health, where she received a Capstone Award for her work on interpretation services in a public health clinic setting.

Marc Boutin, JD, is the executive vice president and chief operating officer of the National Health Council (NHC), an organization that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. In addition to overseeing financial management and operations at the NHC, Mr. Boutin builds consensus among member patient advocacy organizations enabling them to speak with one voice on systemic health research and health care policy initiatives. This united effort results in legislation and regulations that address the collective needs of patients and their family caregivers. In addition, he provides guidance to patient organizations on various association issues, including corporate structure, government relations, fundraising, and outreach. Mr. Boutin is a regular spokesperson before the media, Congress, and policy makers on major issues of interest to the patient community. He has been actively involved in health advocacy, policy, and both federal and state legislation throughout his career. He is a member the International Alliance of Patients' Organizations Governing Board, Community Health Charities Board of Directors, Patient-Centered Outcomes Research Institute (PCORI) Advisory Panel on Patient Engagement, and the North America Advisory Board to the Drug Information Association. He has also served on Institute of Medicine committees, National Institute of Health panels, and the Agency for Healthcare Research and Quality's stakeholder group.

Robert Califf, MD, is vice chancellor for clinical and translational research, director of the Duke Translational Medicine Institute (DTMI), and professor of medicine in the Division of Cardiology at Duke University Medical Center in Durham, N.C. Dr, Califf leads a multifaceted organization that seeks to transform how scientific discoveries are translated into improved health outcomes. Prior to leading the DTMI, he was the founding director of the Duke Clinical Research Institute (DCRI), one of the nation's premier academic research organizations. He is editor-in-chief of the *American Heart Journal*, the oldest cardiovascular specialty journal, and a practicing cardiologist at Duke University Medical Center. Dr. Califf attended Duke University, graduating *summa cum laude* and Phi Beta Kappa in 1973. He remained at Duke for medical school and completed a residency in internal medicine at the University of California, San Francisco, returning to Duke for a cardiology fellowship. Dr. Califf is board certified in internal medicine and cardiology, and was named a Master of the American College of Cardiology in 2006. An international leader in the fields of cardiovascular medicine, healthcare outcomes, quality of care, and medical economics, he has authored or coauthored more than 1,000 peer-reviewed articles and is among the most frequently cited authors in medicine. He is also a contributing editor for TheHeart.org, an online information resource for healthcare professionals working in the field of cardiovascular medicine. Dr. Califf serves as co-chair of the first Principal Investigators Steering Committee of the CTSA and has served on the FDA's Cardiorenal Advisory Panel, and on the Institute of Medicine's (IOM) Pharmaceutical Roundtable, Committee on Identifying and Preventing Medication Errors, and Committee on Nutritional Biomarkers. In 2008, he was part of the subcommittee of the FDA's Science Board that recommended sweeping reform of the agency's science base. He was also a member of the IOM committees that recommended Medicare coverage of clinical trials and the removal of ephedra from the market. Dr. Califf is currently a member of the IOM Forum in Drug Discovery, Development, and Translation and a member of the National Advisory Council on Aging. Reflecting his interests in healthcare quality, Dr. Califf was the founding director of the coordinating center of the Centers for Education & Research on Therapeutics, a public-private partnership that seeks to improve the use of medical products through research and education. He is currently co-chair of the Clinical Trials Transformation Initiative, a public-private partnership focused on improving the clinical trials system. He is also chair of the Clinical Research Forum, an organization of academic health and science system leaders devoted to improving the clinical research enterprise.



John J. Castellani is president and chief executive officer of the Pharmaceutical Research and Manufacturers of America (PhRMA), an organization that represents America's leading biopharmaceutical research companies. The biopharmaceutical sector directly employs over 650,000 Americans working to develop new medicines

that help patients fight disease and live, longer healthier lives. Working at the intersection of public policy, health and business, Mr. Castellani leads PhRMA's efforts to preserve and strengthen a healthcare and economic environment that fosters medical innovation, new drug discovery and access to life-saving medicines. He is a passionate advocate for a strong, innovative and growing American biopharmaceutical research industry that plays a critical role in helping to improve the health of every American and patients the world-over. In 2011, Mr. Castellani was recognized by *The Hill* newspaper as one of America's top health care lobbyists. He also was honored with the Bryce Harlow Foundation's prestigious 2011 Business-Government Relations Award, recognizing his leadership and exemplary life-long contribution to the public affairs and advocacy profession. Mr. Castellani is a former president and chief executive officer of Business Roundtable, an association of chief executive officers of leading U.S. corporations with a combined workforce of nearly 12 million employees and $6 trillion in annual revenues. Prior to Business Roundtable, Mr. Castellani was Executive Vice President of Tenneco, Inc. Mr. Castellani, who began his career as an environmental scientist at General Electric, earned his bachelor's degree at Union College in Schenectady, N.Y.

Elizabeth A. Chrischilles, PhD, is a professor in the Department of Epidemiology and holds the Pomerantz Chair in Public Health in the University of Iowa College of Public Health. Dr. Chrischilles is a co-leader of the Mini-Sentinel Protocol Core. Her research involves using healthcare administrative databases to address drug safety and effectiveness questions, particularly for patients with multiple chronic conditions. She is also involved in cluster-randomized trials of team management interventions, prospective follow-up of prognostic cohorts, linkage of claims data to prospective registries and cohorts, and leading a research team that is investigating multiple uses of an internet-based personal health record designed with older adults. Dr. Chrischilles is principal investigator of the Iowa Developing Evidence to Inform Decisions about Effectiveness (Iowa DEcIDE) Center and co-investigator on a pragmatic trial in the NIH Common Fund's Health Care Systems Research Collaboratory.

Gregory 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 FDA policy issues, comparative effectiveness research, and other biomedical innovation policies. Dr. Daniel was previously vice president, Government and Academic Research at 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, 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, a MPH specializing in biostatistics, a MS in Pharmaceutical Administration, and a BS in Pharmacy, all from The Ohio State University.

Tom Davis, RPh, is vice president of Pharmacy Professional Services for CVS Caremark Corporation. In this capacity, he is responsible for leading the patient safety, quality assurance, and professional practice standards agenda for the company's retail division, CVS/pharmacy. A pharmacist by training, he has been with CVS for over 15 years, leading in a variety of different capacities to include: pharmacy purchasing, regulatory affairs, and strategic product development. Prior to joining CVS, he worked in pharmacy operations for Brooks Pharmacy, a regional chain in the northeast owned by Jean Coutu Group. He was previously the chief of

the Compliance and Regulatory Section for the Rhode Island Division of Drug Control, a state regulatory law enforcement agency. Mr. Davis has also served two terms on the Rhode Island Board of Pharmacy.

James C. Greenwood is president and chief executive officer of the Biotechnology Industry Organization (BIO) in Washington, D.C., which represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the annual BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world. Since his appointment in January of 2005, he has markedly enhanced the trade association's capacity, increasing both its staff and budget by nearly fifty percent. BIO is now a world class advocacy organization playing a leading role in shaping public policy on a variety of fronts critical to the success of the biotechnology industry at the state and national levels as well as internationally. 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 U.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.

Jack Lasersohn, JD, MA, is a founding general partner of The Vertical Group, a leading U.S. venture capital firm. Since 1981, the firm and its partners have founded or funded many of the most successful venture-backed medical device and biotech companies of the past three decades. Mr. Lasersohn was a member of the Executive Committee of the Board of Directors of the National Venture Capital Association (NVCA) and is a past chairman of the Medical Industry Group of the NVCA (the predecessor of MedIC). He received the Outstanding Service Award from the NVCA in 2008 and has led many of its public policy initiatives in U.S. Food and Drug Administration (FDA) reform, patent reform, follow-on biologics, and healthcare reform. In 2011, Mr. Lasersohn was appointed by the President's Office of Science and Technology Policy to serve as a member of the Strategic Team overseeing a major reform initiative at the FDA's Center for Devices and Radiologic Health. In 2012, he was appointed by the Centers for Medicare and Medicaid Services to serve as a voting panel member of the Medicare Evidence Development and Coverage Committee (MEDCAC) which advises Medicare on coverage policy for new technology. Mr. Lasersohn is the named inventor on six U.S. patents and has served on the boards of over 40 medical device and biotech companies. He received a B.S. degree in physics from Tufts University, an M.A. from The Fletcher School of Law and Diplomacy, and a J.D. from Yale Law School.

Mark McClellan, MD, PhD, is a senior fellow and director of the Health Care Innovation and Value Initiative at the Brookings Institution. Within Brookings, his work focuses on promoting quality and value in patient centered 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.

Samuel Nussbaum, MD, is executive vice president of clinical health policy and chief medical officer (CMO) for WellPoint, Inc. He is the key spokesperson and policy advocate for WellPoint and is responsible for the company's public health policy programs. He oversees corporate medical and pharmacy policy and pharmacy and clinical quality programs to ensure the provision of proven effective care. Dr. Nussbaum collaborates with industry leaders, physicians, hospitals and national policy and health care organizations to shape an agenda for quality, safety and clinical outcomes and to improve patient care for WellPoint's 36 million medical members nationwide. In the decade that Dr. Nussbaum has served as CMO at WellPoint, he has led business units focused on care and disease management and health improvement, and provider networks and contracting with accountability for over $100 billion in health care expenditures. Dr. Nussbaum currently serves on the boards of the National Quality Forum (NQF), the OASIS Institute, New England Healthcare Institute (NEHI), and BioCrossroads, an Indiana-based public-private collaboration that advances and invests in the life sciences, and has participated in numerous Institute of Medicine activities, including serving on the Roundtable on Value & Science-Driven Health Care. Prior to joining WellPoint, Dr. Nussbaum served as executive vice president of BJC Health Care, where he led integrated clinical services across the health system and served as president of its medical group. He led a program in basic and clinical research at Harvard Medical School and Massachusetts General Hospital, where he directed the Endocrine Clinical Group. Dr. Nussbaum is a professor of clinical medicine at Washington University School of Medicine and serves as adjunct professor at the Olin School of Business.

Preeti Pinto, MS, MT-ASCP is an independent regulatory consultant with experience in regulatory aspects of both drug development and product promotion. After many years in senior corporate roles, she now heads Preeti Pinto and Associates, LLC. The company provides consultation in all aspects of promotional regulations including risk assessment and regulatory strategies and how to apply regulations to novel digital and social media platforms. Ms. Pinto has over 40 years' experience in Healthcare with over 22 years in regulatory affairs. She has a passion for regulatory science and as an adjunct professor at the School of Pharmacy at Temple University, teaches a course entitled "Advanced Topics: Regulation of Advertising and Promotions." She has been invited to speak at numerous industry conferences on regulatory aspects of product promotion. Ms. Pinto began her journey in healthcare as a medical technologist working at leading teaching hospitals, transitioning to the pharmaceutical industry by working in safety assessment and then moving on to regulatory affairs at DuPont Merck Pharmaceuticals. At DuPont, she was successful in obtaining approval of new indications and line extension for Coumadin. She moved to AstraMerck to join Promotional Regulatory Affairs and led the team through the merger with Zeneca Pharmaceuticals. Her achievements include establishing

the first field-based Promotional Regulatory Affairs (PRA) department and Medical Education office at AstraZeneca, where she was executive director and head of PRA from 1999 to 2010. She was also instrumental in proposing and conducting studies at AstraZeneca to advance knowledge in the area of direct-to-consumer product promotion. During her tenure, she played an essential role in industry negotiations with the U.S Food and Drug Administration (FDA) and represented the Pharmaceutical Research and Manufacturers of America (PhRMA) to discuss FDA/Division of Drug Marketing, Advertising and Communications (DDMAC) PDUFA fee proposal for direct-to-consumer advertising. As a member of the industry Social Media Working Group, Ms. Pinto met with the Office of Prescription Drug Promotion (OPDP) to propose and discuss regulatory guidance for the use of social media in pharmaceutical promotional activities. Under her direction, AstraZeneca was an early adopter of social media in marketing activities. She also led the social media team at AstraZeneca to respond to FDA's Call for Comments regarding regulatory guidance on social media.

Edward J. Septimus, MD, FIDSA, FACP, FSHEA received his medical degree from Baylor College of Medicine in Houston in 1972. Dr. Septimus went on to complete his postgraduate training in internal medicine and infectious diseases at Baylor College of Medicine in Houston. He is board certified in both internal medicine and infectious diseases. His current position is medical director of the Infection Prevention and Epidemiology Clinical Services Group at Hospital Corporation of America (HCA) Healthcare System. Previously, Dr. Septimus was medical director of infectious diseases and employee health at Memorial Hermann Healthcare System until November 2005. He finished a three-year term on the board of directors of the Infectious Diseases Society of America (IDSA) in 2009, and is on the IDSA Antimicrobial Resistance Committee, the IDSA/Society for Healthcare Epidemiology of America (SHEA) Antimicrobial Stewardship Work Group and the SHEA Public Policy and Governmental Affairs Committee. He was the first recipient of the IDSA Annual Clinician Award. Dr. Septimus was awarded the John S. Dunn Sr. Outstanding Teacher Award in 2010, 2011, and 2013, and has received the Clinical Excellence Award from HealthTrust. In 2011, he was appointed to the Healthcare-Associated Infections/Preventable Adverse Events Advisory Panel for the Texas Department of State Health Services. He is on the U.S. Food and Drug Administration's Anti-Infective Drug Advisory Group and co-chairs the National Quality Forum Infectious Disease Steering Committee. He holds a faculty position as professor at Texas A&M Medical School and as professor and Distinguished Senior Fellow, School of Public Health, George Mason University. Additionally, he is the chair of the Scientific Advisory Committee Center for the Study of International Public Policy and Practices at George Mason University. Dr. Septimus is on the board of the International Society for Antimicrobial Resistance and chaired the Institute for Healthcare Improvement's Antibiotic Stewardship Project. He is the past president of the Texas Infectious Diseases Society, and has published over 100 articles and chapters.

Brian Solow, MD, FAAFP, is chief medical officer at OptumRx, a segment of UnitedHealth Group. OptumRx provides innovative pharmacy benefit management (PBM) 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 has been a member of the Board of Trustees of the National Pharmacy and Therapeutics (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 U.S. Food and Drug Administration (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 the 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 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.