ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

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Biographies

Christine K. Cassel, MD, President and CEO of the National Quality Forum, is a leading expert in geriatric medicine, medical ethics and quality of care. Previously, Dr. Cassel served as President and CEO of the American Board of Internal Medicine (ABIM) and the ABIM Foundation. Dr. Cassel is also the co-chair and physician leader of PCAST working groups that have made recommendations to the President on issues relating to health information technology scientific innovation in drug development and evaluation, systems engineering in healthcare, and technology for an aging population. In addition to having chaired influential Institute of Medicine (IOM) reports on end-of-life care and public health, she served on the IOM's Comparative Effective Research Committee mandated by Congress to set priorities for the national CER effort (PCORI). An active scholar and lecturer, she is the author or co-author of 14 books and more than 200 journal articles on geriatric medicine, aging, bioethics and health policy. She edited four editions of Geriatric Medicine, a leading textbook in the field. Her most recent book is *Medicare Matters: What Geriatric Medicine Can Teach American Health Care*.

Dr. Cassel is also respected as a scientific leader, having served on the Advisory Committee to the NIH Director, 1995 – 2002, and as President of the American Federation for Aging Research. She is an Adjunct Professor of Medicine and Senior Fellow in the Department of Medical Ethics and Health Policy at the University of Pennsylvania School Of Medicine. Dr. Cassel's previous positions include dean of the School of Medicine and vice president for medical affairs at Oregon Health and Science University, chair of the Department of Geriatrics and Adult Development at Mount Sinai School of Medicine in New York, and chief of General Internal Medicine at the University of Chicago.

Gregory Daniel, PhD, MPH 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 leads the Engelberg Center's pharmaceutical and medical device policy portfolio that includes developing strategies for better post-market safety surveillance and comparative effectiveness research, improving regulatory science, fostering practical steps for implementing expedited drug development and review tools, improving biomedical innovation, and supporting payment reform. Dr. Daniel is also a senior advisor to the Reagan-Udall Foundation for the FDA.

Prior to joining Brookings, Dr. Daniel was the Vice President of Government and Academic Research at HealthCore, Inc., a research subsidiary of WellPoint, Inc. At HealthCore, 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 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.

Joseph P. Drozda, Jr., M.D., F.A.C.C. is a cardiologist and Director of Outcomes Research at Mercy Health—a 4 state regional health system headquartered in St. Louis. He chairs the American College of Cardiology's Clinical Quality Committee, is a member of the ACC's National Cardiovascular Data Registry Management Board and is the ACC representative to the National Quality Forum. He has been a methodologist for the Physician Consortium for Performance Improvement (PCPI) for over 14 years, chairs the PCPI Measures Advisory Committee, and serves on the Executive Committee. Dr. Drozda was in private practice for over 18 years and has 24 years of experience in managed care including stints as Chief Medical Officer and Executive Vice President of Health Plan Operations at Centene—a publicly traded Medicaid managed care company. From 1996 to 1999 he served as Vice President of Medical Management for SSM Health Care-St. Louis participating in that system's journey to becoming the first healthcare organization to receive the Malcolm Baldrige award.

Dr. Drozda has been involved in clinical trials for over 20 years. The current emphasis of his research at Mercy is on the safety and effectiveness of medical devices. He was principal investigator of an FDA Medical Device Epidemiology Network demonstration in which prototype unique device identifiers were implemented in Mercy's electronic information systems and a database was created for purposes of safety surveillance and research. He leads the Research and Development Team of the Healthcare Transformation Group—a device-focused alliance of Geisinger, Intermountain, Kaiser Permanente, Mayo, and Mercy and serves on the FDA's National Medical Device Surveillance System Planning Board.

Rachael L. Fleurence, PhD, is the Program Director for CER Methods and Infrastructure at the Patient-Centered Outcomes Research Institute (PCORI). She joined PCORI in April 2012. She is responsible for PCORI's initiative to build the National Patient-Centered Clinical Research Network, or PCORnet, a transformational effort to engage patients and leverage electronic health data to improve the speed and efficiency of clinical research in the United-States. She also leads PCORI's Methods program. A health economist and health services researcher by training, Dr. Fleurence previously worked at United BioSource Corporation. Dr. Fleurence received a BA from Cambridge University (United-Kingdom), a MA in business management from ESSEC-Paris (France), and a MSc and PhD in health economics from the University of York (United-Kingdom).

Troy McCall, PhD. has more than twenty years of experience in the pharmaceutical industry, having worked for more than a decade each in increasingly senior positions in specialty pharma and life sciences services companies. He has a proven track record of success in leading and growing start-up, small, and medium-sized organizations. He has been a managing partner and/or CEO at four companies. Dr. McCall has consistently been successful in building value through a disciplined business approach which includes, but is not limited to, cost rationalization and expense management resulting in industry-leading margins, hands-on and effective engagement with clients, FDA, and other stakeholders, active participation with the sales and marketing organizations to significantly improve top-line results, and top-grading talent at all levels. He has extensive experience with growing and transforming companies and developing entities into successful, sustainable organizations. Dr. McCall has significant expertise in acquiring, integrating, and selling companies, having been involved with more than ten such transactions.

Mark McClellan, MD, PhD, is a Senior Fellow and Director of the Initiatives on Value and Innovation in Health Care 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 is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA, is co-chair of the Quality Alliance Steering Committee, chairs the National Quality Forum's partnership for applying clinician quality measures, 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.

Karla M. Miller, Pharm.D., BCPP is the Assistant Vice President of Pharmacy Services & Clinical Therapeutics for Hospital Corporation of America (HCA) in Nashville, Tennessee. In her current position she oversees the medication management system for the Hospitals, Ambulatory Surgery Centers, and Physician Practices in HCA. She oversees the Clinical Pharmacy Program, Antimicrobial Management Program, Barcode Medication Administration, Venous Thromboembolism Prevention, as well other clinical and medication management programs. Prior to her current position she served in the Corporate Medication Use and Safety Position. Her interest in safety started with her work in Safety as a Psychiatric Clinical Specialist at Centennial Medical Center in Nashville, TN. She is a board certified psychiatric pharmacist. Dr. Miller is also an Assistant Professor at the University of Tennessee College of Pharmacy and leads the Medication Safety selective class. She received her Doctor of Pharmacy degree from West Virginia University. She completed a pharmacy practice residency at Johns Hopkins Hospital in Baltimore, Maryland, and a two-year fellowship in neuropsychiatry at The Ohio State University in Columbus, Ohio.

Michael D. Nguyen, MD is the Deputy Director of the Division of Epidemiology in FDA's Office of Biostatistics and Epidemiology at the Center for Biologics Evaluation and Research. He serves as the CBER Center Lead for the Sentinel Program and is involved in postmarketing safety surveillance of vaccines, blood components, and blood-derived products. Prior to working at the FDA, he completed his training in pediatrics and served as an officer in the Epidemic Intelligence Service at the Centers for Disease Control and Prevention.

Richard Platt, MD, MSc is Professor and Chair of the Harvard Medical School Department of Population Medicine, at the Harvard Pilgrim Health Care Institute. He is Principal Investigator of the FDA Mini-Sentinel and Sentinel System programs, which performs post-marketing safety surveillance using the electronic health data from over 175 million people. Dr. Platt is also principal investigator of PCORI's PCORnet coordinating center, a consortium of 29 networks that will use electronic health data to conduct comparative effectiveness research. He co-leads the coordinating center of the NIH Health Care System Research Collaboratory and leads a CDC Prevention Epicenter. He co-chairs the CER Innovation Collaborative of the IOM Roundtable on Value and Science-Driven Healthcare, and is a member of the American Medical Colleges Advisory Panel on Research.

Marsha E. Reichman, PhD. is Senior Advisor and Scientific Lead for Surveillance Programs in the Office of Surveillance and Epidemiology, CDER/FDA, and CDER Sentinel Initiative Lead. She directs implementation of Sentinel Initiative tools and resources within CDER, coordinating multiple post market drug safety assessments and providing FDA scientific leadership on several. She has been heavily involved in developing infrastructure to utilize these tools and resources within CDER. Her past experience has spanned many areas of cancer and chronic disease surveillance, survey design and implementation, and observational data analysis.

A biostatistician, epidemiologist, and molecular biologist by training (AB Barnard College, PhD Massachusetts Institute of Technology) Dr. Reichman came to the FDA in 2010, from the Division of Cancer Control and Population Sciences (DCCPS) at NCI where she was Acting Director of the Cancer Statistics Branch, including Director of the SEER Program of cancer registries. She was NCI lead on the development and deployment of SEER*DMS, a distributed, unified data management system for SEER Cancer Registries, currently deployed at 16 sites, and founder of the SEER Residual Biospecimen Repository Program. While at NCI Dr. Reichman was PI on a controlled diet study that demonstrated, for the first time, effects of alcohol consumption on estrogen metabolism in premenopausal women. Prior to joining DCCPS, Dr. Reichman was Director of Epidemiology and Survey Research at Northrop Grumman IT Health Solutions, and also worked at the National Center for Health Statistics (NCHS), CDC on the National Health and Nutrition Examination Survey. Her research publications focus on cancer surveillance, head and neck, and breast cancer, health disparities, and the use of observational and survey data.

Robert F. Reynolds, MSc, ScD, FISPE is Vice President, Epidemiology in Worldwide Safety at Pfizer. He heads a group of epidemiologists and statistical analysts responsible for developing epidemiologic programs to support drug development and safety assessment. He is also an Adjunct Associate Professor of Epidemiology at Tulane School of Public Health and Tropical Medicine where he teaches pharmacoepidemiology. He is a Fellow and former Board member of the International Society for Pharmacoepidemiology. Currently, he serves on the National Steering Committee of the Centers for Education and Research on Therapeutics (CERTs), the Steering Committee for the Innovative Medicines Initiative PROTECT project, and the Editorial Board of *Pharmacoepidemiology and Drug Safety*. Prior to joining the pharmaceutical industry, he was a Saltonstall Fellow at the Harvard Center for Population and Development Studies. He holds a BA in Biology from Bard College and a MSc in Epidemiology and ScD in Population and International Health from the Harvard School of Public Health. He has presented and published in the area of women's health, international health and epidemiologic methods for drug development and safety evaluation.

Sharon F. Terry, MA is President and CEO of Genetic Alliance, a large network of disease advocacy and other health organizations. Genetic Alliance engages individuals, families and communities to transform health.

She is the founding CEO of PXE International, a research advocacy organization for the genetic condition pseudoxanthoma elasticum (PXE). PXE affects Terry's two adult children. As a lay person, she discovered the gene for the disease, developed a diagnostic test and conducts clinical trials. She is the author of 140 peer-reviewed papers, of which 30 are PXE clinical studies.

Terry is also a co-founder of the Genetic Alliance Registry and Biobank. In her focus at the forefront of consumer participation in genetics research, services and policy, she serves in a leadership role on many of the major international and national organizations, including the Accelerating Medicines Partnership, Institute of Medicine (IOM) Science and Policy Board, the IOM Roundtable on Translating Genomic-Based Research for Health, the PubMed Central National Advisory Committee, the PhenX scientific advisory board, the Global Alliance for Genomics and Health, the International Rare Disease Research Consortium Executive Committee and as Founding President of EspeRare Foundation of Geneva, Switzerland. She is on the editorial boards of several journals and is an editor of Genome. She led the coalition that was instrumental in the passage of the Genetic Information Nondiscrimination Act. She received an honorary doctorate from Iona College for her work in community engagement in 2006; the first Patient Service Award from the UNC Institute for Pharmacogenomics and Individualized Therapy in 2007; the Research!America Distinguished Organization Advocacy Award in 2009; and the Clinical Research Forum and Foundation's Annual Award for Leadership in Public Advocacy in 2011.

In 2012, she became an honorary professor of Hebei United University in Tangshan, China, and also received the Facing Our Risk of Cancer Empowered (FORCE) Spirit of Empowerment Advocacy Award. She was named one of FDA's "30 Heroes for the Thirtieth Anniversary of the Orphan Drug Act" in 2013. In 2012 and 2013, Terry won $400,000 in first prizes in three large competitions for the Platform for Engaging Everyone Responsibly (PEER). PEER was awarded a $1M contract from PCORI in 2014.

Terry is an Ashoka Fellow. With her husband Patrick, she is an avid paragliding pilot, rock climber and weekend farmer.

Claudia Vellozzi, MD, MPH, is chief of the Prevention Branch in the Division of Viral Hepatitis (DVH) at the U.S. Centers for Disease Control and Prevention (CDC). In this position Dr. Vellozzi has the lead responsibility for prevention research and program evaluation in DVH which includes testing and linkage to care activities for those with chronic viral hepatitis. She also oversees DVH training and education materials and works closely with state health department viral hepatitis prevention coordinators. Dr. Vellozzi has been with the CDC since 2003; prior to her work with the DVH she was with the Immunization Safety Office (ISO), CDC for 8 years and the Deputy Director of ISO for 5 of the 8 years. She also served as the Prevention Research Team Lead in the Division of Birth Defects and Developmental Disabilities, leading the global initiative to reduce neural tube defects and strengthen birth defects surveillance globally. Dr. Vellozzi has extensive public health experience both domestically and internationally. She has previously worked with the World Health Organization in Indonesia and Geneva, Switzerland and the Pan American Health Organization in Caracas, Venezuela. She has conducted research with the Commonwealth Fund (New York City) focused on access to health care services for underserved women. Dr. Vellozzi did her undergraduate studies at Loyola Marymount University in Los Angeles, California and she received her Medical Degree at Loyola University, Chicago, Illinois; she also received a Master of Public Health degree at Johns Hopkins University in Baltimore, Maryland. Dr. Vellozzi is Board Certified in both Family Medicine and Preventive Medicine and practiced primary care medicine for over 15 years during her career. She has published numerous manuscripts in peer reviewed literature. Dr. Vellozzi also continues to practice medicine and sees patients weekly at the International Medical Clinic at Grady Hospital in Atlanta, Georgia.

Myrl Weinberg, FASAE, CAE is chief executive officer of the National Health Council (NHC), the only organization that brings together all segments of the health community to provide a united voice for the more than 133 million people living with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient advocacy groups, which control its governance. Other members include professional and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, health insurance, and biotechnology companies.

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 before Congress and federal regulatory bodies and is a frequent speaker on the patient perspective in health policy. Before joining the NHC, she held numerous senior managerial positions at the American Diabetes Association, including Vice President for Corporate Relations and Public Affairs.

Ms. Weinberg pursued advanced graduate study at Purdue University. She holds an MA in Special Education from George Peabody College and a BA in Psychology from the University of Arkansas.

David Wheadon, MD, is Senior Vice President and Head of Global Regulatory Affairs, Patient Safety and Quality Assurance at AstraZeneca Pharmaceuticals. A psychiatrist by training and a former Senior VP of Scientific and Regulatory Affairs for Pharmaceutical Research and Manufacturers of America (PhRMA), David joined AstraZeneca in 2014 from the global organisation JDRF - the world's leading charitable funder of type 1 diabetes research, where he was Executive VP for Research and Advocacy. Educated at Harvard and Johns Hopkins University School of Medicine and with a residency in psychiatry at the Tufts-New England Medical Center, David has also held senior regulatory leadership roles at Abbott Laboratories and GlaxoSmithKline.

David, who started out as a clinical research physician in neuroscience at Eli Lilly, has a wide range of leadership and specialist regulatory experience, and an extensive understanding of the regulatory environment, serving until last year as industry representative at PhRMA on far-reaching scientific and regulatory issues, including PDUFA-V negotiations, and interacting with government agencies and other public stakeholders to shape regulatory reform.

In previous pharma company roles, as well as regulatory affairs, he has been responsible for Global Health Economics and Outcomes Research and Global Medical Services functions. He has also had hands-on experience of overseeing Phase II - IV development of CNS and GI compounds. Early on in his career, David was awarded the American Psychiatric Association National Institute of Mental Health Fellowship and completed numerous major committee assignments in his specialist field, including the Task Force on Continuing Medical Education of the American College of Neuropsychopharmacology and the Executive Board of the Observational Medical Outcomes Partnership of the Foundation for the National Institutes of Health. He has lectured extensively over the years on his main research interests of neurological conditions, depressive disorders and regulatory topics, and has numerous publications, presentations and posters to his credit.

Marcus D. Wilson, Pharm.D. is President of HealthCore, Anthem's wholly-owned outcomes research subsidiary. He has been extensively involved in real world evidence development and clinical decision support for innovators, regulators, providers and payers for more than 20 years. His efforts have focused upon the use of electronic healthcare data to improve the speed, efficiency and relevance of evidence development.

Prior to co-founding HealthCore in 1996, Dr. Wilson spent seven years within a large group practice setting providing physician and patient clinical decision support, effectively integrating ancillary services into a broader health outcomes approach for patient care.

In addition to his role with HealthCore, Dr. Wilson participates on a number of boards, councils and committees including as chair, Innovations in Medical Evidence Development (IMEDS) Steering Committee, Reagan-Udall Foundation for the FDA, the eHealth Initiative Board of Directors, the Board of Visitors & Dean's Professor for the Mayes College of Healthcare Business & Policy at the University of Sciences in Philadelphia and the Dean's Roundtable for the College of Science at Virginia Tech. He is a past member of the Board of Directors for ISPOR and is a reviewer for multiple journals.

Dr. Wilson received his Bachelor of Science in Biochemistry from Virginia Tech and his Doctor of Pharmacy degree from the Medical College of Virginia. He completed a residency in Family Medicine at the Medical University of South Carolina prior to joining the faculty at the Philadelphia College of Pharmacy where he taught didactic and experiential courses in clinical therapeutics and decision support.

Janet Woodcock, MD, is Director of the Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). As of January 2015, Dr. Woodcock also assumed the role of Acting Director of CDER's newly formed Office of Pharmaceutical Quality, (OPQ). Dr. Woodcock first joined CDER in 1994. For three years, from 2005 until 2008, she served FDA's Commissioner, holding several positions, including as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer. Her responsibilities involved oversight of various aspects of scientific and medical regulatory operations. Before joining CDER, Dr. Woodcock served as Director, Office of Therapeutics Research and Review, and Acting Deputy Director in FDA's Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School and 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.