

Engaging Patients: Building Trust and Support for Safety Surveillance

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Biographies



Robert Ball is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), FDA. Dr. Ball shares in the responsibilities for leading OSE staff evaluating drug risks and promoting the safe use of drugs by the American people. From 2008 to 2013, Dr. Ball served as the Director, Office of Biostatistics and Epidemiology (OBE), Center for Biologics Evaluation and Research (CBER), FDA. In this role, Dr. Ball was the principal advisor to the CBER director on all matters pertaining to statistical and epidemiological evaluation of regulated biological products and led post-marketing safety programs for vaccines and blood in the FDA's Sentinel Initiative and with the Centers for Medicare and Medicaid Services. Dr. Ball received his BS in Mathematics and MD from Georgetown University, where he was elected to the Alpha Omega Alpha Honor Medical Society. He interned at the US Naval Hospital Bethesda, completed his MPH and residency in Occupational Medicine at the Uniformed Services University of the Health Sciences, and received the ScM degree in Infectious Disease Epidemiology and Vaccine Science and Policy from Johns Hopkins School of Public Health. Prior to joining the FDA, Dr. Ball served as a US Navy Medical Officer.



Jamie Brocki is Staff Vice President, Member Engagement & Communications of Anthem, Inc. She is a collaborative marketing executive whose career has centered around Communications because of their ability to impact brands, business objectives and relationships. Jamie has been with Anthem for the past 12 years, beginning with the Specialty Marketing division driving cross-sell opportunities with dental, vision, life and disability products. She then served as Staff VP of Anthem's creative and production teams. She championed the "plain language" initiative across 40,000 associates at Anthem during a critical point in time when the industry was pivoting from a largely B2B environment to one heavily influenced by the consumer. The program earned national recognition and brought Communications to the forefront of the organization. In her current role, she is working to pivot the organization's member communications practice into one of engagement. Prior to Anthem, Jamie worked at a local advertising agency and AAA. She holds a bachelor's degree in Communications and a minor in Business from Xavier University.



Gregory Daniel is a fellow in Economic Studies and Managing Director for Evidence Development and Innovation in the Center for Health Policy at the Brookings Institution. In this position, Dr. Daniel leads the 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.



Barbara J. Evans is Professor of Law, George Butler Research Professor, and Director of the Center for Biotechnology & Law at the University of Houston Law Center and is an Affiliated Member of the Center for Medical Ethics and Health Policy at the Baylor College of Medicine. Prior to joining the University of Houston, she was Director of the Center for Pharmacogenomics, Ethics, and Public Policy at the Indiana University School of Medicine and earlier was a partner in the regulatory practice of a large international law firm. She was named a Greenwall Faculty Scholar in Bioethics for the period 2010 – 2013 and has served on the Mini-Sentinel/Sentinel Privacy Panel. She conducts an active portfolio of research projects related to data privacy, ownership, access, and ethical protections for persons whose data are used in research and public health studies. She holds an electrical engineering degree from the University of Texas at Austin; M.S. and Ph.D. degrees from Stanford University; and a J.D. from the Yale Law School, and completed a postdoctoral fellowship at the University of Texas M.D. Anderson Cancer Center.



Nancy Kurilla Falk is currently, Senior Director, Marketing Program Innovation, Kaiser Foundation Health Plan Inc., Kaiser Permanente. Since 1992, Nancy's led teams in marketing, product development, venture development, competitive assessment and market research. Prior to Kaiser Permanente, Falk worked with strategy consulting firm Bain & Company (San Francisco office, 1989-92), and as an International Economist with the U.S. Department of the Treasury and Presidential Management Intern (1986-88). Falk is an alum of Harvard University's Kennedy

School of Government (MPP 1986), Georgetown University's School of Foreign Service (BSFS 1984), and is a 1982 Truman Scholar from New Jersey. She also served as Trustee of Claremont McKenna College (CMC), President of the CMC Parent Network Board (2012-14), and President and Board Chair of Lafayette Partners in Education foundation. Married since '89, Falk is a proud mom, San Francisco Giants baseball fan, metric century cyclist, and is still smiling after walking (all 200+ miles) the John Muir Trail in California.



Eric Gascho is the Assistant Vice President of Government Affairs at the National Health Council. The NHC, a Washington-based non-profit, is the only 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. Its core membership includes the nation's leading patient advocacy groups. Other members include professional and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, and biotechnology companies. In his role with the NHC, Eric helps develop policies that benefit people with chronic conditions and

advocates for these policies on Capitol Hill and within the administration. Prior to joining the NHC in 2009, Eric worked in the government relations department of the Society of Teachers of Family Medicine. He earned BA degrees in Government and Business Management from the University of Redlands in California.



Lyn Ketelsen joined HCA after more than 12 years with Studer Group, an organization that helps healthcare providers improve outcomes, particularly with respect to patient experience. There, Ketelsen helped hundreds of organizations build a culture of operational excellence. A registered nurse for more than 30 years, Ketelsen has worked in a variety of healthcare settings and has clinical experience in pediatrics as well as neonatal intensive care. For the first 17 years of her career she worked with Genesis Health System holding a variety of positions from staff nurse to nurse manager. During her last four years at Genesis, she served as an internal consultant, developing a customer service strategy that led to

significant improvements in patient satisfaction. Ketelsen is most known for her published work regarding Hourly Rounding. This practice has become an internationally accepted standard in nursing practice driving improved outcomes. Ketelsen earned her master's degree in business administration from the University of Iowa and her bachelor's degree in business administration from St. Ambrose University in Davenport, Iowa. She received her associates degree in nursing from Black Hawk College in Moline, IL.



Bray Patrick-Lake supports efforts to actively engage participant partners in Duke research programs, as well as patient advocacy organizations and other stakeholders in CTTI efforts to improve clinical trials. She implements strategies to enhance awareness of CTTI's work, particularly with patient advocates, and extend its impact by working in partnership with the patient advocacy community on research design and conduct, and improvement of the clinical trial enterprise. Ms. Patrick-Lake also serves as the co-chair for the Advisory Committee to the NIH Director on the Precision Medicine Initiative. In 2010, Ms. Patrick-Lake founded the PFO Research Foundation in response to the lack of definitive scientific information regarding the condition of patent foramen ovale (PFO) after being a patient in an aborted clinical trial. Ms. Patrick-Lake has served as a patient representative at the FDA on a variety of advisory committees and panels, in workgroups for EMA and NIH, as a guest lecturer and an external reviewer for IOM, and as a patient stakeholder or co-investigator for AHRQ and PCORI grants. She is a member of the PCORnet Coordinating Center's Executive Leadership Committee where she develops patient engagement strategies, MDEpiNet's National Medical Device Registry Task Force, MDIC's Patient-centered Benefit-Risk Steering Committee, ACC Foundation's Patient-centered Care (PC3) Shared Decision Making Workgroup, DIA's Patient Fellowship Selection Committee, TVT Registry Stakeholder Advisory Committee, and is a board member for the Alliance for Headache Disorders Advocacy.



Mark McClellan is 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.



J. Stephen Mikita: As one of the oldest survivors of Spinal Muscular Atrophy (SMA), Mr. Mikita has been uniquely positioned to advocate for the patient perspective at every stage of drug development. Mr. Mikita has been a Utah Assistant Attorney General for 33 years and represents Utah's three largest agencies serving and protecting individuals with disabilities. He was appointed as a Patient Representative to the Clinical Trials Transformation Initiative's (CTTI) Steering Committee, he has worked on the following projects: Mini-Sentinel Distributed Database Project; Pregnancy Testing Project; Antibacterial Drug Development Project for HAPB/VABP; Informed Consent Project (Expert Interviews co-leader); Registry Trials Project (Project Manager). He is a Patient Representative for Columbia University Medical Center's Neuro NEXT program, as well as a Board Member for the SMA Foundation. Mr. Mikita is a member of the Mini-Sentinel Planning Board and a Patient Engagement Representative for Sentinel.



Sally Okun is the Vice President for Advocacy, Policy and Patient Safety at PatientsLikeMe in Cambridge, MA. She is responsible for patient voice initiatives, participates in health policy discussions at the national and global level, and acts as the company's liaison with government and regulatory agencies. She joined PatientsLikeMe in 2008 as the manager of Health Data Integrity and Patient Safety overseeing the site's medical ontology including the curation of patient reported health data and patient folksonomy. In 2009 she developed the PatientsLikeMe Drug Safety and Pharmacovigilance Platform to meet adverse event reporting obligations of industry partners while collaborating in a social media environment. Okun participates on numerous collaboratives of the Institute of Medicine's (IOM) Roundtable on Value and Science Driven Healthcare and the Committee on Core Metrics for Better Health at Lower Cost. Ms. Okun serves on the Advisory Panel on Patient Engagement for the Patient Centered Outcomes Research Institute's (PCORI); the National Quality Forum's Person-centered Care and Outcomes Committee and the Scientific Advisory Committee for the Reagan-Udall Foundation's Innovation in Medical Evidence Development and Surveillance (IMEDS) Program and the Program Advisory Board of the Schwartz Center for Compassionate Health Care. Sally is a frequent speaker at clinical, advocacy and policy events and in April 2013 was the first nurse invited to give a TEDMED talk at Kennedy Center. Prior to joining PatientsLikeMe Sally, a registered nurse practiced as a community-based palliative and end-of-life care specialist and project consultant contributing to clinical, research, and educational projects with multiple collaborators including Brown University, Harvard Medical School, MA Department of Mental Health, Hospice Education Network, and the Robert Wood Johnson Foundation. Okun received her Master's degree from The Heller School for Social Policy & Management at Brandeis University. She completed study of Palliative Care and Ethics at Memorial Sloan-Kettering Cancer Center and was a fellow at the National Library of Medicine Program in Biomedical Informatics.



Jan Oldenburg is a senior manager in EY's Advisory Health Care Practice. In this role, she leads projects that focus on developing new ways to enhance healthcare customer and patient experience using digital and cross channel tools. She is the former vice president of physician and patient engagement at Aetna Accountable Care Solutions, where she worked with physician groups in accountable care organizations to create and implement population health and patient engagement programs. Prior to Aetna, Jan was a senior leader in Kaiser Permanente's Digital Services Group, designing, building, and implementing clinical and administrative tools for Kaiser Permanente members. Jan is a HIMSS fellow and Co-Chair of the National HIMSS Connected Health Committee. She frequently speaks and writes about patient and physician engagement. She served as the primary editor of editor of *Engage! Transforming Healthcare through Digital Patient Engagement*, published by HIMSS press in March 2013 and the Patient Engagement chapter of the 3rd edition of *Medical Informatics*, published in March, 2015 by HIMSS press.



Jaewon Ryu joined Humana as Segment Vice President and President of Integrated Care Delivery. Prior to joining Humana, he was at the University of Illinois Hospital & Health Sciences System, where he was the Chief Medical Officer of a system including a tertiary care academic medical center, its affiliated clinics, seven health sciences colleges (Medicine, Pharmacy, Nursing, Dentistry, Public Health, Applied Health, and Social Work), and among the largest teaching programs associated with these clinical practices. Dr. Ryu brings expertise in developing health system strategy and leading operational implementation across many areas. He previously served on the executive leadership team within Kaiser Permanente's Mid-Atlantic region, and as Expert Consultant at the Centers for Medicare and Medicaid Services, where he focused on quality and efficiency measurement and its use in alternative payment design. Dr. Ryu also served as a White House Fellow at the Department of Veterans Affairs. Dr. Ryu earned his Bachelor of Arts degree from Yale University, his JD from the University of Chicago Law School, and his MD from the University of Chicago, Pritzker School of Medicine. He is a board-certified physician who completed his residency training in Emergency Medicine at Harbor-UCLA Medical Center. He also remains an active member of the State Bar of California, having previously practiced as a corporate healthcare attorney.



Darla Tufto is Vice President, Consumer Office for UnitedHealthcare, Inc. In this role, she leads strategic development and tactical execution of Consumer Insights, Health Literacy and Health Disparity Programs across UnitedHealthcare's benefits businesses and she also supports strategic execution of the UnitedHealthcare consumer brand campaign. The goal of the Consumer Office is to serve UnitedHealthcare plan members seamlessly through every stage of life by providing brand and service experiences built around their health and healthcare needs. Tufto joined UnitedHealth Group in 2003 and spent three years leading marketing for the business's AARP Medicare Supplement program. She then transitioned to a role focusing on strategic

business initiatives and start-up projects for the company's Medicare business. In 2007, she joined Optum Financial Services, a division of UnitedHealth Group's services business that works with employers, health plans, financial institutions and government agencies to create solutions that make health care simpler, more affordable and more accessible. During her three-year tenure at Optum Financial Services, Tufto held positions in product management and strategic planning. In March 2011, she assumed the role of Chief of Staff for the UnitedHealthcare Medicare and Retirement business, the nation's largest business dedicated to the health and well-being needs of seniors and other Medicare beneficiaries. She was responsible for the administrative management and organization of the CEO and Executive Leadership Team, prioritizing projects and initiatives as well as managing the development of business plans, executive presentations and communications. Prior to joining UnitedHealth Group, Tufto held positions of increasing responsibility in product management and strategic planning at The Clorox Company, Boston Scientific, Pillsbury and U.S. Bank. Tufto earned a Bachelor of Science degree in nutrition from North Dakota State University in Fargo and a Master of Business Administration from the University of Minnesota's Carlson School of Management in Minneapolis. She has previously served on the Board of Visitors for the College of Human Development and Education at North Dakota State University and the Board of Twin Cities Habitat for Humanity.



Consuelo H. Wilkins is the Executive Director of the Meharry-Vanderbilt Alliance, a strategic partnership between Meharry Medical College and Vanderbilt University Medical Center. Her primary responsibilities include developing and supporting collaborative initiatives and programs in biomedical research, community engagement and interprofessional learning. She holds appointments as Associate Professor of Medicine at both Vanderbilt University Medical Center and Meharry Medical College. As co-director of the Meharry-Vanderbilt Community-Engaged Research Core in the Vanderbilt Institute for Clinical and Translational Science, she brings together academic researchers and community members to improve community health and healthcare through community-engaged research. Dr.

Wilkins is widely recognized for her work in stakeholder engagement and is Principal Investigator of a Patient Centered Outcomes Research Institute (PCORI) Research Award focused on Improving Patient Engagement and Understanding its Impact on Research. Dr. Wilkins' prior research has focused on understanding the complex intersection between cognitive impairment, frailty and depression. Prior to joining the faculty at Vanderbilt University Medical Center in 2012, Dr. Wilkins was an Associate Professor in the Department of Medicine, Division of Geriatrics, with secondary appointments in Psychiatry and Surgery (Public Health Sciences) at Washington University School of Medicine in St. Louis. She served as Founding Director of the Center for Community Health and Partnerships in the Institute for Public Health, co-director of the Center for Community Engaged Research in the CTSA, and director of "Our Community, Our Health" - a collaborative program with Saint Louis University to disseminate culturally relevant health information and facilitate community-academic partnerships to address health disparities. Dr. Wilkins serves on numerous national committees and boards including the CTSA Consortium Collaboration/Engagement Domain Task Force (Lead Team), PCORI Advisory Panel on Clinical Trials Subcommittee on Recruitment, Accrual, and Retention, PCORnet Patient and Consumer Engagement Task Force (co-chair), and the NIA Task Force for Diversity in Scholar Development in Aging/Neurocognitive Disease and Research Recruitment. Dr. Wilkins earned a Bachelor of Science in microbiology (magna cum laude, Phi Beta Kappa) and a Doctor of Medicine from Howard University. She completed residency training in Internal Medicine at Duke University Medical Center and a Geriatric Medicine fellowship at Washington University School of Medicine/Barnes-Jewish Hospital. Following her medical training, Dr. Wilkins earned a Master of Science in Clinical Investigation from Washington University School of Medicine.