

Sentinel Initiative Public Workshop

Renaissance Washington, DC Dupont Circle Hotel • Washington, DC

Wednesday, February 3, 2016

Biographies

Steven Anderson, PhD, MPP is currently the Director of the Office of Biostatistics and Epidemiology (OBE) at the FDA Center for Biologics Evaluation and Research (CBER). He provides leadership for all CBER statistical, epidemiological and benefit-risk assessment programs. Previously, Dr. Anderson had been the Deputy Director for OBE since 2005. In 2001, he was hired by CBER as the Associate Director for Risk Assessment to establish a program in quantitative risk assessment for biologic products including vaccines, blood products and others. Since his arrival at FDA he has led numerous risk assessment projects and epidemiological studies that have informed high-level decision-making at FDA on topics including: HIV and Hepatitis B risks associated for blood donors, HIV vaccines, smallpox vaccination and the blood supply, monkey pox, transmissible spongiform encephalopathy agents in blood and plasma-derived products, and many others.

Prior to joining FDA, Dr. Anderson worked at the USDA Food Safety & Inspection Service (FSIS) as a AAAS Risk Assessment Fellow where he was the FSIS lead for the Harvard Bovine Spongiform Encephalopathy Risk Assessment. Dr. Anderson earned a Master's Degree in Public Policy (MPP) at Georgetown University and while there developed the first quantitative risk assessment for antimicrobial resistant pathogens in cattle. Dr. Anderson received his Ph.D. from the University of Cincinnati where he worked on biochemistry, drug resistance and ion pumps, pathogenicity and genomics of unique tropical disease pathogens. He has published a number of articles in risk assessment, infectious diseases, drug development, and genomics and protein structure/targeting.



Kathleen Blake, MD, MPH is Vice President for Performance Improvement at the American Medical Association and Executive Director of the AMA-convened Physician Consortium for Performance Improvement® (PCPI®) which includes among its activities the National Quality Registry Network™ (NQRN™). Dr. Blake is responsible for ensuring the successful execution of all components of the PCPI strategic direction and the integrity of its measure portfolio. She is a member of the HIT Policy Committee Quality Measures Workgroup of the Office of the National Coordinator for Health Information Technology, the FDA-sponsored National Medical Device Postmarket Surveillance Planning Board, the Medical Device Epidemiology Network Council, and the PCORI Dissemination and Implementation Stakeholder Council. She has previously represented the Heart Rhythm Society (HRS) in the AMA House of Delegates and the PCPI and on the PCPI Work Group on congestive heart failure performance measures. As chair of the HRS Health Policy Committee, she led a team of physician volunteers and staff to address policy issues at the federal level and was a Founding Co-Chair of the Society's Measure Development Task Force. Prior to coming to AMA, Dr. Blake was Senior Research Director at the Center for Medical Technology in Baltimore, Maryland, overseeing Public-Private Partnerships, Policy and Education and serving as an advisor to the American Joint Replacement Registry and National Radiation Oncology Registry. Dr. Blake is a clinical cardiac electrophysiologist who earned her medical degree from the University of Chicago, followed by post-doctoral training in internal medicine and cardiovascular diseases at Stanford University. From 1988 until 2011, Dr. Blake practiced at the New Mexico Heart Institute, where she also served as President. In 2011, she earned a Master of Public Health degree from the Johns Hopkins Bloomberg School of Public Health.



Jeff Brown, PhD is an Associate Professor in the Department of Population Medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. He is Research Director of the Therapeutics Research and Infectious Disease program at DPM and Associate Director of the FDA's Mini-Sentinel project. Dr. Brown is a health services researcher with expertise in pharmacoepidemiology and drug safety, with primary research activities involving the development of new methodologies and techniques to facilitate multi-institutional drug and vaccine safety surveillance using automated healthcare administrative and claims data, including the application of sequential analytic and data mining methodologies. Dr. Brown is the lead architect of PopMedNet (www.popmednet.org), an open-source software platform that facilitates the creation and operation of large-scale distributed health data networks. He is co-chair of the Informatics Core of the NCI Cancer Research Network and of the EHR Core of the NIH Health Care System Research Collaboratory. Dr. Brown holds a Master's degree in Economics from Tufts University and a PhD in Social Policy from Brandeis University.



Patrizia A. Cavazzoni, MD is the Senior Vice President for Development Operations at Pfizer. Prior to this role, she was the Senior Vice President for Worldwide Safety and Global Established Products Regulatory. Previous to her joining Pfizer, she held leadership positions within the R&D organizations at Eli Lilly and Sanofi.

Dr. Cavazzoni served as the Pharmaceutical Industry's representative to the Food and Drug Administration's Drug Safety and Risk Management Advisory Committee and is currently a member of the Steering Committee for the Reagan-Udall Foundation's Innovation in Medical Evidence Development and Surveillance Program.

Prior to joining the pharmaceutical industry, she was an Assistant Professor of Medicine at the University of Ottawa, where she was engaged in clinical work, teaching and research of genetic predictors of mood disorders, authoring numerous peer-reviewed scientific publications. After obtaining her medical degree at McGill University, Dr. Cavazzoni served as a Medical Officer in the Canadian Armed Forces and subsequently completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa, becoming a recipient of the American College of Psychiatrists' Laughlin Fellowship.

Dr. Cavazzoni is certified by the American Board of Neurology and Psychiatry, a Fellow of the Canadian Royal College of Physician and Surgeons and a member of the Canadian College of Neuropsychopharmacology.

Francesca (Fran) Cunningham, PharmD is Associate Chief Consultant, Medication Safety in the Department of Veterans Affairs (VA) PBM and the Director of the VA Center for Medication Safety (VAMedSAFE). Her focus has been on assessing new agents where safety data is lacking and older drugs when a newly emerging signal requires evaluation. Dr. Cunningham designed the VAMedSAFE Drug Safety programs. Under her direction, the program has become a major tool in the evaluation of drug safety in the VA and its role in the formulary decision process as well as provider awareness of drug safety issues. It is also VA's major drug safety surveillance program which assesses the potential risks of new molecular entities or older agents with newly identified adverse events. Since joining the VA, Dr. Cunningham has focused her research efforts in the area of drug safety. Dr. Cunningham sits on several internal and external boards and committees that focus on patient and medication safety with an emphasis on pharmacovigilance. Dr. Cunningham's work has led to national awards that focus on her contributions in the areas of pharmacovigilance and medication safety. She is the recipient of the Mark A. Wolcott National Award for Leadership in Healthcare: Medication Safety and the 2013 Arthur S Fleming Award for Medication Safety.



Gerald J. Dal Pan, MD, MHS currently serves as the Director of the Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research, where since 2005 he has been responsible for the Center's programs in adverse event surveillance and analysis, pharmacoepidemiology, risk management, and medication error prevention. In this capacity, he is involved in both the premarket and postmarket regulation of drugs and therapeutic biologics, and in the implementation of the drug safety provisions of the Food and Drug Administration Amendments Act and other initiatives. He is a member of the World Health Organization Advisory Committee on the Safety of Medicinal Products, and has served on working groups of the Council of International Organization of Medical Sciences (CIOMS) and the International Conference on Harmonisation (ICH). He received his MD at Columbia University College of Physicians and Surgeons and his Master of Health Science in Clinical Epidemiology at the Johns Hopkins University School of Hygiene and Public Health. He completed residency training in Internal Medicine at the Hospital of the University of Pennsylvania and in Neurology at the Johns Hopkins Hospital. He is board certified in both Internal Medicine and Neurology. He joined FDA in 2000 as a medical reviewer in the Center's Office of New Drugs. Before working at FDA, he was a faculty member in the Department of Neurology at Johns Hopkins and worked in the pharmaceutical industry.



Gregory Daniel, PhD, MPH is a Clinical Professor in Duke's Fuqua School of Business and Deputy Director in the Duke-Robert J. Margolis Center for Health Policy at Duke University. Dr. Daniel directs the DC-based office of the Center and leads the Center's pharmaceutical and medical device policy portfolio which includes developing policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. This includes post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform. Dr. Daniel is also a Senior Advisor to the Reagan-Udall Foundation for the FDA. Previously, he was Managing Director for Evidence Development & Biomedical Innovation in the Center for Health Policy and Fellow in Economic Studies at the Brookings Institution and Vice President, Government and Academic Research at HealthCore (subsidiary of Anthem, Inc).

Dr. Daniel has executive level experience forming, managing, and growing new lines of business, securing research funding, setting departmental goals and strategic direction, and fostering multi-organizational collaborations. He is also a health care researcher with expertise in health policy, pharmaceutical policy, and designing and leading research in health outcomes and pharmacoconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. He has strong research, analytic and methodology skills and significant experience utilizing electronic administrative claims, laboratory results, registries, and electronic medical records to generate evidence that informs healthcare decisions. Dr. Daniel received a PhD in pharmaceutical economics, policy and outcomes from the University of Arizona, as well as an MPH, MS, and BS in Pharmacy all from The Ohio State University.



Bruce Fireman is a biostatistician and research scientist at the Division of Research, Kaiser Permanente Northern California. His research interests include assessment of the effectiveness and safety of vaccines and drugs. He usually works with population-based data, comparing the effectiveness of alternative treatments and alternative ways of delivering healthcare. He has evaluated disease management programs and primary care teams. He has collaborated with Kaiser Permanente clinicians and administrators in efforts to improve healthcare.

Susan Hariri, PhD is the Scientific Deputy of the Prevention Branch in the Division of Viral Hepatitis at the U.S. Centers for Disease Control and Prevention. She is a member of the leadership team responsible for directing national efforts to reduce the burden of viral hepatitis in the United States. Dr. Hariri's previous work included leading studies to define the epidemiology of human papillomavirus (HPV), monitor population impact of HPV vaccination, and contribute to the development HPV vaccine recommendations.



Martin Kulldorff, PhD is a biostatistician in the Division of Pharmacoepidemiology and Pharmacoeconomics at the Brigham and Women's Hospital. His current research centers on developing new statistical methods for post-market drug and vaccine safety surveillance.

He has developed new sequential statistical methods for near real-time post-market drug and vaccine safety surveillance, where the purpose is to use weekly, monthly or other frequent data feeds to find potential safety problems as soon as possible. He has developed a tree-based scan statistic for post-market drug and vaccine safety surveillance. Keeping the outcome definitions flexible, the method simultaneously evaluates thousands of potential adverse events and groups of related events, adjusting for the multiple testing inherent in such an approach. Another more recent area of methodological work is the development of new statistical methods for evaluating the comparative safety of different childhood vaccine schedules. A fourth major area of methodological research is spatial and spatio-temporal disease surveillance, for which Dr. Kulldorff has developed various scan statistics for disease cluster detection and investigation; and for the early detection of infectious disease outbreaks.

As a biostatistician, Dr. Kulldorff also does collaborative and consulting work with epidemiologists and clinicians, using a wide variety of study designs and methods for many different types of diseases. Dr. Kulldorff received his bachelor's degree in mathematical statistics from Umeå University in Sweden, and his doctorate in operations research from Cornell University.



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 the Robert J. Margolis Professor of Business, Medicine, and Policy, and Director of the Duke-Margolis Center for Health Policy at Duke University with offices at Duke and in Washington DC. The new Center will support and conduct research, evaluation, implementation, and educational activities to improve health policy and health, through collaboration across Duke University and Health System, and through partnerships between the public and private sectors. It integrates the social, clinical, and analytical sciences to integrate technical expertise and practical capabilities to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide.

Dr. McClellan is a doctor and an economist, and his work has addressed a wide range of strategies and policy reforms to improve health care, including such areas as payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and more effective drug and device innovation. Before coming to Duke, he served as a Senior Fellow in Economic Studies at the Brookings Institution, where he was Director of the Health Care Innovation and Value Initiatives and led the Richard Merkin Initiative on Payment Reform and Clinical Leadership. 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, Medicare and Medicaid payment reforms, 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 a member of the National Academy of Medicine and chairs the Academy's Leadership Council for Value and Science-Driven Health care, co-chairs the guiding committee of the Health Care Payment Learning and Action Network, and is a research associate at the National Bureau of Economic Research. He has also 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 as Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. He was previously an associate professor of economics and medicine with tenure at Stanford University, and has twice received the Kenneth Arrow Award for Outstanding Research in Health Economics.



Catherine M. Meyers, MD is the Director of the Office of Clinical and Regulatory Affairs at the National Institutes of Health (NIH), National Center for Complementary and Integrative Medicine (NCCIH). The Office plays a major role in planning, coordinating, and monitoring the NCCIH clinical research program. Dr. Meyers is also one of the lead Project Scientists for the NIH Common Fund Health Care Systems Research Collaboratory, an initiative to conduct pragmatic clinical trials in partnership with clinical investigators, patients and health care systems in the United States.

Dr. Meyers earned her undergraduate degree in Chemistry at the University of Chicago and received her M.D. from the University of Illinois at Chicago. She completed postgraduate residency training in internal medicine at the University of Chicago (Michael Reese Hospital) and a clinical/research nephrology fellowship at the University of Pennsylvania.

Prior to her 2009 arrival at NIH/NCCIH, Dr. Meyers was a Senior Scientific Advisor at the NIH National Institute of Diabetes and Digestive and Kidney Diseases for nearly a decade, where she directed a clinical trials program focused on end-stage kidney disease. Her previous appointments include a three-year tenure at the US Food and Drug Administration, as well as a faculty position at the University of Pennsylvania's School of Medicine, where she was a member of the Department of Internal Medicine, Renal-Electrolyte and Hypertension Division.



J. Stephen Mikita, JD. 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 34 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 CTTI projects: Mini-Sentinel Distributed Database Project; Pregnancy Testing Project; Antibacterial Drug Development Project for HABP/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 Sentinel Planning Board and a Patient Engagement Representative for Sentinel. He leads the Sentinel Engagement Partners Workgroup.



Gregory Pappas, MD, PhD is the Associate Director for National Device Evaluation at the Center for Devices and Radiological Health (CDRH), FDA. He previously served as the Senior Deputy Director of HAHSTA (HIV/AIDS, Hepatitis, STD, and TB Administration) for the District of Columbia, Department of Health. He has worked professionally in over 30 countries. His consultancies include work with WHO, USAID, and CDC. With InterAction—the largest coalition of U.S.-based international nongovernmental organizations (NGOs) focused on the world's poor and most vulnerable people—he worked on pandemic preparedness with 40 African and Asian nations.

Dr. Pappas served as the Noordin M. Thobani Professor at the Aga Khan University (AKU), where he was the Chairman of the Department of Community Health Sciences in Karachi, Pakistan. He has published extensively in international peer reviewed journals on the health of the people of Pakistan and health in other less developed countries. Dr. Pappas led the final report of Tawana Pakistan which documented the improvement in education and nutrition of primary school girls in the poorest districts of the country as a result of a school feeding program in over 4000 schools.

Previously he served as Medical Director of the Futures Group, designing and implementing the monitoring and evaluation plan for the antiretroviral program of AIDS Relief, working in nine countries in Africa and the Caribbean. Dr. Pappas was a major author of the President's Emergency Plan for AIDS Relief (PEPFAR) Five Year Strategy, a report to Congress. Dr. Pappas served in a variety of positions over an 18 year period in the Department of Health and Human Services including his role as Senior Policy Advisor to the Assistant Secretary for Health/Surgeon General, David Satcher. For the Surgeon General, Dr. Pappas worked in a number of areas including disparities in health and global health (HIV/AIDS, other infectious diseases, and health information systems development). Dr. Pappas directed the Office of International and Refugee Health, Department of Health and Human Services, serving on the Executive Board of UNICEF and PAHO, and as a delegate to the World Health Assembly. For ORC Macro, as Deputy Director of the Demographic and Health Survey (DHS) he implemented innovative surveys (including the use of biomarkers) in Uganda, Mali, Uzbekistan, and Dominican Republic.

Dr. Pappas received his MD and PhD (Anthropology) from Case Western Reserve in Cleveland, Ohio. After doing his clinical training, he came to Washington DC, first as a fellowship in Epidemiology, then continuing as a scientist at the National Center for Health Statistics/CDC. At NCHS he worked on many of the large, national data systems. He led the National Health Survey of Pakistan, a nationally representative health examination survey of over 16,000 sample persons. Dr. Pappas is author of numerous articles, including his work in the *New England Journal of Medicine* "The increasing disparity in mortality between socioeconomic groups in the United States" and his book with Cornell University Press, *The Magic City: unemployment in a working class community*. Dr. Pappas is on the faculty of the Bloomberg School of Public Health in the Department of Health Policy and Management, and is on the faculty of Howard Medical School. Dr. Pappas served as Chair of the Science Board and member of the Executive Board of the American Public Health Association. His *Megacities and Global Health* (APHA Press) with Omar Khan was published in 2012.



Doris Peter, PhD is the Director of the Consumer Reports Health Ratings Center, part of the nonprofit organization, Consumer Reports. She leads multidisciplinary teams that develop consumer-friendly translations and presentations of data to help consumers understand comparisons of the quality and value of health care products (e.g., drugs) and services (e.g., hospitals, physicians, insurance plans). These communications reach millions of consumers through Consumer Reports' media channels, and through those of Consumer Reports' partners. Dr. Peter is also the Principal Investigator of a grant from the Consumer and Prescriber Education Grant Project (Consumer Reports Best Buy Drugs) that helps consumers understand the safety, effectiveness, and cost of prescription and over-the-counter drugs by translating and disseminating comparative effectiveness research into actionable advice.



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 Sentinel System. Dr. Platt is also co-principal investigator of PCORI's PCORnet coordinating center, a consortium of 34 networks focused on 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-Drive 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.



Commander (CDR) Melissa Robb is the associate director for regulatory affairs in the Office of Medical Policy within the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). She is involved in various FDA programs and working groups to include leading programs related to expedited drug development, evidence generation, real world evidence, and postmarket surveillance. In 2002, CDR Robb began her career with the Agency as a project manager in CDER's Division of Cardiovascular and Renal Products. She then served as a senior program management officer in the Office of Critical Path Programs within the Office of the Commissioner. Prior to joining the FDA and the U.S. Public Health Service Commissioned Corps, CDR Robb was on active duty in the U.S. Air Force.



Joe Selby, MD, MPH. After obtaining his MD Degree from Northwestern, Dr. Selby moved to Northern California for internship and a family medicine residency and eventually an MPH at UC Berkeley. His fellowship project concerned Behavioral Factors in Cardiovascular Disease. He stayed in the bay area at Kaiser Permanente for 27 years, including 13 as Director of Research supervising up to 50 investigators and 500 staff members. He has had academic appointments at UC Berkeley, UCSF and Stanford. He has authored more than 200 peer reviewed articles on far ranging topics such as quality measurement and improvement, primary care delivery, colorectal cancer screening and many studies that could be classified under the heading of "comparative effectiveness" – largely in the areas of diabetes, HTN and cardiovascular disease. He has received honors from the Public Health Service, the American Epidemiological Society, Kaiser Permanente and in 2009 he was elected into the Institute of Medicine. In July 2011 Dr. Selby became the first Executive Director of the Patient-Centered Outcome Research Institute (PCORI). PCORI's mandate is to improve the quality and relevance of the evidence available in order to help patients, caregivers, employers, insurers and policy makers make informed healthcare decisions.



Azadeh Shoaibi, PhD, MHS is currently the acting CBER Sentinel Lead at the FDA/CBER Office of Biostatistics and Epidemiology where she directs all CBER Sentinel activities. Previously, she was a member of the Sentinel Core Team at the CDER Office of Medical Policy from 2010 to 2015 and worked as the FDA Sentinel Methods Lead and later Scientific Lead. She directed the development and implementation of the scientific infrastructure of the Sentinel Initiative and participated in surveillance and pharmacoepidemiologic evaluation of medical products using Sentinel tools.

Dr. Shoaibi first joined FDA in 2004 and worked at the CDRH Division of Epidemiology where she performed post-market evaluation, surveillance, and research on a variety of medical devices. Azadeh holds a doctorate in epidemiology and a master's degree in molecular microbiology and immunology. Her prior research and public health experience were in the areas of epidemiology of HIV and other sexually transmitted infections, genomics of malaria parasites, and effect of radiosensitizers on cell cycle regulation and cancer development.



Paul Wallace, MD is Chief Medical Officer and Senior Vice President for Clinical Translation at Optum Labs, which was launched in early 2013 with the Mayo Clinic and now includes 22 partners from across health care. Based in Cambridge, Massachusetts, Optum Labs is designed to develop and sustain a community of research and learning partners spanning multiple health sectors who will have access to unprecedented data resources to work collaboratively on some of the most critical problems in health care today.

From 2011-13 he was a Senior Vice President and Director of the Center for Comparative Effectiveness Research at the Washington DC based Lewin Group, and was formerly a Medical Director and clinician with Kaiser Permanente from 1989 to 2011. He was the Executive Director of Kaiser Permanente's Care Management Institute (CMI) from 2000 – 2005 and led and contributed to several KP national initiatives in evidence based medicine, population health and use of Health IT.

Dr. Wallace is currently Chair of the board of directors for AcademyHealth, the professional association for health services and policy research. He has served on national committees and boards for the Institute of Medicine, NCQA, AHRQ, CMS, the Blue Cross and Blue Shield Technology Evaluation Center, the Center for Information Therapy, the eHealth Initiative and the Care Continuum Alliance.



Janet Woodcock, MD is Director of the Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). In 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.