

Ninth Annual Sentinel Initiative Public Workshop

Kaiser Family Foundation-Barbara Jordan Conference Center • Washington, DC

February 2, 2017

Biographies

Steve Anderson, Ph.D., M.P.P., 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 important risk assessment projects and epidemiological studies. He led the first studies at FDA using Centers for Medicare & Medicaid Services (CMS) data to estimate blood utilization and address important blood product safety questions of regulatory concern. He has conducted collaborative studies using the FDA Sentinel system and CMS data to evaluate the safety of blood products and vaccines and worked to integrate use of these data systems into CBER's regulatory processes to improve biologic product safety evaluations and surveillance.

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. Dr. Anderson received his PhD in Biology 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 biologic product safety, risk assessment, epidemiology, pharmacoepidemiology, infectious diseases, biologics safety, and genomics and protein structure/targeting.



Robert Ball, MD, MPH, ScM 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, including managing the Sentinel System. 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, including the CBER mini-Sentinel pilot. Prior to joining the FDA, Dr. Ball served as a US Navy Medical Officer.



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 and Adjunct Associate Professor in the Division of Pharmaceutical Outcomes and Policy at the UNC Eshelman School of Pharmacy. 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's research expertise includes utilizing electronic health data in designing research in health outcomes and pharmacoeconomics, comparative effectiveness, and drug safety and pharmacoepidemiology. 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.



Efe Eworuke, Ph.D. is an epidemiologist in the Division of Epidemiology II, at the Office of Pharmacovigilance and Epidemiology (OSE/CDER/FDA). Efe is involved with postmarketing surveillance of cardiovascular, renal, pulmonary and rheumatology products. She trained as a pharmacoepidemiologist and received her PhD from the University of Florida, College of Pharmacy. Prior to completing her PhD, she received her masters from the University of Oxford, United Kingdom and her pharmacy degree from the University of Benin in Nigeria. Her focus is on conducting sentinel-related projects evaluating drug safety and the development and validation of claims-based algorithms. Efe is also interested in the application of advanced study designs to evaluate drug safety.



Tiffany Farchione, MD, received her medical degree from Wayne State University in Detroit, Michigan, and completed adult residency and child & adolescent fellowship training at the University of Pittsburgh's Western Psychiatric Institute and Clinic. Dr. Farchione is board certified in both general and child & adolescent psychiatry. Prior to joining FDA in 2010, Dr. Farchione was affiliated with the University of Pittsburgh Medical Center, and was on the faculty of the University of Pittsburgh.

As the Deputy Director of the Division of Psychiatry Products at FDA, Dr. Farchione is involved in the oversight of new drug review for all psychiatric drug development activities conducted under INDs, and the review of all NDAs and supplements for new psychiatric drug claims.



Rachael L. Fleurence, PhD, is a Program Director at the Patient-Centered Outcomes Research Institute (PCORI). She joined PCORI in April 2012. She leads 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. In this capacity, she chairs the PCORnet Executive Council and co-chairs the PCORnet Council. PCORnet is a 330 million dollar investment involving 130 health institutions across the country and 20 patient powered research networks. Dr Fleurence serves on a number of Boards and Steering Committees, including most recently the National Medical Device Evaluation

System Planning (NEST) Board and the SMART IRB Steering Committee. A health economist and health services researcher by training, Dr Fleurence previously worked in the private sector outcomes research. 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).



Richard A. Forshee, Ph.D., Richard Forshee leads the Analytics and Benefit-Risk Assessment Team for the Office of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. He works on a wide range of issues related to the risks and benefits of blood and blood products, vaccines, and human cell and tissue products. Before joining the FDA, he was the Director of the Center for Food, Nutrition, and Agriculture Policy at the University of Maryland, College Park.



Christian Hampp, PhD is a senior epidemiologist in the Office of Surveillance and Epidemiology in FDA's Center for Drug Evaluation and Research. He has co-led several Sentinel research projects, especially in the fields of metabolic and endocrine drugs. He serves as the CDER liaison to the Board of Directors of the International Society for Pharmacoepidemiology.

Dr. Hampp is also an Affiliate Clinical Assistant Professor at the University of Florida, College of Pharmacy. He received his pharmacy degree from Saarland University in Saarbrücken, Germany, and a PhD in pharmacoepidemiology from the University of Florida.



Mwango Kashoki, MD, MPH, Dr. Kashoki is the Associate Director for Safety in the Office of New Drugs (OND), in the Center for Drug Evaluation and Research (CDER) at FDA. Dr. Kashoki's responsibilities include ensuring OND's implementation of the policies and processes related to CDER's various safety initiatives, including the Safety First and Sentinel Initiatives. She also leads OND's implementation of FDA's new authorities to require safety labeling changes, postmarketing investigations, and risk evaluation and mitigation strategies, as provided under the FDA Amendments Act (FDAAA).



studies.

Mark Levenson is the Director of the Division of Biometrics 7 in the Office of Biostatistics/Office of Translational Sciences/Center for Drug Evaluation and Research of FDA. At FDA, he has been the primary reviewer or secondary reviewer on many major pre-market and post-market drug safety problems. He has contributed to the methodology of the application of meta-analysis and propensity score analysis to the regulatory setting. As the Director of the biostatistics division in CDER devoted to safety analysis, he contributes to statistical policy in the area of drug safety. He is active in CDER's efforts in the Sentinel Initiative including methods development and surveillance



the development of the Sentinel system. Before joining the FDA, Dr. Martin served in the U.S. Air Force as a flight and occupational medicine physician. He received his bachelor's degree at the Citadel, his medical degree at the Johns Hopkins University School of Medicine, and his master of public health degree at the Johns Hopkins University Bloomberg School of Public Health.

David Martin, MD, MPH is assigned to the FDA Center for Drug Evaluation and Research as the FDA Liaison to the Reagan Udall Foundation Innovation in Medical Evidence Development and Surveillance program. IMEDS enables routine private-sector queries related to medical products using a distributed database approach modeled on the FDA's Sentinel system. Dr. Martin is also the principal investigator for a Patient Centered Outcomes Trust Fund project that is incorporating patient data collected through a mobile device application into Sentinel and PCORnet. As a former Branch Chief and Division Director in the FDA Center for Biologics Evaluation and Research, he led analyses of spontaneous reports, formalized risk management planning, and played a key role in



Brookings Institution and a professor of economics and medicine at Stanford University where he directed the Program on Health Outcomes Research.

Mark B. McClellan, MD, PhD, is a doctor and an economist whose work has addressed a wide range of strategies and policy reforms to improve health care, including payment reforms to promote better outcomes and lower costs, methods for development and use of real-world evidence, and approaches for more effective drug and device innovation. 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. Dr. McClellan has served as a member of the President's Council of Economic Advisors and as Deputy Assistant Secretary of the Treasury for Economic Policy. He was also a Senior Fellow at the



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 Health (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 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 35 years and represents Utah's three largest agencies serving and protecting individuals with disabilities. He was 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 HABP/VABP; Informed Consent Project (Expert Interviews co-leader); Registry Trials Project (Project Manager). He is a Board Member of the SMA Foundation. Mr. Mikita is a member of the Mini-Sentinel Planning Board and a Patient Engagement Representative for Sentinel.

Recently, Mr. Mikita was the only Patient Representative on an International Consortium to develop a global clinical trial network for anti-microbial agents. He is also a Patient Advocate for MDEpiNet.



Richard (Rich) A. Moscicki, M.D., joined the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER), as Deputy Center Director for Science Operations. A nationally recognized expert in clinical research and development, Dr. Moscicki brings to the position executive direction of Center operations and leadership in overseeing the development, implementation, and direction of CDER's programs. Dr. Moscicki received his medical degree from Northwestern University Medical School. He is board certified in internal medicine, diagnostic and laboratory immunology, and allergy and immunology. He completed his residency with a focus on immunology, followed by a four-year fellowship at Massachusetts General Hospital (MGH) in

immunology and immunopathology.

Andrew Mosholder, MD, MPH, is a child and adolescent psychiatrist who first joined FDA in 1992, and initially worked on the premarketing evaluation of new psychiatric drugs. After completing a master's degree in public health from Johns Hopkins University, he transitioned to a position as an epidemiologist, and he currently is a medical officer with CDER's Division of Epidemiology 1.



William V. Murray joined MDIC in August of 2013 as the first President and CEO. He has over 25 years of senior leadership experience spanning the range of privately financed start-up to billion dollar plus global businesses. Bill's small company experience spans 5 years as CEO and executive consultant, including 3 years as CEO of ReShape Medical. His large company experience includes leadership as the Molecular Biology Division President of Applied Biosystems, and at Medtronic where he spent nearly 20 years in various senior leadership positions, including President of the Pacemaker Business. Bill has also served as interim President and CEO of MTS Systems (MTSC) a public \$500M industrial technology company. Bill currently serves on the Boards of MDIC, ILT, Sonex Health and Meso-Flow and previously served on the Boards of MTS Systems, LifeSync Holdings, and ReShape Medical. Bill has also served on various industry association and community leadership boards. He earned a Bachelor of Science Degree in Electrical Engineering from The University of Florida.



Vinit P Nair is a pharmacist & pharmacoepidemiologist with 15 years of experience at large national health plans and health outcomes & policy research organizations. Currently the lead for the Government Research & Academic Partnerships at Humana, Vinit is the Humana primary investigator on federal grants involving the US Food & Drug Administration, Regan Udall Foundation IMEDS Program and the Patient Centered Outcomes Research Institute (PCORI) PCORnet. In addition, Vinit also held academic appointments and serves as a reviewer & editorial board member for peer-reviewed journals and recipient of over \$13 million in grants & contracts. Vinit's passion is in patient and drug safety and working with healthcare technology companies to understand how best to utilize existing networks and build innovative ways to address patient safety



Sally Okun is the Vice President for Advocacy, Policy and Patient Safety at PatientsLikeMe, an online patient research network. She is responsible for bringing patient voice and insight to diverse advocacy and health policy discussions at the national and global level, and is the company's liaison with external organizations, government and regulatory agencies including a Research Collaboration Agreement with the FDA's Office of Surveillance and Epidemiology and co-PI for a sub-award through Scripps Translational Research Institute for the NIH All of Us Research Program's Participant Technology Center. Sally joined PatientsLikeMe in 2008 as the manager of Health Data Integrity and Patient Safety responsible for developing the site's medical ontology and codifying the patient reported health data into standardized terminologies. She coordinated the development of the site's Drug Safety and Pharmacovigilance Platform. Since assuming the VP position in 2013 she's been actively involved in numerous external activities including serving as a member of the PCORI Patient Engagement Advisory Panel; the Advisory Committee for the Reagan-Udall Foundation's Big Data for Patients (BD4P) program and a member of the Scientific Advisory Committee for IMEDS. Sally is on the Strategic Planning Task Force for the American Heart Association Institute for Precision Cardiovascular Medicine, a member of the Leadership Consortium for a Value & Science-driven Health System at the National Academy of Medicine. She is a frequent contributor to expert panels convened by groups such as the National Quality Forum, Agency for Health Care Research and Quality, The Commonwealth Fund, Center for Medical Technology Policy, National Patient Advocacy Foundation, the American College of Cardiology's Diabetes Collaborative Registry, the Schwartz Center for Compassionate Care and many others. In 2017 Sally joined the Board of Directors for Public Responsibility in Medicine and Research (PRIM&R). Okun received her nursing diploma from the Hospital of St. Raphael School of Nursing, her baccalaureate degree in nursing science from Southern Connecticut State University, and her Master's degree from The Heller School for Social Policy & Management at Brandeis University. She was a 2010 Fellow in Biomedical Informatics for the National Library of Medicine and a 2014 Salzburg Global Fellow in New Paradigms for Behavioral and Mental Health.



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 work on 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 serves on the faculty GW School of Public Health. Dr. Pappas served as Chair of the Science Board and member of the Executive Board of the American Public Health Association. His book, *Megacities and Global Health* (APHA Press) with Omar Khan was published in 2012.

Jennifer Rodriguez Pippins, MD, MPH is Deputy Director for Safety for the Division of Metabolism and Endocrinology (DMEP) with FDA’s Office of New Drugs, Center for Drug Evaluation and Research. She oversees post- and pre-marketing safety activities for drug products for diabetes, dyslipidemia, obesity, and general endocrine disorders.



Richard Platt, MD, MSc, is an internist and infectious disease clinician/epidemiologist. He is Professor and Chair of the Harvard Medical School Department of Population Medicine and Executive Director of the Harvard Pilgrim Health Care Institute. He is Principal Investigator of the FDA Sentinel System, co-Principal Investigator of the National Patient Centered Clinical Research Network (PCORnet) Coordinating Center, 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 National Academy of Medicine's Leadership Consortium for a Value & Science-Driven Health System, and is a member of the American Medical Colleges Advisory Panel on Research.



Scott Proestel, MD is Director of the Division of Epidemiology at FDA's Center for Biologics Evaluation and Research, where he oversees active and passive safety surveillance for therapies approved by the center. His research interests include the use of natural language processing and machine learning to enhance safety surveillance of medical products, and he is the principal investigator for a project evaluating the use of IBM's Watson to interpret adverse event reports submitted to FDA. His research interests also include the use of social media for pharmacovigilance.



Robert Reynolds is Vice President, Epidemiology in Worldwide Safety, part of Research and Development 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. 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.



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.

Maria Said is a medical officer in the Analytic Epidemiology Branch in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. She joined the FDA in January 2015, and her work focuses on evaluating the safety and effectiveness of vaccines and blood products. She is a physician trained in internal medicine and infectious diseases. Before joining the FDA, she was a CDC Epidemic Intelligence Service officer based at the Maryland Department of Health and Mental Hygiene.



Azadeh Shoaibi, PhD, MHS is the Sentinel Lead at the FDA/CBER Office of Biostatistics and Epidemiology where she leads and directs the CBER Sentinel program. From 2010 to 2015, she held the position of the FDA Sentinel Methods Lead and later Scientific Lead at CDER. Dr. Shoaibi joined the FDA in 2004 at the CDRH Division of Epidemiology. Azadeh holds a doctorate in epidemiology and a master's degree in molecular microbiology and immunology. Her prior research and public health experience focused on the epidemiology of HIV and other sexually transmitted infections, genomics of malaria parasites, and cell cycle regulation and cancer development.

Mary Ross Southworth, PharmD is the Deputy Director for Safety in the Division of Cardiovascular and Renal Drug Products in the Center for Drug Evaluation and Research at FDA. Her responsibilities include managing postmarketing safety activities in the division including the evaluation of safety signals from a variety of sources, safety labeling and communications, review of postmarketing safety studies and REMS.