Duke | Robert J. Margolis, MD Center for Health Policy

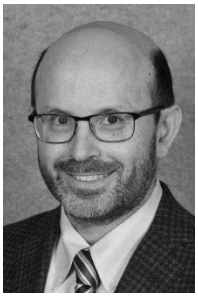
Twelfth Annual Sentinel Initiative Public Workshop

Virtual (Zoom)
Wednesday October 14, 2020

Biographies

Amy P. Abernethy is an oncologist and internationally recognized clinical data expert and clinical researcher. As the Principal Deputy Commissioner of Food and Drugs, Dr. Abernethy helps oversee FDA's day-to-day functioning and directs special and high-priority cross-cutting initiatives that impact the regulation of drugs, medical devices, tobacco and food. As acting Chief Information Officer, she oversees FDA's data and technical vision, and its execution. She has held multiple executive roles at Flatiron Health and was professor of medicine at Duke University School of Medicine, where she ran the Center for Learning Health Care and the Duke Cancer Care Research Program. Dr. Abernethy received her M.D. at Duke University, where she did her internal medicine residency, served as chief resident, and completed her hematology/oncology fellowship. She received her Ph.D. from Flinders University, her B.A. from the University of Pennsylvania and is boarded in palliative medicine.

Steve Anderson 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 risk assessment programs. 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 in inpatient and outpatient setting. 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. He launched the CBER Biologics Effectiveness and Safety (BEST) System to expand and enhance CBER access to new and better data sources, methods, tools, expertise and infrastructure to conduct surveillance and epidemiologic studies for biologic products. 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 PhD 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, infectious diseases, biologics safety, and genomics and protein structure/targeting.



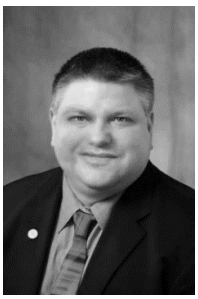
Robert Ball is Deputy Director, Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), FDA. Dr. Ball shares in the responsibilities for leading OSE staff evaluating drug risks and promoting the safe use of drugs by the American people, including managing the Sentinel 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. From 1998 to 2008, Dr. Ball monitored and oversaw post-market safety for all US licensed vaccines. Prior to joining the FDA, Dr. Ball served as a US Navy Medical Officer where he led research to improve the safety and efficiency of deep-sea diving, and provided patient care in US Naval hospitals in Subic Bay, Philippines, and Bethesda, Maryland.

Jeffrey Brown is an Associate Professor in the Department of Population Medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. Within DPM, Dr. Brown serves on the Executive Committee of the Therapeutics Research and Infectious Disease Epidemiology program, overseeing a staff of over 100 researchers and is the Lead Data Scientist for the FDA Sentinel System. His primary research activities involve new approaches to facilitate large-scale multi-institutional research through the use of distributed health data networks to support a learning health system. This research established the basis for several established research networks, including the FDA's Sentinel System and PCORnet. He has leadership roles in FDA Sentinel, PCORnet, the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), the Innovation in Medical Evidence and Development Surveillance (IMEDS) program, and the NIH Health Care Systems Research Collaboratory. Dr. Brown is the inventor of PopMedNet, an open-source software platform that facilitates creation and operation of distributed health data networks. Dr. Brown holds a Master's degree in Economics from Tufts University and a PhD in Social Policy from Brandeis University. He is an 8-time US national champion and 3-time world champion in Ultimate Frisbee and coached the Tufts Men's Ultimate team for 20 years.

Patrizia Cavazzoni is the Acting Director for the Center for Drug Evaluation and Research (CDER). Previously, she served as the Deputy Director for Operations at CDER. In that position, Dr. Cavazzoni provided strategic leadership related to regulatory and scientific programs. Dr. Cavazzoni received her medical degree at McGill University and completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa. She subsequently joined the faculty of medicine at the University of Ottawa as an assistant professor, where she was engaged in clinical work, teaching, and research on genetic predictors of mood disorders, authoring numerous peer-reviewed scientific publications. Following this, Dr. Cavazzoni worked in the pharmaceutical industry for several years, and held senior leadership positions in clinical development, regulatory affairs, and safety surveillance. Dr. Cavazzoni is certified by the American Board of Neurology and Psychiatry, and she is a fellow of the Canadian Royal College of Physician and Surgeons, a member of the Canadian College of Neuropsychopharmacology, and recipient of the American College of Psychiatrists' Laughlin Fellowship.

Gerald J. Dal Pan 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 from Columbia University College of Physicians and Surgeons and his Master of Health Science in Clinical Epidemiology from 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 full-time faculty member in the Department of Neurology at Johns Hopkins and worked in the pharmaceutical industry.

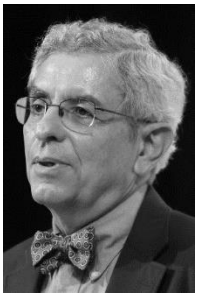
Asif Dhar is Vice Chairman and US Life Sciences and Health Care (LSHC) Industry Leader for Deloitte LLP leading the overall strategic direction for the life sciences and health care practices, including audit, consulting, tax, and advisory services. He is a respected health futurist and sought-after digital disrupter. Asif helps Governments, Life Sciences and Health Care clients reinvent wellness, solve disease, address pandemics and tackle health inequities. He is also Deloitte's Lead Partner for the Firm's US Food and Drug Administration (FDA) relationship and responsible for all work Deloitte performs with and for the Agency. He is currently the Principal Investigator for the FDA's Sentinel Community Building and Outreach Center. His perspectives on real world evidence, regulatory sciences, digital health, and innovation are sought by clients around the world.



Richard Forshee leads the Analytics and Benefit-Risk Assessment Team and the High Performance Integrated Virtual Environment Team for the Office of Biostatistics and Epidemiology (OBE) in the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. Recently he was appointed as the Acting Deputy Director for OBE. 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. Dr. Forshee has won numerous awards including the FDA Service Award and the CBER Hope Hopps Memorial Award, and he has published more than 70 scientific articles. Before joining the FDA, he was the Director of the Center for Food, Nutrition, and Agriculture Policy at the University of Maryland, College Park.

Vincent Lo Re is a tenured Associate Professor of Medicine in the University of Pennsylvania Division of Infectious Disease, Senior Scholar in the Penn Center for Clinical Epidemiology and Biostatistics, and Senior Investigator in the Penn Center for Pharmacoepidemiology Research and Training. Dr. Lo Re leads an NIH-funded research program focused on infectious diseases epidemiology and pharmacoepidemiology, particularly related to chronic viral hepatitis infection and HIV. He has particular expertise in evaluating health outcomes of interest within electronic healthcare databases. His research has been funded by the National Institute of Allergy and Infectious Diseases, National Institute of Diabetes and Digestive and Kidney Diseases, National Cancer Institute, Agency for Healthcare Research and Quality, Department of Veterans Affairs, and the US Food and Drug Administration. He maintains an active clinical practice devoted to the care of patients with infectious diseases, particularly HIV and chronic viral hepatitis. In addition to his clinical and research efforts, he is Co-Director of Penn's Master of Science in Clinical Epidemiology degree program and is President-Elect of the International Society for Pharmacoepidemiology.

Mark McClellan is the Robert J. Margolis Professor of Business, Medicine, and Health Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University. With offices in Durham, NC and Washington, DC, the Duke-Margolis Center is a university-wide, interdisciplinary initiative that is nationally and internationally recognized for its research, evaluation, implementation, and educational initiatives to improve health and health policy. The Center integrates Duke's expertise in the social, clinical, and analytical sciences with health care leader and stakeholder engagement to develop and apply policy solutions that improve health and the value of health care locally, nationally, and worldwide. Dr. McClellan is a physician and an economist who has informed and improved a wide range of strategies and policy reforms to advance health care, including payment reform to promote better outcomes and lower costs, methods for development and use of real-world evidence, and strategies for more effective biomedical 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. With highly distinguished record in public service and academic research, Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These reforms 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. He previously served as a member of the President's Council of Economic Advisers, senior director for health care policy at the White House, and Deputy Assistant Secretary for Economic Policy at the Department of the Treasury. Dr. McClellan is the founding chair and a current board member of the Reagan-Udall Foundation for the FDA and a member of the National Academy of Medicine (NAM), where he chairs the 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 is also a Senior Advisor on the faculty of the University of Texas Dell Medical School and co-chair of the Accountable Care Learning Collaborative. Dr. McClellan is an independent director on the boards of Johnson & Johnson, Cigna, and Alignment Healthcare. 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.



Richard Platt is Professor and Chair of the Harvard Medical School Department of Population Medicine and President of the Harvard Pilgrim Health Care Institute. He is Principal Investigator of the FDA Sentinel System. He led the development, with the Massachusetts Department of Public Health, of ESPnet, a system for doing real time EHR-based surveillance for both syndromes of interest and individually notifiable conditions. He is also co-Principal Investigator of the National Patient Centered Clinical Research Network (PCORnet) Coordinating Center, which is developing standard methods for extracting and using EHR data for multiple uses. Dr. Platt also co-leads the coordinating center of the NIH Health Care System Research Collaboratory and leads a CDC Prevention Epicenter. He co-chairs the Evidence Mobilization Action Collaborative of the National Academy of Medicine's Leadership Consortium for a Value & Science-Driven Health System, and is a member of the Association of American Medical Colleges Advisory Panel on Research.

Sebastian Schneeweiss is a Professor of Medicine and Epidemiology at Harvard Medical School and Chief of the Division of Pharmacoepidemiology, Department of Medicine, Brigham and Women's Hospital. His research focuses on the comparative effectiveness and safety of biopharmaceuticals. He has developed analytic methods to improve the scientific validity of epidemiologic analyses using complex longitudinal healthcare databases for newly marketed medical products. The overarching theme of his research is applying advanced real-world data analytics for regulatory decision making transparently and in rapid cycles. His work is published in >450 articles. His work is funded by NIH, PCORI, Arnold Foundation, IMI, and FDA where he is also a voting consultant. Dr. Schneeweiss is Principal Investigator of the FDA Sentinel Innovation Center funded by FDA/CDER and Methods Lead of the FDA Sentinel program. He is Past President of the International Society for Pharmacoepidemiology and is Fellow of the American College of Epidemiology, the American College of Clinical Pharmacology, and the International Society for Pharmacoepidemiology. He received his medical training at the University of Munich Medical School and his doctoral degree in pharmacoepidemiology from Harvard.

Hui-Lee Wong is Associate Director Innovation and Development at the Office of Biostatistics and Epidemiology at the Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA). In this capacity, she is actively engaged in the CBER Surveillance Program efforts aimed at advancing CBER surveillance systems. At the US FDA since 2009, her regulatory experience encompasses post market surveillance of biologics, drugs at Center for Drug Evaluation and Research and medical devices at Center for Devices and Radiological Health. She also leads projects in building capacity for pharmacovigilance of vaccines in Democratic Republic of Congo and Kenya. She was seconded to the U.S. Centers for Disease Control and Prevention Ebola Response Team in Sierra Leone in 2015. Prior to US FDA, she completed a post-doctoral fellowship at the U.S. National Institutes of Health and received a Ph.D. in Molecular Epidemiology from the University of Southern California.

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