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

Applying Lessons Learned from RWE in the Time of COVID-19 to the Future

Duke-Robert J. Margolis, MD, Center for Health Policy
Virtual Meeting
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Biographies

Amy P. Abernethy is the Principal Deputy Commissioner of the U.S. Food and Drug Administration. In addition to this, Dr. 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.

Brian Anderson is the Chief Digital Health Physician at MITRE, Dr. Anderson is a Harvard trained physician-scientist, digital health innovator and clinical systems engineer. Dr. Anderson became a nationally recognized expert on the use of information technology in support of emerging CDS models and the provision of safe, effective, patient centered care while at athenahealth where he launched a new model of clinical decision support leveraging artificial intelligence. Dr. Anderson has also helped to develop and bring to market nascent technology and clinical workflows to support health system strategies around improved Patient Access. He has served on several national health information technology committees in partnership with the Office of the National Coordinator (ONC). Previously, Dr. Anderson led the Informatics Department at athenahealth where he focused his EHR product development around CDS systems. As MITRE's Chief Digital Health Physician, Dr. Anderson helps to architect, implement, and analyze health information systems for CMS, HHS, the FDA and the VA. Dr. Anderson is also the Co-Principal Investigator of MITRE's largest internally funded R&D project, where he is leading the development of a common data model in Oncology based on FHIR, termed mCODE (minimal Common Oncology Data Elements). Dr. Anderson trained at Massachusetts General Hospital and also practiced at Greater Lawrence Family Medicine. He received his MD with honors from Harvard Medical School, and a BA in Social Anthropology, cum laude from Harvard College.

Crystal P. Browning is a Senior Director of Regulatory Affairs at Pfizer, Inc. Her regulatory role current supports products in the Inflammation and Immunology division. Crystal has worked solely in regulatory for 18 years working on small to large molecules and has direct experience in pre-clinical through commercialization and post-approval development, biosimilars, chemistry manufacturing and control, and combination products. In addition to extensive US experience, she has also been able obtain global regulatory experience with India, Singapore, Europe, Canada and Australia. Crystal earned her B.S. in Biological Sciences with an emphasis in Cell and Molecular Development from University of California Riverside, her M.S. in Regulatory Sciences from San Diego State University.

Robert M. Califf is the Head of Clinical Policy and Strategy for Verily and Google Health. Prior to this Dr. Califf was the vice chancellor for health data science for the Duke University School of Medicine; director of Duke Forge, Duke's center for health data science; and the Donald F. Fortin, MD, Professor of Cardiology. He served as Deputy Commissioner for Medical Products and Tobacco in the U.S. Food and Drug Administration (FDA) from 2015-2016, and as Commissioner of Food and Drugs from 2016-2017. A nationally and internationally recognized leader in cardiovascular medicine, health outcomes research, healthcare quality, and clinical research, Dr. Califf is a graduate of Duke University School of Medicine. Dr. Califf was the founding director of the Duke Clinical Research Institute and is one of the most frequently cited authors in biomedical science.

John Concato is Deputy Director of the Office of Medical Policy Initiatives at the Center for Drug Evaluation and Research, US Food and Drug Administration. After almost 30 years generating research—as both an independent investigator and research center director at Yale University School of Medicine and the U.S. Department of Veterans Affairs—he now works to develop, coordinate, and implement medical policy programs and strategic initiatives. These efforts seek to support and improve medical product development and post-marketing processes, including in emerging areas such as the use of real-world evidence as well as clinical trial conduct during the COVID-19 pandemic.

Nancy Dreyer is Senior Vice President and Chief Scientific Officer for Real World Solutions at IQVIA, and Adjunct Professor of Epidemiology at the University of North Carolina at Chapel Hill. At IQVIA, Dreyer leads the Center for Advanced Evidence Generation, working to raise attention to the use of real-world research to enhance and accelerate evidence generation. Her current work is focused on COVID-19 as well as other issues of regulatory and public health importance. Dreyer received the Red Jacket honor from PharmaVOICE in 2020 and DIA's Global Inspire Award for Author of the Year in 2019.

Laura Esserman is a Professor of Surgery and Radiology at the University of California, San Francisco (UCSF) and the director of the UCSF Breast Care Clinic. Her work in breast cancer spans the spectrum from basic science to public policy issues, and the impact of both on the delivery of clinical care. Dr. Esserman is recognized as a thought leader in cancer screening and over-diagnosis, as well as innovative clinical trial design. She led the creation of the University of California-wide Athena Breast Health Network, a learning system designed to integrate clinical care and research as it follows 150,000 women from screening through treatment and outcomes. The Athena Network launched the PCORI-funded Wisdom Study, which tests a personalized approach to breast cancer screening in 100,000 women. She is also a leader of the innovative I-SPY TRIAL model, designed to accelerate the identification and approval of effective new agents for women with high risk breast cancers. She recently got FDA approval for an I-SPY COVID trial, designed to rapidly screen and confirm high impact treatments to reduce mortality and time on ventilators.

Jennifer Goldsack is the co-founder and serves as the Executive Director of the Digital Medicine Society (DiMe), a 501(c)(3) non-profit organization dedicated to advancing digital medicine to optimize human health. Jen's research focuses on applied approaches to the safe, effective, and equitable use of digital technologies to improve health, healthcare, and health research. She is a member of the Roundtable on Genomics and Precision Health at the National Academies of Science, Engineering and Medicine. Previously, Jen spent several years at the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and the FDA. There, she led development and implementation of several projects within CTTI's Digital Program and was the operational co-lead on the first randomized clinical trial using FDA's Sentinel System. Jen spent five years working in research at the Hospital of the University of Pennsylvania, first in Outcomes Research in the Department of Surgery and later in the Department of Medicine. More recently, she helped launch the Value Institute, a pragmatic research and innovation center embedded in a large academic medical center in Delaware. Jen earned her master's degree in chemistry from the University of Oxford, England, her masters in the history and sociology of medicine from the University of Pennsylvania, and her MBA from the George Washington University. Additionally, she is a certified Lean Six Sigma Green Belt and a Certified Professional in Healthcare Quality. Ms. Goldsack is a retired athlete, formerly a Pan American Games Champion, Olympian, and World Championship silver medalist.

Adrian Hernandez is Executive Director of the Duke Clinical Research Institute, and also serves as Vice Dean and Professor of Medicine, Division of Cardiology, at the Duke University School of Medicine, all in Durham, NC. Dr. Hernandez received his medical degree from the University of Texas-Southwestern Medical Center in Dallas. He completed his residency training in internal medicine at the University of California in San Francisco. Dr. Hernandez completed his fellowship in cardiology at Duke University Medical Center Cardiology in Durham, NC, as well as his MHS. Dr. Hernandez has research interests in the cardiology field, specifically acute, chronic, and advanced heart failure, heart failure and comorbidities, quality of care and outcomes research, clinical trials, comparative effectiveness and health policy. Dr. Hernandez is a member of the American College of Cardiology, the American Heart Association, the Heart Failure Society of America, and the American Society for Clinical Investigation. He has co-authored more than 600 peer-reviewed publications.

Solomon Iyasu is the Vice President and Global Head of Pharmacoepidemiology at Merck and Co, one of the largest global pharmaceutical companies in the world. In his current position at Merck, he leads a team of over 50 highly trained pharmaco-epidemiologists, molecular epidemiologists and database analysts responsible for epidemiology support of Merck's drug and vaccine clinical development including natural history of disease, trial design, endpoint strategy and design and conduct of post-approval safety surveillance and studies. In his current role, Dr. Iyasu also leads Merck's RWE initiatives for regulatory applications and decision making and serves on prominent external scientific initiatives to advance methods and standards for real world evidence (RWE). He serves on the scientific advisory group of the Duke Margolis RWE Collaborative; the expert advisory panel of OPERAND; the steering committee of the IMEDS-Reagan Udall Foundation for the FDA; the RWE Taskforce of the International Society of Pharmacoepidemiology; the CORE Committee of the Trancelerate Consortium RWD Program; and the CIOMS WG XIII on RWE/D in Regulatory Decision Making. Dr. Iyasu' s career in medicine, national and international public health, regulatory science, application of epidemiologic research methods to understanding human diseases and assessment of the safety and effectiveness of therapeutics and vaccines spans over 35 years. Prior to Joining Merck, he worked at the Food and Drug Administration for 13 years in various leadership positions including as Deputy Director of Pediatric Drug Development Director of Epidemiology and Director of CDER's Office of Pharmacovigilance and Epidemiology. He contributed to the formation of FDA's Sentinel System and the evaluation of drug safety, and benefit-risk to support FDA regulatory decision making. He served as a member of the CDER Drug Safety Oversight Board and participated in all the major drug safety decisions of CDER. Prior to that, he worked for over 13 years at the Centers for Disease Control in Atlanta conducting epidemiologic studies to investigate infectious disease outbreaks and later as team leader for maternal and child health epidemiology and collaborated on research projects with state and local health departments, the NIH, the Indian Health Service and the American Academy of Pediatrics. And prior to that, he served in several resource poor countries and famine stricken East African Countries coordinating health care assistance programs and providing consultations to UNICEF and UNHCR on nutritional supplementation programs. Dr. Iyasu has many publications including scientific journal articles and book chapters. Dr. Iyasu received his medical training at the University of Delhi, India and a Master of Public Health at the Johns Hopkins University and completed a Preventive Medicine Residency and Epidemic Intelligence Service (EIS) fellowship training at the Centers for Disease Control in Atlanta, Georgia.

Ernesto Ramirez, PhD is a Design Lead in the Research, Analysis, and Learning team at Evidation Health, a new kind of health and measurement company that provides the world's most innovative healthcare ecosystem players the technology and expertise they need to understand how everyday behavior and health interact. As part of the multi-disciplinary team at Evidation, Ernesto's role involves hands-on work with projects that are exploring digital biomarker development and the unique health-related signals present within large-scale longitudinal patient-generated data, primarily for clients in the biopharma space. Ernesto is responsible for driving numerous internal and client-supported projects through ongoing collaborations with experts from industry, academic, and non-profit institutions. He received his PhD in Public Health from the Joint Doctoral Program at San Diego State University and the University of California, San Diego.

Leonard Sacks is currently the Associate Director for Clinical Methodology in the Office of Medical Policy (CDER) at FDA. Additionally, Dr. Sacks holds an academic position as associate clinical professor of medicine at George Washington University. Dr. Sacks was born in Johannesburg, South Africa where he received his medical education at the University of the Witwatersrand. In 1988 he moved to the USA and completed a fellowship in immunopathology at Upstate Medical Center in Syracuse NY, as well as a fellowship in infectious diseases at the VA Medical Center in Washington DC. Since that time, he has worked as an attending physician in infectious diseases both in Washington DC and in South Africa, with particular interests in antimicrobial therapy, tuberculosis and tropical diseases. Joining the FDA in 1998, Dr Sacks served as a medical reviewer and team leader in the Division of Special Pathogens and Immunological Drug Products, at CDER, before becoming the Associate Director for Clinical Methodology in the Office of Medical Policy CDER.

David Soergel is the Global Head of Cardio-Renal-Metabolic Development at Novartis, joining in 2017. Prior to this role, Dr. Soergel spent 9 years at biotechnology companies working in a variety of therapy areas, building high-performing development teams and conducting complex multi-stage adaptive trials. He has been involved in development of program strategy and design, execution and reporting of clinical trials in acute and chronic pain, acute heart failure, infectious diseases, and renal diseases. Prior to joining biotech, Dr. Soergel worked in early stage clinical development and translational medicine at GlaxoSmithKline, leading programs from the discovery organization into the clinic and through proof of concept. Dr. Soergel originally trained in pediatrics, pediatric cardiology and heart failure and transplant at Johns Hopkins Hospital and Children's Hospital of Philadelphia. During his cardiology fellowship, Dr. Soergel completed an NIH sponsored NRSA post-doctoral fellowship at Johns Hopkins studying myofilament function.

Pamela Tenaerts is the Executive Director at the Clinical Trials Transformation Initiative (CTTI) where she works closely with the Executive Committee to develop and implement strategies to accomplish CTTI's mission. She orchestrates efforts to effectively engage all interested stakeholders to improve the conduct of clinical trials. She is on the Board of Directors for the Society of Clinical Trials and a member of DIA's Advisory Council North America and DiMe Society's Scientific Advisory Board. She is an independent director on the board of TRxADE group, Inc. Tenaerts practiced medicine in both the emergency department and private practice setting before embarking on a career in research. Dr. Tenaerts received her MD from Catholic University of Leuven, Belgium, and her MBA from the University of South Florida. She speaks five languages and has obtained Six Sigma Green Belt certification.

Griffin Weber, is an Associate Professor of Medicine and Biomedical Informatics in the Department of Medicine, Beth Israel Deaconess Medical Center (BIDMC), and the Department of Biomedical Informatics, Harvard Medical School (HMS). His expertise is in leveraging electronic health record (EHR) data for research, with a focus in developing methods to address data quality issues and biases clinical data. He helped create Informatics for Integrating Biology and the Bedside (i2b2), an open source software platform for query, analysis, and visualization of EHR data, which is used at more than 200 institutions worldwide. He also helped build the Shared Health Research

Information Network (SHRINE), which is a federated query tool that connects i2b2 databases across multiple institutions, enabling researchers to access data on more than 100 million patients. He is a technical lead for the Consortium for Clinical Characterization of COVID-19 by EHR (4CE), an international effort studying COVID-19 using the EHR data from 96 hospitals in five countries.

Susan C. Winckler is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. The Foundation is the non-profit organization created by Congress to advance the mission of the FDA. Prior to accepting the Foundation post in May of 2020, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, industry leaders, and consumers with a neutral forum to address domestic and global issues. As FDA Chief of Staff from 2007-2009, Ms. Winckler managed the Commissioner's office; served as his/her senior staff adviser; analyzed policies; and represented FDA before myriad government and external stakeholders. She simultaneously led FDA's Offices of Legislation, External Relations, Public Affairs, and Executive Secretariat. As APhA Vice President Policy/Communications and Staff Counsel, she served as the association's lead spokesperson and senior liaison to Congress, the executive branch, state associations, and allied groups. Ms. Winckler earned a BS from the University of Iowa College of Pharmacy and her JD magna cum laude from Georgetown University Law Center. She is an APhA Fellow.

Moderators

Jeff Allen is the President and CEO of Friends of Cancer Research (Friends). During the past 20 years, Friends has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the fastest and safest way possible. As a thought leader on many issues related to Food and Drug Administration, regulatory strategy and healthcare policy, he is regularly published in prestigious medical journals and policy publications, and has contributed his expertise to the legislative process on multiple occasions. Recent Friends initiatives include the establishment of the Breakthrough Therapies designation and the development of the Lung Cancer Master Protocol, a unique partnership that will accelerate and optimize clinical trial conduct for new drugs. Dr. Allen received his Ph.D. in cell and molecular biology from Georgetown University, and holds a Bachelor of Science in Biology from Bowling Green State University.

Susan Dentzer is Senior Policy Fellow for the Robert J. Margolis Center for Health Policy at Duke University. Based in Washington, DC, where the center's research team is located, she focuses on the COVID-19 pandemic response; health system transformation, such as through telehealth; biopharmaceutical policy; health care issues in the 2020 elections, and other key health policy issues. Dentzer is one of the nation's most respected health and health policy thought leaders and a frequent speaker and commentator on television and radio, including PBS and NPR, and an author of commentaries and analyses in print publications such as Modern Healthcare. She was also the editor and lead author of the book Health Care Without Walls: A Roadmap for Reinventing U.S. Health Care, available on Amazon.com. From March 2016 to February 2018, Dentzer was President and Chief Executive Officer of NEHI, the Network for Excellence in Health

Innovation, a nonprofit, nonpartisan organization then composed of more than 80 stakeholder organizations from across all key sectors of health and health care. From 2013 to 2016, she was senior policy adviser to the Robert Wood Johnson Foundation, the nation's largest philanthropy focused on health and health care in the United States, and before that, was the editor-in-chief of the policy journal Health Affairs. From 1998 to 2008, she was the on-air Health Correspondent for the PBS NewsHour. Dentzer wrote and hosted the 2015 PBS documentary, Reinventing American Healthcare, focusing on the innovations pioneered by the Geisinger Health System and spread to health systems across the nation. Dentzer is an elected member of the National Academy of Medicine (formerly the Institute of Medicine) and also serves on the Board on Population Health and Public Health Practice of the National Academies of Science, Medicine, and Engineering. She is an elected member of the Council on Foreign Relations; a fellow of the National Academy of Social Insurance; and a fellow of the Hastings Center, a nonpartisan bioethics research institute. She is also a member of the Board of Directors of the International Rescue Committee, a leading global humanitarian organization; a member of the board of directors of Research!America, which advocates on behalf of biomedical and health-related research; and a member of the board of directors of the Public Health Institute, a nonprofit organization addressing public health issues and solutions nationwide. Dentzer serves on the global access public policy advisory committee for Roche, the international biopharmaceutical company based in Basel, Switzerland. She is a member of the Boards of Advisors for RAND Health and for the Philip R. Lee Institute of Health Policy Studies at the University of California-San Francisco. From 2011 to 2017 she was public member of the Board of Directors of the American Board of Medical Specialties, which assists 24 medical specialty boards in the ongoing evaluation and certification of physicians. Dentzer graduated from Dartmouth, is a trustee emerita of the college, and chaired the Dartmouth Board of Trustees from 2001 to 2004. She serves on the advisory board for the Center for Global Health Equity at Dartmouth, and previous was a member of the Board of Advisors of Dartmouth's Geisel School of Medicine or more than two decades. Dentzer holds an honorary master's degree from Dartmouth and an honorary doctorate in humane letters from Muskingum University. She and her husband have three adult children.

Mark McClellan is Director of the Margolis Center for Health Policy at Duke University and the Robert J. Margolis Professor of Business, Medicine, and Policy. He is a physician economist who focuses on quality and value in health care including payment reform, real-world evidence and more effective drug and device innovation. He is former administrator of the Centers for Medicare & Medicaid Services and former commissioner of the U.S. Food and Drug Administration, where he developed and implemented major reforms in health policy. He was previously Senior Fellow at the Brookings Institution and a faculty member at Stanford University.