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

AI/Machine Learning: Regulation, Development, and Real-World Performance Evaluation

Duke-Robert J. Margolis, MD, Center for Health Policy
Virtual Meeting
March 22, 2022 12:30 – 4:00 PM EDT

Panelist Biographies

Fireside Chat

Jeffrey Shuren is the Director of the Center for Devices and Radiological Health (CDRH) at FDA. He previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, Dr. Shuren joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. From 1998 to 2003, he served as a Staff Volunteer in the National Institutes of Health's National Institute of Neurological Disorders and Stroke Cognitive Neuroscience Section supervising and designing clinical studies on human reasoning. Dr. Shuren returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009.

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.

Session 1: Frameworks for Regulating AI/ML Medical Device Software

Pat Baird works at Philips as the Head of Global Software Standards. Pat likes to think of his job as "Policy Engineering" – understanding the unmet needs (and frustrations) of regulators and developers, and developing standards, whitepapers, and training to meet those needs. His current passion is related to artificial intelligence in healthcare; he is co-chair of multiple AI committees, including the WHO, and is an industry representative on the IMDRF AI committee.

Kathleen Blake became a Senior Advisor at the American Medical Association in January 2022 after serving as its Vice President for Healthcare Quality. She is an AMA subject matter expert on a wide range of health technology innovations including artificial intelligence, real world data and evidence including clinical registries and electronic health record systems, cybersecurity, appropriate use criteria and the use of clinical algorithms. Dr. Blake was co-chair of the Health Information Technology Policy Committee of the Office of the National Coordinator for Health Information Technology until April 2017. She currently serves on the Governing Committee of the National Evaluation System for health Technology (NEST) coordinating center, a public private partnership advancing innovation and use of real-world evidence throughout the total product life cycle of medical devices. Dr. Blake received her medical degree from the University of Chicago, graduate medical education in internal medicine, cardiology and cardiac electrophysiology at Stanford University, and Master of Public Health degree from the Johns Hopkins Bloomberg School of Public Health. From 1988 until 2011, Dr. Blake practiced at the New Mexico Heart Institute, where she also served as President. She is a part-time faculty member at the Johns Hopkins University.

Cynthia Chauhan is a patient advocate. "My experience as a support advocate and a research advocate at the local, regional, national and international levels is augmented by my professional experience as a social worker. I have been an active research advocate for twenty-two years and was an active support advocate for about fifteen years. I have HFpEF stage 3 and kidney failure stage 4. Because there are currently limited treatment options for HFpEF I regularly participate in clinical trials. Additionally, I have other significant comorbidities including glaucoma, dry amd, multiple arthritises, peripheral neuropathy, am a survivor of renal cell carcinoma and breast cancer and live with chronic pain. Procedures I have undergone include but are not limited to multiple joint replacements, multiple trabeculectomies, right nephrectomy, breast lumpectomy and radiation therapy. I am now in a clinical trial and have participated in 10 clinical trials including a pericardiotomy. My own extensive history of health issues gives me a deep understanding of the challenges patients face."

Matthew Diamond is the Chief Medical Officer for Digital Health at FDA's Center for Devices and Radiological Health (CDRH). At the CDRH Digital Health Center of Excellence, Dr. Diamond serves as the senior clinical expert for digital health medical devices and provides leadership for digital health policy development for emerging technologies including artificial intelligence. Prior to joining the Agency, Dr. Diamond served on leadership teams of large and small technology companies, including as Chief Medical Officer at Nokia, and as Medical Director at Fossil Group and the startup Misfit Wearables. Dr. Diamond served on numerous advisory boards including at the Center for Personalized Health Monitoring at UMass Amherst and for the venture firm NGP Capital. As Vice Chair of the Consumer Technology Association (CTA) Health & Fitness Technology Board of Directors, he promoted public health applications of mobile technology and established an ANSI-accredited standardization committee to develop standards in digital health for wellness-related hardware and mobile applications. Dr. Diamond earned his MD and PhD (biophysics) from the Mount Sinai School of Medicine, and he is board certified in rehabilitation medicine and sports medicine and certified in medical acupuncture. A faculty member at NYU, Dr. Diamond is passionate about helping people improve their mobility and performance through a holistic approach to rehabilitation and technology that promotes wellness.

Mona G. Flores is the global head of medical AI at NVIDIA, where she oversees AI initiatives in medicine and healthcare to bridge the chasm between those industries and technology. Dr. Flores first joined NVIDIA in 2018 with a focus on healthcare ecosystem development. Before joining NVIDIA, she served as the chief medical officer of digital health company Human-Resolution Technologies, following over 25 years working in medicine and cardiothoracic surgery. Dr. Flores received her medical degree from Oregon Health and Science University. She completed a general surgery residency at the University of California, San Diego, a postdoctoral fellowship at Stanford, and a cardiothoracic surgery residency and fellowship at Columbia University. Dr. Flores also has a master's degree in biology from San Jose State University, and holds an MBA from the University at Albany School of Business. She initially worked in investment banking for a few years before pursuing her passion for medicine and technology.

Berkman Sahiner is a senior biomedical research scientist with the Office of Science and Engineering Laboratories at the FDA. He holds a PhD in electrical engineering and computer science from the University of Michigan, Ann Arbor. Before joining the FDA, he was an Associate Professor with the Department of Radiology at the University of Michigan. At the Division of Imaging, Diagnostics and Software Reliability at the FDA, he performs research related to the evaluation of medical imaging and computer-assisted diagnosis devices, including devices that incorporate machine learning and artificial intelligence. He has authored over 130 peer-reviewed journal publications, and is a fellow of the Society of Photo-optical Instrumentation Engineers (SPIE) and American Institute for Medical and Biological Engineering (AIMBE). His interests include machine learning, image perception, clinical study design, and performance assessment methodologies.

Session 2: Good Machine Learning Practices in the US and Globally

Janet Hendry is a senior scientific evaluator in the Medical Devices Directorate, Digital Health Division at Health Canada. She joined Health Canada in 2018 following ten years of experience in medical devices, including industry R&D and clinical perspectives. Janet completed her B.A.Sc. in Engineering Physics at Queen's University and her M.Sc. in Medical Biophysics at Western University. In her current role, she is responsible for scientific evaluations and medical device licensing recommendations for various diagnostic imaging, radiotherapy, and digital health technologies, as well as policy development related to machine learning-enabled medical devices.

Brittany (MiRa) Jacobs is a biomedical engineer for the Digital Health Center of Excellence (DHCoE) at the Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Dr. Jacobs' work is focused on the analysis of and strategy development for emerging digital health technologies. She supports a number of the DHCoE's many ongoing initiatives, including developing new policy and regulatory approaches for the use of Artificial Intelligence (AI) and Machine Learning (ML) in medical devices, as well as efforts to promote international harmonization in these areas to ensure patient safety and advance healthcare. Dr. Jacobs also works to advance the Pre-Certification Pilot program as a subject matter expert, with former experience as a Lead Reviewer and a software and cybersecurity consultant in the Office of Neurological and Physical Medicine Devices in the Office of Product Evaluation and Quality (OPEQ). Prior to joining the FDA, Dr. Jacobs earned her PhD in biomedical engineering from the University of Florida, where her research focused on the characterization of gait modifications in preclinical models of osteoarthritis.

Johan Ordish leads the Software Group within Medicines and Healthcare products Regulatory Agency (MHRA). Software Group are responsible for most aspects of regulating software as a medical device, AI included. Johan has four degrees, the last being a BA in Law from Wolfson College, University of Cambridge. Johan is also an Associate at Hughes Hall, University of Cambridge.

Linda Ricci began her career developing artificial intelligence solutions in the defense industry before moving to the medical device industry as a software engineer. She helped to develop several diagnostic cardiology devices and has participated in all phases of product life cycle development. Ms. Ricci moved to the FDA in 2005 and has had several roles including Scientific Reviewer and Branch Chief within the Division of Cardiovascular Devices and Associate Director for Digital Health within the Office of Device Evaluation. Currently Ms. Ricci is the Director for the Division of All Hazard Response, Science and Strategic Partnerships (DARSS). She has degrees in Electrical Engineering, Medical Engineering, and Public Health.

Scott Thiel has over 35 years of experience in the medical device, health information technology, in-vitro diagnostics ("IVD"), and combination product industries. Scott joined Hologic in January 2021 as the Global Head of Regulatory Policy & Intelligence, reporting to the VP of Global Quality and Regulatory Affairs. In his role, he drives the development of a global strategy and framework for Regulatory Policy and Intelligence facilitating all global regulatory positioning. He is accountable to partner effectively across geographies and businesses to establish advocacy positions that are supportive of Hologic, our patients, and our stakeholders. He ensures and advocates for transparent understanding of regulatory policy and drives efficiency and speed across the enterprise. Prior to Hologic, Scott was a Director at Guidehouse, where he provided consulting support for regulatory and quality aspects of medical devices, including SaMD and IVDs. His clients varied from start-ups to existing global medical device, pharmaceutical and software companies. Prior to consulting, Scott worked at Roche Diagnostics within their Diabetes Care division for nearly 25 years. During his time there, he was involved in research and development, incoming and in-process quality control, technical product support, product development and transfer leadership, and global regulatory affairs. The global regulatory affairs work included support of product development teams towards successful premarket submissions. While his primary focus was on pre-market support for global launch of new and modified product, but also was involved in post-market product marketing and sales material support and product issue remediation, including responses to FDA 483's, warning letters and an import ban.

Session 3: Evaluating Real-World Performance of AI/ML SaMD

Andrew Auerbach is Professor of Medicine at the University of California San Francisco School of Medicine, in the Division of Hospital Medicine. Dr. Auerbach is a widely recognized leader in Hospital Medicine, having authored or co-authored the seminal research describing effects of hospital medicine systems on patient outcomes, costs, and care quality. He leads a 30-hospital research network focused on new discoveries in healthcare delivery models in acute care settings, and more recently has founded a national collaborative seeking to understand how to adopt and use digital health tools in care delivery. Dr. Auerbach serves as a Hospital Medicine Section Editor for Up to Date, a chapter Author for Cecil's Textbook of Medicine, and is the past Editor in Chief of the Journal of Hospital Medicine. He has mentored dozens of students, residents, fellows, and junior faculty over the years, and supported the academic development of hundreds more through his decade-long participation in the Academic Hospitalist Academy. Dr. Auerbach's research has been published in prominent journals including the New England Journal of Medicine, JAMA, Annals of Internal Medicine, and Archives of Internal Medicine. He has received the Mack Lipkin Award for Outstanding research as a fellow, and the Western Society for Clinical Investigation Outstanding Investigator, and is a member of the American Society for Clinical Investigation.

Barbara J. Evans is Professor of Law and Stephen C. O'Connell Chair at University of Florida's Levin College of Law and Professor of Engineering at UF's Herbert Wertheim College of Engineering. Her work focuses on data privacy and the regulation of machine-learning medical software, genomic technologies, and diagnostic testing. She is an elected member of the American Law Institute, a Senior Member of the Institute of Electrical and Electronics Engineers and was named a Greenwall Foundation Faculty Scholar in Bioethics for 2010-2013. Before coming to academia, she was a partner in the international regulatory practice of a large New York law firm and is admitted to the practice of law in New York and Texas. She holds a BS in electrical engineering from the University of Texas at Austin, an MS & PhD from Stanford University, a JD from Yale Law School, an LLM in Health Law from the University of Houston Law Center, and she completed a post-doctoral fellowship in Clinical Ethics at the MD Anderson Cancer Center.

Vinay Pai is a General Engineer in FDA's Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation (OST), Division of Digital Health (DDH), having joined the FDA in Sept. 2019. Prior to that, Vinay was in the National Institutes of Health, first as a staff scientist in the National Heart, Lung, and Blood Institute (NHLBI) (working on MRI and CT technology development and image processing, and researched cardiac function in humans and mice models) and then as an program officer and division director for biomedical imaging informatics and health informatics in the National Institute of Biomedical Imaging and Bioengineering (NIBIB). Before NIH, Vinay was a faculty at New York University School of Medicine developing techniques using proton and hyperpolarized helium magnetic resonance imaging to study cardiac and lung function. Vinay has a PhD in mechanical engineering from Florida State University, and an MBA from Johns Hopkins University. He has one son and 2 cats who make sure he has no free time at home.

Nick Petrick is Deputy Director for the Division of Imaging, Diagnostics and Software Reliability at the Center for Devices and Radiological Health, U.S. Food and Drug Administration and is a member of the FDA Senior Biomedical Research Service. The Division of Imaging, Diagnostics and Software Reliability Division conducts regulatory research in medical imaging physics and image analysis techniques to optimize medical image interpretation. Dr. Petrick received his Ph.D. from the University of Michigan in Electrical Engineering-Systems developing time-of-flight positron emission tomography (PET) techniques. He is a Fellow of the Americana Institute of Medical and Biomedical Engineering and SPIE. His current research focuses on quantitative imaging and imaging biomarkers, medical artificial intelligence and robust assessment methods for a range of medical imaging hardware systems and medical artificial intelligence tools.

Robbert Zusterzeel is a senior director in the U.S. Regulatory Science and Strategy team located within IQVIA's Real-World Solutions. He leads regulatory science activities in the area of real-world evidence for medical devices and drugs across the total product lifecycle. He leverages his experience as a physician-scientist and epidemiologist at the U.S. Food and Drug Administration (FDA) and leadership roles at the Medical Device Innovation Consortium (MDIC), to provide scientific oversight and strategic direction on the expanded use of real-world evidence for regulatory decision making. He has also worked with the Duke-Margolis Center for Health Policy on the safety and effectiveness of artificial intelligence (AI) and machine learning (ML) tools in healthcare settings. Robbert received his M.D. and Ph.D. from Maastricht University in the Netherlands and also holds an M.P.H. in epidemiology from Harvard University.

Business Roundtable

Jen Baird is the CEO and founder of Fifth Eye, a venture-funded provider of intuitive real-time clinical analytics spun out of the University of Michigan. The company's flagship product, the AHI System™, is FDA-cleared clinical decision support software that monitors hospital patients and continuously predicts the risk of hemodynamic instability earlier than is possible with vital signs. Early awareness of emerging problems provides clinicians with additional time that may facilitate early intervention to mitigate or avoid a crisis. Under Ms. Baird's leadership, Fifth Eye was granted FDA De Novo status for the Analytic for Hemodynamic Instability (AHI) in March 2021. AHI leverages AI/ML to noninvasively detect hemodynamic instability continuously from a single ECG lead. Fifth Eye received FDA clearance for the AHI System, which adds predictive capabilities with its second analytic, in December 2021. Ms. Baird is a serial entrepreneur who has founded, raised funds and led multiple successful start-ups as CEO over 20 years. Previously, she held a leadership role in consulting, and she began her career in commercial banking. She received her MBA from the Kellogg Graduate School of Management, where she shared Top-of-Class honors, and a BA degree from the University of Michigan.

Jodi Daniel is a partner at Crowell & Moring where she leads the firm's Digital Health Practice. Jodi is also a managing director at Crowell Health Solutions and a director at C&M International. She provides strategic, legal, and policy advice to healthcare providers and health plans that are bringing innovation into practice, and to health technology clients navigating the dynamic health regulatory environment. Jodi was the founding director of the Office of Policy in the Office of the National Coordinator for Health IT (ONC) at HHS, where she led the agency's federal advisory committees and established national health IT policy on privacy, security, consumer e-health, telehealth, and safety and oversight. Jodi established ONC's regulatory capacity, led the development of health IT standards and certification regulations, and advised CMS on health IT incentive programs. Also, Jodi was a key drafter of the original HIPAA Privacy and Enforcement Rules and served as HHS's first senior counsel for health IT. Jodi received a BA in Economics from Tufts University, an MPH from Johns Hopkins School of Public Health, and a JD from Georgetown University Law Center.

David Golan is the co-founder and CTO of Viz.ai - a digital healthcare company harnessing deep learning to analyze medical data and improve clinical workflow. Prior to founding Viz.ai, David was a Fulbright postdoctoral scholar at Stanford University, working on leveraging deep learning for the analysis of medical imaging and genetic data. David holds a PhD in Statistics and Machine learning from Tel-Aviv University, and has co-authored more than 20 scientific papers including three publications in the journal Science. Prior to his academic career, David founded the ML team of b-hive Networks, an Israeli startup which was acquired by VMWare in 2008.

Duke-Margolis Moderators

Suresh Balu serves as Associate Dean for Innovation and Partnership for the School of Medicine and as Director, for the Duke Institute for Health Innovation (DIHI). In his role as Associate Dean, Suresh is responsible for creating, implementing, and sustaining innovation and partnership initiatives for the School of Medicine, specifically, to support the strategic priorities for clinical and translational research. As Director for DIHI, Suresh leads the development and implementation of innovation frameworks and approaches across healthcare delivery, education and research. His responsibilities include application and integration of algorithm-based solutions into clinical practice along with development of AI/ML tools and best practices.

Rachele Hendricks-Sturrup is the Research Director of Real-World Evidence at the Duke-Margolis Center for Health Policy. As a researcher, bioethicist, and policy practitioner, her work centers on addressing implementation and ethical, legal, and social implications issues at the intersection of health policy and innovation.

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.

Christina Silcox is the Digital Health Policy Fellow at the Duke-Margolis Center for Health Policy, working on policy solutions to advance innovation in health and health care and improve regulation, reimbursement, and long-term evaluation of medical products, with a focus on digital health. Dr. Silcox's portfolio includes multiple areas in digital health policy and real-world evidence, with a focus on medical devices. Currently, she is concentrating on challenges to regulating and adopting of artificial intelligence-enabled software as a medical device, using mHealth to collect real-world data, and characterizing real-world data quality and relevancy. Her projects have included the use of patient-generated health data in medical device evaluations, the exploration of value-based payments for medical devices, and the convening the National Evaluation System for health Technology (NEST) Planning Board. Before she joined Duke-Margolis, Dr. Silcox was a senior fellow at the National Center for Health Research, focused on federal regulation of and policies for medical products. She earned a M.S. from the Massachusetts Institute of Technology (MIT) in Electrical Engineering and a Ph.D. in Medical Engineering and Medical Physics from the Harvard-MIT Division of Health Sciences and Technology (HST).