Trust, But Verify:
Informational Challenges Surrounding AI-Enabled Clinical Decision Software

1201 Pennsylvania Ave NW, Suite 500, Washington, DC 20004
January 23, 2020

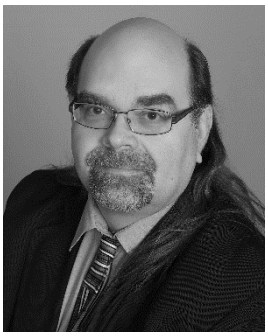
Speaker Biographies

Michael Abramoff

Dr. Michael Abramoff, MD, PhD, (FARVO) is an internationally renowned physician scientist at the University of Iowa Hospitals & Clinics and the Iowa City VA Health Care System. He is the Robert C. Watzke, MD Professor of Ophthalmology and Visual Sciences at the University of Iowa, with joint appointments in the College of Engineering where he teaches classes on the use of artificial intelligence in medicine. Dr. Abramoff is also the founder and CEO of IDx Technologies, an AI-based diagnostics company that is the first company in any field of medicine to get FDA approval for automated detection of diabetic retinopathy in primary care and the first clearance for marketing autonomous AI-based diagnostic.

For the past 20 years, Dr. Abramoff has studied how Artificial Intelligence (AI) - based algorithms can be used to improve the lives of patients with retinal disease, focusing on autonomous AI based diagnostic and quantification algorithms, and determining the role of neuropathy in diabetes complications. Dr. Abramoff 's research has been continuously funded since 2004 by the National Eye Institute, the Veterans Administration, the Beckman Foundation and other federal, state and philanthropic funding agencies in the U.S. and Europe. He has authored over 270 peer-reviewed publications that have been cited over 29,000 times. He is the inventor on 16 issued patents and many patent applications. Dr. Abramoff has mentored dozens of graduate students, ophthalmology residents, and retina fellows. His passion is not only to improve health care for patients in the retina clinic, but to find ways to improve healthcare for all patients.

Pat Baird



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 working to develop standards, whitepapers, and training to meet those needs. Past roles have included software developer, engineering manager, project manager, lead engineer, and most recently he was the Director of Risk Management at Baxter Healthcare. Drawing on 20 years' experience in product development, he has published and presented over 50 papers regarding product development. He has an MBA from Marquette and a Masters in Healthcare Quality and Patient Safety from Northwestern University.

Kathleen Blake

Dr. Blake is Vice President, Healthcare Quality at the American Medical Association where she leads payment and quality initiatives of the AMA's Professional Satisfaction and Practice Sustainability strategic focus initiative. From 2013 until 2016, she was executive director of the PCPI®, which includes the National Quality Registry Network™. 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 is a member of 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. She is an AMA subject matter expert on a wide range of health technology innovations including artificial intelligence, terminology, clinical registries, appropriate use criteria and clinical decision support tools.

Dr. Blake is a clinical cardiac electrophysiologist who received her education and training from the University of Chicago, Stanford University and 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 member of the Johns Hopkins University medical faculty.

Michele Conover

Michele Conover has been an IP attorney for over 25 years and is currently Senior Counsel for Siemens Medical Solutions, Inc. Michele has worked with the Siemens Healthineers Digital Technology Innovation (DTI) group in Princeton, New Jersey for the past 17 years. Prior to working at Siemens, Michele was a Senior IP attorney at AT&T focusing on software inventions relating to network communications and e-commerce. Michele started her career as a patent examiner and then worked as a patent agent for a Pennsylvania IP law firm.

As part of Michele's responsibility for developing and managing the patent portfolio for the DTI group, Michele focuses on software and AI inventions related to medical imaging technologies. In addition to focusing on IP topics, Michele also has significant experience in technical transactions such as software license agreements, master research agreements, open source software clearing and data license agreements.

Michele is a registered patent attorney with admission to the New Jersey Bar. Michele holds a JD from Rutgers Law School and a BS in Electrical Engineering with a Biomedical concentration from Rutgers University.

Kate Gaudry

Kate Gaudry is a partner at in the Washington, D.C., office of Kilpatrick Townsend & Stockton LLP. She focuses her practice on data-driven and strategic patent prosecution. She has authored over sixty publications sharing results of various analyses. Her work was also pivotal in the shutting down of the USPTO's SAWS program, which secretly subjected select patent applications to increased examination scrutiny. LexMachina and Law360 recognized her research and data focus by selecting her to be one of five attorneys from all practice areas to receive their Data-Driven Lawyer Award in its inaugural year of 2018.

Kate has a Ph.D. in computational neurobiology and bachelor's degree in physics. Most of her clients are innovating in the A.I. and/or computational biology fields.

Brigham Hyde

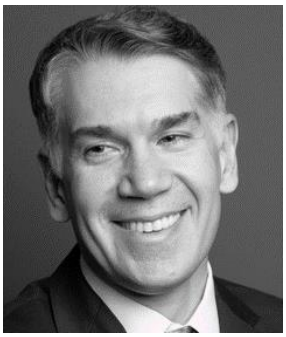
Brigham is a general partner at FinVC, a $300M venture capital firm investing in technology at the intersection of Financial and Healthcare technology. Prior to FinVC, he served as a founding member of Symphony AI, a $1B VC/PE firm, where he led the investment and was an operating founder of Concerto Health AI an RWD an AI Platform technology company focused on improving outcomes in Oncology. Dr. Hyde holds adjunct positions at Tufts University and M.I.T. Media Lab and is a regular lecturer on Real-World Data and AI in Healthcare.

Mark McClellan

Mark McClellan, MD, PhD, 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. 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.

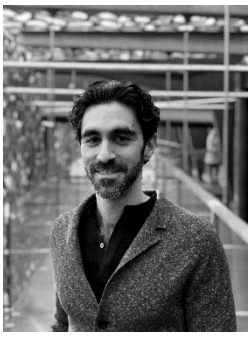
Carey Morewedge



Carey K. Morewedge is a Professor of Marketing and Everett W. Lord Distinguished Faculty Scholar at Boston University. His PhD is in Social Psychology from Harvard University. Prior to joining the Questrom School of Business at Boston University, Professor Morewedge was a Postdoc at Princeton University in the Woodrow Wilson School of Public and International Affairs, and served on the faculty as the Director of the Center for Behavioral and Decision Research at Carnegie Mellon University.

His research examines the psychological causes, consequences, and correction of bias in judgment and decision making. Using a mix of laboratory, field, and longitudinal experiments, he tackles basic and applied problems from why people won't bet on the failure of their child or favorite team to developing interventions that improve decision making by producing long-term reductions in cognitive bias. He has published over 40 papers in top academic journals including Science, Psychological Science, Trends in Cognitive Sciences, and Management Science, and contributed to popular outlets including Harvard Business Review and The New York Times. Awards for his work include recognition as a Marketing Institute Scholar, one of the Top 40 Under 40 MBA Professors by Poets & Quants, writing The Most Theoretically Innovative Article of the Year as judged by the Society of Personality and Social Psychology in 2010, and receipt of an Ideas of the Year from The New York Times.

Ziad Obermeyer



Ziad Obermeyer is an Associate Professor (Acting) at UC Berkeley, where he does research at the intersection of machine learning, medicine, and health policy. He previously was an Assistant Professor at Harvard Medical School, where he received the Early Independence Award, the National Institutes of Health's most prestigious award for exceptional junior scientists, and the Young Investigator Award from the Society for Academic Emergency Medicine. He continues to practice emergency medicine in underserved parts of the US. His work has been published in Science, The New England Journal of Medicine, JAMA, The BMJ, and Health Affairs, and his research is supported by the National Institutes of Health, the Robert Wood Johnson Foundation, and the Laura and John Arnold Foundation. Prior to his career in medicine, he worked as a consultant to pharmaceutical and global health clients at McKinsey & Co. in New Jersey, Geneva, and Tokyo. He is a graduate of Harvard College (magna cum laude) and Harvard Medical School (magna cum laude), and earned an M.Phil. from Cambridge.

Bakul Patel

Bakul Patel is Associate Director for Digital Health, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel leads regulatory policy and scientific efforts at the Center in areas related to emerging and converging areas of medical devices, wireless and information technology. This includes responsibilities for mobile health, health information technology, cyber security, medical device interoperability, and medical device software.

Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC). Since its inception in 2013, Bakul chairs the International Medical Device Regulators Forum (IMDRF) "software as a medical device" working group, a global harmonization effort.

Before joining FDA, Mr. Patel held key leadership positions working in the telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations.

Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.

Laura Peter

Laura Peter is the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office (USPTO). She is the principal advisor to the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, and responsible for all agency operations. This includes oversight for the four USPTO Regional Offices, managing 13,000 employees, and executing the policies, priorities and programs for an annual budget of $3.5 billion.
Prior to joining the USPTO, Ms. Peter was the Deputy General Counsel of A10 Networks, a publicly-traded IT company where she oversaw daily legal matters related to commercial agreements, litigation, and intellectual property (IP) portfolio development. In 2014, she helped shepherd the company through its initial public offering.

Ms. Peter has practiced IP law for over 20 years. Previously, she was Vice President and General Counsel of Immersion Corporation, where she led all aspects of the company's legal issues, including its IP portfolio. She was also Assistant General Counsel and Director of Intellectual Property at Foundry Networks, where she built a successful patent portfolio and litigation program. She began her career as a commercial and IP litigator at Townsend, Townsend and Crew (now Kilpatrick Townsend & Stockton LLP).

Ms. Peter received a Bachelor of Science in industrial engineering from Cornell University and a master's in public policy from the University of Chicago. She also holds a Juris Doctor from Santa Clara University School of Law and a Master of Law degree in international business law from King's College London.

Arti Rai

Arti Rai, Elvin R. Latty Professor of Law and co-Director, The Center for Innovation Policy at Duke Law, is an internationally recognized expert in intellectual property (IP) law, innovation policy, administrative law, and health law. Rai's research on innovation law and policy in biotechnology, pharmaceuticals, and software has been funded by NIH, the Kauffman Foundation, and the Woodrow Wilson Center. She is the editor of Intellectual Property Law and Biotechnology: Critical Concepts (Edward Elgar, 2011) and the co-author of a 2012 Kauffman Foundation monograph on cost-effective health care innovation.

Rai has served as the chief policy advisor to the Director of the U.S. Patent and Trademark Office; a member of the National Advisory Council for Human Genome Research; and as a public member of the Administrative Conference of the United States. Rai has also served on, or as a reviewer for, numerous National Academies of Science committees. In 2013, she was elected to the American Law Institute. She won the World Technology Network Award for Law in 2011. Rai graduated from Harvard College with a degree in biochemistry and history (history and science), attended Harvard Medical School, and received her J.D. from Harvard Law School.

Christina Silcox

Christina Silcox, PhD, MS is a Managing Associate 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.

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 around the regulation and adoption of artificial intelligence-enabled software in healthcare and understanding best practices for using mobile health technologies to collect real-world data for regulatory decision-making. Past projects have included methods for characterizing real-world data quality and relevancy, 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).

Coke Stewart

Coke Morgan Stewart is Coke Morgan Stewart is the Acting Chief of Staff for the United States Patent and Trademark Office (USPTO). Prior to this position, Ms. Stewart served as the Senior Policy Advisor to the Under Secretary and Director of the USPTO, advising the Director and other senior leaders on a wide variety of patent policy issues, including patent eligibility and AIA proceedings.

The Chief of Staff serves as the Director's principal advisor and helps coordinate a $3.5 billion budget in support of the bureau's nearly 13,000 employees to execute the daily operations, policies, priorities, and global communications of the President's intellectual property agenda. In addition, the Chief of Staff manages the day-to-day policy coordination process with the White House, Department of Commerce, and other federal agencies.

Ms. Stewart has worked at the USPTO since 2011 in a number of important roles, including as Associate Solicitor, Acting Deputy Solicitor, Senior Advisor to the Director, and Acting Chief of Staff.

In her principal role in the Office of the Solicitor, Ms. Stewart has served as lead counsel in over 20 patent cases before the Federal Circuit and has appeared as counsel of record in at least 30 other patent cases. She has also advised the Department of Justice Civil Appellate Staff and the Office of the Solicitor General on patent, trademark, and copyright cases before the U.S. Supreme Court. She has handled numerous administrative law cases, defending agency practices and procedures in the U.S. District Court for the Eastern District of Virginia and the U.S. District Court for the District of Columbia. While at the USPTO, Ms. Stewart has received two Special Act Awards, a Director's Award for Excellence in Litigation, a Department of Commerce Award for Exceptional Service, and a Department of Commerce Bronze Medal.

Prior to joining the USPTO, Ms. Stewart practiced law for 14 years—most recently at Kaye Scholer LLP in Washington, D.C., where she litigated complex patent infringement cases on behalf of patent holders and accused infringers.

Ms. Stewart is a graduate of Duke University and the University of Virginia School of Law, where she served as Executive Editor of the Virginia Tax Review and Editor-in-Chief of the Virginia Law Weekly. After law school, Ms. Stewart clerked on the U.S. Court of Federal Claims, which primarily hears monetary claims against the U.S. government.

Li Zhou

Li Zhou, MD, PhD, FACMI, FAMIA, is an Associate Professor at Harvard Medical School and a Lead Investigator at the Division of General Internal Medicine and Primary Care of the Brigham and Women's Hospital. She has served as a Senior Medical Informatician at Partners HealthCare System for more than 10 years. Her research has focused on various subfields of artificial intelligence and their applications to medicine, including temporal reasoning, natural language processing, machine learning and decision support. Dr. Zhou directs the MTERMS Lab (http://mterms.bwh.harvard.edu/) and has led the design and development of multiple NLP systems. Her teams have applied NLP and machine learning to diverse clinical domains, including phenotyping, medication reconciliation, adverse drug reaction detection, nurse assessment, family histories, social-behavioral factors, hospital readmission, and mortality predication. They are developing innovative methods for detecting errors in clinical notes generated by speech recognition software. They are also combining NLP and machine learning to extract knowledge from malpractice claims data to enhance coding and analytics for risk management. Dr. Zhou is a Fellow of the American College of Medical Informatics. She serves as an Associate Editor for the International Journal of Medical Informatics. She has served as principle investigator and co-investigator on numerous research projects funded by AHRQ, NIH, PCORI, and CRICO/RMF.

Dr. Zhou received her medical degree from Shanghai Medical University (now Fudan University), a Master of Science degree in business computer information systems from Baruch College, NYC, and a PhD in biomedical informatics from Columbia University, NYC.

Funding for this meeting was made possible in part by a grant from the Greenwall Foundation. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Greenwall Foundation nor does mention of trade names, commercial practices, or organizations imply endorsements.