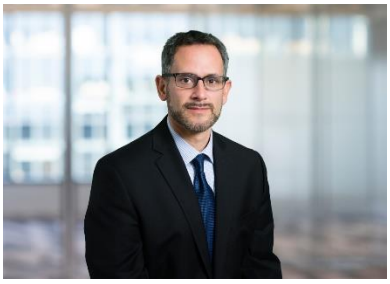
Introduction to Medical Device Law and Regulation
November 16-17, 2022
Speaker Biographies

DEBORAH BAKER-JANIS joined NSF International in 2013 after working in the medical device industry for over 10 years, including in both regulatory affairs and product development. Her experience includes the development of pre-clinical testing protocols, risk documentation, quality system and regulatory affairs standard operating procedures, sales training materials, safety reports and domestic and international regulatory strategies and submissions. Ms. Baker-Janis has supported the development and commercialization of a wide range of products including cardiovascular devices, general and plastic surgery devices, gastroenterology devices and general hospital devices. Her educational background is in biomedical engineering.

JAMES A. BOIANI is a partner at Epstein Becker & Green, PC. He has extensive experience in FDA and CLIA legal and regulatory matters, having worked with large and small medical device companies (including many in vitro diagnostic companies), pharmaceutical companies, clinical laboratories, and trade associations in the life sciences industry on a variety of FDA- and CLIA-related issues.

JANET BOOK is a Principle Consultant for NSF, one of the world's leading consulting and service companies in medical technology. She has more than 35 years' experience in quality management systems, auditing and training for medical devices. Prior to joining NSF, Janet has worked in a wide variety of industries, including blood banking, food processing, quality consulting, chemicals, pharmaceuticals and medical devices. Janet has broad expertise in U.S., EU and other global regulations, as well as extensive training expertise in the fields of auditing, CAPA and root cause analysis. She conducts audits, due diligence evaluations as well as capability assessments. Additionally, she has experience establishing audit programs, developing quality management systems, and developing and presenting quality-related training and seminars. Janet holds a Master of Business Administration from Phoenix University, a Bachelor of Arts in Biology from Wittenberg University and a Certificate in Privacy Law and Cybersecurity from Seton Hall University.

McKENZIE E. CATO is an associate at Hyman, Phelps & McNamara, P.C. She assists clients with pre- and post-market FDA regulatory topics, including developing regulatory strategy, preparing regulatory submissions, drafting regulatory policies and procedures, and reviewing advertising and promotional materials. In the premarket area, Ms. Cato prepares IDEs, 510(k)s, de novos, and PMAs. She also prepares pre-submissions, and assists clients in preparing for and represents clients at pre-submission meetings with FDA. In the postmarket area, she advises clients on complaint handling, MDRs, field actions, and QSR compliance. Ms. Cato joined the firm in 2012 and worked as a Legal Assistant and Law Clerk for six years prior to becoming an Associate. She graduated with honors from the George Washington University Law School. While in law school, Ms. Cato was a member of the George Washington Law Review and the Moot Court Board.



SCOTT D. DANZIS is a partner at Covington & Burling LLP's Food & Drug and Health Care practice groups. His practice focuses on the regulation of medical devices and diagnostics. Mr. Danzis regularly works with companies in developing strategies for interacting with the U.S. Food and Drug Administration (FDA), including strategies for clinical development and premarket review (including appeals and dispute resolution, when needed). He also advises on compliance with postmarket requirements, including advertising and promotion restrictions, quality system and manufacturing requirements, postmarket reporting, recalls, and enforcement actions.

ALLISON FULTON is a partner in the Life Sciences and FDA Team in the Washington, D.C. office of Sheppard, Mullin, Richter & Hampton LLP. She advises life sciences companies, including pharmaceutical, medical device, dietary supplement, food and cosmetic companies, in matters relating to the development, manufacture and marketing of products regulated by the US Food and Drug Administration (FDA). Allison's areas of focus include assisting US and international companies with complying to pre-market and post-market FDA requirements, including marketing authorization, clinical trials, compliance with GxP, product promotion and labeling, recalls and other product safety issues. She regularly advises companies on preparing for FDA inspections, responding to FDA Form 483s and Warning Letters, remediating GMP and data integrity issues and handling adverse events and medical device reports (MDRs). Allison also provides regulatory advice during acquisitions of life science companies, and counsels clients on a variety of life science transactions, including supply agreements, quality agreements and product licenses. Allison is passionate about novel technologies and advises clients on product approval and clearance strategies for innovative products, including digital health technologies, precision medicine and combination products. She has led numerous internal investigations involving allegations of product tampering, non-compliance with GMP and off-label promotion. Allison acts as FDA counsel on civil litigation matters, such as false advertising and False Claims Act litigation. Prior to attending law

school, Allison was a software engineer, specializing in software validation. She earned her law degree from the University of Texas School of Law, where she was the managing editor of the Texas Intellectual Property Law Journal. She received a BS degree in Industrial Engineering from Northwestern University.

KRISTIN M. KAPLAN is of counsel at Shook, Hardy & Bacon LLP. She is a recognized leader in FDA regulatory practice with extensive experience working in the tobacco, animal health, pharmaceutical and medical device and food industries. She provides critical leadership—legal insights, advice and recommendations—to clients on sensitive and controversial regulatory topics affecting their products. Kristin counsels on the approval, marketing and defense of FDA-regulated products and guides clients on their responses to actions taken by regulatory agencies. She also negotiates with regulatory agencies on behalf of clients, and assists clients in creating and implementing best practices. She advises her clients on proactive steps to avoid litigation and to implement risk mitigation recommendations. Before joining Shook, Kristin was the deputy general counsel in charge of global regulatory legal support and litigation at a global animal health company. She also worked for more than eight years as associate chief counsel for FDA, advising the agency on sensitive, controversial and precedent-setting matters, including the approval of novel drug applications. She also developed, reviewed and evaluated various legal and regulatory documents while at FDA. She uses her insider's knowledge of the U.S. government regulatory environment to clients' advantage in their legal matters.

AMY LEISER is an associate in the Food, Drug & Device group at Covington & Burling LLP in San Francisco, CA. With a focus on medical device, digital health, and diagnostic products and laboratory services, Amy regularly advises clients on a variety of federal and state regulatory, legislative, and compliance matters, as well as considerations for strategic engagement with the Food and Drug Administration (FDA). In her work with both new and established companies, Amy regularly counsels clients on development and marketing strategies for new products, compliance with medical device postmarketing requirements, and responding to domestic and international enforcement actions. She also regularly assists clients in advocating for legislative and regulatory policies through drafting of public comments, and supports life sciences transactions with regulatory diligence. Amy is a graduate of Georgetown University Law Center, where she was elected to the Order of the Coif, and received an undergraduate degree from the University of Texas at Austin, where she graduated with highest honors.

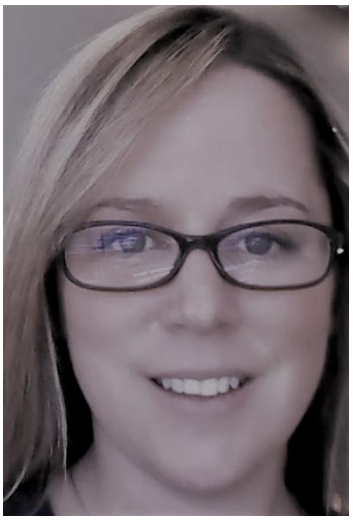
VÉRONIQUE LI is a Senior Medical Device Regulation Expert at Hyman, Phelps & McNamara where she provides counsel to medical device and in vitro diagnostic (IVD) manufacturers with regard to both premarket and postmarket matters. In the premarket area, she assists clients with registration and listing activities and works with them on marketing applications (e.g., Emergency Use Authorizations (EUAs), IDEs, 510(k)s, de novos, and PMAs). She advises clients in preparation for pre-submission meetings with FDA. In the postmarket area, she advises clients on complaint handling, MDRs, field actions, and QSR compliance. Véronique also conducts internal investigations to provide tailored recommendations to clients based on her findings. She also supports clients engaged in mergers and acquisitions. She conducts comprehensive FDA-related due diligence on the compliance and regulatory status of assets or targets and reviews supply, distribution, and manufacturing agreements. Prior to joining HPM, she worked at Abbott (formerly St. Jude Medical), PwC, and FDA. Ms. Li earned her BSE in Biomedical Engineering from Case Western Reserve University and her MBA from Boston University.

ANISA MOHANTY advises medical device, biotech and pharmaceutical companies on FDA premarket strategy and post-market compliance issues, from advertising and promotion to disclosure and periodic reporting. Her experience encompasses such matters as premarket pathways, Good Laboratory Practice and Good Clinical Practice and Good Manufacturing Practice (cGMP) and Quality System requirements. She offers guidance to her clients on the regulatory requirements and industry standards for the development, creation and review of advertising and promotional materials for drugs and medical devices. Prior to joining McDermott, Anisa served as a Regulatory Counsel in the Office of Compliance and Enforcement in FDA's Center for Tobacco Products (CTP). During her tenure at FDA, she advised agency policy-makers and regulatory personnel on the development and implementation of interpretative guidance and regulatory policies. Anisa received her B.A. from the University of North Carolina at Chapel Hill and her JD from the University of Richmond School of Law.

MEGAN ROBERTSON approaches her practice with enthusiasm that stems both from her personal experiences and her overall passion for the intersection of science, medicine, and the law. Her background, including an undergraduate degree in genetics, allows her to understand the unique compliance challenges faced by, and the development opportunities available to, companies in the life sciences industry. These include drug and device manufacturers, clinical laboratories, research sponsors, clinical research sites, contract research organizations ("CROs"), and cannabis product developers, among others. Megan also coordinates due diligence efforts on behalf of private equity firms to perform risk based regulatory and compliance assessments of investments in these types of businesses. In addition, Megan has worked closely with providers of Applied Behavior Analysis (ABA) services to individuals with autism spectrum disorder, and previously interned with the

advocacy group Autism Speaks. From these experiences, Megan has developed an understanding of the issues related to ABA billing and coding compliance, as well as certain nuances of contracting to provide such services with both private and government payers. Megan also enjoys working on different pro bono initiatives, including representing clients in hearings in front of the Social Security Administration as part of the appeal process to secure disability benefits.

CYBIL ROEHRENBECK is a shareholder at Polsinelli PC where she is dedicated to helping clients achieve their objectives by employing a comprehensive, interdisciplinary approach to their legal and business challenges. She counsels clients on federal legislative and regulatory opportunities in the following areas: Payor coverage and reimbursement, innovative health care delivery models, mHealth and telehealth, and precision medicine and genomics. Cybil's prior experience includes serving as a lobbyist and attorney for the American Medical Association (AMA), legislative counsel to a senior member of Congress and Committee liaison for four years, and an associate with US Representative JC Watts, Jr. (R-OK). Cybil works with clients to help them effectively present their values and challenges to Congress and federal regulators and obtain the best possible results for their businesses. She has had significant success in securing favorable amendments to federal legislation and regulation, including obtaining valuable informal guidance and feedback from federal regulators. In 2017, Cybil was appointed by American Bar Association (ABA) President Hilarie Bass to the ABA's Standing Committee on Governmental Affairs. Cybil is also an active member of the ABA Health Law Section, where she serves as Vice Chair of the annual ABA Health Law Summit in Washington, D.C. Cybil is a judge for the annual American University Washington College of Law National Health Law Writing Competition and a frequent speaker at national health law and policy conferences.



SARAH RYS is Senior Principal Regulatory Affairs Specialist at Medtronic on the Global Regulatory Strategy &Policy team. In her role, Sarah supports U.S. FDA regulatory policy work as well as global policy work relating to digital health technologies. Prior to Medtronic, Sarah worked at Fitbit on digital health wearable devices and at 23andMe on direct to consumer genetics.