Introduction to Medical Device Law and Regulation
March 2-4, 2021 | Live Virtual Event
Speaker Biographies

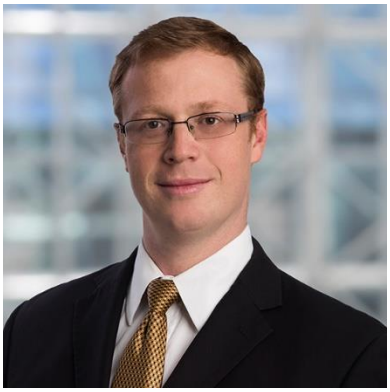
DEBORAH BAKER-JANIS joined NSF International in 2013 after working in the medical device industry for over 10 years, including in both regulatory affairs and product development. Her experience includes the development of pre-clinical testing protocols, risk documentation, quality system and regulatory 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.

MAHNU DAVAR is a partner in the Washington, DC office of Arnold & Porter. His practice focuses on assisting FDA-regulated entities with complex regulatory and compliance matters. He has represented early stage medical technology companies, clinical labs, major academic research institutions, and some of the largest multinational drug and device companies in the oncology, ophthalmology, pain, and diabetes care spaces. Mr. Davar routinely counsels clients on the regulatory and compliance aspects of promotional launch campaigns, clinical research, educational grants and charitable giving, manufacturing and supply chain, deal diligence, and other mission-critical activities. He has conducted significant compliance investigations and audits for business operations in the US, Europe, and Asia, and has extensive experience defending companies in criminal and civil healthcare fraud investigations. He has also assisted clients to prepare for and navigate state and federal regulatory inspections. Mr. Davar is a lecturer at the University of Pennsylvania Law School, a Fellow of the Salzburg Global Seminar, and a former Fulbright Scholar to India.

ALLISON FULTON is a partner in the Life Sciences and FDA Team in the Washington, DC 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.

SUZANNE LEVY FRIEDMAN is a Senior Associate in the FDA/Medical Devices practice group in Hogan Lovells LLP's Washington, DC office. Her responsibilities include advising diverse clients on all aspects of medical device premarket and post-market issues, including helping companies determine the appropriate regulatory pathway for their new or modified products and preparing the associated submissions. A significant part of her practice involves guiding medical device and combination product manufacturers on the lawful promotion and advertising of their products, both as investigational devices before they are cleared/approved and once they are authorized for marketing. She also advises companies extensively on the "lines" differentiating regulated from unregulated software functions and products (including clinical decision support software, mobile apps, etc.). Suzanne is a member of the Regulatory Affairs Professional Society and the young lawyers division of the Food & Drug Law Institute. Suzanne received her BA in politics/international relations from Princeton University and her JD and Masters in Bioethics from the University of Pennsylvania.



MICHAEL (MOSHE) KASSER is the Director of Regulatory Sciences at Hogan Lovells US LLP. He has been involved in the regulation of medical devices since he obtained his PhD in materials science and engineering. His thesis focused on novel materials used in joint replacement, and upon graduation, he immediately put this knowledge to use at the FDA as a scientific reviewer of orthopaedic devices. Michael brought a powerful and unique blend of the regulatory know-how and technical understanding required to comprehend and address the FDA's scientific concerns with novel technologies. Today, Michael has combined that understanding with a knack for explaining technical concepts in a way that both the industry and FDA can easily understand. He uses his knowledge and communications skills to assist medical device companies to clear FDA hurdles and bring novel technologies to the US market. While he was at the FDA, Michael focused on novel technologies, such as combination products, Magnetic Resonance Imaging (MRI) safety testing of devices, and new biomaterials. He published articles in both scientific and regulatory journals on a variety of topics.

ANISA MOHANTY is counsel at McDermott Will & Emory LLP where she advises life sciences companies on US Food and Drug Administration (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. Anisa 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. She also supports investors and companies on scoping and developing appropriate due diligence strategies for transactions and investments involving FDA-regulated drugs, medical devices and other products. Her tenure as a Regulatory Counsel at the FDA provides valuable perspective for clients in the life sciences industry. Anisa received her BA in Biology and Political Science from University of North Carolina and her JD from University of Richmond School of Law.

IAN M. PEARSON is a senior associate at Jones Day. His practice focuses on FDA regulatory matters, with an emphasis on medical devices, combination products, and the evolving digital health sector. Before joining Jones Day, Ian served for more than seven years in FDA's Office of Chief Counsel. At FDA, Ian worked across product areas and was a member of the device counseling, combination products, and information disclosure teams. He has significant first-hand experience navigating the Federal Food, Drug, and Cosmetic Act, as well as the Administrative Procedure Act, Freedom of Information Act, Privacy Act, and provisions of the Public Health Service Act applicable to FDA regulatory matters.

PREEYA NORONHA PINTO is a partner at King & Spalding LLP where she assists life science manufacturers with strategic reimbursement planning during all stages of the product life cycle. She also engages in healthcare regulatory and policy advocacy before government agencies and the US Congress. A former Health and Human Services Acting General Counsel and Department of Justice litigator, she helps healthcare clients seek regulatory and policy change and combat adverse government action arising from the Medicare and Medicaid programs, Food and Drug Administration regulation, fraud and abuse matters, and ongoing healthcare reform.

SERRA J. SCHLANGER is a director at Hyman, Phelps & McNamara, P.C., where she advises clients on regulatory strategy as well as compliance and enforcement issues. She assists clients with compliance with the rules and regulations governing product advertising and promotion, interactions with healthcare providers, telemedicine and telehealth, state drug price transparency efforts, the Sunshine Act and state marketing restrictions and reporting requirements. Serra counsels clients on corporate compliance, federal and state health care fraud and abuse matters, and defends clients in connection with government investigations, qui tam actions, and other enforcement inquiries. She helps clients with contract matters and regulatory due diligence related to corporate transactional matters. Serra also advises clients on legal and regulatory issues associated with the privacy of health information (HIPAA), state licensure, and the Clinical Laboratory Improvement Amendments (CLIA).

SOUSAN S. SHELDON, PhD, MT (ASCP) is the President of Medical Devices Consultants, LLC, an independent consulting firm. She is a senior medical products consultant recognized for leading high quality investigational medical products review teams in the field of antimicrobial drugs, medical device, medical devices containing antimicrobial agents, in vitro diagnostics, companion diagnostics and combination products. Dr. Sheldon is a medical technologist and has been working in clinical labs since 1982. After her career in academia as Assistant Professor of Pediatrics and Director of Microbiology Laboratory at the Children's Hospital of State University of New York in Buffalo, she joined FDA in 1995. She began her FDA career as a primary reviewer in the Office of Antimicrobial Products in CDER. In 2001 she became the Chief of Immunology and Hematology Devices Branch in Office of Device Evaluation in CDRH and later became the Scientific Policy Advisor in the Office of In Vitro Diagnostics and Radiology Devices in CDRH. She joined Office of International Programs in March, 2009 as the Assistant Regional Director for the Middle East and North Africa Office and in January 2013 transitioned to the Office of Regional and Country Affaires. Dr. Sheldon has a long history of developing consensus standards in various standards developing organizations such as Global Harmonization Task Force, International Standards Organization, American Tissue Culture Collection, Clinical Laboratory Standards Institute, and American Society for Testing and Materials. Dr. Sheldon is the author and coauthor of many international standards, FDA guidance documents and peer reviewed journal articles.

FREDERICK A. STEARNS is a partner in Keller and Heckman LLP's Washington, DC, office. Rick's practice involves a wide range of issues facing manufacturers of prescription and over-the-counter drugs, medical devices, dietary supplements, foods, and cosmetics. He helps product manufacturers evaluate the need for marketing approval from FDA, pursue appropriate clearance when necessary, and address regulatory compliance issues with marketed products (including OTC drug monographs, product labeling and promotion, and current good manufacturing practices). Rick works with clients to respond to FDA enforcement activities, navigate the interrelationship of the patent laws and the FDA drug approval process, communicate with Agency officials, and develop innovative strategies to deal with evolving FDA regulatory requirements. In addition, Rick has worked with numerous companies to conduct FDA due diligence reviews, both for internal control purposes and as part of product line or corporate acquisitions. He is a frequent speaker at conferences on the legal issues involving the regulation of drugs, medical devices, food, cosmetics, and dietary supplements. Rick received his BS in applied and engineering physics from Cornell University and his JD with honors from The George Washington University Law School.

SARAH H. STEC is Senior Counsel, Medical Device Regulatory Law at Johnson & Johnson. She has experience in assisting healthcare and life sciences companies understand new and evolving regulatory duties, including how those international regulations can work together as well as providing guidance on international corporate accreditation and regulatory issues. Her background in quality systems and experience with international regulators gives her a unique view on the legal and regulatory requirements for medical device, pharmaceutical, and food manufacturers.