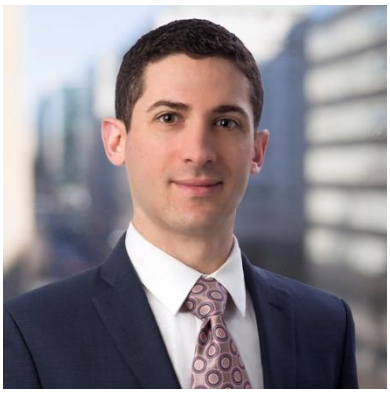
Introduction to Drug Law and Regulation
November 9-10, 2022
Speaker Biographies

JACQUELINE R. BERMAN is a partner in Morgan Lewis' FDA Practice. Jackie counsels pharmaceutical and biologic companies, manufacturers, investigators, contract research organizations, and investors, as well as pharmacies, distributors, and healthcare institutions on U.S. Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), and U.S. Department of Health and Human Services (HHS) regulatory, transactional, compliance, and enforcement matters. She advises clients on product development strategies, clinical and pre-clinical trials, expanded access, marketing applications, recalls, labeling, and promotion and advertising. Jackie also works with companies on post-marketing obligations including adverse event reporting and compliance with current good manufacturing practices (cGMP). She is a frequent writer and lecturer on these issues. Jackie is a graduate of American University, Summa Cum Laude, and The George Washington University Law School with Highest Honors.

REBECCA L. DANDEKER is a partner at Morgan, Lewis & Bockius LLP where she represents clients in matters involving products regulated by the U.S. Food and Drug Administration (FDA), including prescription and nonprescription pharmaceuticals, dietary supplements, cosmetics, and alternative therapies. Ms. Dandeker advises on diverse regulatory, policy, and compliance issues pertaining to pharmaceuticals, including preapproval pathways for innovators and generics, clinical studies, Hatch-Waxman issues, Drug Efficacy Study Implementation (DESI) drugs, over-the-counter (OTC) monograph drugs, homeopathics, Rx-to-OTC switches, and post approval compliance. Her clients range from manufacturers, distributors, and pharmacies to healthcare providers, clinical investigators, and entrepreneurs. Ms. Dandeker's experience includes US federal, state, and international drug regulation, as well as interaction with the FDA, the Federal Trade Commission (FTC), the US Drug Enforcement Administration (DEA), and the U.S. Customs Service. She routinely advises clients on regulatory strategy, compliance issues, enforcement actions, and matters involving labeling and advertising. She helps clients challenge FDA policies and administrative decisions through informal correspondence, rulemaking proceedings, citizen petitions, and litigation. Ms. Dandeker also drafts policy papers and congressional testimony for clients involved in legislative disputes. She publishes and speaks on a range of FDA-related topics, including the agency's generic drug approval process, 505(b)(2) NDA requirements, inspections/compliance audits, and labeling and advertising rules. Prior to joining Morgan Lewis, she was a partner in the food and drug practice of another international law firm, resident in Washington, D.C.

JENNIFER DAVIDSON focuses her practice on representing clients of all sizes. She excels at finding the most efficient ways to navigate the intricate regulations set in place by the FDA, the FTC, and related State and Federal agencies. Her clients in the pharmaceutical, dietary supplement, medical device, and cosmetic industries turn to her to help them to create and execute a comprehensive plan to ensure their companies stay in compliance with a variety of legal and regulatory requirements. Jennifer has counseled pharmaceutical clients on a wide variety of matters related to life-cycle management, exclusivity questions, promotional and marketing practices, other post-approval requirements, user fees, and issues arising under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, and subsequent legislation. She also spends a great deal of time assisting clients in presenting complex issues to the FDA via the agency's Citizen Petition procedures as well as representing industries in registration and scheduling proceedings before the DEA. Jennifer also counsels on all aspects of promoting and marketing dietary supplements, OTC drug products, cosmetics, and medical devices, including product labeling. In addition to this, Jennifer has a deep understanding of the rules and regulations surrounding dietary supplements and she frequently advises clients on product labeling, determining whether a product satisfies the definition of a dietary supplement, evaluating whether a new dietary ingredient notification is required, and evaluating potential promotional claims. Jennifer advises on a range of issues related to the development of advertising and labeling claims, including the adequacy of substantiation, the express and implied claims conveyed by promotional messages, and the evaluation of consumer perception surveys. She has worked closely with her clients in defending and initiating challenges against competitors marketing practices before the FDA, and before the National Advertising Division of the Council of Better Business Bureaus, Inc. Prior to joining Kleinfeld, Kaplan and Becker LLP in 1999, Jennifer practiced in the Washington D.C. office of a large, international law firm, specializing in civil litigation.

LAUREN A. FARRUGGIA is an associate in Goodwin's Technology and Life Sciences groups and a member of the firm's FDA regulatory practice. She counsels pharmaceutical, biologic, medical device, digital health, and consumer product companies on FDA regulatory compliance issues, including advertising, promotion, and labeling review, drafting and review of standard operating procedures, drug and device development issues, interactions with FDA, internal corporate investigations, and responding to FDA inspection observations and enforcement actions. Ms. Farruggia also advises FDA-regulated entities in corporate transactions, offerings, and licensing matters.



SCOTT KAPLAN is a counsel at Hogan Lovells US LLP where he helps pharmaceutical and biotechnology clients achieve and maintain compliance with complex Food and Drug Administration (FDA) requirements. Drawing on his deep understanding of the FDA's civil and criminal enforcement, Mr. Kaplan prepares clients for FDA inspections and works with them to respond to FDA 483s, Warning Letters, import alerts, investigations by the Office of Criminal Investigations, and other FDA enforcement actions. He provides experienced counsel on Current Good Manufacturing Practice regulations, data integrity issues, product labeling, and Drug Supply Chain Security Act implementation, among others. Before joining Hogan Lovells, he served as Associate Chief Counsel for Enforcement in the FDA's Office of the Chief Counsel. At the FDA, Mr. Kaplan helped the agency resolve seizures, injunctions, administrative detentions, and criminal prosecutions. He also acted as counsel for compliance matters to FDA's district offices. Prior to his tenure at FDA, he clerked for the Hon. Helene N. White of the U.S. Court of Appeals for the Sixth Circuit.

PETER J. LEININGER is a member of King & Spalding's FDA & Life Sciences Practice in Washington, D.C. He represents medical device, pharmaceutical, and biotech companies in FDA regulatory and enforcement matters, including civil and criminal government investigations. From 2012-2017, Mr. Leininger served as an Associate Chief Counsel for Enforcement in FDA's Office of Chief Counsel. Pete's enforcement practice at FDA covered the range of FDA-regulated products, often focusing on product quality, GMP/QSR compliance, MDR reporting, and promotional activity. He frequently handled criminal investigations arising out of qui tam lawsuits filed against drug and medical device manufacturers under the False Claims Act.

STEPHEN NICHOLS is an associate at Shook, Hardy & Bacon where he focuses his practice on product liability complex defense litigation issues, including multidistrict drug litigation. Stephen worked on MDL - 2740 Taxotere (Docetaxel) product liability litigation involving allegations that the breast cancer chemotherapy drug Taxotere causes permanent hair loss, serving as part of the trial team for the second bellwether trial and conducting MDL-wide briefing and litigation management. In this case, the jury returned a defense verdict in less than two hours after a two-week trial. He also worked on the recently consolidated MDL - 3023 Taxotere (Docetaxel) eye injury product liability litigation, participating in MDL-wide briefing and coordination. In addition, he has represented Pfizer and Medtronic. Stephen received his JD from the University of Kansas School of Law, and clerked for the Honorable Daniel D. Crabtree, U.S. District Judge for the District of Kansas before joining Shook.

LEE ROSEBUSH is a partner at BakerHostetler. With a background as a defense, regulatory, and registered patent attorney who has also worked as a registered pharmacist, Lee Rosebush provides his clients with legal counsel that is grounded in first-hand experience. Whether his clients are confronted with legal issues related to the naming of a drug, clinical trials, marketing, promotions, or advertising, Lee possesses a strong understanding of the pharmaceutical industry which, combined with his attention to detail and experience working with biologics, medical device, and healthcare companies, gives clients a single source for regulatory and litigation counsel. With post-graduate degrees in finance and business, Lee is frequently sought out to help expedite corporate deals involving healthcare entities. He also advises private equity and public and private companies in due diligence matters and buy-sell transactions.

JUR STROBOS has spent more than 30 years providing legal, regulatory, strategic development, management, and policy advice to life science companies that manufacture, import, or sell medical products (drugs, devices, biologics, cell and gene therapy, human tissues), foods, cosmetics, and tobacco products regulated by the US Food and Drug Administration (FDA) or comparable international authorities. Dr. Strobos is a medical doctor and formerly a credentialed federal law enforcement officer. He previously served as a legal, regulatory, and policy official in the Commissioner's Office at FDA. During his legal practice, Dr. Strobos has had the opportunity to work as a senior executive directly in charge of clinical and regulatory development at 5 start-ups and as the VP Clinical and Regulatory Affairs at a NYSE-traded company. His work as an executive has resulted in approval of 5 new drugs, 2 premarket-approved medical devices, a cell therapy and a biological product. This work – as with his legal work – included strategic policy and evaluation of in-licensing, out licensing, merger/acquisition, and joint development. Dr. Strobos also worked for the Bill and Melinda Gates Foundation to assist and support the approval, by FDA, EMA, and numerous other international regulatory authorities of Pre-Exposure Prophylaxis for HIV. Dr. Strobos started a graduate level course in drug development at the University of California, Berkeley at this time, which he continued to teach until 2017. Dr. Strobos has numerous publications on drug development, clinical trial design, statistics, and pharmacovigilance. Along with legal and regulatory work, Dr. Strobos also supports and has intimate expertise with mergers and acquisitions, licensing, and joint ventures. He is particularly adept, based on this wide-ranging experience including at FDA, in developing creative solutions to regulatory impediments that could delay marketing authorization on both sides of the Atlantic, and more recently in the Asia Pacific. He can assist with inspectional readiness, compliance agreements, delegation subcontracts with clinical sites, research and manufacturing organizations, Sunshine Act, False Claims Act, promotion, and food safety, among others.

MARC WAGNER is an associate at BakerHostetler LLP where he focuses his practice on regulatory and transactional matters, primarily in the healthcare and life sciences industries. He has experience advising clients on Food and Drug Administration (FDA) regulatory matters, including food, drug, device, dietary supplement and cosmetic issues, as well as matters related to compounding pharmacies operating pursuant to Section 503A of the Federal Food, Drug and Cosmetic Act (FD&C Act) and outsourcing facilities operating pursuant to Section 503B of the FD&C Act. Marc also has experience assisting clients with matters related to Drug Enforcement Administration (DEA) compliance. In addition, he helps drug manufacturer, pharmacy, wholesaler and third-party logistics provider clients navigate state licensing, pharmacy practice and drug control act issues. Marc's educational and professional background as a registered pharmacist provides him with a substantial understanding of a variety of pharmaceutical compliance measures. This background enables him to assist with life science transactions and navigate federal and state licensing for human and veterinary drug manufacturers, wholesale distributors, pharmacies and outsourcing facilities.

BENJAMIN ZEGARELLI is of counsel at Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. where he provides counsel on compliance and regulatory issues to clients in the pharmaceutical, medical device, and biotech industries. With a clear focus on FDA regulatory counseling, Benjamin advises a breadth of health care industry clients, including pharmaceutical, medical device, and bio tech companies, on the federal and state laws surrounding medical product development and marketing. He has extensive experience guiding medical device companies through the FDA regulatory process to identify the correct regulatory pathway, assisting with communications and meetings with FDA, ensuring that regulatory submissions meet regulatory requirements, and helping to establish robust post-market quality system and compliance controls. In particular, Benjamin has counseled numerous medical device software developers, in particular software that includes artificial intelligence or machine learning functionalities, on FDA regulatory strategy, including preparing for pre-submission meetings with FDA and submitting premarket notifications (510(k)) and de novo reclassification requests. His practice also includes advising life sciences clients on regulatory compliance relating to distribution, sales, promotion, and negotiating contractual relationships with suppliers and other contractors. Benjamin has substantial experience representing medical device companies in responding to significant unfavorable observations from FDA investigators, including regulatory violations cited in Untitled Letters or Warning Letters. He helps companies with compliance issues to navigate the process of communicating with FDA and remediating the identified compliance issues, including the development of corrective action plans and implementation of corrective and preventive actions. In his practice, Benjamin participates in the coordination of diligence reviews of transactions involving large pharmaceutical and medical device manufacturers. He is well versed in the process of developing policy positions for life sciences clients and advocating such positions before FDA or other governmental bodies through written comments or in-person meetings . His practice also includes representing both clinical trial sponsors and clinical sites on clinical research issues, including

government grant regulations, as well as drafting and negotiating the agreements necessary to perform clinical research. Benjamin has co-authored several books titled, Promotion of FDA-Regulated Medical Products and Introduction to the Due Diligence Process, Second Edition, both published by the Regulatory Affairs Professional Society. He has given numerous presentations on current health care industry topics, with titles such as Advertising and Promotion for Drugs, Devices and Biologics Using Social Media and Promotion of Investigational Drugs and Devices. He previously worked as a research chemist in the discovery group of a major research-based health care and pharmaceutical company. While in law school, he held the position of Executive Editor of the Cardozo Law Review.