Introduction to Drug Law and Regulation
April 20-22, 2021 | Live Virtual Event
Speaker Biographies

ALEXANDER V. ALFANO is an associate in Axinn, Veltrop & Harkrider LLP's Intellectual Property and Food and Drug Administration practice groups. His patent litigation practice focuses on biotechnology, pharmaceuticals, medical devices, diagnostics, and the life sciences. His experience includes pre-litigation client counseling, inter partes proceedings, cases brought under the Hatch-Waxman Act, and counseling relating to FDA matters.

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 US Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), and US 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 US 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 US 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, DC.

HEIDI GERTNER is a partner in Hogan Lovells' Washington, DC office, where she works at the forefront of the drug regulatory industry. She provides insight to large and small pharmaceutical companies and research institutions in dealing with government regulators to maximize business potential. Heidi began her professional career with a focus on bioethics and law, completing two post-doctoral bioethics fellowships, one at the Cleveland Clinic Foundation, and another at the National Institutes of Health. At the National Institutes of Health, her work focused primarily on human subject protection and research ethics issues. She honed her legal skills at FDA's Office of Chief Counsel, where she advised government regulators on almost all aspects of drug regulation for 13 years. At FDA, her portfolio focused on drug advertising and promotion, combination products, drug safety, clinical trials and human subject protection, Rx-OTC switches, and over-the-counter drug regulation. Heidi joined Hogan Lovells in 2014 and calls the DC office her home base.

LINDSAY P. HOLMES is an associate at BakerHostetler where she focuses her practice on regulatory and transactional matters, primarily in the healthcare and life sciences industries. She 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 503B outsourcing facilities operating pursuant to the Drug Quality and Security Act (DQSA), and entities subject to the Drug Supply Chain Security Act (DSCSA). She also has experience assisting clients with matters related to the US Department of Agriculture (USDA) and Drug Enforcement Agency (DEA) compliance. In addition, Ms. Holmes helps pharmacy, wholesaler and third-party logistics provider clients navigate state licensing and pharmacy practice act issues. Her background also includes counseling clients on data privacy and security matters, fraud and abuse, and Medicare Part D.

TIFFANY HUMPHRIES is an associate in the North America Food and Drug Administration Practice Group for Baker McKenzie. Prior to joining Baker McKenzie, Tiffany worked as an Associate Chief Counsel at the US Food and Drug Administration, Office of the Chief Counsel. While there, she gained over 6 years of experience on the foods, cosmetics, and drugs teams. Tiffany focuses her practice on assisting clients with regulatory, compliance and enforcement matters for FDA-regulated products, including food, cosmetics, drugs and medical devices. She represents clients in research, pre-launch, launch, commercialization and licensing activities for first-in-class products and other innovative products. Clients also seek Tiffany's counsel on developing innovative strategies for FDA approval and compliance with FD&C Act and Public Health Service Act regulatory requirements for investigational and marketed products including current good manufacturing practices (cGMPs), promotion and marketing, interstate conveyance sanitation, supply chain and quality issues. Moreover, Tiffany advises clients on strategies for addressing critical regulatory matters, including inspection observations, untitled letters, warning letters, voluntary and mandatory recalls, dispute resolution issues and advisory committee comments. Tiffany also advises cosmetics, food and dietary supplement clients on FDA and Federal Trade Commission (FTC) regulated labeling, advertising and promotion matters. Further, in Tiffany's practice, she works with large, mid-size and emerging life sciences clients on a variety of transactional issues including acquisitions, divestitures, collaborations, clinical trials and related agreements.

JOHN F. JOHNSON III is counsel at Shook, Hardy & Bacon LLP where he works with companies to develop and implement solutions for complying with the laws administered by Food and Drug Administration (FDA), US Department of Agriculture (USDA), Customs and Border Protection (CBP) and other federal and state agencies. He works with manufacturers, distributors, brand owners, importers and retailers of food, drugs, medical devices, cosmetics and animal products to satisfy their regulatory obligations. John represents companies before FDA and other government agencies subject to inspections or compliance activities, including a judicial action, Warning Letter, Untitled Letter, regulatory meeting, administrative detention, import detention and import alert, and FDA Form 483. Additionally, he helps companies evaluate complaints to determine if a recall is necessary, and if so, he works with clients to manage the product recall to remove the product from market. John counsels clients throughout the product life cycle, including product development and specifications, marketing and labeling, and manufacturing, importation, distribution and sales. This includes determining the possible registrations, permits, licenses and pre-market submissions. Also, he works with clients to create, implement, and maintain internal programs to help foster smooth compliance.

BERT LAO is a senior associate in the Pharmaceutical and Biotechnology practice at the law firm of Hogan Lovells. In his practice, Bert has counseled innovator pharmaceutical and biotechnology companies, investment groups, and contract research organizations on matters ranging from new drug approval to advertising and promotion compliance. With a background in biomedical engineering, Bert offers an interdisciplinary perspective on legal challenges that can become heavily intertwined with underlying scientific issues.

MARIAN J. LEE is a partner and the co-chair of the FDA & Health Care Practice at Gibson, Dunn & Crutcher. She advises clients on strategic FDA regulatory and compliance matters, risk management, and enforcement actions. She is a frequent speaker and author on emerging developments in FDA law, including the regulation of digital health, hemp-based products, and commercial speech. The Best Lawyers in America® recognizes Ms. Lee in FDA law. Law360 selected her as a "Rising Star," one of four attorneys chosen in her field nationwide. She is a member of the Food and Drug Law Journal's Editorial Advisory Board and the Law360 Life Sciences Editorial Advisory Board. Ms. Lee is a graduate of Harvard Law School and Harvard College, magna cum laude and Phi Beta Kappa.

JOSEPH E. McGUINNESS is an independent consultant at EAS Consulting Group where he utilizes extensive experience in the pharmaceutical industry to assist EAS clients with preparation for and execution of both internal and FDA audits. He designs protocols for SOPs, GMPs and training programs ensuring an understanding of regulatory compliance requirements and assists with remediation and responses of CAPA findings and deviations. He also helps with the preparation of CMC in support of FDA submissions.

ELIZABETH MULKEY is a senior 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. Mulkey also advises FDA-regulated entities in corporate transactions, offerings, and licensing matters.

HILLARY NICHOLAS is an associate at Shook, Hardy & Bacon LLP where focuses her practice on complex product liability litigation defense, as well as regulatory counseling for medical device, pharmaceutical, consumer product and agribusiness companies. Hillary also represents pharmaceutical and medical device companies in large multidistrict litigation. Her regulatory practice includes FDA-regulated clients of all sizes and across a range of industries. She has counseled clients on product labeling, marketing and advertising, risk assessment and management.

MICHELLE R. RYDER is a Principal Consultant in the Regulatory Practice of Lachman Consultants with 20+ years' experience as a Regulatory professional in the pharmaceutical industry. With her expert knowledge of pharmaceutical regulations, standards, current industry practices, and strong practical experience, she delivers strategic leadership to Lachman's clients, including for ANDA, NDA, and IND, [505(j), 505(b)(1) and 505(b)(2)] applications as well as throughout the entire project lifecycle: product feasibility, development, scale-up, submission, pending application management, approval / launch, post-approval changes, and compliance. Her expertise includes generic topical and extended-release injectable formulations and she has previous experience in solid oral dosage forms.