Introduction to Drug Law and Regulation
November 9-10, 2021 | Live Virtual Event
Speaker Biographies

HEATHER BANUELOS is counsel in King & Spalding's Washington, DC office and a member of the firm's FDA & Life Sciences practice group. Her primary practice is focused on regulatory strategies and initiatives for the labeling, promotion and advertising of FDA-regulated products. She has served on over 20 different promotional review committees and medical and scientific review committees, with a knack for practical advice and recommendations to help clients find a path forward. Ms. Bañuelos' experience in FDA law spans 19 years and includes positions as a former Associate Chief Counsel in the FDA's Office of the Chief Counsel and senior in-house regulatory counsel for multiple clients, including two large pharmaceutical companies and a leading food company. Her experience in government and in-house give her a unique and valuable perspective as outside counsel.

MERYL BARTLETT is an associate in the Washington, DC office of Latham & Watkins. Ms. Bartlett represents pharmaceutical, biotechnology, medical device, digital health, food, dietary supplement, cosmetic, and consumer product companies on FDA regulatory compliance and enforcement matters. She counsels at all stages of the product lifecycle, including, among others, pre-market regulatory communications and submissions, contract matters relating to clinical trials, non-patent exclusivity, post-market actions and recalls, and administrative interactions and appeals. She also provides counsel on matters involving the Drug Enforcement Administration (DEA), US Department of Agriculture (USDA), and Federal Trade Commission (FTC). With the enactment of the Farm Bill in 2018, she also represents companies seeking to market CBD consumer products to navigate the evolving legal framework governing the industry. In the transactional space, Ms. Bartlett advises investment banks, venture capital firms, private equity firms, and commercial lenders on regulatory diligence and disclosure matters in connection with mergers and acquisitions, equity offerings, financings, and other transactions in the life sciences sector. Ms. Bartlett attended law school at the Georgetown University Law Center where she was a member of the Georgetown Law Journal and served as editor-in-chief of the Georgetown Law Journal's Annual Review of Criminal Procedure. Prior to joining Latham, Ms. Bartlett was an FDA regulatory associate at a national law firm in Washington, DC.

NATHAN A. BEATON is an associate at Latham & Watkins LLP where he focuses his practice on regulatory and transactional matters involving the healthcare and life sciences industries. Mr. Beaton counsels clients on matters involving the Food and Drug Administration (FDA), Department of Health & Human Services Office of Inspector General, Centers for Medicare & Medicaid Services, Federal Trade Commission, and other governmental authorities. Mr. Beaton has experience advising clients in all stages of the biotechnology product life cycle, including pre-market regulatory communications and submissions, contract matters relating to clinical trials, promotion and labeling, compliance with the Quality System Regulation and Good Manufacturing Practice requirements, reimbursement strategy, post-market inspections and recalls, and administrative appeals. He also advises financial institutions, healthcare providers and suppliers, and pharmaceutical, medical device, and biotechnology companies on healthcare and FDA regulatory matters in connection with mergers and acquisitions, equity offerings, financings, and other transactions. Mr. Beaton earned his Juris Doctor from the University of Chicago Law School, with honors, and his Master of Public Policy from the University of Chicago Harris School, with a Certificate in Health Policy. While in law school, he served as a legal intern at Ann & Robert H. Lurie Children's Hospital, and participated in the Law School's Corporate Lab, a transactional-focused legal clinic.

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.

CHRISTOPHER GALLO holds a PhD in Biochemistry and Molecular Genetics. His practice is focused on patent counseling and litigation and advocacy before FDA. His experience includes matters before federal district and appellate courts and the United States International Trade Commission. He has been heavily involved in all aspects of litigation, from pre-filing investigation, through fact and expert-witness discovery, claim-construction, and trial. Christopher also has experience in proceedings before the Patent Trial and Appeal Board at the USPTO, responding to Citizen Petitions filed with FDA, and challenging FDA decisions before federal district courts. He previously worked as a postdoctoral fellow at the Johns Hopkins University School of Medicine, where he investigated the role of RNA-protein complexes in regulating fertility and cell fate specification in the model organism Caenorhabditis elegans.

ALEXANDRE (ALEX) GAPIHAN is an associate at Morgan, Lewis & Bockius LLP where he counsels clients in matters involving products regulated by the US Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) including the approval, regulation, promotion, and sale of drugs, medical devices, and dietary supplements.

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.

PETER V. LINDSAY is a partner in Paul Hasting's FDA Regulatory and Enforcement group and is based in the firm's Washington DC office. He regularly counsels life science companies on a range of FDA-related matters, including clinical trial activities, promotional conduct, supplier management and supply chain risks, GMP and manufacturing activities, safety reporting and other post market requirements. He also provides crisis management support and has helped companies address product recalls and other significant field actions. Peter routinely represents manufacturers in administrative and enforcement actions by FDA, including Untitled and Warning Letters. Peter's experience also includes advising companies in internal and government investigations involving criminal and civil allegations of potential violations of the federal Food, Drug, and Cosmetic Act and related statutes.

DEBORAH L. LIVORNESE is Director at Hyman, Phelps & McNamara, PC in Washington, DC. Ms. Livornese has extensive experience in a broad range of FDA regulatory issues. She assists pharmaceutical drug companies of all sizes on regulatory requirements and strategies related to obtaining FDA approval and other paths to market, as well as on post-marketing regulatory requirements. Ms. Livornese also assists clients in connection with commercial transactions and public offerings by conducting FDA regulatory due diligence on behalf of regulated companies and potential investors or purchasers. Prior to joining Hyman, Phelps & McNamara, Ms. Livornese spent seven years in the Office of Regulatory Policy in FDA's Center for Drug Evaluation and Research. As a Senior Regulatory Counsel at FDA, she was involved in a wide variety of policy issues in the areas of drug approvals and withdrawals, the regulation of unapproved and over-the-counter drugs, and opioid drugs, and user fee programs. Prior to joining FDA, Ms. Livornese was Of Counsel with an FDA boutique law firm in Washington DC where she advised drug companies on promotional activities for compliance with FDA, FTC and HHS requirements, and assisted clients in responding to investigational findings, warning letters, and inquiries from the FDA and other agencies.

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.

LEE ROSEBUSH is a partner at BakerHostetler where he 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. Lee's ability to smoothly shift between the legal, governmental, and pharmaceutical environments further helps him to efficiently secure operating licenses or assist drug manufacturers avoid compliance actions from governmental agencies. Active with the Drug Quality and Security Act (DQSA), as well as the Federal Food and Drug Administration's (FDA) regulation of pharmacy compounding, Lee speaks and writes on both issues, and is passionate about orchestrating and advocating for pharmacists and pharmacies. Additionally, Lee is Leader of BakerHostetler's Pharmacy and Reimbursement team and Co Leader of the FDA, Products Promotion, and Defense team.

GILLIAN M. RUSSELL is counsel in King & Spalding's FDA and Life Sciences Practice Group. She advises pharmaceutical, biotechnology and medical device companies on a variety of US Food and Drug Administration (FDA) and healthcare regulatory compliance matters, including product advertising and promotion, federal healthcare compliance programs, clinical trial regulation, and FDA enforcement actions. In addition, she regularly counsels clients in the cosmetics industry and has advised clients in the food industry. Ms. Russell's practice also focuses on regulatory requirements imposed by the US Drug Enforcement Administration (DEA), the Federal Trade Commission (FTC) and state boards of pharmacy. Ms. Russell graduated from the University of Virginia School of Law, where she served as Executive Editor for the Virginia Environmental Law Journal and as a Hardy Cross Dillard fellow for legal research and writing. Gillian earned her BA magna cum laude from Princeton University.

ANGELA M. SEATON is a partner with Shook, Hardy & Bacon LLP. She has 20 years of experience focusing on complex litigation, with an emphasis on pharmaceutical product liability defense and smoking-and health-lawsuits. She has represented product manufacturers in a highly-regulated industries and has been an integral part of trial teams defending product manufacturers across the country. Ms. Seaton has developed a deep knowledge of the scientific and medical aspects of product liability litigation. She has worked with experts in the areas of cardiology, pulmonology, pathology, oncology, radiology, urology, hepatology, thoracic surgery, otolaryngology, epidemiology, toxicology, neurology, psychiatry, and industrial hygiene. She also has extensive experience deposing plaintiffs' experts and treating physicians in these fields.

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.