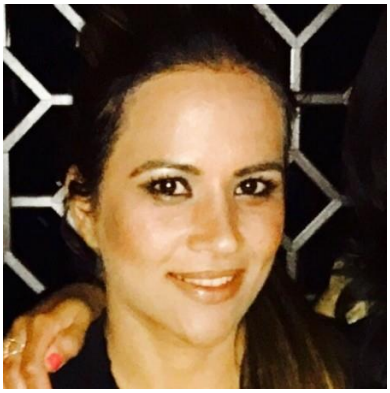
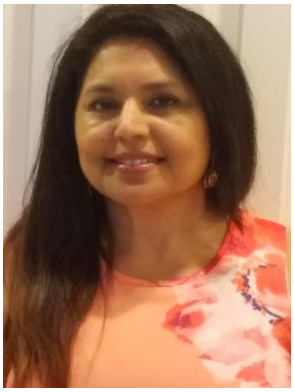
Introduction to Drug Law and Regulation
November 9-10 & 12, 2020 | Virtual Course
Speaker Biographies

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.



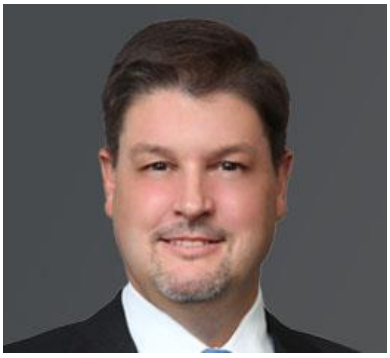
MANTEJ (NIMI) CHHINA is Senior Director, Regulatory Policy and FDA Engagement at BioMarin Pharmaceutical Inc. She is a regulatory policy expert with strong understanding of FDA, ICH, and other global laws, regulations, policies, and guidances for regulation of medical products. She also has extensive biotechnological, translational, and clinical research experience. Ms. Chhina has strong scientific educational background with deep insight of biotechnology; and is highly specialized in human genetics and biomedical genetics. She got her BS (honors school, 2002) and MS (honors school, 2004) in human genetics from Guru Nanak Dev University in India. She undertook graduate studies in biomedical genetics from 2004 to 2006 at University of Rochester, NY, and got her PhD in biotechnology and functional genomics in 2010 from George Mason University, VA. She got the Regulatory Affairs Certification (RAC) in 2015. During her time at the FDA, Ms. Chhina served in various positions in CDER's Office of Medical Policy, including health science policy analyst and as team lead in the Division of Medical Policy Development. She joined BioMarin Pharmaceutical Inc. in 2017 as Director of Regulatory Policy & FDA Engagement. In her current role as Senior Director, she provides strategic advice to the development programs, including gene therapy development. She works closely with internal teams on important topics including regulatory CMC, expedited program considerations, patient engagement, etc. She has interest in continuing education and professional development.

REBECCA 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 postapproval 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.



PRIYA JAMBHEKAR is an independent consultant at EAS Consulting Group, LLC. She has served in senior regulatory positions at prominent pharmaceutical companies, including Bristol Myers Squibb, Baxter Healthcare, Ethicon (a Johnson and Johnson company), Paramount BioSciences, Alkermes, Block Drug Company, and Chelsea Laboratories.

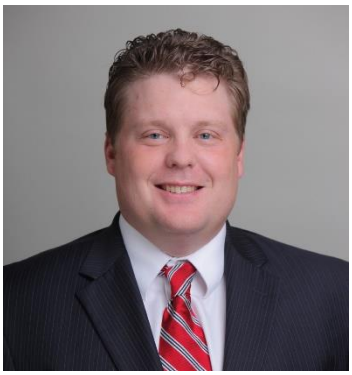
PETER J. LEININGER is a member of King & Spalding's FDA & Life Sciences Practice in Washington, DC. He represents medical device, pharmaceutical, and biotech companies in FDA regulatory and enforcement matters, including civil and criminal government investigations. From 2012-2017, Mr. Leininger served 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.



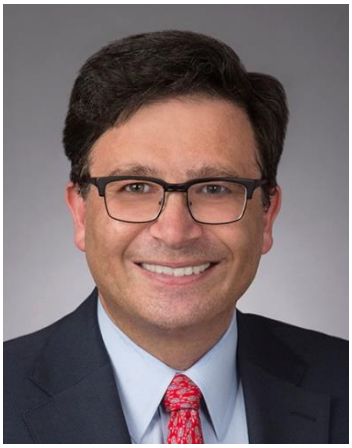
CHRISTOPHER M. MIKSON is a partner at DLA Piper LLP where he advises and represents clients in Food and Drug Administration regulatory matters and complex litigation and transactional matters involving healthcare and the life sciences. He is currently a partner at DLA Piper LLP. Mr. Mikson has extensive experience in the regulation of drugs, biologics, human cell and tissue products (HCT/Ps), and medical devices by FDA and other federal and state agencies. He has counseled and represented clients in regulatory matters across all stages of the product life cycle, from research and development to nonclinical testing, clinical trials, premarket clearance and approval, manufacturing and distribution compliance, and post-market surveillance and reporting, including a broad range of agency proceedings such as Orange Book listing disputes, comments during rulemaking, citizen petitions, establishment inspections, responses to agency letters, and enforcement actions. Mr. Mikson has completed FDA's Clinical Investigator Training and NIH's Clinical Research Training, affording him a multi-disciplinary understanding of current and evolving regulatory conditions as well as state-of-the-art science and technology that are critical to the design, conduct, and ultimate success of clinical trials for small molecule drugs, biologics, HCT/Ps, and medical devices. Mr. Mikson has comprehensive experience in a broad range of complex litigation matters. He has represented some of the world's largest pharmaceutical, medical device, consumer product, and technology companies in patent infringement, trade secret, false advertising, and product liability litigation. Mr. Mikson focuses his litigation practice on FDA regulatory disputes and cases where FDA regulation intersects with other areas of the law, such as product liability and intellectual property, including Hatch-Waxman and biosimilar cases. In addition to his litigation practice, Mr. Mikson regularly performs transactional work related to FDA-regulated products, including material and service contracts, licensing agreements, and due diligence of major deals.

KOMAL KARNIK NIGAM is a senior associate in the FDA Pharmaceuticals and Biotechnology group at Hogan Lovells, in Washington, DC. Her practice includes a broad range of regulatory matters, including assisting pharmaceutical clients with lifecycle management and product development issues, regulatory due diligence for mergers and acquisitions in the life sciences industry, and responses to FDA enforcement actions and related government investigations. She routinely advises pharmaceutical companies on advertising and promotion issues and has served on multiple promotional review committees. Ms. Nigam received her JD from Harvard Law School and MPH from the Harvard TH Chan School of Public Health.

GENEVIEVE M. RAZICK is an associate in the Healthcare and Food and Drug Practices at Arnall Golden Gregory LLP. Ms. Razick has advised pharmaceutical, biologic, medical device, cosmetic, and dietary supplement companies on legal and regulatory matters relating to the US Food and Drug Administration. She has served as the legal representative for a number of promotional review committees to advise on pharmaceutical advertising and promotion. She also has experience advising clients on Sunshine Act reporting obligations and drug price transparency requirements.

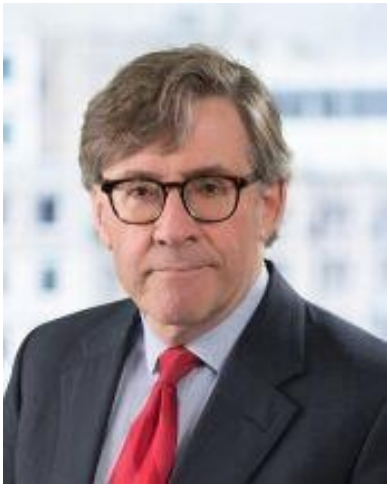


LEE ROSEBUSH is a partner at BakerHostetler. With a background as a defense, regulatory, and registered patent attorney who has also worked as a registered pharmacist, Mr. Rosebush provides his clients with legal counsel that is grounded in first-hand experience. Whether his clients are confronted with legal issues related to the naming of a drug, clinical trials, marketing, promotions, or advertising, Mr. Rosebush 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, Mr. Rosebush 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. Mr. Rosebush'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, Mr. Rosebush speaks and writes on both issues, and is passionate about orchestrating and advocating for pharmacists and pharmacies. Additionally, Mr. Rosebush is Leader of BakerHostetler's Pharmacy and Reimbursement team and Co-Leader of the FDA, Products Promotion, and Defense team.



HOWARD R. SKLAMBERG is a partner at Arnold & Porter where he counsels clients on a wide range of compliance and enforcement issues related to US Food and Drug Administration (FDA) regulation and policy. His experience is rooted in a deep understanding of US and foreign food, drug and medical devices law and policy, and is able to guide domestic and international clients through the regulatory challenges they face. Areas of expertise include inspections and warning letters, investigations, civil and criminal enforcement, medical product applications and clinical research, food and hemp regulation, imports, the development of FDA policy and FDA-related legislation, and business transactions involving FDA-regulated companies. Prior to entering private practice, Mr. Sklamberg held a variety of roles at the FDA from 2010 to 2017, including Deputy Commissioner for Global Regulatory Operations and Policy; Director of the Office of Compliance, Center for Drug Evaluation and Research; Deputy Associate Commissioner for Regulatory Affairs; and Director in the Office of

Enforcement. While at the agency, he directed an office of over 5,000 employees in more than 200 offices, laboratories and import facilities across the United States, Asia, Europe, and Latin America. As Deputy Commissioner, Mr. Sklamberg was FDA's top enforcement official. He oversaw the agency's inspections, enforcement, recalls, and import operations programs. Mr. Sklamberg also led FDA's international program, including its agreements and cooperation with foreign regulators, harmonization initiatives, and oversight over the global supply chain. He also interacted with and testified before Congress on behalf of the agency, co-led FDA's implementation of the FDA Food Safety Modernization Act and was the lead official at FDA on a variety of issues including cannabis and hemp, counterfeit drugs, and FDA's Mutual Recognition Agreement with the European Union. Earlier in his career, Mr. Sklamberg served as a prosecutor in the US Attorney's Office in Washington, DC, and in the Public Integrity Section of the Criminal Division at the Department of Justice.



JUR STROBOS is a partner in the Washington, DC office of Potomac Law Group. Dr. 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, tobacco regulated by the US Food and Drug Administration (FDA) or comparable international authorities. Dr. Strobos is a medical doctor and a credentialed federal law enforcement officer. He previously served as a legal, regulatory, and policy official in the Commissioner’s Office at FDA.

CAROLINA WIRTH is of counsel in the Food and Drug practice and is a member of the Dietary Supplements and Pharmaceuticals & Biologics industry teams at Arnall Golden Gregory LLP. She provides clients with FDA regulatory guidance related to food, dietary supplements, drugs, cosmetics, and medical device products. Carolina’s prior experience as regulatory counsel in CDER’s Office of Regulatory Policy at the FDA and as an in-house lawyer at a biotechnology company has aided her work with domestic and international clients on regulatory issues associated with the marketing, labeling, packaging, and advertising of conventional foods, prescription and over-the- counter (OTC) drugs, medical devices, and dietary supplements. She also assists clients with Federal Trade Commission (FTC) and Better Business Bureau National Advertising Division inquiries. In addition, Carolina counsels clients on clinical trial issues, including reviewing informed consent documents and master clinical trial agreements.