Introduction to Drug Law and Regulation
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Speaker Biographies

FREDERICK (RICK) R. BALL serves as a team lead for the Duane Morris Life Sciences and Medical Technologies industry group. Mr. Ball helps pharmaceutical companies, biologics manufacturers, medical device manufacturers, contract service providers, food companies (including supplement manufacturers), pharmacies, long term care providers, and other health care providers navigate the complex challenges faced by state and federal regulation of their industries including complying with current Good Manufacturing Practices, price reporting (AMP, AWP, ASP, etc.), the Foreign Corrupt Practices Act, False Claims Act, and Anti-Kickback Statute, as well as meeting labeling and advertising requirements. Mr. Ball assists companies bring product to market through patent analysis, identifying marketing and approval pathways, and, when necessary litigation. Mr. Ball is experienced in conducting internal investigations and advising companies on actions following the investigation. Finally, Mr. Ball helps entities when they are adverse to state or federal governments, including in administrative, civil and criminal matters, with the FDA, FTC, DEA, CMS, OIG and other federal and state regulatory agencies. Mr. Ball emphasizes a team approach to client problem solving and manages matters to achieve client goals both financial and legal.

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.

VANESSA K. BURROWS is Counsel in Simpson Thacher & Bartlett's Washington, DC office. She has advised pharmaceutical, medical device, dietary supplement, and tobacco manufacturers in connection with regulatory and compliance needs, as well as M&A and capital-raising transactions. Before entering private practice, Vanessa held several government positions focused on FDA matters, healthcare regulation, and public health. She served as the HIPAA Privacy Officer for the City of Chicago and Attorney for the Chicago Department of Public Health, where she addressed issues including medical countermeasures, emergency preparedness, and quarantine and isolation. Earlier, she advised Members of Congress and their staff on FDA legislation and issues as a Legislative Attorney with the Congressional Research Service. Vanessa handled FDA, healthcare, administrative law and constitutional law matters during the creation and passage of the Patient Protection and Affordable Care Act (ACA), the Family Smoking Prevention and Tobacco Control Act, FDA user fee laws, and the 2009 H1N1 pandemic.

DAVID L. CHESNEY is the Principal and General Manager for DL Chesney Consulting, LLC, providing GMP and GCP compliance consulting and training services to clients worldwide. Previously he served for over twenty years as Vice President, Strategic Compliance Services for PAREXEL Consulting. Prior to joining PAREXEL Consulting, he served twenty-three years with the FDA as an Investigator, Supervisory Investigator, Director of Investigations, and ultimately as District Director in San Francisco, managing all FDA operations in Northern California, Nevada, and Hawaii. Mr. Chesney holds an MS in Jurisprudence, concentrating in Pharmaceutical and Medical Device Law, from Seton Hall University School of Law, a Bachelor's degree in Biology from California State University, Northridge, plus three years of graduate study in Biology at CSU Northridge and CSU San Diego. Mr. Chesney is a member of the Parenteral Drug Association, where he serves on the faculty of the PDA Training and Research Institute. He serves as a Guest Lecturer for the Maine Regulatory and Ethics Training Center, University of Maine School of Law, and is also active in the Food and Drug Law Institute and RAPS.

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.

DOUGLAS B. FARQUHAR is a leading expert on current good manufacturing practices who served as a federal prosecutor representing the FDA in enforcement cases. Since joining the prominent FDA law firm Hyman, Phelps & McNamara, PC, in 1997, he has advised pharmaceutical and medical device manufacturers, wholesalers, pharmacies, and individuals on a wide range of enforcement activities, including consent decrees, criminal investigations, debarment issues, civil seizures, FDA inspection issues, and injunctions. Mr. Farquhar also advises companies and individuals on adverse findings after FDA and other regulatory agency inspections. He has argued cases and conducted trials in federal court defending companies and individuals against both civil and criminal FDA enforcement efforts, and has sued FDA on several occasions, with two notable successes. Mr. Farquhar's legal career includes seven years of service as an assistant US Attorney in the District of Maryland from 1990 to 1997. He has an undergraduate degree from Boston University and a law degree from Yale Law School.

ALEXANDRE 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.

EMILY MARDEN is counsel in Sidley's Food and Drug Regulatory group. Emily trained in the life sciences, and has a deep understanding of the emerging science shaping therapeutic products, agriculture, foods, and dietary supplements. Emily's practice focuses on regulatory and strategic questions at the cutting edge, including: regenerative medicine; complex drugs and biological products; genomics, and synthetic biology; regulatory exclusivity; and innovations in food and dietary supplements. In addition to her regulatory practice, Emily directs research on genomics and innovation in agriculture and medicine at the University of British Columbia and teaches there in the Faculty of Law. Her current research focuses on the intersection of legal frameworks governing access and use of genetic resources with research. She also publishes and speaks widely on interrelated issues of policy, regulation, and innovation. Emily received degrees in Biology and the History of Science from Harvard University and she received her JD from the New York University School of Law.

ALAN G. MINSK is a partner and leader of the Food and Drug Practice Team at Arnall Golden Gregory LLP. Alan is licensed to practice in Georgia and Washington, DC. He works out of AGG's Atlanta and Washington offices. Alan is recognized by Chambers USA America's Leading Lawyers for Life Sciences, Regulatory/Compliance and has been selected for inclusion in the International Who's Who of Life Sciences Lawyers from 2013 – 2020. Nominees are selected based upon comprehensive, independent survey work with both General Counsel and private practice lawyers worldwide. He serves as general counsel of The Sharing Alliance Inc., a pharmaceutical trade organization focused on compliance with the Prescription Drug Marketing Act and sample accountability. Alan focuses his practice on advising pharmaceutical, biologic, medical device, cosmetic, food (including dietary supplements and medical foods) companies, on all legal and regulatory matters relating to the US Food and Drug Administration. For companies in the pre-approval phase, he counsels on the following areas: clinical trial issues, communications with the FDA during the review process, imports and exports, regulatory strategy including 505(b)(2) new drug applications, orphan drug designation, Fast Track and Breakthrough Therapy designations, combination product determinations, market exclusivity, premarket notification (510(k)) submissions, premarket approval applications, and pre-approval discussions. In addition, Alan works with life science companies and venture capital firms on regulatory diligence matters involving acquisitions, divestitures, regulatory opinion letters, co-promotions and licensing agreements. He also drafts and reviews agreements relating to clinical trials, quality, and contract manufacturing. He conducts in-house training on FDA and fraud and abuse topics. Alan's client base is primarily focused on early-stage to mid-sized life science companies, where he must clearly articulate the legal and regulatory issues for consideration while also recognizing the client's business realities and needs. He currently serves on a number of editorial boards for

professional publications, including the RAPS Focus magazine and the Food and Law Drug Institute's Food and Drug Law Journal.

CHARLES G. RAVER is an associate at Hyman, Phelps & McNamara where he assists a broad range of clients from small biotechnology startups, multinational pharmaceutical companies and contract research organizations to the academic research community and patient advocacy organizations. His practice focuses on assisting clients across a range of FDA-related regulatory matters, including new drug and biologic development as well as navigating complex regulatory issues. Mr. Raver joined Hyman, Phelps & McNamara after more than a decade in biomedical research spent studying the neurobiological mechanisms of chronic pain and sensory processing. He now leverages his deep knowledge of neuroscience, pre-clinical animal research, study design, as well as laboratory management and compliance to help clients understand the regulatory landscape faced by the life sciences industry. Mr. Raver graduated with honors from the University of Maryland Carey School of Law. While in law school, Mr. Raver served as a staff editor and the first social media chair for the Journal of Health Care Law & Policy. He also received two CALI awards after nabbing the top grade in courses on Animal Law and Written and Oral Advocacy. Throughout law school, Mr. Raver continued his neurobiology research career full-time. His research has resulted in nine peer-reviewed original research publications demonstrating potential therapeutic targets for treating chronic pain and revealing functions of neural circuits responsible for sensory processing. Mr. Raver also has extensive knowledge and direct experience with the advanced techniques driving development of current biomedical therapies, such as optogenetics, chemogenetics, viral vector-mediated gene delivery, and targeted stimulation techniques.

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.

DAVID L. ROSEN is a partner and public policy lawyer with Foley & Lardner LLP. He has extensive experience in health law, life sciences and food and drug regulation, including a range of Food and Drug Administration (FDA) regulatory issues affecting prescription and over-the-counter pharmaceuticals, medical devices and biologics. He is co-chair of the firm's Life Sciences Industry Team and is also a member of the firm's Government & Public Policy Practice and the Health Care and Food & Beverage Industry Teams. David was formerly a partner with two other law firms. He was also employed by the FDA for 14 years, progressing to various supervisory positions involving virtually all aspects related to the drug approval process, combination products, jurisdictional issues and related compliance activities.