Introduction to Drug and Device Law and Regulation for Patient Organizations
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Virtual Event

REMY BRIM is a scientist and health care policy expert focused on strategic policy and advocacy support for clients with FDA-regulated products and activities. As co-head of BGRs Health Care Practice, she helps clients effectively navigate the complex regulatory and political landscapes required to advance the discovery, development, and delivery of innovative products to patients and consumers. Her success for clients is rooted in her deep technical understanding, thoughtfulness, and commitment to sound public health policy. Prior to joining BGR Group, Remy served as Senior FDA Policy Advisor to the Senate HELP Committee's Ranking Member, Patty Murray (D-Wash). In this role, she was lead negotiator and advisor for U.S. Senate Democrats on FDA medical device, prescription drug, biologic, food safety, and cosmetic policy initiatives, including the 21st Century Cures Act and the FDA Reauthorization Act of 2017. She managed FDA-related policy development and relationships for the Ranking Member, both internally with Senate leadership, other Senate offices, and their House counterparts, and externally with the FDA and other governmental organizations, regulated industry companies and trade associations, patient advocacy organizations, and other key stakeholders. Previously, Remy served under Sen. Elizabeth Warren (D-Mass.), including as the Senator's Senior Health Policy Advisor from 2015 to 2016. She managed a comprehensive health care portfolio, with emphasis on policies relevant to the biotech, medical device, and health care industries rooted in Massachusetts. Remy earned her BS in Microbiology and Molecular Genetics from Michigan State University and her PhD in Pharmacology from the University of Michigan Medical School, where she advanced pre-clinical research to support an investigational new drug application at the FDA for a Breakthrough-designated biologic currently under clinical investigation. Remy served as a Bioethics Post-Doctoral Fellow at the National Institutes of Health from 2011 to 2013, where she analyzed ethical issues in clinical research, public health, and health care, applying frameworks from philosophy, ethics, and law.

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.

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 thirteen 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.

RYAN HOHMAN currently serves as Vice President, Public Affairs at Friends of Cancer Research (Friends). Previously, he was Friends' Managing Director of Policy & Public Affairs. At Friends, Ryan leads the strategic development and execution of public-policy and legislative initiatives to enhance U.S. Food and Drug Administration regulatory policies, its institutes, and research programs. Additionally, Ryan oversees the organization's targeted outreach, comprehensive communications strategy, federal affairs, advocacy relations, and the organization's development programs. As Vice President, Public Affairs at Friends, Ryan has the privilege of serving on many important boards and committees of organizations who share Friends' mission. During his diverse career, Ryan has experienced first-hand the vital need and incredible impact that sustained federal funding of the biomedical field has on physicians, researchers, and scientists and the difficulties many of these communities face when engaging in and navigating the regulatory process. Before joining Friends, Ryan was Director of Corporate and Institutional Partnerships at Georgetown University Medical Center-Lombardi Comprehensive Cancer Center. While at Georgetown, Ryan focused on the development and execution of strategic corporate and philanthropic engagement to support the center's biomedical research and cancer treatment and education programs. During this time, Ryan was appointed to the Board of Directors of the Cancer Research Alliance and worked to support and expand the programs of the Capital Breast Care Center, which provides comprehensive, culturally appropriate breast cancer screening services and health education to women in the Washington, DC metropolitan area. Prior to his time at Georgetown, Ryan was an associate with a DC- and Boston-based public relations firm, specializing in health and trade association media and governmental strategy. Ryan has also served in numerous political campaigns and offices.

RICHARD KLEIN is an internationally recognized expert in pre-approval or expanded access to unapproved therapeutic agents. He serves as Director, Expanded Access Programs & Policy for the GE2P2 Global Foundation, following a more than forty-one-year career with the Food and Drug Administration (FDA). Working in various capacities at FDA provides him with a well-rounded understanding of the regulatory issues that affect patients. He helped develop the revised expanded access regulations and guidelines, led the creation of the FDA expanded access website, and played an active role in the development of the streamlined application for individual patient access, and the Reagan-Udall Foundation Expanded Access Navigator. Mr. Klein spearheaded the effort to create the waiver of full-board IRB review for individual patient access to unapproved drugs and biologics. Mr. Klein served as director of the FDA's Patient Liaison Program in the agency's Office of Health and Constituent Affairs, the primary agency interface with patients and patient advocate communities. He interacted extensively with outside communities and within the agency's scientific and policy offices to advocate for patient interests, and to facilitate patient engagement in regulatory activities. He worked closely with patient communities to actively address issues and concerns of patients in a variety of areas, including treatment access to unapproved drugs, product safety, and clinical trial design. Before taking on that role, he created the FDA's HIV/AIDS program, working with AIDS activists and advocates to coordinate their input and participation in regulatory policy and decision-making related to HIV/AIDS. Prior to working in patient engagement, he was engaged in policy development and regulation of protections for human research subjects and provided guidance for institutional review boards (IRBs).

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

ALLYSON B. MULLEN is a director at Hyman, Phelps & McNamara, P.C. where she provides counsel to medical device and in vitro diagnostic (IVD) manufacturers. Ms. Mullen assists clients with a wide range of pre- and postmarket regulatory topics, including developing regulatory strategy, preparing regulatory submissions, drafting regulatory policies and procedures, reviewing advertising and promotional materials, and addressing enforcement matters. In the premarket area, Ms. Mullen prepares IDEs, 510(k)s, de novos, and PMAs. She also prepares pre-submissions, breakthrough device designation requests, and assists clients in preparing for and represents clients at pre-submission meetings with FDA. In the postmarket area, she advises clients on complaint handling, MDRs, field actions, advertising and promotion, and QSR compliance. Ms. Mullen also helps clients with contract matters and regulatory due diligence. Prior to joining the firm in 2013, Ms. Mullen

worked as in-house counsel at Waters Corporation, an IVD company. In this role, Ms. Mullen conducted a range of legal and regulatory functions.

LEE H. 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.

AMI E. SIMUNOVICH serves as executive vice president and chief regulatory officer for BD (Becton, Dickinson and Company), a leading global medical technology company headquartered in Franklin Lakes, New Jersey. She is also a member of the BD Executive Leadership Team. Prior to her current role, Simunovich served as chief regulatory counsel, advising in the management of complex global regulatory law and international regulatory legal matters. Simunovich previously served as associate general counsel of regulatory and compliance, at C. R. Bard, Inc., a leading medical technology company in the fields of vascular, urology and surgical specialty products, which BD acquired in 2017. Prior to Bard, Simunovich was associate general counsel of regulatory at Catalent, Inc., a Blackstone Portfolio Company and global contract manufacturer of pharmaceuticals, biologics and dietary supplements. She also has served as legal counsel in litigation, regulatory law and intellectual property at New York-based law firm. Simunovich earned her doctorate in pharmacy from the Ernest Mario School of Pharmacy at Rutgers University and a doctorate in law from Seton Hall University School of Law.

STEVEN TJOE is an associate in Goodwin Procter LLP's Technology & Life Sciences Group and a member of the firm's FDA practice. Mr. Tjoe advises drug, biologic, medical device, and diagnostic clients on a range of FDA regulatory matters, including product development strategies, lifecycle management and competition issues, advertising and promotion, regulatory compliance, and risk analyses for offerings and transactions. Prior to joining Goodwin, from 2014 to 2018, Mr. Tjoe served as regulatory counsel in FDA's Center for Devices and Radiological Health. During that time, Mr. Tjoe regularly advised agency officials on regulatory and policy matters related to in vitro diagnostics, digital health products, and laboratory developed tests. He received his JD from the Antonin Scalia Law School at George Mason University, a MS in Applied Anatomy from Case Western Reserve University, and a BA in English from Duke University.