Introduction to Biological Products, Including Vaccines, Biosimilars, Cell and Gene Therapies, and Other Advanced Therapies
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Speaker Biographies

NATHAN A. BEATON is an associate in the Washington, D.C. office of Latham & Watkins and a member of the firm's Healthcare & Life Sciences Practice. He assists clients with their most complex regulatory, transactional, litigation, and legislative matters involving the Food and Drug Administration (FDA) and other regulatory authorities with jurisdiction over healthcare and biotechnology.

NATHAN A. BEAVER is a partner and food and drug lawyer with Foley & Lardner LLP, where his practice focuses on the representation of companies whose products and activities are regulated by the Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), US Department of Agriculture (USDA) and the Federal Trade Commission (FTC). He advises clients on regulatory issues affecting prescription and over-the-counter drug products (including animal drugs), medical devices, dietary supplements, cosmetics and foods. Nate is a member of the firm's Government Solutions and FDA Practices and the co-chair of the Food & Beverage Industry Team. He is also a member of the Cannabis and Life Science Industry Teams.

KATHRYN CULVER is an associate in the Washington, D.C. office of Latham & Watkins and a member of the firm's Healthcare & Life Sciences Practice. She assists clients with their complex regulatory, transactional, investigational, and legislative matters involving the Food and Drug Administration (FDA).

MICHELLE DIVELBISS is an associate in Covington & Burling LLP's Washington, D.C. office, where she is a member of the Food, Drug, and Device Practice Group. She advises pharmaceutical and biotechnology companies on a variety of regulatory and compliance issues.

CHRISTOPHER FANELLI is a former FDA enforcement lawyer and a partner in Sidley's Food, Drug and Medical Device Compliance and Enforcement group. First in government as an Associate Chief Counsel for Enforcement in FDA's Office of the Chief Counsel and now in private practice, Fanelli focuses his practice on compliance with GMP and GLP requirements at the pre-clinical, clinical, and post-approval stages; data integrity responsibilities; import and export issues; and pharmacovigilance obligations. His clients include pre-commercial and early-stage commercial life sciences companies, as well as global small molecule drug manufacturers, large molecule biologics manufacturers, CAR T and gene therapy manufacturers, API manufacturers, animal health companies, combination product manufacturers, and device manufacturers. Clients count on Fanelli to anticipate, provide strategic guidance on, and resolve their critical FDA enforcement and compliance matters. He also supports private equity clients investing in FDA-regulated entities by performing FDA compliance due diligence assessments and by developing and implementing business-friendly compliance strategies at portfolio companies to ensure sustained compliance with FDA's regulations. Fanelli is actively involved in Sidley's China Life Sciences Practice, and regularly speaks at Peking University's International Pharmaceutical Engineering Management (IPEM) program on FDA compliance and enforcement matters and international crisis management. Fanelli earned his JD from Boston University School of Law and his BA from Juniata College.

JESSICA GREENBAUM is a Counsel in King & Spalding's FDA and Life Sciences practice in Washington, D.C. Prior to joining King & Spalding, Jessica served as a Regulatory Counsel in FDA's Office of Therapeutic Biologics and Biosimilars. In that position, Jessica developed and implemented regulatory policy related to biosimilars and other therapeutic biological products, including with respect to combination products, biosimilar labeling, reference product exclusivity, the Purple Book, and the review and approval of biologics license applications.

GAIL JAVITT is a director at Hyman, Phelps & McNamara, P.C. where she provides strategic FDA regulatory advice for leading medical device, diagnostics, pharmaceutical, biological products, and human cellular, and tissue-based products (HCT/Ps) throughout the product life cycle and has successfully resolved disputes at both the pre- and post-market stage. She also has significant experience advising clinical laboratories on FDA and CLIA requirements for laboratory developed tests. Ms. Javitt's experience prior to joining Hyman, Phelps & McNamara includes serving as a partner in a leading Washington, DC health law practice and as a law and policy director at the Genetics and Public Policy Center, part of Johns Hopkins University. At the Center, she was responsible for developing policy options to guide the development and use of reproductive and other genetic technologies. Earlier in her legal career, Ms. Javitt clerked for the Honorable Gary Taylor of the US District Court for the Central District of

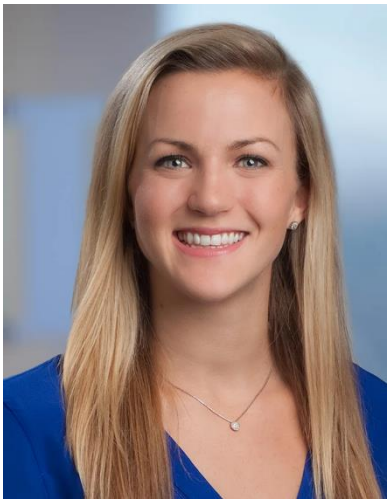
California. In addition, Ms. Javitt has published and spoken widely on issues at the intersection of law, science, ethics and policy, including FDA regulation of genetic testing, precision medicine, and next-generation sequencing. Her academic experience has included serving as a faculty member at the Berman Institute of Bioethics at Johns Hopkins University and as an adjunct professor at the Georgetown University Law Center, American University's Washington College of Law, and the University of Maryland School of Law. She was previously a Greenwall Fellow in Bioethics and Health Policy, a collaborative effort between Johns Hopkins University and Georgetown University.

JEWELL MARTIN serves as the Associate Director for U.S. Policy on the Global R&D and Regulatory Policy team at BioMarin Pharmaceutical Inc. Prior to joining BioMarin in 2020, Jewell spent 10 years at the U.S. Food and Drug Administration (FDA), where she served in multiple roles including as the Executive Operations Staff Lead in the Office of New Drugs, in the Center for Drug Evaluation and Research (CDER). Jewell received her MA in Medical Sciences from Boston University and MBA from Howard University in Washington, D.C. Additionally, she received certifications including the Project Management Professional (PMP) and Regulatory Affairs Certification (RAC).

ANNE MARIE POLAK is a principal based in Washington, D.C. In her role, Anne Marie provides policy counsel and analysis to clients on matters involving regulations, legislation, and their business implications. Anne Marie's experience includes developing strategic messages and policy positions for Capitol Hill, administration, trade associations, and corporate audiences. Prior to joining Leavitt Partners, Anne Marie was a vice president for Faegre BD Consulting in the firm's health and biosciences group. She also spent five years with the Podesta Group in Washington, D.C., while completing her law degree in the evenings at the George Mason University School of Law and graduating cum laude in 2010. Anne Marie also worked in the government and legal affairs office of Novo Nordisk in Washington, D.C., and served as a congressional aide to Rep. Michael Ferguson of New Jersey. In 2004, Anne Marie served as a policy research assistant on the Bush-Cheney campaign after graduating, with distinction, from the University of Virginia. Anne Marie was also an assistant to the Chief of Staff for House Majority Leader Dick Armey (R-TX-26). Anne Marie received her law degree from the George Mason University School of Law and a bachelor's degree in government from the University of Virginia.

EVA TEMKIN is a partner in the King & Spalding U.S. Food and Drug Administration (FDA) and Life Sciences practice where she provides strategic counsel to clients on a wide variety of FDA regulated products, ranging from biosimilars to cell and gene therapies and complex combination products. Temkin advises pharmaceutical and biotechnology companies at every stage of product development and life-cycle, from data generation (including clinical investigations and real-world evidence) to application submissions, exclusivity matters, and dispute resolution. Before joining King & Spalding, Eva acted as Director for Policy at the FDA's Office of Therapeutic Biologics and Biosimilars, where she oversaw regulatory policy related to biosimilars and other therapeutic biologics. Additionally, as Associate Chief Counsel at the FDA's Office of Chief Counsel, Eva provided strategic counseling to FDA's biomedical product centers on a wide range of drug, biologic, and combination product issues.

ELIZABETH TRENTACOST counsels life sciences, food, and consumer products companies on a broad range of Food and Drug Administration (FDA) regulatory, compliance, enforcement, and strategic matters. She routinely advises on issues related to product development and applications, clinical research, inspections, promotional review matters, interacting with FDA, policy advocacy, and business transactions involving FDA-regulated companies. Prior to joining Arnold & Porter, she spent several years as a Regulatory Counsel in the Office of Regulatory Policy in FDA's Center for Drug Evaluation and Research. At FDA, she was involved in a wide variety of policy issues involving drug approvals, responded to citizen petitions, developed guidance for industry, and counseled on matters relating to Hatch-Waxman marketing exclusivities. Previously, Ms. Trentacost worked at a law firm in Washington, D.C. where she focused on international trade investigations and appellate litigation.



REBECCA WILLIAMS focuses her practice on FDA regulatory matters and advises life sciences and health care clients on a broad range of regulatory and compliance issues under the Food, Drug and Cosmetics Act and related laws. Rebecca routinely provides regulatory counsel for corporate transactions, license and collaboration agreements, manufacturing and supply arrangements, and public and private securities offerings involving drug, device, cosmetic, food, and dietary supplement companies. Rebecca also regularly provides legal and strategic advice to pharmaceutical and biotech clients on advertising and promotion issues. Rebecca maintains an active pro bono practice with a focus on immigration, health care, and child welfare issues.