



Experienced FDA Regulatory Counsel and Patent Attorney Brings Robust Product Life Cycle, Litigation, and Compliance Background to Spencer Fane in D.C.

Spencer Fane LLP is pleased to welcome [Brian J. Malkin](#) to the firm's Washington, D.C., office as a partner in the Intellectual Property Practice Group, where he will enhance the firm's FDA and life sciences focus areas.

With more than three decades of regulatory experience, including nine years as regulatory counsel at the FDA Office of the Commissioner and the Center for Drug Evaluation, and over two decades of patent experience, Brian streamlines processes for clients navigating the complex intersection of patent law and food and drug law.

Leveraging his unique public and private sector experience and advanced negotiation tactics, Brian's comprehensive practice includes FDA and patent litigation for FDA-regulated manufacturers and pharmacies, patent prosecution for life sciences companies, and robust regulatory counsel and market access for products spanning human and animal drugs and biologics, medical devices, foods and dietary supplements, tobacco products, and cosmetics. His practice also includes wellness products and emerging areas such as AI-enabled or generated products and regenerative medicine as well as primarily state-regulated products such as cannabis and psychedelics.

Prior to joining Spencer Fane, Brian served as FDA and IP counsel for several boutique and international law firms, and, most recently, associate general counsel to a leading multinational biopharmaceutical company. He is well-versed in managing the entire product life cycle, including guiding product financing and development, negotiating and drafting agreements, obtaining approvals, enforcing IP protection, implementing regulatory affairs strategies and leadership, conducting due diligence,

and managing all associated risks.

“Brian joins us with not only a prosperous practice rooted in diverse public and private sector insights but also a strong external influence on the pharmaceutical, biotechnology, and related industries at large,” said [Bill Powers](#), office managing partner for Spencer Fane in Washington, D.C. “We look forward to welcoming both his vast regulatory knowledge and niche tools developed over decades of accumulating and curating efficient IP legal strategies for optimal outcomes.”

Outside of his private practice, Brian has served as an adjunct professor at Yeshiva University’s Katz School of Science and Health and a guest lecturer at Georgetown University Law Center since 2018 and American University’s Washington College of Law since 2020, where he develops and teaches courses related to IP, global drug law, biologics, and health law as well as associated regulation and patent / exclusivity protections.

In addition, Brian is a leader across multiple sections and committees within both the New York State and D.C. Bar Associations and is engaged in several other legal and community initiatives. He has served as a recognized thought leader at dozens of regional and national conferences and training programs as well as authored articles in leading industry publications.

Brian earned both his bachelor’s degree *cum laude* with special honors in economics and Juris Doctor from The George Washington University, later obtaining an additional biochemistry degree from the University of Maryland to develop and support his patent law practice with a focus on pharmaceutical and biotechnology products, including combination drug / device products and products with AI components.