SpencerFane®

Brian J. Malkin

Partner

Contact

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Overview

Brian Malkin streamlines processes for clients navigating the complex intersection of patent law and food and drug law, leveraging unique public and private sector experience, in-depth creative and strategic analysis, and advanced negotiation tactics to meet and exceed stakeholder expectations.

This skill set is evident across Brian's focus areas, which include U.S. Food and Drug Administration (FDA) and patent litigation for FDA-regulated manufacturers and pharmacies, patent prosecution for life sciences companies, and robust regulatory counsel 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 artificial intelligence (AI)-enabled or generated products and regenerative medicine as well as state-regulated products such as cannabis and psychedelics.

Boasting more than three decades of regulatory experience, Brian spent nine years as regulatory counsel at the FDA Office of the Commissioner and the Center for Drug Evaluation and Research. After returning to university to obtain a bachelor's degree in biochemistry and passing the USPTO Bar, he then served as FDA and intellectual property (IP) counsel for several boutique and international law firms for more than two decades. Most recently, he served as associate general counsel – regulatory in the IP Department at Teva Pharmaceuticals. Since joining Spencer Fane, he created and now leads the FDA Pharmaceutical and Biologics Market Team and continues to develop additional FDA and life sciences focus areas for the firm.

Brian uniquely combines these viewpoints to effectively guide clients through the entire product life cycle. This includes leading product financing and development, negotiating and drafting agreements, obtaining approvals, enforcing IP protection, implementing regulatory affairs strategies and leadership, conducting due diligence, and managing associated risks. For example, acting as a regulatory consultant, he has supported clients in obtaining and representing companies in FDA meetings; however, as an attorney, his persuasive arguments and negotiation skills have proven effective to streamline or resolve stalled product development. Also, unlike a regulatory consultant, Brian has navigated attorney-client and work product privileges as appropriate to help develop strategies and regulatory responses for clients.

Outside of his practice, Brian has served as an adjunct professor at Yeshiva University's Katz School of Science and Health since 2018, where he developed and teaches a course called "Intellectual Property, Regulation and Compliance for Biotechnology." He has also been a guest lecturer at Georgetown University Law Center since 2018 and American University's Washington College of Law since 2020, where he teaches courses on global drug law and biologics, health law, and associated regulation. In addition, he has served as a recognized thought leader at dozens of professional conferences and training programs as well as authored articles in leading industry publications, strategically shaping current and future conversations surrounding pharmaceuticals and biotechnology as well as medical devices and the full spectrum of FDA-regulated products.

Brian's areas of focus include:

- Pre-investigational new human and animal drug applications (INDs and INADs), new human and animal drug applications (NDAs and NADAs), orphan / specialty drug designations, and abbreviated new human and animal drug applications (ANDAs and ANADAs).
- 505(b)(2) ('hybrid") NDAs, including new indications, dosage forms or regiments, strengths, or combination products.
- Risk evaluation and mitigation strategies (REMS), including some with elements to assure safe use (ETASU).
- Biologic license applications (BLAs) and biosimilars (351(k) applications).
- Medical devices, including 510(k) clearances and premarket approval applications (PMAs), laboratory developed tests (LDTs), and combination drug / device products.
- Foods and food additives, dietary supplements, and cosmetics.
- Tobacco products.
- Cannabis and cannabis-derived products including cannabidiol (CBD) products as well as psychedelics.

Education

- University of Maryland, 2004 (B.S.)
- George Washington University Law School, 1991 (J.D.)
- George Washington University, 1988 (B.A.), *cum laude*

Bar Admissions

- Maryland, 1991
- District of Columbia, 1992
- New York, 2005
- U.S. Patent and Trademark Office, 2005

Court Admissions

- U.S. District Court for the District of Maryland
- U.S. District Court for the Southern District of New York
- U.S. District Court for the Eastern District of New York

Community Involvement

- MassChallenge, Start-Up Mentor, 2015-present
- Sea Colony Harbour House Council, Treasurer, 2025-present
- The Harbor School, Board Member, 2017-2020

Distinctions

- *Marquis Who's Who*, 2023
- *New York Super Lawyers*, 2014
- JD Supra Readers' Choice Awards, 2016, 2017

Memberships

- New York State Bar Association
  - Food, Drug and Cosmetic Law Section, Chair, 2014-2020; Executive Committee, NYSBA House of Delegates, 2014-present
  - Committee on Continuing Legal Education, 2018-present
  - Committee on Legislative Policy, 2016-present
  - Non-Resident Community Committee, 2015-present
- D.C. Bar
  - Intellectual Property Community Section, Co-Chair, 2017-2025; Steering Committee, Public Statement Coordinator, FDA & IP Committee Co-Chair, 2017-present
  - Cannabis Law Section, Founding Member
- Maryland State Bar Association, Health Law Group, student mentor
- National Vaccine Law Association, Conference Committee, 2025-present
- Food and Drug Law Institute, Committee on Cannabis-Derived Products, 2019-2020; Drugs/Biologics Committee, 2015-2019; Primer Committee, 2013-2015

Presentations and Publications

- "Decoding Policy and Legal Watchouts for Impacts on Markets," Trade & Channel Strategies Conference, December 2025
- "Vaccine Law and Future Developments," "Vaccine Pipeline," and "I Have a Bad Feeling About This: Federal Development of Vaccines & IP Impact," National Vaccine Law Conference, Planning Committee, September 2025
- "Practicing Administrative Law Under the Current Administration: IP, Health, and Antitrust Intersections and Best Practices," DC Bar, Intellectual Property, Health Law, and Antitrust Communities, April 2025
- "FDA 2025: What to Expect After the Election," and "FDA Impact of *Loper Bright* and *Chevron* Reversal," New York Bar Association (NYSBA), Annual Meeting, Food, Drug and Cosmetic Law Section, January 2025
- "Key Pharmaceutical Regulation Issues for the New Administration," *FDA Watch*, Inaugural Podcast, January 2025
- "FDA for IP Lawyers," DC Bar, Intellectual Property Community, September 2024
- "Perspectives on Advancing the Risk Mitigation Strategy (REMS) Program," Food and Drug Law Institute (FDLI) Annual Conference, May 2024
- "The Economics of Pharmaceutical Patents in 2024: Understanding the Next Ledge of the Patent Cliff Will Reshape PIV Strategy," American Conference Institute (ACI), 20th Paragraph IV Disputes, 40th Anniversary of the Hatch-Waxman Act, April 2024
- "AI in Drug Development" and "Florida's Gamble to Lower Prescription Drug Prices with Canadian Imports: Will Other States Follow or Will It Backfire?," NYBA Annual Meeting, Food, Drug and Cosmetic Law Section, April 2024
- "Regulatory and Patent Drivers for Vaccines and Other Treatments for Infectious Diseases and Considerations for Balancing Innovation and Collaboration for Future Public Health Emergencies," American Bar Association Press, *First National Vaccine Law Conference: Papers and Proceedings*, March 2024
- "FDA and DEA Regulation of Opioid Drugs and the Opioid Drug Crisis," DC Bar CLE, March 2024

- "Data Exchange Platforms: Future of Regulatory Intersections and Submissions," Association of Accessible Medicines, GRx and Biosims, October 2023
- "UPTO-FDA Collaboration: Progress Towards Patently True Interagency Coordination," FDLI Special Webinar, October 2023
- "Regulatory Nuts & Bolts of Vaccine Approval," "IP Nuts & Bolts for Vaccines," and "Vaccine IP Ownership," National Vaccine Law Conference, September 2023
- "Fundamental Considerations for Qualifying REMS Assessments," Dynamic Global Events, 4th Aligning Drug Safety Functions and REMS Summit, August 2023
- "Improving Patient Access to Medical Cannabis and Prioritizing Research Needs," FDLI, Legal and Practical Issues in Cannabis Regulation, June 2023
- "Federal and NY State Regulation of Hemp-Based Cannabinoids," NYSBA CLE, February 2023
- "FDA and DEA Regulation of Opioid Drugs and the Opioid Crisis of 2023," DC Bar CLE, January 2023
- "Orphan Drug Challenges: Life Beyond *Catalyst* Without an Anticipated Legislative Fix," NYSBA Annual Meeting, Food, Drug and Cosmetic Law Section, January 2023
- "Hatch-Waxman and BPCIA in the Trenches: Exclusivity and Patents," ACI FDA Bootcamp, September 2022
- "FDA, USPTO, and Patents – Possible Next Steps to Collaborate," DC Bar, IP Community, November 2022
- "505(b)(2) NDAs and Value-Added Medicines Roundtable," Medicines for Europe Legal Affairs Conference, June 2022
- "Identifying and Meeting Cannabis Research Needs for Effective Federal Regulation," FDLI, Legal and Practical Issues in Cannabis Regulation, May 2022
- "FDA and Patents? FDA's Letter to the USPTO and Possible Next Steps," NYSBA Annual Meeting, Food, Drug and Cosmetic Law Section, January 2022
- "Regulatory Agency Transparency for Drugs and Biologics: A Comparative Survey of the U.S. Food and Drug Administration, the European Medicines Agency, and Health Canada," FDLI, *Food and Drug Law Journal*, September 2021
- "Health Records Interoperability," National Association of Specialty Pharmacy, Specialty Pharmacy Law Conference, September 2020
- "Regulatory Strategies for Successful Market Entry," SGS Nutrasource Nature to Pharma Summit, June 2020
- "FDA Law for IP Lawyers – Tips for Effectively Integrating FDA Regulatory Law Into an IP Law Practice," DC Bar, IP Community, April 2020
- "Intellectual Property Issues Impacting High Schoolers," Melvin R. Wright Youth Law Fair, DC Bar Communities, March 2020
- "Legal Perspective: Regulatory Landscape & Use of CBD in Food Products," Q1 Productions Food Labeling: Evolving Regulatory Compliance Conference, February 2020
- "Off Label Promotion Update," NYSBA, Food, Drug and Cosmetic Law Section Annual Meeting, January 2020

Please find all presentations and publications from 1999-2019 here.

Related Experience

- Worked with innovator drug companies to develop strategies for approval of new drug applications (NDAs), including those filed as 505(b)(2) NDAs and biologics license applications (BLAs) (including biosimilar products filed as 351(k) applications. The approval strategies included developing clinical strategies, pre-investigational new drug applications (INDs) and pre-NDA / pre-BLA FDA meetings.
- Conducted life cycle company / product audits resulting in follow-on products, new patents or exclusivities, and enforcement opportunities.
- Drafted citizen petitions including those related to orphan products, biosimilar products, and complex generic drugs including persuasive scientific and bioequivalence arguments and expert declarations.

- Reviewed commercial agreements including contract research and manufacturing, consulting, supply, and material transfer agreements, including those related to IP and market access.
- Worked with companies to develop strategies for approval of combination drug / device and combination drug products, including clinical programs, for example, an artificial pancreas incorporating marketed glucose monitors and insulin pumps and smartphone applications and algorithms, in view of FDA's mobile medical application and information technology guidance.
- Worked with innovator and generic companies to address and evaluate FDA's filing, complete response, and other regulatory correspondence / compliance letters.
- Drafted clinical trial audit agreements and managed clinical trial audits and responses to FDA deficiency letters.
- Reviewed food and dietary ingredient structure / function-type claims, including recommending or developing clinical trials for adding new claims.
- Reviewed formulations (ingredients) for FDA compliance and proposed labeling for new cosmetic products, including making recommended labeling changes to avoid regulatory actions such as potential-drug-versus-cosmetic claims.
- Drafted and obtained multiple patents for alternate REMS program to allow switching from a reference listed drug's REMS to the alternate REMS including stand-alone REMS program.
- Reviewed proposed new tobacco products to determine whether they qualified as substantially equivalent or as new or modified-risk products and submitted to FDA annual ingredient listings for reconstituted tobacco product manufacturer.
- Litigated Hatch-Waxman, BPCIA, FDA, and FTC cases for both innovator / branded and generic / biosimilar clients, including prelitigation opinions or strategies, including antitrust considerations for settlements or standalone actions.
- Provided support for patent infringement litigations, including reviewing status of product approvals and regulatory requirements (including guidance documents), developing expert reports and litigation documents for stays and other actions, and otherwise integrating patent litigation and regulatory strategies.
- Reviewed trademarks, copyrights, and trade secret information for potential for infringement and developed strategies to protect new products in development.
- Revived pharmaceutical patent portfolio with stalled prosecution during protracted patent inventorship litigation to obtain new patents for the patent family for innovative use of historical pharmaceutical product.
- Drafted patent term restoration/extension applications, Orange Book listings, and handled inter-related regulatory issues regarding determining which patent to seek extension and how to maximize regulatory exclusivities.
- Advised biotechnology company regarding a method to sort data for complex biological compositions without the need for a reference standard and obtained business method patents related to the technology.
- Drafted or provided persuasive client or trade association comments on proposed legislation, regulations, or guidance.
- Developed internal company operating procedures or compliance guidelines, including those related to advertising and promotion, as well as compliant patient-centric product development.
- Prepared and presented testimony at FDA public meetings, e.g., a 510(k) device including software application.
- Conducted IP and FDA stock offerings / investment bank / debt financing due diligence for startup-up drug, biotechnology, and medical device companies, in addition to reviewing prospectus documents, press releases, and roadshows.
- Worked with regulatory authorities to permit marketing on gray-area consumer products, including cannabis-derived and psychedelic products with federal and state regulatory implications.