ArentFox Schiff LLP
Attorneys

Brian P. Waldman

FIRMWIDE MANAGING PARTNER

A nationally recognized life sciences FDA lawyer and ArentFox Schiff Firmwide Managing Partner, Brian helps food, drug, medical device, and cosmetic companies bring products to market and keep them compliant.



Industries

Beverage & Food
Consumer Products
Fashion & Retail Law
Life Sciences

Practices

Advertising & Promotions
Complex Litigation
— Class Actions
Food, Drug, Medical Device & Cosmetic

International

Europe

Education

University of California, Los Angeles, School of Law, JD, 1992

University of Chicago, MBA, 1987

University of Chicago, BA, Phi Beta Kappa, 1986

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Brian is a life sciences FDA lawyer who represents in-house counsel, regulatory professionals, and business leaders at food, drug, medical device, and cosmetic companies. Skilled at developing strategies for introducing new products and ensuring post-market compliance, Brian works with companies in the pharmaceutical, medical device, food, dietary supplement, and cosmetic space. In recognizing Brian as one of the top lawyers in the country, *Chambers USA* reported that he stands out for his “great business sense.”

Brian is a member of ArentFox Schiff’s Executive Committee and has previously served as co-manager of the firm’s Regulatory Department and practice leader for the Food, Drug, Medical Device & Cosmetic group.

Client Work

FDA Regulatory & Product Lifecycle Counseling

As a life sciences FDA lawyer, Brian advises food, drug, medical device, and cosmetic companies on regulatory issues across all phases of a product’s life cycle, including:

- (i) developing appropriate strategies for the introduction of new ingredients and finished products,
- (ii) coordinating pre-market safety, efficacy, and claims evaluations,
- (iii) preparing FDA-related applications and notifications,
- (iv) designing compliant and effective labeling, advertising, and promotional materials, as well as educational materials,
- (v) ensuring post-marketing regulatory compliance, including compliance with adverse event reporting requirements and limitations on off-label promotion, and
- (vi) responding to threatened enforcement action and litigation.

As part of this work, Brian coordinates efforts between product developers, contract research organizations, site management organizations, institutional review boards, investigators, and the FDA.

Recalls, Investigations & Crisis Management

Much of Brian's practice involves crisis management support. Brian assists clients in preparing for and during government investigations, as well as in evaluating and responding to adverse product information. He has coordinated numerous recalls, market withdrawals, and other product corrective actions.

Regulatory Compliance Audits & Advocacy

Brian conducts regulatory compliance audits to ensure that both product manufacturers and distributors are in full compliance with applicable laws and regulations. Further, he has drafted proposed federal and state legislation in support of the interests of manufacturers and distributors and represented these interests before legislators and regulators.

Life Sciences Transactions & Diligence

Brian works extensively with attorneys in the firm's Health Care, Intellectual Property, and Corporate Transactional practices. He has negotiated numerous licensing, supply, and distribution agreements, conducted numerous due diligence audits of acquisition targets, prepared regulatory compliance opinions in support of public offerings, and supported food and drug-related litigation.

Publications, Presentations & Recognitions

Brian recently co-wrote a chapter on dietary supplements in the Food and Drug Law Institute's "Food and Drug Law and Regulation." He also co-wrote an article titled "Cosmeceuticals: The Legal Problem and Feasible Solutions," published in *The Food, Drug, Cosmetic, and Medical Device Law Digest*. Brian frequently lectures on food and drug approval and regulatory compliance issues for the Food and Drug Law Institute, the Biotechnology Industry Organization, the Center for Professional Advancement, the American Conference Institute, and other seminar sponsors.

Brian has been recognized as a leading lawyer by *Chambers USA* in the areas of Food & Beverage and Healthcare: Pharmaceutical and Medical Device. He is annually rated among the *Best Lawyers in America* for FDA Law and Advertising Law. He was recognized as a 2022 *Best Lawyers* "Lawyer of the Year" for Advertising Law. Brian has also been named to the BTI Client Service All-Stars 2024, a client-driven ranking that assesses novelty of ideas, responsiveness, and the ability to anticipate clients' needs.

Bar Admissions

District of Columbia