ALSTON & BIRD

Brendan Carroll

Partner

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Related Services

Health Care ▪ FDA/Food, Drug & Device ▪ FDA Enforcement & Litigation ▪ Food, Beverage & Agribusiness ▪ FDA Compliance & Enforcement ▪ Corporate Compliance Programs

Brendan's years of experience inside the manufacturing facilities of clients all over the world allows him to take a hands-on approach to understanding his clients' issues, help them tackle the intersection of highly technical and scientific issues with complex FDA laws and regulations, and zealously advocate on their behalf.

Brendan Carroll helps clients navigate the dense and ever-changing FDA legal landscape to not only identify regulatory risks for his clients, but to find practical solutions to help his clients achieve desired business objectives and outcomes. As a partner on Alston & Bird's Food, Drug & Device/FDA Team, Brendan relies on his wealth of knowledge of highly scientific and technical manufacturing, product development, and product life-cycle issues to counsel clients on novel legal, regulatory, and legislative issues that are unique to each client's business. He has represented a variety of industry stakeholders engaged in the manufacture, sale, and distribution of a wide range of FDA-regulated products, including drugs, biologics, medical devices, dietary supplements, food, and cosmetics.

With the recent influx of significant compliance and enforcement matters stemming from FDA inspections, Brendan regularly travels to client locations to provide hands-on solutions and practical advice catered to each client's facility and business needs. Brendan also tackles the nuanced intersection of the FDA with other regulatory agencies, including the DEA, USDA, TTB, and other state and local agencies. *Chambers USA* 2019 ranked Brendan in its "Associates to Watch" category for District of Columbia – Healthcare: Pharmaceutical/Medical Products Regulatory.

Representative Experience

- Spent years inside pharmaceutical manufacturing facilities in China, India, and Eastern Europe to help manage FDA inspections, respond to Form FDA 483s and Warning Letters and significant remediation efforts stemming from these inspections.
- Advised OncoSec in its $30 million strategic transaction with Grand Decade Developments Limited, a subsidiary of China Grand Pharmaceutical and Healthcare Holdings Limited.
- Conducted FDA and health care due diligence for a Japanese pharmaceutical manufacturer as part of its successful $1 billion acquisition of a Minnesota-based drug manufacturer.
- Assisted a foreign API manufacturer in lifting two import alerts and a close-out to a Warning Letter.
- Provided regulatory counsel and support across multiple sites and facilities of a foreign manufacturer of APIs, intermediates, and finished drug products in an effort to address outstanding issues related to production and process controls; adequacy of investigation into OOS, OOT, discrepancies, and other failures of a batch; and issues related to aseptic processing and related controls designed to prevent microbiological contamination.

- Advised a biotechnology company seeking orphan drug designation and access to expedited drug review programs for proposed new indications for an existing approved drug, with significant pre-clinical research.
- Managed remediation efforts in response to a Warning Letter and Form FDA 483, and provided strategic direction for the implementation of new, and more robust, data integrity practices, particularly as they related to electronic records and computerized systems, and related validation of those processes and systems.
- Offered practical and cost-effective solutions and provided counsel to a manufacturer and drug distributor on compliance with complex, nuanced, and variable state laws in 50 states dictating drug licensing and registration, sale and distribution, or related ownership issues.
- Provided advice and counsel on pharmacy compounding issues at the state and federal levels, including new requirements under the Drug Quality and Security Act.
- Evaluated the regulatory implications of health-care-related software and software-related service offerings for a medical device manufacturer.
- Counseled a dietary supplement manufacturer in preparation for an FDA meeting, and prepared responses to the Agency following an inspection, Form FDA-483 and subsequent Warning Letter regarding various manufacturing, advertising and promotional practices.
- Negotiated a settlement agreement with the Alcohol and Tobacco Tax and Trade Bureau action against an alcohol distributor.
- Conducted a review of a food manufacturer's labeling and advertising practices.
- Developed regulatory comments on behalf of generic drug manufacturers.
- Advocated before Members of Congress and the Executive Branch on behalf of a wide range of small businesses.

Publications & Presentations

Publications

- "Industry Needs to Better Prepare for Drug Supply Chain Compliance," *Bloomberg Law*, January 10, 2023.
- "Regulation of Drugs, Biologics, Controlled Substances, Cannabis, and Compounded Drugs," in A Practical Guide to FDA's Food and Drug Law and Regulation, 7th ed., Food and Drug Law Institute, 2020.
- "How COVID-19 is Affecting Drug Supply Regulation," *Law360*, May 14, 2020.
- "A Social Experiment: 2015 Outlook for FDA's Social Media Policy," *Bloomberg BNA Social Media Law & Policy Report*, January 20, 2015.
- "A Roadmap to Meaningful Use: FDA Releases More Social Media Guidance," *Bloomberg BNA*, September 19, 2014.

Professional & Community Engagement

- Capital Area Immigrants' Rights (CAIR) Coalition, board of directors
- Bar Association of DC, Young Lawyer of the Year 2018
- Legal Aid Society of the District of Columbia, Klepper Prize for Volunteer Excellence (2016)
- Legal Aid Generous Associates Campaign, citywide coordinator (2015 – present)
- Alston & Bird's Washington pro bono committee, vice chair

Education

- American University (J.D., 2011)
- Princeton University (B.A., 2006)

Admitted to Practice

- District of Columbia
- Maryland