ALSTON & BIRD

# Brendan Carroll

Partner

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***Related Services***

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

***Life sciences and FDA-regulated companies rely on Brendan to understand their business, tackle nuanced regulatory issues, and provide practical solutions to meet their business needs as they navigate complex and highly technical FDA laws and regulations.***

Brendan Carroll represents a variety of industry stakeholders engaged in the design and development, manufacture, sale, and distribution of a wide range of FDA-regulated products. General counsel come to Brendan to help them find practical solutions to highly scientific and technical product and manufacturing.

For two decades, Brendan has represented the life sciences industry, focusing his practice on FDA regulatory, compliance, and enforcement matters. After starting his career working on one of the largest drug product liability matters to date, for Wyeth (now Pfizer), Brendan helps clients navigate the dense and ever-changing FDA legal landscape for drugs, devices, and other FDA-regulated products.

When significant compliance and enforcement matters stemming from FDA inspections arise, 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 Drug Enforcement Administration, U.S. Department of Agriculture, Alcohol and Tobacco Tax and Trade Bureau, and Customs and Border Protection.

*Chambers USA: America's Leading Lawyers for Business* identified Brendan in their annual rankings for Healthcare: Pharmaceutical/Medical Products Regulatory.

## *Representative Experience*

***Compliance and Enforcement***

- Prepared for and managed FDA inspections in the U.S., Europe, India, and China.
- Assisted manufacturing facilities navigating "Official Action Indicated" status, lift Warning Letters, resolve Import Alerts, address agency Requests for Information and close out inspections.
- Advised on FDA enforcement action related to changes to the design of a medical device against FDA-approved specifications and applications.
- Managed major data integrity investigations, including one spanning 10 years.

- Represented clients in front of the FDA and participated in regulatory meetings involving key Center for Drug Evaluation and Research officials within the FDA's Office of Compliance, Office of Regulatory Affairs, Office of Chief Counsel, and Office of Pharmaceutical Quality.
- Expert FDA witness in a Court of International Arbitration proceeding, which led to the dismissal of a multimillion-dollar lawsuit involving the FDA's Emergency Use Authorization (EUA).
- Drafted complaints letters to the FDA containing allegations of regulatory misconduct.
- Negotiated a memorandum of agreement with the Department of Justice and the Drug Enforcement Administration on behalf of a pharmacy handling controlled substances.
- Negotiated a settlement agreement with the Alcohol and Tobacco Tax and Trade Bureau action against an alcohol distributor.

***Regulatory and Transactional***

- Negotiated manufacturing, supply, and distribution agreements, including critical quality agreements.
- Conducted FDA and health care due diligence for a Japanese pharmaceutical manufacturer as part of its $1 billion acquisition of a Minnesota-based drug manufacturer.
- Advised a private equity firm on multiple acquisitions to acquire 503B compounding facilities.
- Provided advice and counsel on pharmacy compounding issues at the state and federal levels, including new requirements under the Drug Quality and Security Act.
- 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.
- Advised medical device companies on product development and regulatory pathway issues for novel devices, including evaluation of AI and software-related service offerings.
- Developed a compliance program and training modules for a health and wellness and medtech company following acquisition of Class II prescription medical devices to the company's product portfolio.
- Advised on drug and device licensing issues in all 50 states, including change of ownership requirements.
- Spearheaded a coalition of manufacturers of cannabidiol (CBD) and other ingredients derived from hemp.

## *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*

- "Associates to Watch," *Chambers USA* 2019 Healthcare: Pharmaceutical/Medical Products Regulatory in District of Columbia
- Alston & Bird's Washington Pro Bono Committee, co-chair
- Capital Area Immigrants' Rights (CAIR) Coalition, board of directors (2020–present)
- 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 (2015–2020)
- Alston & Bird's Mentor of the Year (2022)

### *Education*

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

### *Admitted to Practice*

- District of Columbia
- Maryland