ALSTON & BIRD

Cathy L. Burgess

Partner

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FDA-regulated entities benefit from Cathy's common-sense advice for achieving business objectives that avoid compliance and enforcement risks. With more than 30 years of extensive experience in the areas of CGMP regulation and product risk management, she provides strategic counseling and works with clients to identify and address potential risks throughout the product life cycle.

Cathy Burgess leads the firm's FDA Compliance and Enforcement Team and co-leads the firm's FDA practice.

Cathy advises clients on a range of matters affecting prescription and OTC drugs, biologics, medical devices, foods, and cosmetics, and has extensive experience regarding current good manufacturing practice (CGMP) regulation and supply chain management. For products regulated under the Federal Food, Drug, and Cosmetic Act (FDCA), Cathy conducts liability risk assessments and works with clients to identify and analyze potential legal risks associated with their products. She advises clients on quality system remediation, adequacy of SOPs, investigation reports, inspection management, recalls, and responses to Form FDA 483s and warning letters. Cathy also conducts whistleblower investigations and special audits related to FDA compliance. She assists clients in designing compliance programs, internal audit programs, and other risk mitigation strategies. She is recognized as a leading practitioner for life sciences in *Who's Who Legal*, ranked in *The Best Lawyers in America©* in FDA and Food and Beverage Law, and ranked Band 2 in *Chambers USA* in Pharmaceutical/Medical Products Regulatory. Cathy was named Lawyer of the Year in Food & Beverage Law for 2020 by *Best Lawyers* and was identified as a "Life Science Trailblazer" by *The National Law Journal*.

Before joining Alston & Bird, Cathy served as associate general counsel for the American Red Cross, where she was responsible for regulatory matters.

Representative Experience

- Advising and counseling foreign and domestic manufacturing facilities regarding FDA inspections, regulatory meetings, warning letters, import alerts, and consent decrees. This work has included extended on-site support in India, Central Europe, and China.
- Assisted with the submission of an Investigational New Drug (IND) application on behalf of the developer of a SARS-CoV-2 vaccine. Alston & Bird's work included a protocol review, as well as advice regarding the delivery system for the vaccine and assistance addressing FDA questions regarding the application.
- Advising numerous companies regarding blood plasma products and related regulatory and health and safety concerns.
- Advising foreign and domestic pharmaceutical manufacturers on the implications of FDA inspection delays as a result of the coronavirus.
- Advising commercial manufacturers seeking to develop diagnostic test kits and personal protective equipment for health care workers.
- Served as the defense team's first chair for expert testimony on CGMPs and analytical method validation in United States v. Barr Laboratories, widely recognized as the leading case on CGMPs.

- Advising and counseling domestic and foreign pharmaceutical manufacturers on issues related to data integrity.
- Negotiated the successful resolution of import alerts and warning letters related to CGMPs, data integrity, and inspection refusal.
- Defended a targeted medical device executive in a criminal referral.
- Negotiated an FDA consent decree in a case involving the mass seizure of a generic drug company's inventory.
- Developed medical device company compliance plans and remediation strategies in response to recidivist warning letters.
- Provided advice and counsel on drug and medical device regulation, as well as development of preparedness strategies and crisis communications, related to the SARS and H1N1 influenza pandemics.
- Provided advice and counsel regarding FDA Emergency Use Authorizations.
- Counseled on a wide range of regulatory compliance matters affecting blood banks.
- Counseled on pharmacy compounding and outsourcing facility issues.
- Preparing clients for FDA inspections.
- Counseled on supply chain management.
- Assisted in comprehensive CGMP audits.
- Counseled on regulatory due diligence in the prescription and OTC drug, pharmacy compounding, and medical device areas.
- Counseled on new drug applications for marketed unapproved products.
- Provided regulatory advice, development of a legislative strategy, and compliance audits on behalf of a major food client.
- Assisted a medical device client in responding to FDA import holds and detentions.
- Counseled the principal investigator of an investigational device whose research was suspended pending resolution of a warning letter.
- Counseled on Material Review Board decisions.
- Provided legal assistance and strategic advice to Red Cross senior management and the board of governors' Audit Committee on matters related to the Red Cross amended consent decree.
- Drafting testimony and responses to questions for the Committee on Energy and Commerce Subcommittee on Oversight and Investigations.

Publications & Presentations

Publications

- "Data Integrity Guidance Revisions by FDA and PIC/S Deepen Industry's DI Resource Pool," *International Pharmaceutical Quality*, April 23, 2019.
- "CGMP Enforcement Alternatives in the United States," "FDA Inspection Process," and "FDA Pre-approval Inspections," in *Good Manufacturing Practices for Pharmaceuticals,* 7th ed., CRC Press, 2019.

- "Overlapping Jurisdiction with Other Agencies and Law Enforcement Entities," in *Medical Devices Law and Regulation Answer Book*, 2019 ed., Practising Law Institute, 2018.
- *How to Comply with Drug CGMPs,* 2nd ed., Food and Drug Law Institute, April 2017.
- "3D Printed Medical Devices: More Lawsuits and More Questions," *Bloomberg BNA Medical Devices Law & Industry Report*, February 4, 2015.
- "A Social Experiment: 2015 Outlook for FDA's Social Media Policy," *Bloomberg BNA Social Media Law & Policy Report*, January 20, 2015.
- "Agency Action," *Top 20 Food and Drug Cases, 2014 and Cases to Watch*, FDLI, 2015.
- "Understanding, Anticipating, and Preventing Pharmaceutical Recalls," *Bringing Your Pharmaceutical Drug to Market*, FDLI, 2015.
- "Alameda County's Drug Take-Back Ordinance," *Industry Today*, October 22, 2014.
- "A Roadmap to Meaningful Use: FDA Releases More Social Media Guidance," *Bloomberg BNA*, September 19, 2014.
- "FDA's Latest Social Media Draft Guidance: Proceed with Caution," *Bloomberg BNA*, January 18, 2014.
- "Pharmacy Compounding and the Potential Impact of CGMPs," *Drug Topics*, January 10, 2014.
- "The Next Hot Thing," *Pharmaceutical Processing*, October 28, 2013.
- "How to Respond When FDA Knocks," *Law360*, September 26, 2013.
- "FDA Urges Manufacturers to Tighten Cybersecurity on Medical Devices and Creates Cybersecurity Lab to Prevent Cyber Attacks on Human Health," *Bloomberg BNA Medical Devices Law & Industry Report*, August 21, 2013.
- "How to Comply with CGMPs," *Primer,* The Food and Drug Law Institute, April 2013.
- "Dietary Supplement Manufacturer 'Likes' Post on Facebook; FDA Does Not," *Bloomberg BNA Pharmaceutical Law & Industry Report*, March 22, 2013.
- Buyer Beware: FDA's New Authority Under FDASIA Has Significant Implications for Supply Chain Management
- "What's in a Claim? Would a Food Not Labeled "Natural" Taste as Sweet?" *INFORM (International News on Fats, Oils, and Related Materials),* AOCS, Vol. 24, No. 3, March 2013.

Presentations

- "Continuing Impact of FDA's Inspection Approach on Industry and What Happens Next," Food and Drug Law Institute Enforcement, Litigation, and Compliance Conference, December 9–10, 2021.
- "Communicating with the FDA: How to Expedite an Inspection and Escape the Queue," 16th Annual FDA Inspections vSummit, November 16–17, 2021.
- "How Does FDA's Recent Guidance on Remote Interactive Evaluations Change the Inspections Landscape?" Food and Drug Law Institute Annual Conference, webinar, May 26, 2021.

Professional & Community Engagement

- Food and Drug Law Institute, board of director
- Food and Drug Law Institute, Audit Committee, chair

- Food and Drug Law Institute, FDLI curriculum advisor for COVID-19 course
- 2017 FDLI Enforcement Conference, Planning Committee, chair
- American Health Lawyers Association
- Food and Drug Law Institute, in-house training team to FDA
- Food and Drug Law Institute, Drugs and Biologics Committee, co-chair (2012–2015, 2015–2018)
- Regulatory Affairs Professionals Society
- American Red Cross, Tiffany Circle

Court Admissions

- U.S. Supreme Court
- The United States District Court for the District of Columbia

Education

- The Catholic University of America (J.D., 1988)
- Georgetown University (B.S.F.S., 1982)

Admitted to Practice

- District of Columbia

Related Services

FDA/Food, Drug & Device | FDA Enforcement & Litigation | Life Sciences | Health Care | Legislative & Public Policy | Chemical & Product Regulation | Health Care Litigation | Corporate Compliance Programs | Toxic Substances Control Act (TSCA) | Biotechnology, Pharmaceutical & Life Sciences Patent Litigation | Food, Beverage & Agribusiness | FDA Compliance & Enforcement