Jennifer L. Bragg

Skadden

Partner, Washington, D.C.

Life Sciences and Health Care; Litigation

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Education
J.D., University of Maryland School of Law, 1996 (with honors)

B.A., University of Maryland, 1993

Bar Admissions
District of Columbia

Maryland

Maryland District Court

U.S. District Court for the District of Columbia

Government Service
Associate Chief Counsel, U.S. Food and Drug Administration (1998-2003)

Experience
Law Clerk, Hon. William W. Wenner, Court of Special Appeals of Maryland

Associations
Immediate Past Chair, Board of Directors, The Food and Drug Law Institute

Jennifer Bragg, head of the firm's Washington, D.C. litigation practice, is a nationally recognized lawyer advising Food and Drug Administration (FDA)-regulated companies facing complex regulatory challenges, government investigations and related litigation. Since serving in the FDA's Office of Chief Counsel as associate chief counsel for enforcement, Ms. Bragg has represented companies in investigations by the U.S. Department of Justice (DOJ) and in a variety of FDA enforcement actions. This work also includes conducting internal investigations to assess allegations of wrongdoing or violations of law or policy. In addition, she counsels on corporate compliance program development and other protective measures designed to mitigate the risk of litigation.

Ms. Bragg advises pharmaceutical and medical device companies in connection with complex regulatory issues to minimize litigation and enforcement risks and to overcome transactional hurdles. Additionally, she frequently conducts due diligence and related counseling in connection with transactions in the life sciences and health care industries, and has litigation and trial experience. Her recent representations include:

Litigation/Investigations

- Purdue Pharma L.P. in connection with emerging developments relating to the marketing of opioid medications, including its successful resolution of DOJ civil and criminal investigations concerning sales and marketing
- Pfizer Inc. in securing an order to vacate an Amended Consent Decree entered into with the FDA and DOJ. In granting the order, the court found that Pfizer had satisfied the conditions for relief from the amended decree and that it should be vacated
- Miraca Holdings, Inc. in securing the dismissal of claims brought by a *qui tam* relator under the federal False Claims Act and the California and North Carolina state analogues
- CareFusion Corporation in securing the settlement and resolution of a DOJ claim alleging that CareFusion sold medical devices not approved by the FDA
- Mallinckrodt Pharmaceuticals in negotiating and implementing a corporate integrity agreement
- DENTSPLY SIRONA Inc. in securing a favorable summary judgment decision in a federal civil False Claims Act case pursued by a *qui tam* relator regarding allegations involving improper marketing and promotion of dental products
- Veloxis Pharmaceuticals A/S as plaintiff in filing a federal action against the FDA to reverse its decision to delay approval of Veloxis' new drug Envarsus XR based on marketing exclusivity given to an earlier-approved competing drug
- a senior executive from a leading medical device company in securing a dismissal after being individually named in a consent decree of permanent injunction for the company with the FDA and the Consumer Protection Branch of the Civil Division of the DOJ
- CTD Holdings in Freedom of Information Act litigation against the United States, securing a settlement and attorneys' fees
- a global pharmaceutical company in connection with an internal investigation into allegations that various device quality system regulations were not being followed
- Terumo Cardiovascular Systems Corporation in enforcement proceedings by the DOJ and FDA in connection with the company's manufacturing practices
- a pharmaceutical company in connection with multiple DOJ and state attorneys general investigations into its marketing practices and parallel congressional investigations

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Regulatory

- a pharmaceutical company in connection with strategic regulatory and litigation issues associated with a competing product's orphan exclusivity
- a global pharmaceutical and device company in connection with sophisticated digital health issues
- a biopharmaceutical company in connection with a request to the FDA to change the determination to permanently bar a former FDA employee subsequently employed by the company from participating in matters involving the company's non-disclosure agreement
- multiple pharmaceutical companies in connection with providing strategic regulatory advice for reimbursement support activities
- a multinational food company in connection with the recall of millions of units of a nonalcoholic beverage due to defective glass bottles
- a biomedical research company in connection with various FDA regulatory and compliance issues
- a biopharmaceutical company in advising its senior management and board of directors on the development and implementation of a comprehensive corporate compliance program
- an international medical device company in successfully persuading the FDA to issue an export certificate, despite ongoing FDA inspection issues
- an international medical device company in the appeal of a decision by the FDA to reject the company's flagship medical device for marketing in the United States. Ms. Bragg convinced the FDA to reverse its decision and clear the product for sale
- an international medical device manufacturer in providing strategic regulatory and litigation advice in connection with adverse event reporting issues
- an international pharmaceutical manufacturer in providing regulatory guidance in connection with the company's preparations to launch a new drug in the United States

Mergers and Acquisitions

- Cardinal Health, Inc. in its $6.1 billion acquisition of the patient care, deep vein thrombosis and nutritional insufficiency businesses of Medtronic plc
- Miraca Holdings, Inc. in the acquisition of its subsidiary Miraca Life Sciences, Inc. by Avista Capital Holdings, L.P.
- Stryker Corporation in its:
  - $3 billion acquisition of Vocera Communications, Inc.
  - acquisition of a 51% stake in Vexim SA
  - $662 million acquisition of Entellus Medical, Inc.
- The Coca-Cola Company in its strategic partnership with Monster Beverage Corporation
- Biogen, Inc. in the spin-off of its Hemophilia business into a separate, publicly traded company called Bioverativ
- Human Genome Sciences, Inc. in connection with the regulatory aspects of its initially unsolicited, but subsequently agreed upon, $3.6 billion acquisition by GlaxoSmithKline plc
- JAB in its acquisition of Compassion-First Pet Hospitals at a total enterprise value of $1.2 billion
- Amicus Therapeutics, Inc. in its acquisition of Celenex, Inc.
- Otsuka Pharmaceutical Co., Ltd. in its acquisition of Visterra, Inc.
- Keurig Green Mountain in its merger with Dr Pepper Snapple Group, Inc.
- BioCryst Pharmaceuticals, Inc. in its merger with Idera Pharmaceuticals, Inc.
- Juno Therapeutics, Inc. in its acquisition by Celgene Corporation
- HealthSpring Inc. in connection with the federal and state regulatory aspects of its $3.8 billion acquisition by CIGNA Corporation

From 1998 to 2003, as the FDA's associate chief counsel, Ms. Bragg advised its Office of Criminal Investigations. She tried to verdict four criminal jury cases involving violations of the Federal Food, Drug and Cosmetic Act (FDCA) and other federal statutes. Her matters involved compounding pharmacies, unapproved pharmaceuticals, controlled substances, misbranded devices and food-related good manufacturing practices. She also was designated by the DOJ to serve as a special assistant U.S. attorney in districts throughout the country regarding ongoing criminal investigations under the FDCA. Additionally, Ms. Bragg served as the FDA Office of Chief Counsel's primary liaison with the Office of Criminal Investigations relating to policy issues.

She is a frequent speaker at leading industry conferences, including for the Food and Drug Law Institute (FDLI), AdvaMed and DRI.

Ms. Bragg is a proud member of Skadden's Women's Initiatives Committee, which promotes the retention and advancement of women in the firm. She also is a member of Skadden's Hiring Committee.

Ms. Bragg has been repeatedly recognized in the highest band in *Chambers USA* for her work in the pharmaceutical and medical device space. She also has been regularly named to *The Best Lawyers in America*, chosen as one of Lawdragon's 500 Leading Litigators in America and noted as a Star by *LMG Life Sciences*. In addition, she has been honored as a Life Sciences MVP by *Law360*, as well as an Expert in *Who's Who Legal: Life Sciences*' Regulatory chapter and as one of *Who's Who Legal*'s Thought Leaders: Global Elite. She also has been repeatedly selected as a Stand-Out Lawyer by *Thomson Reuters* (including in its 2024 edition).

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Recent Book Publications

"Medical Devices Law and Regulation Answer Book," *Practising Law Institute*, August 2022

"FDCA Statutory Supplement, 2021 (2nd Edition)," *Food and Drug Law Institute*, May 31, 2021

"Healthcare Enforcement & Litigation 2021," *Lexology*, August 2020

Recent Speeches

"Responding to 483/Warning Letters," Pharma Conference, Inc. Current Hot GMP Topics, February 8, 2023

"DOJ, FDA, and Compliance in Criminal Violations of the FDCA (Oh My!)," FDLI Enforcement, Litigation and Compliance Conference: For the Drug, Device, Food and Tobacco Industries, December 8, 2022

"FDA & Restaurants: The Intersection of Health, Safety and the Supply Chain," 2022 Restaurant Legal Summit, October 25, 2022

"Understanding the Scope of FDA Enforcement Authority and Actions," American Conference Institute FDA Bootcamp, September 15, 2022

"What the Inflation Reduction Act Means for Your Company," Skadden webinar, August 18, 2022

"Evaluating the Potential Fraud and Abuse Risks Associated with Personalized Medicine," American Conference Institute Fraud and Abuse in the Sales and Marketing of Drugs and Medical Devices Conference, July 20, 2022

"Understanding the Scope of FDA Enforcement Authority and Actions," American Conference Institute FDA Bootcamp, March 24, 2022

"An Update on DOJ and FDA Enforcement Activity," Skadden webinar, January 12, 2022

Recent Publications

"Key Questions Remain Despite FDA Attempts To Clarify Guidance on Clinical Decision Software," *Skadden, Arps, Slate, Meagher & Flom LLP*, January 30, 2023

"DOJ Doubles Down on Efforts To Incentivize Early Self-Reporting and Cooperation," *Skadden, Arps, Slate, Meagher & Flom LLP*, January 19, 2023

"Trend Toward Broader Communication Continues as Congress Codifies Life Sciences Companies' Ability To Share Product Information With Payors Prior to FDA Approval," *Skadden, Arps, Slate, Meagher & Flom LLP*, January 5, 2023

"Circuit Split Doesn't Slow DOJ False Claims Act Settlements Based on FDCA Allegations Bloomberg Law," *Bloomberg Law*, November 29, 2022

"What DOJ Enforcement Shift Means For Life Sciences Cos.," *Law360*, September 22, 2022

"Senate Passes Landmark Bill With Climate, Tax, Energy and Health Care Implications," *Skadden Insights*, September 21, 2022

"Deputy Attorney General Monaco Announces Additional Measures Targeting Corporate Criminal Conduct: The Impact for Life Sciences Companies," *Skadden, Arps, Slate, Meagher & Flom LLP*, September 16, 2022

"Biden Signs Landmark Bill With Health Care Implications," *Westlaw Today*, August 29, 2022

"Senate Passes Landmark Bill With Climate, Tax, Energy and Health Care Implications," *Skadden, Arps, Slate, Meagher & Flom LLP*, August 7, 2022

"Comparing FDA Medical Device Proposal With Global Rules," *Law360*, March 10, 2022

"FDA Proposes Amendments to Medical Device Quality System Regulation," *Skadden, Arps, Slate, Meagher & Flom LLP*, March 1, 2022

"Corporate Integrity Agreements: A Year in Review," *Skadden, Arps, Slate, Meagher & Flom LLP*, February 25, 2022

"Will FDA and DOJ Reassert Their Enforcement Muscle With Life Sciences in 2022?" *Skadden, Arps, Slate, Meagher & Flom LLP*, January 19, 2022