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

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 government investigations and related enforcement challenges. Since serving in the FDA's Office of Chief Counsel as associate chief counsel for enforcement, Ms. Bragg has represented companies in criminal and civil litigation and strategic regulatory matters. She is frequently called upon to conduct due diligence and related counseling in connection with transactions in the life sciences and health care industries, and has extensive litigation and trial experience.

Ms. Bragg's primary practice involves advising pharmaceutical and medical device companies in connection with complex regulatory issues in an effort to minimize litigation and enforcement risks, as well as overcome transactional hurdles. Her recent representations include, among others:

Litigation/Investigations

- 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;
- 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 between 2007 and 2014 CareFusion sold medical devices that were not approved by the FDA;
- 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;
- 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;
- an over-the-counter distributor in connection with a nationwide product recall and associated litigation issues;
- 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;
- a global medical device company in connection with an internal investigation into allegations that recalls and complaints were not being evaluated in accordance with FDA regulations;
- a global cosmetics company in connection with a DOJ investigation into its commercial and import operations;
- a medical device company and an individual defendant in negotiating a consent decree with the FDA;
- a pharmaceutical company in connection with filing a citizen petition response;
- a pharmaceutical company and a medical device company in connection with a DOJ criminal and civil investigation;
- Terumo Cardiovascular Systems Corporation in enforcement proceedings by the DOJ and FDA in connection with the company's manufacturing practices; and
- a pharmaceutical company in connection with multiple DOJ and state attorneys general investigations into its marketing practices and parallel congressional investigations.

Regulation

- 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 caused by defective glass bottles. In addition to successfully managing the recall with the FDA, Ms. Bragg favorably negotiated an indemnification agreement with the bottle supplier on behalf of the company; 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; and
- 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 acquisition of a 51% stake in Vexim SA;
- 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;
- Stryker Corporation in its $662 million acquisition of Entellus Medical, Inc.; and
- 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, she advised its Office of Criminal Investigations. During that time, she tried to verdict four criminal jury trials 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 various 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 serves as chair of the board of directors of the FDLI, and as an adjunct food and drug law faculty member at the Georgetown University Law Center. She also has authored articles related to health care investigation trends, enforcement, the FDA and DOJ.

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 co-chair of the firm's Hiring Committee.

Ms. Bragg has been recognized in the highest band in *Chambers USA* for her work in the pharmaceutical and medical device space, in which sources report "she has a lot of business savvy and is very strategic and practical." In addition, she has been named in *The Best Lawyers in America* every year since 2013 and was named a 2020 BTI Client Service All-Star. She also was included in *The Legal 500 U.S.*, Lawdragon 500 Leading Lawyers in America and repeatedly cited as a Star by *LMG Life Sciences*. Ms. Bragg was named as an Expert in the 2019 edition of *Who's Who Legal: Life Sciences*' Regulatory chapter.

Recent Speeches

"IADC Midyear Meeting 2021," International Association of Defense Counsel (IADC) virtual conference, February 16, 2021

"10th Annual Pharmaceutical and Medical Device Webinar Series: Part Four: FDA Enforcement Trends and a Look Forward to 2021," Skadden webinar, February 11, 2021

"Election 2020 | Life Sciences Roundtable: A Discussion on How the 2020 Election May Impact FDA-Regulated Companies," Skadden webinar, November 20, 2020

"Pharmaceutical, Medical Device and Biotech Enforcement and Litigation Updates 2020 Part Two: FDA Enforcement Update: COVID-19 and Other Key Topics," Skadden webinar, May 13, 2020

"2019 Year in Review: An Increase in DOJ Life Sciences Settlements and Trends to Look for in 2020," Skadden webinar, January 28, 2020

"Enforcement Update: Department of Justice and Office of the Inspector General," FDLI Advertising and Promotion Conference, Washington, D.C., October 17, 2019

"REMS as an Enforcement Tool," FDLI Enforcement, Litigation, and Compliance Conference: For the Drug, Device, Food and Tobacco Industries, Washington, D.C., December 12-13, 2018

"Recent Developments In Life Science M&A," (Co-hosted With KPMG), November 12, 2018

"First Amendment Considerations And Off-Label Communica-tions," AdvaMed 9th Annual Advertising and Promotion of Medical Devices Conference, November 7, 2018

"Embracing Diversity In Your Law Firm: A How-To For Firms Large And Small," DRI Annual Meeting, October 8, 2018

Recent Publications

"Joint Promotional Programs With Physicians Raise Compliance Risks," *Skadden, Arps, Slate, Meagher & Flom LLP*, May 19, 2021

"DOJ and FDA Target Companies That Undermine FDA Oversight," *Skadden, Arps, Slate, Meagher & Flom LLP*, May 11, 2021

"Navigating Relationships With Practice Support and Other Tech Vendors," *Skadden, Arps, Slate, Meagher & Flom LLP*, May 4, 2021

"DOJ's Evolving Enforcement Approach to Off-Label Promotion," *Skadden, Arps, Slate, Meagher & Flom LLP*, April 27, 2021

"DOJ Introduces Novel Theories of Liability and Requires Unprecedented Controls in Speaker Program Settlement," *Skadden, Arps, Slate, Meagher & Flom LLP*, April 21, 2021

"HHS-OIG Year in Review: Despite Challenges Posed by the Pandemic, 2020 Saw an Uptick in Enforcement Action," *Skadden, Arps, Slate, Meagher & Flom LLP*, February 10, 2021

"Biden Administration's Expected Impact on Health Care and Life Sciences Enforcement," *Skadden's 2021 Insights*, January 26, 2021

"HHS-OIG Signals Increasing Skepticism of Speaker Programs, Identifies Practices That Raise Compliance Red Flags," *Skadden, Arps, Slate, Meagher & Flom LLP*, November 23, 2020

"As FDA Resumes Domestic Inspections While Keeping Foreign Inspections on Hold, Questions Remain About the Agency's Ability to Keep Tabs on the Global Supply Chain," *Westlaw*, October 20, 2020

"Novartis' $678 Million Settlement Sets Guideposts for Life Sciences Industry Speaker Programs," *Skadden, Arps, Slate, Meagher & Flom LLP*, August 24, 2020

"Lessons From Recent Medical Device Criminal Resolutions," *Food and Drug Law Institute*, Fall 2020

"FDA Announces That Domestic Inspections Will Resume," *Skadden, Arps, Slate, Meagher & Flom LLP*, July 13, 2020

"FDA Issues Guidance on Prescription Drug Sample Distribution During COVID-19," *Skadden, Arps, Slate, Meagher & Flom LLP*, June 10, 2020

"Prosecutors Are Taking Aim At Medical Technology Companies. Here Are the Biggest Risk Areas," *The National Law Journal*, May 29, 2020

"Enforcement Spotlight: US Prosecutors Continue To Target Medical Technology Companies," *Skadden, Arps, Slate, Meagher & Flom LLP*, April 28, 2020

"Drug and Device Manufacturers Remain in DOJ's Crosshairs," *The National Law Journal*, January 31, 2020

"Drug Pricing Concerns Drive Continued DOJ Focus on Life Sciences Companies," *Skadden's 2020 Insights*, January 21, 2020

"HHS-OIG Year in Review: Pharma and Medical Device CIAs Increase, Include Novel Provisions," *Skadden, Arps, Slate, Meagher & Flom LLP*, January 21, 2020

"Inside DOJ's Recent Charitable Copay Foundation Settlements," *Law360*, April 22, 2019

"Sweeping Changes Proposed to Safe Harbors for Drug Discounts to Health Plans," *Skadden, Arps, Slate, Meagher & Flom LLP*, February 5, 2019

"Medical Devices Law and Regulation Answer Book – FDA Criminal Enforcement," *PLI Press*, 2019 Edition

"2018 Trends in HHS Corporate Integrity Agreements," *Law360*, January 16, 2019

"Failure to Report Adverse Events Results in Criminal Misbranding Settlement and Individual Liability," *Skadden, Arps, Slate, Meagher & Flom LLP*, December 14, 2018

"The Responsible Corporate Officer Doctrine: Protections are Needed Despite DOJ's Cautious Approach," *Food and Drug Law Institute's Update*, December 2018 - January 2019

"10 Steps to Modernizing Corporate Integrity Agreements," *Law360*, June 20, 2018

"FDA Strives to Adapt Regulatory Approach To Rapidly Evolving Digital Health Space," *Skadden, Arps, Slate, Meagher & Flom LLP*, June 19, 2018

"3 New Settlements Highlight DOJ Scrutiny of Device Makers," *Law360*, April 4, 2018

"Health Care Investigation Trends: Corporate Integrity Agreements No Longer a Given," *Skadden, Arps, Slate, Meagher & Flom LLP*, March 26, 2018

"As Congress Struggles With ACA Repeal, Trump Administration Moves Forward With Regulatory Reform," *Wolters Kluwer's Health Law Daily*, February 7, 2018

"Will Life Sciences Companies Face More Scrutiny in 2018?" *Law360*, January 9, 2018

"Getting The Deal Through: Healthcare Enforcement & Litigation (United States)," *Law Business Research Ltd.*, 2018

Recent Settlements Suggest Off-Label Cases Aren't Extinct," *Law360*, August 30, 2017

"Trends In Corporate Integrity Agreements Reflect New HHS OIG Guidance On Use Of Exclusion Authority," *Westlaw Practitioner Insights For Health*, May 4, 2017

"Republicans Chart New Course For U.S. Health Care System," *Westlaw Journal Insurance Coverage*, March 3, 2017

"Getting the Deal Through: Healthcare Enforcement & Litigation (United States)," *Law Business Research Ltd.*, 2017