

Partner, Washington, D.C.

Life Sciences and Health Care; FDA Regulatory; Litigation



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Education

J.D., University of Pennsylvania
Law School, 2008

M.B.A., Florida A&M University, 2004

B.S., Florida A&M University, 2004

Bar Admissions

District of Columbia

Georgia

U.S. District Court for the
Northern District of Georgia

Professional Experience

Law Clerk, Hon. Marvin J. Garbis,
U.S. District Court for the District of
Maryland (2009-10)

Avia Dunn provides strategic, solutions-oriented counsel to FDA-regulated companies on complex government investigations, regulatory enforcement matters, compliance program design and oversight, and high-stakes transactions.

Ms. Dunn has substantial experience handling the various challenges faced by FDA-regulated companies, including compliance with federal and state fraud and abuse laws, FDA regulatory enforcement matters and HIPAA privacy restrictions. Additionally, she counsels life sciences companies on matters related to the development, implementation and oversight of their health care compliance programs, both proactively and in connection with the negotiation of corporate integrity agreements. She has also served as a subject-matter adviser on more than 150 life sciences-related transactional matters. Ms. Dunn relies on these varied experiences to assess over-the-horizon risk and offer personalized solutions to clients.

Ms. Dunn has been repeatedly recognized as one of Lawdragon's 500 Leading Litigators in America and named to *Chambers USA*.

Representative clients include:

Litigation, Enforcement and Investigations

- Miraca Holdings in securing the dismissal of claims brought by a *qui tam* relator under the federal False Claims Act and California and North Carolina state analogues
- a pharmaceutical company in successfully persuading the DOJ to close its investigation of certain product support activities with no enforcement action. The relators voluntarily dismissed the underlying *qui tam* action brought under the False Claims Act after the government declined to intervene
- a major medical system in connection with a voluntary self-disclosure regarding financial relationships with secondary care facilities
- a specialty pharmaceutical company in the negotiation and implementation of a corporate integrity agreement
- the board of directors of a multinational life sciences company in connection with an assessment of the company's compliance with health care compliance provisions of its deferred prosecution agreement
- a specialty pharmaceutical company in two separate investigations by the DOJ involving the U.S. Attorney's Offices in Boston (District of Massachusetts) and Philadelphia (Eastern District of Pennsylvania) regarding the company's sales and marketing practices and relationship with co-pay assistance charities
- a global pharmaceutical company in an investigation by the U.S. Attorney's Office in New York (Southern District of New York) in connection with the company's drug promotion strategy
- a specialty pharmaceutical company in criminal and civil investigations by the DOJ and more than 10 U.S. Attorney's Offices and state attorneys general's offices
- a medical device company in enforcement proceedings by the DOJ and FDA in negotiating a consent decree relating to manufacturing issues at the company's plants
- a food manufacturer in successfully petitioning FDA to remove a facility from an FDA import alert

Regulatory Advice and Strategy

- a group purchasing organization in connection with the submission and receipt of a favorable U.S. Department of Health and Human Services Office of the Inspector General advisory opinion
- an emerging specialty pharmaceutical company in submitting a citizen petition to FDA
- a global pharmaceutical company in providing strategic guidance regarding its evaluation of alternative sites of care in response to the COVID-19 pandemic
- a multinational food company in connection with a product recall
- an importer in connection with a hand sanitizer recall
- a pharmaceutical company in connection with emerging developments relating to the marketing of opioid medications
- numerous pharmaceutical and medical device manufacturers in providing strategic counsel regarding health care compliance program design and policy implementation, patient support activities, promotion strategies, medical affairs activities, educational grants and interactions with patients and health care professionals
- various life sciences clients in connection with matters related to HIPAA, including the review and negotiation of business associate agreements

Transactions

- Mars, Incorporated in its \$35.9 billion acquisition of Kellanova
- Otsuka Pharmaceutical Co., Ltd. in its acquisition of Jnana Therapeutics Inc. for \$800 million upfront and up to \$325 million in future milestone payments
- Waldencast Acquisition Corp. in connection with its business combination transaction with Obagi Cosmeceuticals and Milk Makeup
- JAB Holdings B.V. in connection with equity financing and other arrangements between JAB and certain of its equity partners in connection with JAB's \$13.9 billion acquisition of Keurig Green Mountain, Inc.
- Peet's Coffee & Tea, Inc. in its acquisition of a majority stake in Intelligentsia Coffee & Tea, Inc.
- Joh. A. Benckiser GmbH, a holding company based in Germany, in its \$374 million acquisition of Einstein Noah Restaurant Group, Inc.
- Krispy Kreme Doughnut Corporation in its acquisition of a majority stake in Insomnia Cookies LLC
- Compute Health Acquisition Corp. in its merger with Allurion Technologies Inc. at an enterprise value of \$500 million
- Mayne Pharma Group Limited in its \$475 million sale of Metrics Contracts Services to Catalent, Inc.
- Biogen, Inc. in the spin-off of its Hemophilia business into a separate, publicly traded company called Bioverativ
- The Coca-Cola Company in its strategic partnership with Monster Beverage Corporation
- Livongo in its \$18.5 billion acquisition by Teladoc Health
- Miraca Holdings, Inc. in the acquisition of Miraca Life Sciences, Inc., its subsidiary, by Avista Capital Holdings, L.P.
- OceanSound Partners in its acquisition of Netrix, a provider of cloud infrastructure and a substance abuse and medication management system
- a pharmaceutical company in its sale of a controlled substance manufacturing facility
- multiple biopharma SPAC acquisitions