Maya P. Florence

Skadden

Partner, Boston

Life Sciences and Health Care; FDA Regulatory; Litigation

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Education

J.D., Harvard Law School, 2004 (*cum laude*)

B.A., University of Pennsylvania, 2001 (*summa cum laude*)

Bar Admissions

Massachusetts

New York

District of Columbia

Experience

Law Clerk, Hon. Colleen Kollar-Kotelly, U.S. District Court for the District of Columbia (2006-08)

Maya Florence is a trusted adviser to life sciences industry companies, boards of directors, general counsel and other key executives. She has extensive experience advising on government enforcement matters, regulatory compliance, high-stakes transactions and bet-the-company litigation.

Ms. Florence has counseled on matters involving fraud and abuse enforcement, federal and state anti-kickback laws, advertising and promotion issues, GMP/QSR compliance, artificial intelligence and cybersecurity, HIPAA and False Claims Act defense, among other representations. She excels at advising clients facing complex challenges, quickly and efficiently assessing the wide spectrum of unique issues impacting life science and health care companies, and providing practical, business-minded advice.

Ms. Florence's extensive experience across multiple matter types allows her to keep one step ahead of potential issues and proactively identify impact areas for clients in the industry. She applies this insight in advising FDA-regulated companies, genomic laboratories and other health care providers regarding fraud and abuse and FDA regulatory compliance in several contexts, including in connection with internal investigations, corporate integrity agreement implementation and corporate compliance programs assessments. In addition, Ms. Florence frequently serves as a subject-matter expert on high-stakes transactions, and has advised clients on more than 300 transactional matters.

Ms. Florence's recent representations include:

Enforcement/Investigations

- Purdue Pharma L.P. in connection with emerging developments relating to the marketing of opioid medications, including its successful resolution of U.S. Department of Justice (DOJ) civil and criminal investigations concerning the sale and marketing of opioid products
- a pharmaceutical manufacturer in concurrent criminal and civil investigations by the DOJ and numerous state attorneys general relating to product marketing
- a leading genomic laboratory in a self-disclosure of health care fraud and abuse concerns identified through an internal investigation, as well as the subsequent government investigation
- a rare disease biotechnology company in an internal investigation of allegations regarding improper product promotion, as well as strategic counseling regarding product promotion, reimbursement and patient support services, and medical affairs activities
- a multinational medical device manufacturer in an internal investigation of potential fraud and abuse in connection with a patient support program, including counseling regarding potential self-disclosure mechanisms

Regulatory/Compliance

- a major medical product trade organization in drafting comments for submission to two FDA dockets
- Veloxis Pharmaceuticals A/S as plaintiff in filing a federal action against the FDA to reverse the agency's decision to delay approval of Veloxis' new drug, Envarsus XR, based on marketing exclusivity given to an earlier-approved competing drug
- multiple pharmaceutical and medical device manufacturers in providing strategic counseling regarding marketing and promotion strategies, medical affairs activities, engagements with health care professionals, and reimbursement and patient support services

Transactions

- POINT Biopharma in its $1.4 billion sale to Eli Lilly
- Intercept Pharmaceuticals in its $800 million sale to Alfasigma
- Mayne Pharma Group Limited in its $475 million sale of Metrics Contracts Services to Catalent, Inc.
- Alnylam Pharmaceuticals, Inc. in its $2.8 billion co-development and co-commercialization agreement with Roche Holding AG to develop and commercialize its hypertension drug Zilebesiran
- Honeywell in its $1.3 billion acquisition of Sparta Systems, a provider of enterprise quality management software for the life sciences industry, from New Mountain Capital and other stockholders

In recognition of her work, Ms. Florence has been repeatedly selected for inclusion in *Chambers USA: America's Leading Lawyers for Business*. She also has been recognized by *LMG Life Sciences* in its Regulatory category, as well as named one of *Lawdragon*'s 500 Leading Litigators in America, a 2024 BTI Client Service All-Star and a Go To Life Science/Health Care Lawyer by *Massachusetts Lawyers Weekly*. In addition, Ms. Florence serves as hiring partner for Skadden's Boston office.

Selected Presentations

"DOJ and HHS-OIG Developments," Skadden's annual Pharmaceutical and Medical Device Webinar Series, March 27, 2024

Medical Device Manufacturers Association Compliance Roundtable, March 12, 2024

"The Implications of HHS-OIG's New General Compliance Program Guidance for Life Sciences Companies," Skadden webinar, December 5, 2023

"Ethical Considerations: An Update on Privilege in the Investigations Context," Government Investigations and Civil Litigation Institute's 9th Annual Meeting, November 16-17, 2023

"Evolving Board of Directors and Compliance Committees Oversight Obligations," 24th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress, October 25-26, 2023

American Conference Institute 41st Annual FDA Boot Camp, September 20, 2023

"Product Support Programs: Legal and Compliance Considerations for Life Sciences Companies," Skadden webinar, July 27, 2023

Selected Publications

"Joint FDA/HHS Initiative Targeting Direct-to-Consumer Pharmaceutical Advertising Garners Much Attention, but Legal Basis and Likely Impact Are Unclear," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*, September 11, 2025

"FDA Pivots on Publishing Complete Response Letters, Raising SEC Disclosure and Securities Litigation Implications," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*, August 26, 2025

"DOJ Settlement With Medical Technology Company Signals Expanding Cybersecurity FCA Risk for Life Sciences Companies," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*, August 7, 2025

"HHS and DOJ Launch FCA Working Group With New Joint Enforcement Priorities," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*,July 7, 2025

"OIG Issues Unfavorable Advisory Opinion: Provision of Free Services to Referral Sources Creates Kickback Risk," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*, July 2, 2025

"FDA Commissioner Launches Pilot Program To Speed Review of Certain Drugs," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*, June 18, 2025

"A 20-Minute Speech Provides the Clearest Road Map Yet for FDA Policy," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*, May 22, 2025

"Speaker Program Settlement Highlights Compliance Risks for Life Sciences Companies," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*, May 6, 2025

"Mass Layoffs at FDA Could Have the Greatest Impact on Products in Development," *Skadden Publication / Trump's First 100 Days*, April 30, 2025

"President Trump Issues Executive Order Intended To Lower Drug Prices," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*, April 18, 2025

"FDA at the Start of the Trump Administration: A Cheat Sheet," *Skadden Publication / The Nucleus: Life Sciences Enforcement and Regulatory Updates*, April 8, 2025