Maya P. Florence

Skadden

Partner, Boston

Health Care and Life Sciences

T: 617.573.4805
F: 617.305.4805
maya.florence@skadden.com

Education

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

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

Bar Admissions

District of Columbia
New York
Massachusetts

Experience

Law Clerk, Hon. Colleen Kollar-Kotelly, U.S. District Court for the District of Columbia (2006-2008)

Maya Florence represents pharmaceutical, biotechnology and medical device manufacturers in Food and Drug Administration (FDA) enforcement and regulatory matters, federal and state government civil and criminal investigations, and litigation. Ms. Florence has extensive experience in matters involving advertising and promotion issues, GMP/QSR compliance, fraud and abuse enforcement, federal and state anti-kickback laws, HIPAA and False Claims Act defense. Her work often involves assisting clients in balancing the competing demands and navigating risks involved in concurrent investigations by federal authorities and state attorneys general.

Ms. Florence also frequently provides legal and strategic advice to FDA-regulated companies, as well as hospitals and other health care providers, regarding fraud and abuse and compliance in several contexts, including FDA regulatory compliance, Corporate Integrity Agreement implementation, internal investigations and strategic transactions. She has significant experience developing, implementing and assessing corporate compliance programs for pharmaceutical and medical device companies. In addition, Ms. Florence frequently conducts due diligence and strategic counseling in connection with life sciences and health care industry transactions, and has advised clients on more than 150 transactional matters.

Ms. Florence's recent representations include:

- two pharmaceutical manufacturers in concurrent criminal and civil investigations by the U.S. Department of Justice (DOJ) and numerous state attorneys general relating to the marketing of opioid medications, as well as general FDA regulatory issues, health economics and proactive health care compliance matters;
- Biogen, Inc. in the defense of multiple consolidated *qui tam* suits brought under the federal False Claims Act in the District of Massachusetts;
- a major medical product trade organization in drafting comments for submission to two FDA dockets;
- Becton, Dickinson and Company in its $24 billion acquisition of C. R. Bard, Inc.;
- Veloxis Pharmaceuticals A/S as plaintiffs 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;
- a leading biotechnology company on FDA, health care and global regulatory compliance matters in connection with several acquisitions and strategic commercial transactions;
- a major medical device manufacturer in providing strategic regulatory and compliance advice in connection with the company's marketed products, and in connection with a DOJ investigation;
- a leading pharmaceutical company in connection with emerging developments relating to the marketing of prescription medications, general FDA regulatory and health care compliance matters, and in conducting internal investigations of regulatory and compliance matters;
- Humana Inc. in its contemplated merger with Aetna for $37 billion in cash and stock; and
- multiple pharmaceutical and medical device manufacturers in providing strategic counseling regarding reimbursement and patient support services.

Ms. Florence has repeatedly been selected for inclusion in *Chambers USA: America's Leading Lawyers for Business*. In addition to her practice, Ms. Florence is a member of the firm's Women's Initiative Committee, which works to promote the retention and advancement of women in the firm.

Maya P. Florence

Continued

Selected Publications

"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

"The 10 Most Important Changes in the New and Improved AdvaMed Code of Ethics," *Skadden, Arps, Slate, Meagher & Flom LLP*, January 31, 2019

"Trump Policy Actions Could Reshape Health Care and Life Sciences Landscape," *Skadden's 2019 Insights*, January 17, 2019

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

"HHS OIG Closes 2018 With New Fraud Risk Indicator for Corporate integrity Agreements," *Skadden, Arps, Slate, Meagher & Flom LLP*, January 15, 2019

"The Responsible Corporate Officer Doctrine: Protections are Needed Despite DOJ's Cautious Approach," *Skadden, Arps, Slate, Meagher & Flom LLP*, December 2018-January 2019

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

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

"Aegerion Settles Criminal and Civil Probe of Promotional Practices, REMS and HIPAA Compliance, and Patient Assistance Programs," *Skadden, Arps, Slate, Meagher & Flom LLP*, September 28, 2017

"8 Years of Health Care Enforcement: Doing Less With More," *Law360*, August 10, 2017

"Trends in Corporate Integrity Agreements Reflect New HHS OIG Guidance on Use of Exclusion Authority," *Westlaw Practitioner Insights For Health*, May 4, 2017

"FDA Publications Double Down on Agency's Ability to Prohibit Off-Label Communications, but Narrow Scope of Debate," *Skadden, Arps, Slate, Meagher & Flom LLP*, February 1, 2017

"Inciting Innovation in Drug and Medical Device Development," *Law360*, December 14, 2016

"The 21st Century Cures Act: FDA Reforms Aim to Spur Innovation in the Pharmaceutical, Medical Device and Health Research Sectors," *Skadden, Arps, Slate, Meagher & Flom LLP*, Deecmber 13, 2016

"Financial Relationships Likely To Be Focus In Life Sciences Enforcement And Litigation," *Westlaw Journal*, May 18, 2016

"Risk Of Future Misconduct Will Guide HHS Investigations," *Law360*, April 26, 2016

"New HHS OIG Criteria to Guide Resolution of Health Care Investigations," *Skadden, Arps, Slate, Meagher & Flom LLP*, April 21, 2016

"Financial Relationships Likely to Be a Focus in Life Sciences Enforcement and Litigation," *Next Practitioner Insights*, April 8, 2016

"Amarin Settlement Erodes Off-Label Promotion Enforcement," *Law360*, March 11, 2016

"Amarin Settlement Order and Vascular Solutions Acquittal Further Erode Off-Label Promotion Enforcement Regime," *Skadden, Arps, Slate, Meagher & Flom LLP*, March 8, 2016

Selected Presentations

"A Dialogue with Corporate Counsel: Skadden's Eight Annual Pharmaceutical and Medical Device Seminar," Skadden Seminar, December 11, 2018

"Enforcement and Litigation Strategies: Skadden's Eighth Annual Pharmaceutical, Biotechnology and Medical Device Seminar," Skadden Seminar, Palo Alto, CA, March 29, 2018

"American Conference Institute FDA Boot Camp, Adverse Events Monitoring, Pharmacovigilance, Risk Management, and Recalls," New York, March 9, 2018

"Managing Risk in the Whistleblower Nation," Health Care Law & Compliance Institute, Dallas, March 5, 2018

"A Dialogue With Corporate Counsel: Skadden's Seventh Annual Pharmaceutical and Medical Device Seminar," Skadden Seminar, November 14, 2017