Kayla J. Cristales

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PRACTICES Healthcare Transactions and Regulatory, Healthcare and Life Sciences, Fraud, Abuse, and Compliance , Food, Beverage and Restaurant, FDA Regulatory and Compliance, Advertising, Marketing, and Promotional Law, Corporate, Precision Medicine and Digital Health, Telehealth, Retail, Procurement and Supply Chain Management, Life Sciences, Pharmaceuticals

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Kayla Cristales is an associate in Haynes Boone's FDA Regulatory and Compliance Group. Her practice focuses on transactional and regulatory matters for FDA-regulated clients, particularly in the beauty/wellness and life sciences spaces. For example, Kayla regularly counsels cosmetic and OTC drug and device brand owners, retailers, and distributors in connection with packaging and label compliance and claim-related risk assessments; substantiation reviews; product classification analyses; manufacturing, development, commercialization, and/or supply agreement negotiation; and advertising, marketing, and other promotional communications, among many other areas involving the wide range of often complex and overlapping federal and state laws and regulations governing cosmetics, drugs (including biologics), and medical devices, respectively.

Kayla also has substantial experience in conducting diligence, negotiating key contractual terms, assisting with post-closing transitions, and other key elements of mergers and acquisitions involving FDA-regulated parties, as well as in advising issuers and underwriters on material regulatory matters and related considerations in connection with securities offerings and SEC filings in the life sciences space.

In addition, Kayla has significant experience with state and federal healthcare laws, which allows her to provide helpful guidance to life sciences companies that are subject to both FDA regulations, as well as applicable healthcare laws, such as the Anti-Kickback Statute, the Stark Law, the Sunshine Act, and analogous state laws (among others).

QUALIFICATIONS

EDUCATION

- J.D., Southern Methodist University Dedman School of Law, 2017, summa cum laude; Order of the Coif; *SMU Law Review*
- B.A., University of Oklahoma, 2012

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ADMISSIONS

- Texas

PUBLICATIONS AND SPEAKING ENGAGEMENTS

- "INSIGHT: Maximizing Immunity Under the PREP Act for Covered Countermeasures," co-author, *Bloomberg Law*, September 8, 2020.

SELECTED CLIENT REPRESENTATIONS

- Conduct labeling reviews of food products, dietary supplements, cosmetics, OTC drugs, and other consumer products.
- Regularly provide healthcare and FDA regulatory guidance to issuers and underwriters in connection with Exchange Act filings and related activities.
- Review and negotiate agreements with customers, purchasing organizations, and vendors, including product supply, purchasing, licensing, marketing, distribution, co-branding, franchising, and similar agreements.
- Draft professional services agreements, such as employment, consulting, medical director, and other similar and ancillary agreements.
- Draft, review, and revise research-related documents and agreements with contract research organizations, hospitals and health systems, and physician groups.
- Assist with mergers and acquisitions involving healthcare and/or FDA-regulated entities.
- Advise on new and existing financial relationships and interactions with healthcare providers, including speaker engagements, consulting arrangements, CME events, and gifts/dinners/travel/promotional items.
- Provide regulatory and compliance advice regarding federal and state Anti-Kickback and self-referral statutes, FDA regulations, Sunshine Act and reporting and disclosure obligations, HIPAA and data privacy and security laws, and antitrust laws.
- Review, develop, and provide education and training on fraud and abuse laws as well as audits and compliance program policies and procedures for FDA-regulated companies, including sales force compliance and marketing strategies.
- Provide risk management counseling, including self-evaluative audits, designing corrective action plans, and handling of possible past or existing regulatory violations or events of non-compliance.
- Provide guidance and crisis management during threatened or actual recalls.
- Perform comprehensive state and federal regulatory analyses and provide compliance advice in connection with numerous operational endeavors proposed by healthcare entities.
- Review and revise patient paperwork and internal policies for physician groups and other healthcare entities.
- Provide guidance regarding provider enrollment and claim submission requirements in relation to Medicare, Medicaid, CHIP, TriCare, and Medicare Advantage.
- Conduct surveys of material state laws applicable to healthcare and FDA clients, including those related to patient abandonment, informed consent, the corporate practice of medicine, data privacy, genetic testing, and hemp-derived CBD.
- Advise restaurant chains and retailers regarding FDA menu labeling requirements, consumer advisory warnings, and other related matters.

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