Kayla J. Cristales

Associate

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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

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Kayla Cristales is an associate in the Healthcare and Life Sciences Practice Group in the Dallas office of Haynes and Boone. Her practice focuses primarily on transactional and regulatory healthcare and FDA matters. While she advises clients on pure FDA matters and pure healthcare matters, her unique expertise in both areas makes her a valuable asset to the many clients whose businesses are subject to both FDA *and* healthcare laws, regulations, and rules, such as, for example, companies engaged in the manufacture, distribution, marketing, sale, promotion, or purchase of pharmaceuticals, biologics, or medical devices and the many ancillary activities in which such companies may be involved.

On the healthcare side, Kayla routinely advises clients on a wide range of issues involving key regulatory areas, including the Stark Law; the Anti-Kickback Statute; state fraud and abuse laws; the Sunshine Act; state examining board rules; the Administrative Procedure Act; state corporate practice of medicine prohibitions, among a number of others. In doing so, she has added critical regulatory insight to a number of transactional operations and compliance reviews and helped healthcare clients address obstacles and navigate through the often overlapping state and federal healthcare laws.

On the FDA side, Kayla has assisted with matters confronting a number of evolving FDA-regulated areas, including compliance with state and federal laws and regulations governing the marketing and/or distribution of products containing hemp-derived CBD (after the enactment of the 2018 Farm Bill). She also regularly counsels FDA-regulated clients in connection with labeling reviews; product classification analyses; manufacturing, development, commercialization, and/or supply agreement negotiation; and advertising, marketing, and other promotional communications, among many other areas.

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

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.