EPSTEIN
BECKER
GREEN

James A. Boiani

Member of the Firm

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JAMES A. BOIANI is a Member of the Firm in the Health Care and Life Sciences practice, in the firm's Washington, DC, office. He has extensive experience in FDA and CLIA legal and regulatory matters, having worked with large and small medical device companies (including many *in vitro* diagnostic companies), pharmaceutical companies, clinical laboratories, and trade associations in the life sciences industry on a variety of FDA- and CLIA-related issues.

Mr. Boiani's practice focuses on the following:

- Advising on FDA compliance matters, with an emphasis on current good manufacturing practices ("cGMPs") and quality systems; post-market surveillance and safety reporting; recalls; and advertising and promotion
- Representing clients in the FDA product approval and clearance process (e.g., NDAs, BLAs, PMAs, 510(k)s, and CLIA waivers)
- Identifying and capturing regulatory opportunities in product development and lifecycle management
- Ensuring clinical laboratory regulatory compliance (e.g., CLIA compliance)

Mr. Boiani's experience includes:

- Assisting companies in pre-enforcement situations by helping them manage FDA inspections; working on responses to FDA-483 observations, untitled letters, and warning letters; developing and implementing remediation strategies to correct compliance issues; evaluating and helping address CLIA audit findings; and advising clients on handling difficult FDA- or CLIA-related compliance issues more generally
- Advising clients on adverse event (AE) and medical device report (MDR) reporting, recalls, and associated issues; of recent note, Mr. Boiani has served as the primary outside legal advisor to a major medical device company for more than over two years, providing extensive support on all facets MDR reportability, recall decisions, recall communications to customers, recall reports to regulatory agencies and associated agency

communications, and recall-related issues (such as root cause investigations and CAPAs), from both a case-specific and global corporate policy standpoint
- Founding and serving as General Counsel of the Coalition for CLIA Waiver Reform, which is working to advance point-of-care diagnostic testing
- Representing individual medical device manufacturers in matters involving CLIA waivers
- Helping companies address advertising and promotional issues, including the review of promotional pieces, policy development regarding off-label uses and associated issues (e.g., handling unsolicited requests for off-label information and good reprint practices), the development of communication strategies, and conducting intensive advertising and promotional trainings for marketing and sales, scientists, and management
- Working with compounding pharmacies and trade associations to address new FDA regulatory oversight and compliance matters
- Representing and counseling clients in FDA drug, medical device, and biological approval- and clearance-associated matters, such as application submissions (i.e., NDAs, BLAs, ANDAs, PMAs, and 510(k)s), responses to FDA complete response/deficiency letters, administrative appeals of adverse FDA decisions, clinical and nonclinical trial design issues, and complex 505(b)(2) and combination drug policy issues
- Counseling clients on issues regarding combination products (e.g., preparing requests for designation and advising on cGMPs, registration, and listing) and the development of companion diagnostics, and supporting policy initiatives of trade associations in the area of companion diagnostics
- Advising drug developers on lifecycle management issues and opportunities
- Assisting pharmaceutical and biotechnology firms in obtaining pediatric market exclusivities, Hatch-Waxman exclusivities, and patent term extensions
- Representing clients in matters involving drug and medical device development (i.e., IND and IDE issues) and other pre-approval and pre-clearance issues (e.g., Emergency Use Authorizations)
- Representing small and start-up biotechnology firms pursuing FDA user fee waivers, and advising clients on user fee issues

Mr. Boiani has also worked for the Veterans Pro Bono Consortium, which provides free legal services to veterans.

In 2014, Mr. Boiani was selected to the *Washington DC Rising Stars* list in the area of Food and Drugs.

Prior to becoming a lawyer, Mr. Boiani earned degrees in chemistry from the Massachusetts Institute of Technology and Cornell University, and worked as an environmental regulatory consultant. In the fall of 2018, Mr. Boiani returned to Cornell as a guest lecturer, co-teaching digital health law at Cornell Tech.

Education

- George Mason University School of Law (J.D., 2004)
- Cornell University (M.S., 1998)

- Massachusetts Institute of Technology (B.S., 1996)

Court Admissions

- U.S. Court of Appeals for the District of Columbia Circuit
- U.S. District Court, District of Columbia

Bar Admissions

- District of Columbia
- Virginia

Practice Areas

- Digital Health
- Food and Drug Law
- Product Marketing

Industries

- Artificial Intelligence
- Health Care and Life Sciences Industry
- Life Sciences Industry
- Medical Devices and Combination Products
- Pharmaceuticals
- Technology, Media & Telecommunications

Memberships

- American Bar Association