EPSTEIN
BECKER
GREEN

Delia A. Deschaine

Member of the Firm

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DELIA A. DESCHAINE is a Member of the Firm in the Health Care and Life Sciences practice, in the firm's Washington, DC, office. Named to the *Washington DC Rising Stars* list in the area of Food and Drugs (from 2018 to 2020), Ms. Deschaine focuses her practice on advising pharmaceutical and biotechnology clients on a broad range of FDA regulatory matters. Her services include:

- Providing advice on pharmaceutical and biotechnology development and approval
- Advising on pharmacovigilance, current Good Manufacturing Practices ("cGMPs") compliance, Risk Evaluation and Mitigation Strategies (or "REMS"), registration and listing, field alert reporting, import and export controls, recalls, labeling, advertising and promotion, and Drug Supply Chain Security Act compliance
- Conducting internal investigations, and defending clients in government investigations and litigation
- Representing manufacturers and their suppliers in responding to FDA Form 483s, Warning Letters, and Import Alerts
- Drafting and negotiating commercial agreements and conducting diligence in corporate transactions

Ms. Deschaine has a deep understanding of FDA requirements related to cGMP and FDA Quality System Regulations ("QSR"). She routinely counsels client on their obligations related to cGMP and QSR, including quality systems, data integrity, supply chain management, aseptic processing, validation, and sterilization.

In addition, Ms. Deschaine focuses her practice on the federal and state regulation of controlled substances. She defends clients, including pharmaceutical and biotechnology companies, distributors, pharmacies, hospitals, physician groups, academic medical centers, and other researchers, in government investigations and litigation, and advises them on:

- Controlled substances scheduling matters
- Compliance with U.S. Drug Enforcement Administration ("DEA") and state law regulatory requirements

- Conducting internal investigations

Ms. Deschaine also counsels clients on cannabis law matters. She was named to the *Washington DC Rising Stars* list in the area of Cannabis Law in 2020, and has advised pharmaceutical, researcher, conventional food, dietary supplement, and cosmetic companies on FDA, DEA, U.S. Department of Agriculture, and states' regulation of cannabis (including hemp), cannabis-derived products, and synthetic cannabinoids.

Prior to joining the firm, Ms. Deschaine served for six years as an attorney for an international law firm in the areas of pharmaceutical and biotechnology law, and two years at a boutique FDA law firm , both in Washington, DC. Before then, she was an Attorney Advisor for the DEA through the Attorney General's Honors Program, where she received a Performance Award in 2011. She was also a legal intern for Magistrate Judge Susan K. Gauvey of the U.S. District Court for the District of Maryland.

Representative Experience

- Represented a pharmaceutical company in an appeal of a Complete Response Letter, leading to a favorable FDA Advisory Committee Meeting and approval of the drug.
- Drafted citizen petitions for pharmaceutical and biotechnology clients on novel issues of drug approval.
- Assisted a biotechnology client nearing launch on construction of an FDA compliance program, including contract manufacturing arrangements, pharmacovigilance, drug registration and listing, NDC/labeler code requirements, and state licensing matters.
- Drafted and negotiated contract manufacturing agreements, and related quality agreements, on behalf of gene therapy companies and other pharmaceutical and biotechnology clients.
- Revised supply and distribution agreements for a pharmaceutical manufacturer of controlled substances.
- Defended a client in a high-profile government investigation and litigation regarding the client's compliance with DEA's suspicious order monitoring requirements, leading to a court enjoining DEA's immediate suspension order and a favorable outcome of an administrative proceeding.
- Defended a pharmaceutical manufacturer in a government investigation, leading to a *nulle proseque* of allegations of criminal federal Food, Drug, and Cosmetic Act violations.
- Represented several manufacturers in responding to Form FDA 483s and Warning Letters, in every case resulting in no (or no further) enforcement action from the FDA.
- Represented a client in obtaining a letter from the DEA finding that the client's development of a cannabinoid drug product was not Schedule I.
- Advised a pharmaceutical manufacturer of a cannabinoid drug product on navigating the DEA scheduling process while the cannabinoid-drug product was undergoing FDA review.
- Advised a prominent Canadian cannabis company on a broad range of U.S. cannabis law matters, including the federal and state regulation of cannabis topicals, edibles, and smokeables, and regulation of cannabidiol.

- Advised a biosynthetic manufacturer of cannabis products on U.S. cannabis law matters.
- Represented a client in an application for a DEA cannabis cultivation registration for research.
- Represented a client in an application for a Maryland cannabis cultivation license for purposes of supplying legitimate research in the United States.

Education

- University of Maryland Francis King Carey School of Law (J.D., cum laude, 2010)
    - Health Law Certificate
    - Health Law Moot Court
- Manhattanville College (B.A., 2004)
    - Board of Trustees Scholar

Bar Admissions

- District of Columbia
- Maryland

Practice Areas

- Behavioral Health
- Dietary Supplements
- Food and Drug Law
- Government Investigations and Litigation
- Opioids

Industries

- Cannabis Law
- Health Care and Life Sciences Industry
- Life Sciences Industry
- Medical Devices and Combination Products
- Pharmaceuticals

Memberships

- Member, New to Food and Drug Law Planning Committee, Food and Drug Law Institute (2018-2020)