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FOCUS ON

Life Sciences Issues

Navigating a Constantly Changing Life Sciences Landscape

For life sciences companies that develop new technologies and treatments to improve lives, success hinges on far more than following the letter of the law. At Epstein Becker Green, we translate legal advice into practical action. Our team of lawyers and non-lawyer consultants and advisors offers real-world experience from careers in all corners of the life sciences industry.

Support every step of the way

We understand the unique legal, regulatory, compliance, operations, and technology challenges facing life sciences companies. Because of our breadth of experience, innovative strategic thinking, and sound judgment, we can successfully meet the needs of our life sciences clients, from early pre-clinical research to commercialization and product launch through commercial operations, providing support for compliance with legal requirements over the entire product life cycle.

A trusted advisor to your company

We are trusted as transactional, regulatory, and compliance counsel—from day-to-day advice to core "bet the ranch" decisions. Our clients, which range from startups to established companies (as well as investors), are often on the leading edge of new technologies, and they count on us to guide them in areas where the regulatory picture remains unclear. We help them understand not just the law, but also its practical implications, so they can adopt workable approaches to their legal, regulatory, and business issues.

Immersed in your corporate transactions

Investors, as well as life sciences companies, turn to us to help them evaluate targets for mergers, acquisitions, sales, joint ventures, and strategic affiliations, and to successfully structure and close their deals. Using our in-depth knowledge of the life sciences industry, and the laws and regulations that apply to it, we are able to easily spot and resolve potential challenges that can arise during these transactions.

Advocates for your interests in disputes

When enforcement actions or lawsuits arise, our litigation attorneys, including some with high-level governmental prosecutorial backgrounds, work hard to protect our life sciences clients' interests and reputations and to preserve their assets. Clients look to us to represent and defend them in federal and state trial and appellate courts and before administrative agencies in civil and criminal cases.

Service areas

- Academic and Clinical Research
- Artificial Intelligence
- Corporate Compliance Program Development, Implementation, and Effectiveness
- Digital Health
- Drug and Medical Device Coding, Coverage, and Payment
- Drug and Medical Device Distribution
- Drug Pricing Policy & Reporting
- FDA Inspections and Enforcement
- Federal and State False Claims Act (Including Qui Tam)
- Federal Research Grants: Compliance, Investigations & Enforcement
- General Counsel Services
- Health Care and Life Sciences Investigations and Enforcement
- Health Care and Life Sciences Investor Services
- Health Care Mergers and Acquisitions
- Health Policy and Legislation
- Industry Research and Clinical Trials
- Life Sciences Due Diligence
- Mergers, Acquisitions & Divestitures
- Product Marketing and Compliance
- Regulatory Strategy, Product Development, and Product Approvals

Strategies that help life sciences companies achieve their goals

Due diligence review ensures smooth acquisition

Conducted health regulatory due diligence of a distributor of infusion equipment in connection with its acquisition by a private equity investor. We advised the client on the health regulatory aspects of the transaction and helped it comply with regulatory authority notice and licensure obligations.

Product marketing and compliance objectives accomplished

Assisted a large medical device manufacturer in developing and successfully implementing a comprehensive system of Good Promotional Practices that achieved both the manufacturer's compliance and marketing objectives.

Remediation efforts satisfy FDA regulators

Helped a global biotechnology company respond to multiple Food and Drug Administration (FDA) inspections that resulted in Forms 483 with dozens of observations. After extensive remediation and communication with the FDA, the agency was satisfied with the company's remediation efforts and declined to pursue enforcement action.

Post-transaction enhancements support integration

Supported the post-transaction integration efforts of a contract research organization (CRO). We developed enhancements to the CRO's customer and vendor contracting practices and templates for use by its U.S. and global affiliates.

Advice helps manufacturer launch therapy product

Advised a development-stage pharmaceutical manufacturer launching a novel cellular therapy in coordination with its global pharmaceutical manufacturer commercialization partner. We provided health regulatory counsel for negotiations with U.S. and global research services providers and guided the expansion of the company's commercial operations.

Continuing support for laboratory's innovations

Provided health regulatory counsel and compliance support to a molecular diagnostic laboratory with a proprietary next-generation sequencing platform enabling molecular profiling of cancer patients' tumor tissue.

DIAGNOSING HEALTH CARE®

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Provides cutting-edge commentary on legal issues affecting health care and life sciences organizations

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An affiliated consultancy:

EBG advisors

A national business strategy and management advisor

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The Legal 500 United States

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