

# FDA and Life Sciences

Regulation has posed increased challenges for the life sciences industry. The emerging role of artificial intelligence and the ongoing change in political landscape continue to create uncertainty in the industry. Our highly regarded FDA and Life Sciences team strategically guides life sciences companies through the entire scope of the evolving framework of FDA and CMS. We assist our clients on the entire spectrum of FDA-regulated products, including pharmaceuticals, biotech, devices, food, supplements, cosmetics, and tobacco, through all aspects of U.S. and EU regulatory compliance challenges. We draw from decades of industry experience to work through every issue at every stage of a product's life cycle. Manufacturers, investors, and other regulated entities value our practical advice and relationships with U.S. state, federal and EU regulatory bodies. The team's 40+ lawyers and consultants have held senior positions in government, industry, academia and the medical profession. Through benchmarking from over 350 industry clients, our annual marquee conferences, and cutting-edge webinars and client alerts, our attorneys share and analyze key developments and practical insights on the most relevant and novel issues in the life sciences space.

Our regulatory attorneys draw on decades of experience to successfully guide clients through:

- Clinical trial matters, such as IDE and IND submissions and BIMO inspections
- FDA approval process and premarket clearance
- Government price reporting obligations and associated economic implications
- Reimbursement -- coverage, coding and payment

## Capability Lawyers



Jeffrey K. Shapiro  
*Washington, D.C.*



Keri Borders  
*Los Angeles*



Geneviève Michaux  
*Brussels*



Lisa M. Dwyer  
*Washington, D.C.*



Nikki Reeves  
*Washington, D.C.*



Jessica Ringel  
*Washington, D.C.*

## Recognition

Ranked Tier 1 for FDA:  
Medical Device

LMG LIFE SCIENCES 2024

Ranked Tier 1 for FDA:  
Pharmaceutical

LMG LIFE SCIENCES 2024

2024 FDA Litigation &  
Enforcement Firm of the  
Year

- FDA requirements and policies applicable to pharma, device, cosmetic, and food labeling and promotion
- FDA inspections, Warning Letters, and administrative litigation (appeals of adverse FDA decisions)
- FDA administrative, civil, and criminal enforcement actions
- Investigations and all related interactions with FDA, CMS, OIG, and DOJ

We are distinguished not only by our outstanding attorneys, but also by our industry consultants, including physicians and former senior FDA officials focused on quality and safety, good manufacturing practices, inspections and product approvals. Our consultants work under privileged legal supervision to provide companies with integrated medical and technical assessments and recommendations.

Our team in the EU focuses on EU and national (French, Belgian and German) issues associated with the legal requirements of the pharmaceutical, biologic, medical device, cosmetic and food industries. They advise life sciences clients on successful strategies for addressing significant EU policy developments and the EU regulatory regimes. The EU team represents our clients in litigation cases before German and European courts, including the General Court and the Court of Justice of the European Union, and in investigations.

#### Cases & Deals

*March 31, 2025*

King & Spalding Secures Victory for The American Clinical Laboratory Association Challenging a Final Rule Issued by the FDA

*July 20, 2016*

King & Spalding Advises Jounce Therapeutics on Deal Worth Up to \$2.5 Billion

*March 24, 2016*

King & Spalding Represents GSK on Strategic Collaboration with Miltenyi Biotec

[VIEW ALL](#)

- Fraud and abuse compliance, including the FCA, AKS, FCPA, AdvaMed and PhRMA codes, and physician consultant arrangements, **2024 Impact Case of the Year**

LMG LIFE SCIENCES

- Federal Physician Payments Sunshine Act and similar state ranked Tier 2 for Life Sciences Industry

LEGAL 500 2024

- Due diligence evaluations on behalf of life sciences companies, private equity funds, and venture capital firms **Ranked Band 1 for Food & Beverages: Regulatory & Litigation**

- Complex food regulatory matters and food false advertising litigation **CHAMBERS USA 2024**

**Ranked Band 2 Nationwide for Life Sciences: Regulatory/Compliance**

CHAMBERS USA 2024

**Ranked Band 1 Product Liability & Mass Torts: The Elite**

CHAMBERS USA 2024

**Ranked Tier 1 (USA Nationwide and DC) for FDA Law**

BEST LAW FIRMS 2024

LMG Life Sciences named 19 K&S lawyers as "Life Sciences Starts" in the 2024 edition

Four-time winner of Life Sciences Practice Group of the Year

LAW360

Practice Group of the Year' for the Life Sciences Practice

LAW360, 2016-2019

## Insights

### CLIENT ALERT

*May 12, 2026*

FDA's New Oversight Tool: One-Day Inspectional Assessments

### NEWSLETTER

*May 4, 2026*

Health Headlines – May 4, 2026

### NEWSLETTER

*April 20, 2026*

Health Headlines – April 20, 2026

### [VIEW ALL](#)

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## Events

### SPEAKING ENGAGEMENT

*June 1, 2026*

Brian Bohnenkamp to Speak at Seton Hall Law's U.S. Healthcare Compliance Certificate Program

### WEBINAR

*May 14, 2026*

A Review of the FY 2027 IPPS and LTCH PPS Proposed Rule: Highlights and What to Expect

### WEBINAR

*May 12, 2026*

Food & Beverage: Ultra-Processed Foods

### [VIEW ALL](#)

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## News

### IN THE NEWS

*May 4, 2026*

David Farber discusses how policy is reshaping the future of health

### IN THE NEWS

*April 22, 2026*

David Farber, a member of the Coalition of Independent Dispute Resolution Entities, discusses how the arbitration process established by the No Surprises Act is affecting those who serve as arbitrators

### IN THE NEWS

*March 19, 2026*

Liv Kiser represents Dave's Killer Bread in a class action settlement regarding a mislabeling dispute

### [VIEW ALL](#)

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