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 commercial and strategic 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
- Fraud and abuse compliance, including the FCA, AKS, FCPA, AdvaMed and PhRMA codes, and physician consultant arrangements,
- Federal Physician Payments Sunshine Act and similar state transparency laws
- Due diligence evaluations on behalf of life sciences companies, private equity funds, and venture capital firms
- Complex food regulatory matters and food false advertising litigation

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

LMG LIFE SCIENCES

2024 Impact Case of the Year

LMG LIFE SCIENCES

Ranked Tier 2 for Life Sciences Industry

LEGAL 500 2024

Ranked Band 1 for Food & Beverages: Regulatory & 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

ARTICLE
December 9, 2025
The Legal 500 Country Comparative Guides: United States Pharmaceutical Advertising

NEWSLETTER
November 24, 2025
Health Headlines – November 24, 2025

ARTICLE
November 20, 2025
FDA Leaders Propose New “Plausible Mechanism Pathway” for Development and Approval of Drugs and Biologics

VIEW ALL

Events

WEBINAR
December 18, 2025
Drug Compounding Litigation Review: Cases by Drug Compounders vs. FDA and Private Enforcement Cases

WEBINAR
December 17, 2025
What Healthcare Providers That Sponsor ERISA Plans Need To Know for 2026

SPEAKING ENGAGEMENT
December 8, 2025
Ulf Grundmann to Speak at Frankfurt School of Finance and Management’s International Healthcare Management MBA program

VIEW ALL

News

IN THE NEWS
December 2, 2025
Lauren Roth comments on the Food and Drug Administration’s uptick of pilot programs launched this year

RECOGNITION
November 18, 2025
King & Spalding’s German Banking & Finance Team and Partner Ulf Grundmann Named as Finalists for 2026 Legal 500 Germany Awards

IN THE NEWS
November 4, 2025
David Farber explains why the expansion of telehealth has driven the increase in compounding in recent years

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