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

November 17, 2022
King & Spalding represents Novartis on landmark ECJ pharma packaging victory

June 22, 2022
Cathay Capital Private Equity and 3i Enter into an Agreement to Sell Havea Group to BC Partners

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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

NEWSLETTER
April 22, 2025
Health Headlines – April 21, 2025

NEWSLETTER
April 14, 2025
Health Headlines – April 14, 2025

CLIENT ALERT
FDA's LDT Rule Struck Down by Court: FDA Has Lost the Battle, But Is the War Over?

VIEW ALL

Events

CONFERENCE
May 1, 2025
Annual California Life Sciences Summit

WEBINAR
April 29, 2025
FCA Enforcement and Litigation: How Recent Decisions and Policy Announcements Signal Key Changes

WEBINAR
April 10, 2025
Combination, Personalized, and Advanced Therapy Medicinal Products

VIEW ALL

News

IN THE NEWS
April 11, 2025
Jeff Bucholtz counsels Zyla Life Sciences before the Fifth Circuit, which revived the company's lawsuit seeking to block Wells Pharma from selling rheumatoid arthritis drug suppositories that are not FDA-approved

IN THE NEWS
April 10, 2025
Preeya Noronha Pinto comments on Medicare payments for skin substitutes and the industry's successful effort to delay changes to the policy

IN THE NEWS
April 7, 2025
Data, privacy and security partner Charly Helleputte joins the firm's Government Matters and Regulation practice group in Brussels

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