

# FDA and Life Sciences

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Regulation has posed increased challenges for the life sciences industry. Companies now face a changing political landscape. Our FDA and Life Sciences team guides companies regulated by the FDA, including in pharmaceuticals, biotech, devices, food, supplements, cosmetics, and tobacco, through all aspects of U.S. and EU regulatory compliance challenges. We draw on years 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 300 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 issues in the life sciences space.

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, including for FDA interfaces, meetings and submissions; system audits and mock inspections; and crisis management.

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

## Capability Lawyers



Mark S. Brown  
*Washington, D.C.*



Seth H. Lundy  
*Washington, D.C.*



Ulf H. Grundmann  
*Frankfurt*



Elaine H. Tseng  
*San Francisco*

## Recognition

Named "Law Firm of the Year" for FDA Law

U.S. NEWS & WORLD  
REPORT

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Named 'Practice Group of the Year' for the Life Sciences Practice

LAW360, 2016-2019

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Ranked Tier 1 (National and in DC) for FDA Law

U.S. NEWS AND WORLD  
REPORT

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LMG Life Sciences named 20 K&S lawyers as "Life

cases before German and European courts, including the General Court and the Court of Justice of the European Union, and in investigations.

### Cases & Deals

*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

King & Spalding Advises Insulin-Related Digital Health Apps/Software Company

[VIEW ALL](#)

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### Insights

#### CLIENT ALERT

*April 30, 2024*

LDT Final Rule: Shifting the LDT Battlefield

#### NEWSLETTER

*April 29, 2024*

Health Headlines – April 29, 2024

#### CLIENT ALERT

*April 25, 2024*

FDA Updates Draft Guidance on Promotional Labeling and Advertising Considerations for Biological Reference Products and Biosimilars

[VIEW ALL](#)

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### Events

#### CONFERENCE

*May 15, 2024*

Annual King & Spalding California Life Sciences Summit

#### WEBINAR

*March 29, 2024*

The Machines Are Coming (And Lawsuits Too): Mitigating Risks of Product Design, Manufacture, and Sale Amidst the AI Revolution

#### SPEAKING ENGAGEMENT

*March 15, 2024*

Ulf Grundmann to Speak at 27th Marburg Discussions

[VIEW ALL](#)

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### News

#### IN THE NEWS

*April 15, 2024*

Dale Giali and Keri Borders represent Nestle in a false ad

Sciences Stars” in the 2019 edition

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K&S Frankfurt team recognized in pharmaceuticals, medical products & food law

JUVE HANDBOOK

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Food practice ranked as one of the leading practices in the nation

CHAMBERS USA

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Ranked as one of the leading firms in Pharmaceutical and Medical Products Regulatory

CHAMBERS USA

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Named Medical Device "Firm of the Year"

LMG LIFE SCIENCES

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Selected as a leading firm in the nation in the Life Sciences industry

LEGAL 500

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Tier 1 for Product Liability, Mass Tort and Class Actions: Defense – Pharmaceuticals and Medical Devices

LEGAL 500, 2020-2021, 2023

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case before a California federal court

### IN THE NEWS

*April 8, 2024*

Ashley Parrish, John Shakow and Nicole Bronnimann counsel AbbVie before a Louisiana federal court in a dispute involving the federal 340B drug discount program

### IN THE NEWS

*April 8, 2024*

Lisa Dwyer comments on the FDA's drug center gearing up to issue guidance on use of artificial intelligence to enhance its regulatory decision-making

[VIEW ALL](#)

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