KING & SPALDING

FDA and Life Sciences

Our FDA and Life Sciences team guides companies through all aspects of U.S. and EU regulatory compliance challenges. We 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 regulators (including FDA; CMS; U.S. Congress; DOJ; U.S. Attorney's Offices; DEA; OCR; VA; State Boards of Pharmacy; State Attorneys General; the European Commission; Notified Bodies in the European Union; the European Medicines Agency; the European Food Safety Authority; and the European National Competent Authorities). The team's 50+ lawyers and consultants have held senior positions in government, industry, academia and the medical profession. Through benchmarking from our over 250 industry clients, our annual Medical Device Summit and Pharmaceutical University, 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.

Regulation has posed increased challenges for the life sciences industry. Companies now face a changing political landscape. Our dedicated team is ready to assist with client-focused advice based on years of industry experience.

We work with companies regulated by the FDA, including in pharmaceuticals, biotech, devices, food, supplements, cosmetics and tobacco. We address every type of legal issue touched by federal, state or EU regulation for every type of company, from seeding start-ups, to mergers and acquisitions, to IPOs, to product approvals, to pricing and coverage, to inspections, to investigations, to lobbying agencies and legislatures.

We are distinguished by our outstanding attorneys, but also by our industry specialist consultants, including physicians and former senior FDA officials focused on quality and

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

Named 'Practice Group of the Year' for the Life Sciences Practice
LAW360, 2016-2018

Ranked Tier 1 (National and in DC) for FDA Law
U.S. NEWS AND WORLD REPORT

LMG Life Sciences named 22 K&S lawyers as "Life Sciences Stars" in the 2017

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.

Cases & Deals

July 30, 2019
American Clinical Laboratory Association (ACLA) Wins Jurisdictional Decision in D.C. Circuit Court

August 16, 2018
King & Spalding Advises Cancer Prevention Pharmaceuticals on $185 Million Licensing Deal With Mallinckrodt

June 4, 2018
Linden Capital Partners acquires leading direct-to-patient DME supplier

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Insights

NEWSLETTER
September 16, 2019
Health Headlines – September 16, 2019

NEWSLETTER
September 9, 2019
Health Headlines – September 9, 2019

NEWSLETTER
September 3, 2019
Health Headlines – September 3, 2019

VIEW ALL

Events

SPEAKING ENGAGEMENT
November 14, 2018
Ulf Grundmann to Speak at CBI/UBM's Global Compliance Congress for Life Sciences

CONFERENCE
November 12, 2019
12th Annual King & Spalding Pharmaceutical University

SPEAKING ENGAGEMENT
November 6, 2019
John Richter, Richard Walker, Nikki Reeves to Speak at 20th Annual Pharmaceutical and Medical Device Compliance Congress

edition

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

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

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

Named Medical Device "Firm of the Year"
LMG LIFE SCIENCES

Selected as a leading firm in the nation in the Life Sciences industry
LEGAL 500

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News

IN THE NEWS

August 13, 2019

Lisa Dwyer comments on the current regulatory environment for CBD

IN THE NEWS

August 8, 2019

Seth Lundy discusses Medicare's proposal to add three new payment-reporting categories for device and drugmakers

IN THE NEWS

August 6, 2019

Ashley Parrish, Jeff Telep, Lisa Dwyer and Jesse Snyder are counsel to Amarin Pharma on a new U.S. Supreme Court petition

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