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 40+ 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 West Coast Pharmaceutical and Medical Device University, 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

**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, 2016-2019
- Ranked Tier 1 (National and in DC) for FDA Law  
  U.S. NEWS AND WORLD REPORT
- LMG Life Sciences named 20 K&S lawyers as “Life Sciences Stars” in the 2019
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 cases before German and European courts, including the General Court and the Court of Justice of the European Union, and in investigations.

Cases & Deals

**June 1, 2020**
Alexion Pharmaceuticals Secures Favorable Resolution and Termination of Challenge to SOLIRIS® Patents

**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

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Insights

**CLIENT ALERT**
**October 26, 2020**
France - Trial Period for Medical Use of Cannabis-Based Products

**NEWSLETTER**
**October 19, 2020**
Health Headlines – October 19, 2020

**CLIENT ALERT**
**October 6, 2020**
FDA Announces Updates to Two Guidance Documents Concerning Breast Implant Safety and Transparency

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Events
SPEAKING ENGAGEMENT
November 12, 2020
Ulf Grundmann to Speak at Association of the German Confectionery Industry Event

WEBINAR
November 10, 2020
Challenging Payers’ New Specialty Pharmacy Policies That Reduce Payment to Hospitals

WEBINAR
November 10, 2020
13th Annual King & Spalding Medical Device Summit

News
PRESS RELEASE
October 26, 2020
Former Acting Assistant Attorney General Ethan Davis Returns to King & Spalding

IN THE NEWS
October 13, 2020
Law360 profiles 2020 Compliance MVP Nikki Reeves

RECOGNITION
Law360 Recognizes Jim Boswell and Nikki Reeves as 2020 MVPs