

Pharmaceuticals and Biotechnology Regulatory

Drug companies face pressure from many directions – a foreboding regulatory landscape, competitors with alternative brands or generics, and pushback from insurers.

At the same time, they can find opportunities in maximizing the benefits of statutes that encourage new drug development. Whether you're a global pharmaceuticals company or a biotechnology startup, accomplishing business goals in such a highly regulated industry requires practical, integrated legal analysis and advice.

We are creative in solving your problems thanks to our background and experience. We not only know the law, we know the nuances of the law because many of our lawyers have worked in the U.S. Food and Drug Administration. Others have worked in industry, which means we also understand your business, the science behind your business, and your marketplace. And to provide integrated advice across jurisdictions, our pharma/biotech lawyers in Europe, Asia, and Latin America collaborate closely with our U.S. team, which is the largest in the nation dedicated to providing regulatory legal services to the industry.

Our services are as varied as the challenges you face. We offer timely, effective counsel on matters that include product development, approval, post-approval compliance, and the development of next-generation products. Our lawyers concentrate on particular areas of the law, such as advertising, manufacturing compliance, regulatory exclusivities, and

Key contacts

Philip Katz,
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London

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Amsterdam

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Trending Topics

The liability implications of
new health care
technologies

Patent law in Europe

What pharmaceutical
companies need to know

Areas of focus

Cell, Tissue, and Gene
Therapies

Clinical Trials

controlled substances. And when your issues overlap with other disciplines, such as intellectual property, litigation, or health care compliance, we reach across the firm to tap into the needed expertise, especially in our strong health practice.

Representative experience

Instrumental in persuading FDA to change longstanding regulatory position on awarding exclusivity to fixed-dose combination products, benefiting Gilead's products in HIV and Hepatitis C fields.

Convinced FDA to give 5-year exclusivity to fixed dose combination products that include a new chemical entity and a previously approved active ingredient.

Successfully sued FDA to overturn denial of orphan drug exclusivity.

Help respond to FDA Form 483 observations, warning letter to close out FDA investigation.

Negotiate settlement of FDA lawsuit alleging cGMP noncompliance.

Conduct internal investigation of promotional practices and help develop and implement enhanced practices.

Audit clinical trial study reports to ensure compliance with adverse event reporting obligations.

Advise on FDA/DEA interplay during drug development and approval process, scheduling under CSA.

Conduct due diligence of FDA and EU regulatory law for IPO.

Advising a research-based pharmaceutical company with respect to a government demand for price reductions under its federal contracts with the U.S. DVA.

Advising private equity firm on FDA regulatory aspects of potential investments.

Awards and rankings

Controlled Substances and DEA

Transaction and Securities Disclosure Support and Due Diligence

OTC Drugs and Cosmetics

Product Approvals and Dispute Resolution

Regulatory Exclusivities, Hatch-Waxman, and Similar Statutes

Regulatory Inspections and cGMP

Related industries

Life Sciences and Health Care

- Band 1 for Healthcare: Pharmaceutical/Medical Products Regulatory in the District of Columbia, *Chambers USA*, 2020
- Band 1 in Brussels in EU Regulatory for Pharmaceuticals and Biotechnology, *Legal 500 EMEA*, 2020
- Band 1 in Life Sciences, *Chambers Global*, 2020
- Band 2 in France for Pharma/Life Sciences, *Chambers Europe-wide*, 2020
- Band 2 for Regulatory: Life Sciences/Pharma, *Chambers Europe-wide*, 2020
- Regulatory Firm of the Year, *LMG Life Sciences*, 2019
- Tier 1 for TMT: Pharmaceutical & Biotechnology, *Legal 500 UK*, 2019
- Best Pharmaceutical Law Firm of the Year, *TopLegal Industry Award – Italy*, 2018
- Law Firm of the Year for Pharmaceutical Law, *Best Lawyers Germany*, 2018

Latest thinking and events

Awards and Rankings

LMG Life Sciences recognizes Hogan Lovells as Regulatory Firm of the Year for third year in a row 2020

Insights

UK regulation of medical devices from 1 January 2021

News

FDA advises drug manufacturers on best practices for restarting operations during COVID-19 pandemic

News

The EFPIA's response to the EMRN's strategy to 2025 focuses on real world evidence

News

China's NMPA releases proposal for modified "Hatch Waxman" following patent law reform

News

COVID-19 Report for Life Sciences and Health Care Companies (21 - 24 September 2020)

