Hogan Lovells

Pharmaceuticals and Biotechnology Regulatory

Drug companies face pressure from many directions a foreboding regulatory landscape, competitors with alternative brands or generics and push back 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,
Washington, D.C.

Hein Van den Bos,
Amsterdam

Ernesto Algaba Reyes,
Mexico City

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 DEA

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

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.

Wrote successful petition seeking denial of "A" rating to purported generic products.

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.

Develop SOPs for compliant promotional activities.

Develop and negotiate with FDA over the elements of a REMS.

Represent reference product sponsor in shared REMS negotiations with generics.

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

Counsel client on labeling changes proposed in response to emerging safety signals.

Help develop product approval strategy.

Help draft FDA meeting requests, briefing packages.

Advise client on standards for interchangeability of biosimilars.

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

Due Diligence and Transaction and Securities Disclosure Counsel

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

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

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

Awards and rankings

- Band 1 for Healthcare: Pharmaceutical/Medical Products Regulatory in the District of Columbia, *Chambers USA*, 2018 - 2020
- Band 1 in Brussels in EU Regulatory for Pharmaceuticals and Biotechnology, *The Legal 500 EMEA*, 2018 - 2020
- Band 1 in Life Sciences, *Chambers Global*, 2018 - 2020
- Band 1 for Life Sciences Europe-wide, *Chambers Europe*, 2018 - 2020
- Band 2 for Pharma/Life Sciences, *Chambers France*, 2020
- Band 2 for Life Sciences Nationwide, *Chambers UK*, 2018 - 2019
- 41 individual recommendations in life sciences, *Who's Who Legal: Life Sciences*, 2019
- Regulatory Firm of the Year, *LMG Life Sciences*, 2018 & 2019
- Pharma, Medical Devices Law & Transactions, *JUVE Handbook Germany*, 2019
- Highly Recommended for FDA Pharmaceuticals, *LMG Life Sciences*, 2017 - 2019

Latest thinking and events

News

COVID-19 Report for Life Sciences and Health Care Companies

News

HHS now requires public posting of a decade of clinical trial results that were previously exempted

Awards and Rankings

Global law firm Hogan Lovells is pleased to announce the firm has been shortlisted in 11 categories for the eighth Annual LMG Life Sciences Americas Awards 2020

News

Buy American EO applies domestic preferences for "essential medicines" and "medical countermeasures"

News

COVID-19 Report for Life Sciences and Health Care Companies (3 - 7 August 2020)

Hogan Lovells Publications

Podcast: Talking the cure