Hogan Lovells

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

Key contacts

Philip Katz,
Washington, D.C.

Jane Summerfield,
London

Hein Van den Bos,
Amsterdam

Ernesto Algaba Reyes,
Mexico City

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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

Combination Products

Controlled Substances and DEA

products. Our lawyers concentrate on particular areas of the law, such as advertising, manufacturing compliance, regulatory exclusivities, and 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 exclusively 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.

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

Hospitals and Health Care Providers

Licensing and Commercial Transactions

Related industries

Life Sciences and Health Care

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

Awards and rankings

- Tier 1 in Germany in Healthcare and Life Sciences: Drug Advertising Law, *Legal 500 EMEA*, 2022
- Tier 1 in Brussels in EU Regulatory for Pharma, Device and Biotech, *Legal 500 EMEA*, 2022
- Band 1 in Life Sciences, *Chambers Global*, 2020 - 2022
- Band 1 for Healthcare: Pharmaceutical/Medical Products Regulatory in the District of Columbia, *Chambers USA*, 2020 - 2021
- Band 1 in Brussels in EU Regulatory for Pharmaceuticals and Biotechnology, *Legal 500 EMEA*, 2020 - 2021
- Band 2 in France for Pharma/Life Sciences, *Chambers Europe-wide*, 2020 - 2021
- 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

News

CMS issues initial guidance on Drug Price Negotiation Program

News

Agreement reached on new maritime biodiversity treaty

News

The False Claims Act Guide: 2022 and the road ahead

News

After the Public Health Emergency: Implications for Medicare and U.S federal health care policies

Webinar

APAC Life Sciences and Health Care Webinar Series - Spotlight on Greater China - Session 5

News

HHS OCR creates new HIPAA enforcement arm and enhances focus on cybersecurity and privacy oversight