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

Lynn Mehler,
Washington, D.C.

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
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.
Advising 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*, 2020 - 2023
- Band 1 for Life Sciences: Regulatory/Compliance, *Chamber USA*, 2023
- Tier 1 in Germany in Healthcare and Life Sciences: Drug Advertising Law, *Legal 500 EMEA*, 2023
- Tier 1 in Belgium in EU Regulatory: Pharma, Medical Devices and Biotech, *Legal 500 EMEA*, 2023
- Band 1 in Life Sciences, *Chambers Global*, 2020 - 2023

Latest thinking and events

News
Podcast: Talking the cure

Insights and Analysis
The Japan-India Investment Corridor: Trends, challenges, and practical solutions

Sponsorships and Speaking Engagements
FDLI Introduction to Drug Law and Regulation

News
OIG’s first-ever General Compliance Program Guidance covering all health care parties released

News
FTC challenges around 100 FDA Orange Book patent listings

News
The Genesis case: The beginning of the end of HRSA’s “patient” definition?