Hogan Lovells

Philip Katz

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Biography

Philip Katz helps pharma/biotech companies successfully navigate FDA and related regulatory matters. He counsels them on compliance; helps anticipate and address regulatory issues in their day-to-day business operations and strategic planning; and advocates for them before the FDA, other agencies, and in court. His clients develop, manufacture, and distribute drugs and biologics, spanning from large public companies with extensive product portfolios to start-ups trying to bring their first product to market.

Phil heads the firm's Pharma/Biotech practice group, which has 25+ lawyers – many with years of experience at the FDA – who work collegially and in collaboration with our clients to help them achieve their business goals in a highly regulated environment in which good long-term relations with the FDA are essential. The excellence of the group is reflected in its *Chambers* ranking as a Band 1 D.C. Pharmaceutical/Medical Products Regulatory practice.

Phil and his team bring together a detailed and nuanced knowledge of the law and FDA precedents, an informed understanding of the client's business goals, and an experienced appreciation of the public policy implications to craft thoughtful, creative, and practical solutions. He and his team focus particularly on product development, approval, and lifecycle

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Product Approvals and Dispute Resolution

Regulatory Exclusivities, Hatch-Waxman, and Similar Statutes

Hogan Lovells China Desk

Cell, Tissue, and Gene Therapies

management; responding to agency enforcement activities; and counseling on business transactions. He has deep knowledge of the Hatch-Waxman Act, Orphan Drug Act, and Biosimilars Price Competition and Innovation Act.

Phil recently served as Chairman of the board of directors of the Food and Drug Law Institute (FDLI), which capped years of activity at the institute. As a result of his dedicated work, he received the FDLI Distinguished Service and Leadership Award. Phil's leading role in the food and drug bar is reflected in his many recognitions, including *Legal 500*, *Best Lawyers in America*, *Who's Who Legal*, *LMG Life Sciences* "Regulatory Star," and *Chambers*.

Representative experience

Represented Depomed at FDA and in court to obtain orphan exclusivity for Gralise.

Represented senior executive in negotiating and operating under FDA consent decree and subsequent DOJ investigation.

Authored successful FDA petition ensuring patent certification and opportunity for litigation and 30-month stay with competitor's 505(b)(2) NDA.

Successfully advocated to FDA Exclusivity Board for favorable decision on scope of 3-year exclusivity.

Worked with senior management to help a company develop and implement an NDA resubmission strategy after a Complete Response Letter.

Represented reference listed drug sponsor in negotiating shared REMS with generic competitor and advocating at FDA on related issues.

Represented overseas manufacturer in responding to Form FDA 483 inspectional observations and subsequent Import Alert.

Education and admissions

Education

J.D., Georgetown University Law Center, magna cum laude, Order of the Coif, 1992

B.A., University of Virginia, with distinction, 1981

Bar admissions and qualifications

District of Columbia

Court admissions

U.S. Supreme Court

U.S. District Court, District of Columbia

Advised company with FDA strategy for approval of first product, responded to competitor petitions, and interacted with underwriters in IPO.

Awards and rankings

- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), *Chambers USA*, 2016-2019
- FDA Law, *Best Lawyers in America*, 2015-2019
- Healthcare: Life Sciences, *Legal 500 US*, 2013-2015, 2017-2019
- Regulatory Star, *LMG Life Sciences*, 2014
- Regulatory, *PLC Life Sciences Cross-border Handbook*, 2011-2012
- USA – Life Sciences: Regulatory, Recommended, *PLC Which Lawyer?*, 2009

Latest thinking and events

- News
  - FDA eases some postmarket adverse event reporting deadlines during COVID-19 pandemic
- News
  - COVID-19: Daily Report for Life Sciences and Health Care Companies
- News
  - COVID-19: Daily Report for Life Sciences and Health Care Companies
- Hogan Lovells Publications
  - Talking the Cure: Discussing how the coronavirus pandemic is affecting the pharmaceutical industry and FDA *Life Sciences and Health Care Podcast*
- Hogan Lovells Publications
  - Podcast: Talking the cure
- Insights
  - "Misleading" to suggest a biosimilar is inferior, FDA

draft guidance warns