Hogan Lovells

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Biography

As counsel in our FDA Pharmaceuticals and Biotechnology group, Komal Karnik Nigam uses her background in public health and scientific research to understand the business and policy aspects of complex legal and scientific issues in the pharmaceutical industry.

Her practice includes a broad range of regulatory matters, including assisting pharmaceutical clients with lifecycle management and product development issues, regulatory due diligence for drug company mergers and acquisitions, and responses to FDA enforcement actions and related government investigations. She routinely advises pharmaceutical companies on advertising and promotion issues and has served on multiple promotional review committees. In her pro bono practice, she has successfully represented clients in asylum and special immigrant juvenile status cases.

Komal received her J.D., M.P.H. through the joint-degree program at Harvard Law School and the Harvard T.H. Chan School of Public Health. Komal previously worked as a research assistant in a molecular biology laboratory at the University of Virginia, where she learned how to parse abstract scientific language and communicate it to others. She has also worked in advocacy positions at nonprofit public interest and public health organizations in Waltham, Massachusetts and in Washington, D.C.

Representative experience

Languages

English
Hindi
Spanish

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Pharmaceuticals and Biotechnology

Education and admissions

Counsel numerous pharmaceutical companies on pre-launch and post-marketing Commercial and Medical Affairs activities, including extensive experience on promotional review committees.

Citizen petition regarding issues raised by an Abbreviated New Drug Application for a generic topical product that differed from the reference product.

Assist multiple pharmaceutical companies in responding to FDA enforcement letters, Form FDA 483 inspectional observations, and related government investigations.

Represent multiple pharmaceutical companies in formal dispute resolution before FDA regarding issues arising from stalled clinical trial programs

Successfully advocate for small business waiver of Prescription Drug User Fee Act fees for biotechnology company with external shareholders and venture capital funding

Latest thinking and events

- News
  - FDA signals potential shift toward interchangeability for all biosimilars
- News
  - Podcast: Talking the cure
- News
  - FDA explains "confirmatory evidence" for sponsors seeking approval based on a single clinical trial
- Press releases
  - Hogan Lovells welcomes the New Year with 38 new partner and 77 new counsel promotions
- News
  - Eleventh Circuit decision could significantly expand scope of orphan exclusivity
- News
  - FDA finalizes guidance on Orphan Drug "sameness" of gene therapies

Education

J.D., Harvard Law School, cum laude, 2014

M.P.H., Harvard School of Public Health, 2014

B.A., University of Virginia, with distinction, 2011

Memberships

South Asian Bar Association

National Asian Pacific American Bar Association

Bar admissions and qualifications

District of Columbia

Virginia

Court admissions

U.S. District Court, Eastern District of Virginia