Hogan Lovells

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Biography

As a senior associate 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

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Pharmaceuticals and Biotechnology

Education and admissions

Education

public health organizations in Waltham, Massachusetts and in Washington, D.C.

Representative experience

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

Citizen petition regarding safety and efficacy concerns raised by an Abbreviated New Drug Application for a generic topical product.

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

Latest thinking and events

- Hogan Lovells Publications
  - FDA and OHRP finalize joint guidance on IRB meeting minutes *Focus on Regulation*
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  - FDA and OHRP Finalize Joint Guidance on IRB Meeting Minutes
- Publications
  - There'll be some changes made: President signs prescription drug and biologic user fee reauthorization act *Pharmaceutical Client Alert*
- Hogan Lovells Publications
  - The New Hatch-Waxman Regulations: A First Look *Pharmaceutical and Biotechnology Alert*
- Blog Post
  - Finally! FDA Announces Highly-Anticipated and Long-Awaited Public Hearing on “Off-Label” Communications
- Hogan Lovells Publications
  - International Product Liability Review - Issue 61

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

Bar admissions and qualifications

District of Columbia

Virginia

Court admissions

U.S. District Court, Eastern District of Virginia