Hogan Lovells

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Biography

Jane Kalinina draws on her interdisciplinary pharmacy and legal experience, bringing a wealth of knowledge to her clients on an array of complex U.S. Food and Drug Administration (FDA) regulatory matters.

Since beginning her legal career, Jane has focused her practice on pharmaceutical and biotechnology product development, biologics license and new drug applications, life cycle management, advertisement and promotional issues, and assisting clients in navigating FDA's intricate regulatory framework. In particular, Jane draws on her scientific background to bring a novel perspective on addressing legal challenges that are heavily intertwined with underlying scientific issues. While attending law school, Jane completed a dual-degree program to receive her Pharm.D. and had previously worked in a research laboratory during her undergraduate studies in microbiology and cell science.

Jane is also part of the firm's Cell, Tissue, and Gene Therapies working group, a cross-disciplinary team that advises companies in this emerging space on the evolving regulatory and business challenges they face. As part of this team, Jane works closely with companies developing stem cells, gene therapies, proteins, and other cellular and tissue products to help people with serious health problems.

Languages

English

Practices

Pharmaceuticals and Biotechnology Regulatory

Marketing and Advertising

Industries

Life Sciences and Health Care

Latest thinking and events

- Hogan Lovells Publications
  - FDA's "Project Facilitate" pilot to collect metrics on sponsor expanded access denials *Focus On Regulation*
- Hogan Lovells Publications
  - FDA's Bendeka decision reverses approvals of Treanda generics *Focus On Regulation*
- Blog Post
  - FDA's Bendeka decision reverses approvals of Treanda generics
- Hogan Lovells Publications
  - FDA pushes "consumer-friendly" presentation of quantitative data in DTC promotions *Pharmaceuticals and Biotechnology Alert*
- Hogan Lovells Publications
  - A new right for American patients: The Right to Try *Pharmaceutical and Biotechnology Alert*
- Blog Post
  - FDA shows that it means business in stopping stem cell clinics that put patients at risk

Areas of focus

Cell, Tissue, and Gene Therapies

Clinical Trials

Education and admissions

Education

J.D., University of Maryland, Francis King Carey School of Law, 2016

Pharm.D., University of Maryland School of Pharmacy, 2016

B.S., University of Florida, 2010

Memberships

Member, American Bar Association

Member, Austern Writing Awards Committee, Food and Drug Law Institute (2018-2019)

Editor in Chief, *Maryland Journal of International Law*, 2016

Bar admissions and qualifications

District of Columbia