Hogan Lovells

Susan S. Lee

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Biography

Prior to practicing law, Susan S. Lee served as both a vice president for economic policy at a Washington, D.C. policy institute and as a consultant and manager at a premier global management consulting firm, where she provided strategic business advice to innovative life sciences and health care companies.

Today, she applies her prior economic and business experience to advise life sciences companies with an approach that is legally rigorous, but also pragmatic and grounded in a solid understanding of each client's business objectives and corporate dynamics.

Susan focuses on the U.S. Food and Drug Administration's (FDA) regulation of drugs and biological products. She addresses legal issues involving advertising and promotion; interactions with health care professionals and payers; and regulatory issues that arise in acquisitions, collaborations, and other types of transactions.

Susan has reviewed promotional and medical information materials in numerous therapeutic areas, served on promotional review committees, and reviewed and drafted policies and procedures. She has also conducted internal investigations and audits, developed and delivered compliance training, and defended companies under government investigation.

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Product Development and Approval

Regulatory Exclusivities, Hatch-Waxman, and Similar Statutes

Pharmaceuticals and Biotechnology

Digital Health

Transaction and Securities

In addition, Susan identifies potential approval pathways for products under development, helps clients prepare for interactions with FDA, and guides clients in emerging areas such as digital health. In her transactional practice, she conducts and supports regulatory due diligence; develops definitions, representations, and warranties for agreements; and advises companies on appropriate regulatory disclosures in U.S. Securities and Exchange Commission (SEC) filings.

Susan graduated from Harvard College summa cum laude, where she studied neurobiology, and from Harvard Law School, where she was a member of the Board of Student Advisers.

Representative experience

Led extensive review and evaluation of promotional materials across 10 promotional review committees of a biotechnology company.

Provided regulatory and transactional support to facilitate a leading information technology company's entry into the life sciences sector.

Secured orphan designation and related tax benefits for a drug that received FDA approval prior to granting of orphan drug designation.

Supported filings and preparations for unprecedented Part 15 hearing on FDA's proposed withdrawal of an indication for a biological product.

Awards and rankings

- Healthcare: Life Sciences, Next Generation Partner, *Legal 500 US*, 2017-2020

Latest thinking and events

- Media Mention
  - Drug promotion during pandemic: Website links to telemedicine prescribers require caution *Pink*

Disclosure Support and Due Diligence

Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., Harvard Law School, 2002

A.B., Harvard College, summa cum laude, 1996

Memberships

Member, Publications Peer Review Committee, Food and Drug Law Institute (2017-2019)

Bar admissions and qualifications

District of Columbia

New York

Sheet

- Announcements
  - Hogan Lovells assists EyePoint Pharmaceuticals on transformative follow-on public offering of common stock
- News
  - 2020 OPDP Wrap-up: FDA monitoring drug manufacturers' use of online communication platforms
- Press Releases
  - Hogan Lovells advises Novartis on Vedere Bio acquisition
- News
  - FDA cracks down on pharmaceutical firm for misbranding drug as COVID-19 treatment
- News
  - FDA proposes clarification in long-running tussle over "intended use" rules for drugs and devices