Hogan Lovells

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Biography

Global clients in the medical device sector call on Suzanne Levy Friedman to help them navigate key legal and business issues. Suzanne's practice focuses primarily on matters related to the U.S. Food and Drug Administration's (FDA) regulation of medical devices.

Suzanne assists device companies in a wide range of activities across the life cycle of their products, including preparing regulatory submissions for clearance or approval of new devices, advising manufacturers on the lawful promotion and advertising of their devices, and addressing postmarket enforcement issues. Suzanne is well-versed regarding FDA's evolving paradigm for software and digital health products, and she has helped clients determine the appropriate regulatory pathway for various products in this space and bring them to market. She also conducts regulatory due diligence in preparation for mergers and acquisitions.

Suzanne frequently works on human tissue and combination products that combine a medical device element with a drug or a biologic. In conjunction, she helps advise clients on regenerative medicine and cell/gene therapies, which often raise questions that touch on multiple areas of FDA regulation.

Suzanne brings significant experience in FDA space to her work at the firm. During law school, she interned for FDA's Office of Chief Counsel, where she learned firsthand about the range of legal and regulatory issues addressed by the agency's Food, Drug, Device,

Languages

English
French
Spanish
Hebrew

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Advertising and Promotion Compliance

Premarket Review

Veterinary, and Tobacco centers. Prior to law school, Suzanne spent two years with a health policy consulting firm in Washington, D.C., advising clients on the business impacts of FDA actions and related legislation. Suzanne also has a master's degree in bioethics.

In law school, Suzanne co-led Penn Law's health law and policy pro bono group, and she remains actively involved in pro bono service at Hogan Lovells.

Representative experience

Advised companies with various types of medical devices on balancing FDA rules for device promotion with business needs in developing their websites and marketing materials.

Drafted legal arguments for premarket clearance of various innovative medical devices.

Conducted comprehensive audit of device and manufacturing process modifications for PMA-approved device and helped client properly notify FDA and obtain approval for same.

Advocated to obtain client's desired outcome to have its wound dressing classified solely as a medical device rather than a combination product.

Helped a woman (political dissident) from the Democratic Republic of Congo obtain asylum in the United States.

Assisted an international client with drafting a PMA for its device and ensuring a successful pre-approval FDA inspection.

Latest thinking and events

- Hogan Lovells Podcasts
  - Podcast: Talking the cure
- News
  - FDA launches list of AI and machine learning-enabled medical devices
- News

Cell, Tissue, and Gene Therapies

In Vitro Diagnostics

Medical Device Artificial Intelligence

Education and admissions

Education

J.D., University of Pennsylvania Law School, 2014

M. Bioethics, University of Pennsylvania School of Medicine, 2014

B.A., Princeton University, cum laude, 2008

Bar admissions and qualifications

District of Columbia

New York

- After a long and winding road, FDA finalizes much-debated “intended use” rule

- News
  - HHS withdraws proposal to exempt 84 medical device types from FDA 510(k) process

- News
  - FDA proposes clarification in long-running tussle over “intended use” rules for drugs and devices

- News
  - FDA proposes clarification in long-running tussle over “intended use” rules for drugs and devices