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/approval of new devices, advising manufacturers on the lawful promotion and advertising of their devices, and evaluating post-market product modifications. 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, and bring to market, various products in this space. She also works with clients on internal investigations into promotional, quality system, or other issues related to compliance with the Federal Food, Drug, and Cosmetic Act.

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 the FDA space to her work at the firm. During law school, she interned for FDA's Office of Chief Counsel. Prior to law school, Suzanne spent two years with a health policy

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

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 device companies 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 internal investigation into whistleblower allegations of violations of several FDC Act requirements around clinical trials, advertising/promotion, and other topics

Advocated before FDA 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 and her green card, and then secure approval for her husband and daughter to join her in the U.S.

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

Served as guardian ad litem to advise the court on the best interests of two children whose parents were in custody disputes in DC Family Cour

Latest thinking and events

- News
  - Podcast: Talking the cure
- Press releases
  - Hogan Lovells advises Xenex in securing FDA De Novo authorization for its UV microbial reduction

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

- robot for use in health care facilities
- News
  - FDA device software premarket submission content guidance re-categorizes documentation requirements
- Hogan Lovells Events
  - AI Health Law & Policy Summit
- News
  - The next era of digital therapeutics
- News
  - FDA promotes pre-approval for changes to AI devices via Predetermined Change Control Plans