Hogan Lovells

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Biography

Janice Hogan has been involved in medical technology for over 25 years. From her engineering training at the Massachusetts Institute of Technology to work in the pharmaceutical industry, to her current practice representing medical device companies before the U.S. Food and Drug Administration (FDA), Janice has focused her career on the intersection of technology, regulation, and health care.

Widely recognized as a leader in FDA regulation of devices, Janice is co-director of the FDA Medical Device practice. She leverages her technical background to help companies with cutting-edge technologies navigate and optimize the FDA approval process.

Janice focuses on FDA regulation of high-tech products in women's health, diagnostics, neurology, cardiovascular, and orthopedics. She has assisted companies to obtain "first-of-a-kind" FDA approvals, providing guidance on regulatory strategy, clinical study design, advisory panel proceedings, and tools to expedite product approval.

Janice brings her lifelong passion for science and innovation to bear in her client advocacy. Through her extensive experience representing companies in a wide range of FDA interactions, Janice has been at the

Languages

English

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Advisory Panel Preparation

forefront of several of the most innovative medical device approvals, including the first successful FDA/Centers for Medicare and Medicaid Services parallel review project, as well as first-in-class approvals for devices used in treatment of breast cancer, diabetes management, obesity, spinal surgery, and neurology, as well as a variety of drug/device combination products. Janice also has substantial experience using newer FDA approval mechanisms such as the de novo process to reduce review time and bring products to market earlier, accelerating patient access.

Awards and rankings

- Healthcare: Life Sciences, *Legal 500 US*, 2014-2015, 2017-2019
- Most Highly Regarded Firm for Life Sciences 2018, *Who's Who Legal*, 2018
- Life Sciences Star, *LMG Life Sciences*, 2018
- Who's Who Legal Life Sciences: Regulatory Lawyers, *Who's Who Legal*, 2008-2018
- Regulatory: Medical Devices, *PLC Life Sciences Cross-border Handbook*, 2011-2012

Latest thinking and events

- News
  - Senate bill proposes laboratory developed tests to be regulated under CLIA process
- Insights
  - Diagnostics regulation reform proposals move forward again with an updated VALID Act
- Insights
  - Variable De Novo review metrics -- Plan ahead
- News
  - Pilot program for 510(k) electronic submissions is requesting participants
- News

Combination Products, FDA
Jurisdictional Issues, FDA
Postmarket Compliance Issues

In Vitro Diagnostics

Medical Devices

Premarket Review

Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., Georgetown University Law Center, magna cum laude, Order of the Coif, 1995

B.S. Mechanical Engineering and Literature, Massachusetts Institute of Technology, 1988

Memberships

Member, American Bar Association

Member, Maryland State Bar Association

Member, National Health Lawyers Association

Bar admissions and qualifications

Pennsylvania

District of Columbia

- FDA's new decision tree for medical device PMAs and De Novos accompanies final uncertainty guidance

- News
  - Final guidance provides additional clarity to the Humanitarian Device Exemption program