Hyman, Phelps & McNamara PC

Jennifer D. Newberger

Director

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MERCK EX1113
Merck Sharp & Dohme LLC v. The Johns Hopkins University
IPR2024-00647

Education

BA, Washington University in St. Louis
MPH, Emory University School of Public Health
JD, University of Miami School of Law, magna cum laude

Admissions

District of Columbia

Practice Areas

Compliance
Due Diligence & Transactions
Enforcement & Litigation
Government Investigations
Internal Investigations
Labeling, Advertising & Promotion
Manufacturing & Quality
Product Development & Authorization

Industries

Manufacturers
Research & Development

FDA Regulatory Categories
Medical Devices

Jennifer Newberger has spent nearly 20 years providing counsel to medical device manufacturers of all sizes, across all product types, throughout the product lifecycle. Her primary objective is to help clients achieve their business objectives while maintaining a strong record of FDA compliance. To this end, Ms. Newberger assists clients in matters including development of regulatory strategy, preparation of regulatory submissions, development and implementation of policies, procedures, and compliance programs, review of advertising and promotional materials, and responding to enforcement matters from FDA or other agencies, including the Department of Justice. She also supports clients in mergers and acquisitions on both the buyer and seller side, conducting FDA-focused regulatory due diligence and advising on applicable contract and transaction matters as well as public filings.

In addition to preparation of pre-submission and submission materials for FDA, Ms. Newberger assists clients in responding to inquiries from FDA during the review process and participating in meetings with clients to address FDA concerns. She also advises clients on post-market compliance matters, including complaint handling, reporting of adverse events and medical device malfunctions, field actions including recalls, promotional review, and compliance with the requirements of the quality system regulations. A key part of this work includes advising clients as to when notification to the agency is needed with respect to product changes, malfunctions, adverse events, or other product concerns. She has supported clients in negotiating agreements involving the FDCA and the False Claims Act, responding to FDA inspectional observations and Warning Letters, and conducting internal investigations.

Ms. Newberger was with the firm from 2011-2017, when she transitioned to in-house roles at Apple Inc., Abbott Laboratories, and Cognito Therapeutics. She returned to the firm in 2024, utilizing the expertise gained in-house to assist clients in remaining compliant and anticipating agency response to company actions.

Experience

- At Apple, led executive-level meetings, including with the Chief Operating Officer, regarding regulatory and legal challenges associated with shipping regulated health features.
- Managed the cross-functional team responsible for obtaining Apple's first *de novo* authorizations for the ECG app and irregular rhythm notification.
- Successfully partnered with engineering, clinical, operations, and marketing teams to successfully launch products.
- Drive cross-functional collaboration to develop and implement medical device policies and procedures.
- Advise medical device companies on pre-market strategies, including selection of appropriate regulatory pathway.
- Draft medical device pre-market submissions and lead meetings with FDA regarding those submissions.
- Serve on promotional review committees for clients to approve marketing materials.
- Draft and negotiate clinical trial and research agreements between device companies and universities, clinical investigators, and contract research organizations.

Speaking Engagements

- Jennifer Newberger is speaking at Taylor Wessing Spotlight on Medical Devices Conference,
  Regulatory challenges in the US, EU, and UK, with a particular focus on clinical data requirements and the ability to engage with regulators/notified bodies in advance of submissions, September 10, 2024