Noreen Hibbard Onimus

Counsel

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OVERVIEW

Noreen counsels pharmaceutical and medical device companies on a wide variety of FDA regulatory issues. She has in-depth knowledge of federal regulations governing the FDA application process, the conduct of clinical trials, product labeling, adverse event reporting and analysis, promotional claims, regulatory inquiries, and the external communication of medical information. In addition to her counseling practice, she assists clients with the preparation of SEC filings and conducts due diligence in conjunction with securities offerings and mergers and acquisitions. Her practice also includes the defense of pharmaceutical companies in civil and criminal actions and government investigations.

REPRESENTATIVE MATTERS

- Counseling pharmaceutical companies in regulatory compliance and risk avoidance.
- Evaluating promotional claims for prescription drugs and medical devices.
- Counseling pharmaceutical companies with respect to research and development practices and procedures.
- Defense of pharmaceutical companies in matters concerning investigational new drugs and marketed products, including multidistrict litigation.
- Defense of a pharmaceutical company in matters relating to a failed clinical trial.
- Counseling and defending pharmaceutical companies in federal and state civil and criminal investigations regarding sales and marketing practices.

TOP AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences
- Life Sciences Transactions
- Pharmaceutical + Medical Device Litigation + Counseling

ALL AREAS OF FOCUS

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- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences
- Life Sciences Transactions
- Litigation + Trial
- Pharmaceutical + Medical Device Litigation + Counseling
- Product Liability

EDUCATION AND CERTIFICATIONS

EDUCATION

- Georgetown University Law Center, J.D., 1989, member, *The Georgetown Law Journal*
- Villanova University, B.A., *magna cum laude*, 1986, political science

BAR ADMISSIONS

- Pennsylvania

COURT ADMISSIONS

- U.S. Court of Appeals, Third Circuit
- U.S. District Court, Eastern District of Pennsylvania