Marc N. Wagner

Partner

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Marc devotes his practice to FDA and DEA compliance, regulatory enforcement and transactional matters in the healthcare and life sciences industries.

He advises pharmaceutical, biotechnology, medical device, dietary supplement, food and healthcare companies on the full spectrum of FDA regulatory issues throughout the product lifecycle, from product development and commercialization to inspections, enforcement and post-market compliance.

Marc represents drug manufacturers, outsourcing facilities, compounding pharmacies, wholesale distributors, third-party logistics providers, healthcare providers and other regulated entities in navigating complex federal and state regulatory requirements.

His FDA practice includes counseling clients on:

- Good manufacturing practice (cGMP) requirements.
- Quality systems.
- Product classification.
- Labeling and promotional compliance.
- Adverse event reporting.
- Import and export issues.
- Recalls.
- FDA inspections.
- Form FDA 483 responses.
- Warning letters, consent decrees and regulatory strategy.

He also advises clients on DEA registration, controlled substance compliance, state licensing and interactions with state boards of pharmacy.

Investigations and Enforcement

Marc regularly represents clients in high-stakes government investigations and enforcement matters involving the FDA, DEA, the Department of Justice, state attorneys general and state regulatory agencies. He guides companies through inspections,

import detentions, warning letters, product seizures, injunction actions and other regulatory proceedings, helping clients resolve complex compliance issues while minimizing business disruption.

Transactions

In addition to his regulatory practice, Marc advises private equity sponsors, strategic investors and life sciences companies on mergers, acquisitions, divestitures and other strategic transactions. He leads regulatory due diligence for healthcare and pharmaceutical transactions, identifies regulatory and compliance risks, evaluates licensure and operational requirements, and develops strategies to facilitate successful transactions and post-closing integration.

Drug Shortage and Supply Chain Issues

Marc is particularly recognized for his work involving pharmaceutical compounding, outsourcing facilities and drug supply chain regulation. He works closely with manufacturers, healthcare providers and FDA-registered outsourcing facilities on quality systems, inspection readiness, regulatory advocacy and strategies to address drug shortages and improve patient access to essential medications. He also advises clients on emerging FDA policy initiatives and federal and state legislative developments that shape the healthcare and life sciences industries.

A registered pharmacist with a Doctor of Pharmacy degree, Marc brings an unusual level of scientific and operational perspective to his regulatory counsel. He is also deeply committed to drug shortage policy and works closely with outsourcing facility clients on mitigation strategies.

Services

- Corporate
- Life Sciences
- Pharma & Biotech
- Health Law

Representative Matters

- Counseled multiple pharmaceutical firms in connection with the sale of stock to private equity groups.
- Advised a private equity group in the acquisition of a specialty pharmacy.
- Provided ongoing counsel to a national pharmacy transitioning state regulatory licenses and permits following a change of ownership.
- Advised a pharmaceutical firm under FDA and DOJ investigation.
- Assisted a chemical firm in the acquisition of an active pharmaceutical ingredient manufacturer.
- Counseled firms seeking Emergency Use Authorizations during the COVID-19 pandemic.
- Advised a hospital on COVID-19 vaccination provider obligations and the Public Readiness and Emergency Preparedness Act.
- Developed comments to the FDA on regulatory topics for industry trade associations and individual companies.

Before Fox Rothschild

Prior to joining us, Marc practiced as an associate at a national law firm in Washington, D.C. and served as General Counsel to a drug industry trade association. He also completed internships at the DEA's Office of Chief Counsel and the FDA's Office of Policy, and previously practiced as a licensed pharmacist

While in law school, he was Articles Editor of the *Dickinson Law Review.*

Beyond Fox Rothschild

Marc volunteers with the Catholic Charities Legal Network, where he has provided pro bono representation in criminal defense matters.

Bar Admissions

- District of Columbia
- Pennsylvania

Education

- Pennsylvania State University Dickinson School of Law (J.D., 2019)
- Pennsylvania State University (M.B.A., 2019)
- University of the Sciences, Philadelphia College of Pharmacy (Pharm.D., *cum laude*, 2016)
    - Certificate in Corporate Compliance with Concentration in Healthcare
- University of the Sciences, Philadelphia College of Pharmacy (B.S., *cum laude*, 2014)

Memberships

- American Society for Pharmacy Law
- End Drug Shortages Alliance
- Food and Drug Law Institute
    - Veterinary Products Task Force
    - Publications Peer Review Committee
    - New to Food and Drug Law Planning Committee

Board of Directors

- American Society for Pharmacy Law (2025-2027)

Honors & Awards

- Selected to a list of Star Associates (2025) and Associates to Watch (2024) in the Chambers USA Guide in the category of Healthcare: Pharmaceutical/Medical Products Regulatory, District of Columbia
- Selected by JD Supra to a list of Readers' Choice Award Winners in the category of Life Sciences (2021)
- Awarded the American Society for Pharmacy Law Fink Family Scholarship (2018)