Hogan Lovells

Meredith Manning

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Biography

For over 20 years, Meredith Manning has counseled clients on emerging legal issues of pharmaceutical regulatory law. Her goal is to help companies get drugs approved and help them succeed. Her first client was the FDA, and she now advises companies of all sizes on cutting-edge regulatory compliance issues. Clients value her "client service-oriented nature" and "the practicality of her advice."

Meredith's focus extends from clinical trials to good manufacturing practices, drug safety, and advertising and promotion. She watches emerging issues over time, applies her insights into regulators' thinking, and works with clients to build practical approaches to critical business processes and strategies.

Meredith works on major investigations into off-label promotion, client responses to FDA warning and untitled letters, and competitor complaints. She also guides client decisions about drug advertising, drug sampling, patient support programs, and comprehensive pharmaceutical compliance programs. In this role, she has helped develop business strategies for several of the largest drug launches in recent years.

She began her legal career in the Office of Chief Counsel at the FDA and moved to the DOJ as an

Practices

Investigations, White Collar, and Fraud

Marketing and Advertising

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

False Claims Act and Qui Tam

Advertising and Copy Clearance

Assistant United States Attorney for the District of Columbia. She's been at Hogan Lovells since 2002, has served as the co-director of the firm's Pharmaceutical Practice Group, and currently sits on the steering committee for its Life Sciences industry team.

Meredith is nationally ranked in *Chambers USA*, *Legal 500*, and *LMG Life Sciences*. In 2012, the American Health Lawyers Associate named her a Pro Bono Champion for her work on an HIV and AIDS project in D.C. She also serves on the Board of Trustees of the Emma Willard School in Troy, New York.

Representative experience

Lead regulatory counsel in a major federal misbranding investigation.

Lead a team advising on patient support programs designed to support launch of a major oncology drug.

Handled an OIG advisory opinion request regarding a free drug program.

Routinely review proposed promotional materials and programs for major drug products sold in the U.S.

Craft responses to FDA enforcement letters on GMP and drug advertising.

Awards and rankings

- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), *Chambers USA*, 2010-2018
- Food and Drugs, *Washington, D.C. Super Lawyers*, 2007, 2013 - 2018
- Washington's Top Lawyers: Food and Drug, *Washingtonian*, 2004, 2009, 2011, 2014
- Administrative Law, *Washington, D.C. Super Lawyers*, 2007, 2013-2018
- Healthcare: Life Sciences, *Legal 500*, 2014

Sales Promotions

Product Development and Approval

Clinical Trials

Pharmaceuticals and Biotechnology

Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., University of Minnesota Law School, Order of the Coif, 1993

M.S., University of California, Los Angeles, Fielding School of Public Health, 1990

B.A., Duke University, cum laude, 1984

Memberships

American Health Lawyers Association

Member, Food, Drug, and Law Institute

Bar admissions and qualifications

Colorado

District of Columbia

Court admissions

U.S. Court of Appeals, District of Columbia Circuit

- Pro Bono Champion, *American Health Lawyers Association*, 2012
- Regulatory, *PLC Life Sciences Cross-border Handbook*, 2011-2012
- Healthcare/Pharma, *Ethisphere, Attorneys Who Matter*, 2010-2012
- USA - Life Sciences: Regulatory, Highly Recommended, *PLC Which Lawyer?*, 2007-2009
- Food and Drug Administration, *Washington, D.C. Super Lawyers*, 2007

Latest thinking and events

- Webinar
  - How landmark OTC drug reform legislation will affect your business
- News
  - At long last, landmark OTC Drug reform legislation is enacted
- News
  - First emergency use authorization for COVID-19 drugs may open door for more EUAs
- News
  - The global impact of COVID-19 on clinical trials and countermeasure development
- Insights
  - “Misleading” to suggest a biosimilar is inferior, FDA draft guidance warns
- Insights
  - 2019 OPDP enforcement letters target how drug risk information is conveyed in promotional materials

U.S. District Court, District of Columbia

Accolades

"[C]lient service-oriented nature."

Chambers USA

"Meredith Manning focuses her energies on both routine and on extraordinary client needs for drug companies. This dual approach serves her clients well, as it prevents emergent issues from growing. On-going service to her clients includes counseling on day-to-day compliance problems such as clinical trials, [and] advertising and promotion..."

LMG Life Sciences