Hogan Lovells

Lynn Mehler

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Biography

As Co-Head of the firm's Life Sciences & Health Care industry sector and Head of the Pharmaceuticals and Biotechnology practice, Lynn Whipkey Mehler advises clients on a range of FDA and DEA regulatory matters. She has worked extensively on the approval processes for new drugs and biologics; on safety issues that include Risk Evaluation and Mitigation Strategies (REMS); and on unique regulatory issues raised during the development and marketing of controlled substances.

Drawing on her 12 years with the FDA's Office of the Chief Counsel, Lynn has a deep understanding of the FDA. Her experience as the primary attorney handling all FDA issues related to controlled substances provides her with unique insights into both the FDA's and DEA's regulatory processes for controlled substances. She advised the agency on drug safety matters, including at approval and those leading to labeling changes, REMS, and even product withdrawal, and she applies that understanding to help clients create effective solutions for FDA regulatory matters.

Lynn has worked with a range of clients, getting their products approved, developing and modifying REMS, and negotiating shared REMS with generic applicants. She draws on her deep experience in the FDA approval process to represent pharmaceutical clients in formal dispute proceedings within the agency.

Having counseled the FDA on the Prescription Drug User Fee Act, she now guides clients in the submission

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Product Development and Approval

Clinical Trials

Controlled Substances and DEA

Pharmaceuticals and Biotechnology

Education and admissions

Education

of user fee waiver requests and helps them understand the agency's administrative management of drug applications. She has extensive experience in the FDA and DEA drug scheduling process and has worked with clients to effectively manage the process to minimize the delays to product launch. She has a deep understanding of the web of regulatory requirements governing the research and development of controlled substances and guides companies on matters from initial clinical trials to approval and marketing.

Representative experience

Represent multiple innovator companies during the negotiation and development of shared REMS.

Advising a pharmaceutical client in preparation for, during, and to a successful close-out of an FDA pharmacovigilance inspection.

Advising a pharmaceutical client through the DEA scheduling process for controlled substances and to successful marketing of the product.

Awards and rankings

- FDA Commissioner's Award of Excellence
- FDA Commissioner's Award of Merit
- FDA Outstanding Service Award

Latest thinking and events

- News
  - Successful product launches across the EU, UK, and U.S.
- Hogan Lovells Events
  - Boston: Life Sciences and Health Care Horizons 2023
- News
  - A change of pace: Accelerated Approval reform passed by U.S. Congress
- News
  - FDA asks Congress to legislate CBD approval pathway, as new law permits marijuana & CBD

J.D., William & Mary Law School, Order of the Coif, 1997

B.A., The College of Wooster, Phi Beta Kappa, 1994

Bar admissions and qualifications

District of Columbia

Virginia

research

- Hogan Lovells Events
  - Dinner, drinks, and discussion on the impacts of the Inflation Reduction Act of 2022
- News
  - “Advancing Real-World Evidence Program” offers drug sponsors early FDA meeting opportunity