Hogan Lovells

David Horowitz

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Biography

David Horowitz brings 25 years of combined experience at the FDA and U.S. Department of Health and Human Services (HHS) to help clients anticipate and navigate complex regulatory compliance challenges.

David's practice focuses on pharmaceutical compliance issues, including Current Good Manufacturing Practice (CGMP), inspections, recalls, post-market reporting, import/export, drug supply chain security, pharmacy issues, and OTC drug issues. During his time at HHS and FDA, David developed a deep understanding of the institutions, organizational structures, procedures, and cultures through which regulatory policy and compliance decisions are considered, developed, and implemented across all branches of government. The combination of his deep technical knowledge and years of experience allows David to provide strategic and tactical advice to proactively avoid regulatory problems, as well as respond effectively to unanticipated challenges.

As Deputy General Counsel at HHS (2010-2017), David oversaw and coordinated legal services in support of FDA and other HHS public health agencies. His work focused on FDA regulatory policy and compliance-related issues. During his tenure at FDA – which included five years as head of the Office of Compliance for drugs, and three years as Assistant Commissioner for Compliance Policy – David played a leadership role in numerous major initiatives, including the

Practices

Pharmaceuticals and Biotechnology Regulatory

Administrative and Public Law

Government Relations and Public Affairs

Industries

Life Sciences and Health Care

Areas of focus

Pharmaceuticals and Biotechnology

Cell, Tissue, and Gene Therapies

Product Development and Approval

Regulatory Inspections and cGMP

OTC Drugs and Cosmetics

modernization of FDA's approach to pharmaceutical manufacturing quality and the agency's efforts to develop and implement a more scientific, risk-based approach to inspection and enforcement. He also led the development of FDA's first risk-based quantitative model used to prioritize drug manufacturing inspections.

Representative experience

Advise companies on responding to FDA inspectional observations (483s) and Warning Letters relating to CGMP requirements, resulting in successful resolution of FDA findings.

Assist companies in resolving drug approval issues and FDA complete response letters related to manufacturing quality and GMP concerns.

Provide actionable advice to companies to navigate FDA's complex requirements for importing and exporting biological materials and drug products.

FDA leader in developing internationally harmonized pharmaceuticals guideline on Quality Risk Management, ICH Q9*

*Matter handled prior to joining Hogan Lovells.

Awards and rankings

- Healthcare: Life Sciences, *Legal 500 US*, 2018
- Meritorious Service, *Presidential Rank Award*, 2016
- Distinguished Service and Leadership Award, *Food and Drug Law Institute*, 2015
- NIH Director's Award, *NIH*, 2011
- FDA Award of Merit, *FDA*, 1999, 2007
- FDA Commissioner's Special Citation, *FDA*, 1994, 1998, 2005, 2006, 2015
- HHS Certificate of Appreciation, *HHS*, 2010, 2015
- Healthcare: Pharmaceutical/Medical Products Regulatory, Rank 4, *Chambers USA*, 2022

Latest thinking and events

Education and admissions

Education

J.D., University of Virginia School of Law, 1991

B.A., Brown University, magna cum laude, 1986

Bar admissions and qualifications

District of Columbia

Pennsylvania

Court admissions

U.S. Supreme Court

U.S. Court of Appeals, Fifth Circuit

- News
  - Can sterile drug manufacturers implement EU GMP Annex 1 requirements before August?
- News
  - FDA expands inspection obstruction guidance to apply to device facilities
- News
  - Modernization of U.S. cosmetics regulation will be phased in over time
- News
  - New FDA pilot offers expedited drug program sponsors expanded FDA meeting opportunities on manufacturing issues
- Hogan Lovells Podcasts
  - Podcast: Talking the cure
- News
  - FDA may permit Rx-to-OTC switch using additional conditions beyond traditional labeling