Hogan Lovells

David Horowitz

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Biography

David Horowitz brings 25 years of combined experience at the U.S. Department of Health and Human Services (HHS) and the FDA to help clients anticipate and navigate regulatory challenges, and participating in the policy-making process.

As Deputy General Counsel at HHS (2010-2017), David oversaw and coordinated legal services in support of FDA, the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and international and emergency preparedness programs. His work focused on FDA regulatory policy and litigation. 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 major initiatives, including the 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.

Over the course of his career at HHS and FDA, David developed substantial knowledge pertaining to FDA law and policy, with particular emphasis on pharmaceuticals, compliance, and the application of administrative law. He also developed a deep understanding of the institutions, organizational

Practices

Pharmaceuticals and Biotechnology Regulatory

Administrative and Public Law

Government Relations and Public Affairs

Industries

Life Sciences and Health Care

Areas of focus

Cell, Tissue, and Gene Therapies

Education and

structures, procedures, and cultures through which regulatory policy and compliance decisions are considered, developed, and implemented across all branches of government, including Congress and the courts, as well as various components of FDA, HHS, Office of Management and Budget, Department of Justice, and the White House.

Representative experience

Lead agency counsel for all HHS legal issues relating to Ebola outbreak, including FDA Emergency Use Authorizations and vaccine development and liability matters*

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

Lead agency counsel for final rules pertaining to human subject protection and clinical trial reporting*

*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

Latest thinking and events

- Blog Post
  - Will FDA be forced to implement a drug importation program?

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

- Blog Post
  - FDA launches temporary “TRIP” program to help HCT/P sponsors gain regulatory clarity
- Hogan Lovells Publications
  - FDA doubles down on MUsT studies for sunscreens and issues final guidance on absorption studies that will likely be needed for continued marketing *Focus On Regulation*
- Hogan Lovells Publications
  - New FDA draft guidance on voluntary recalls highlights importance of recall initiation plans *Focus on Regulation*
- Hogan Lovells Publications
  - With the statutory deadline approaching, FDA issues a proposed sunscreens rule *Focus On Regulation*
- Hogan Lovells Publications
  - Likely FDA impact of the government shutdown: Regulatory submission reviews, inspections, and research projects *Focus On Regulation*