

David M. Fox

Partner

Washington, D.C.

Biography

David Fox is a leading authority on the regulation of prescription and over-the-counter drugs, biological products, combination products, and controlled substances.

He advises management teams, from start-ups to the largest global pharmaceutical and biotechnology companies, on matters before the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA). David is closely integrated with funding sources for the industry and is frequently retained as a strategic advisor on assessing the value of life sciences assets. Known for his collaborative approach to complex regulatory issues, David has successfully resolved numerous disputes between sponsors and staff at FDA on products that raise novel regulatory issues. As a former senior lawyer for FDA and throughout his career in private practice, David has been deeply immersed in the regulatory side of the Hatch-Waxman Act, including pioneer-generic disputes and numerous cases of first impression involving exclusivity issues, Orange Book listings, and patent term extensions.

David previously led our Pharmaceutical and Biotechnology practice group and served on the firm's global Life Sciences management team.

During his FDA tenure, David received the Secretary's Award of Merit and an FDA Special Citation for his work on the FDA Tobacco Rule. David is a founding member of the Kitalys Institute to support interventions



Phone

+1 202 637 5678

Fax

+1 202 637 5910

Email

david.fox@hoganlovells.com

Practices

Pharmaceuticals and Biotechnology
Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Controlled Substances and DEA
Pharmaceuticals and Biotechnology
Regulatory Exclusivities, Hatch-
Waxman, and Similar Statutes
Cell, Tissue, and Gene Therapies
Combination Products

Education and admissions

that delay the onset of diseases of aging, and David is on the Advisory Board of the Cancer Support Community. David also serves as pro bono counsel on a variety of programs to improve patient and care-giver welfare.

Awards and rankings

- Life Sciences: Regulatory/Compliance (Nationwide), Rank 1, *Chambers USA*, 2007-2022
- Life Sciences: Regulatory/Compliance (USA), *Chambers Global*, 2021
- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), Rank 1, *Chambers USA*, 2010-2022
- Life Sciences Hall of Fame, *LMG Life Sciences*, 2020
- FDA Law, *Best Lawyers in America*, 2018-2022
- Healthcare: Life Sciences, Hall of Fame, *Legal 500 US*, 2019-2020
- Healthcare: Life Sciences, Leading Lawyer, *Legal 500 US*, 2013-2014, 2016-2018
- Life Sciences, *Who's Who Legal*, 2017
- Selected to Super Lawyers, 2013-2018
- Washington's Top Lawyers: Food and Drug, *Washingtonian*, 2009, 2011, 2013, 2014
- Most Highly Regarded Firms for Life Sciences, *Who's Who Legal*, 2013
- Regulatory, *PLC Life Sciences Cross-border Handbook*, 2011-2012
- USA – Life Sciences: Regulatory, Recommended, *PLC Which Lawyer?*, 2007-2009
- FDA Award of Merit and Special Citation
- Secretary's Award for Distinguished Service

Latest thinking and events

- News
 - FDA outlines rescission of Breakthrough Therapy Designation

Education

J.D., New York University School of Law, 1989

B.A., College of William & Mary, 1985

Bar admissions and qualifications

District of Columbia

New York

- News
 - FDA finalizes guidance on Orphan Drug “sameness” of gene therapies
- News
 - Federal Circuit affirms GSK labeling carve-out ruling in favor of innovator
- News
 - Biden signs bill limiting new drug exclusivity awards to innovations in active moiety
- News
 - Life sciences and health care horizons 2021
- News
 - New Orange & Purple Book laws increase transparency of patent information for drugs, biologics