

**Hogan
Lovells**

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 now serves on the firm's global Life Sciences management team.



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Practices

Pharmaceuticals and Biotechnology
Regulatory

Industries

Life Sciences and Health Care

Awards and rankings

- Life Sciences: Regulatory/Compliance (Nationwide), *Chambers USA*, 2007-2020
- Life Sciences: Regulatory/Compliance (USA), *Chambers Global*, 2020
- Life Sciences Hall of Fame, *LMG Life Sciences*, 2020
- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), *Chambers USA*, 2010-2020
- FDA Law, *Best Lawyers in America*, 2018-2019
- 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
 - Final FDA combination product guidance encourages application-based feedback pathways
- News
 - Labeling carve-out does not shield generic drug makers from induced infringement claims, CAFC

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

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

Accolades

rules

- Sponsorships and Speaking Engagements
 - Metabesity 2020
- Awards and Rankings
 - LMG Life Sciences recognizes Hogan Lovells as Regulatory Firm of the Year for third year in a row 2020
- Awards and Rankings
 - Global law firm Hogan Lovells is pleased to announce the firm has been shortlisted in 11 categories for the eighth Annual LMG Life Sciences Americas Awards 2020
- Insights
 - FDA Guidance on Combination Product Agreement Meetings lacks specificity, comments say

"David Fox is recognized for the quality of his strategic counsel on engagements with the FDA for 505 (b)(2) New Drug Applications. 'I would never do a pharmaceuticals deal without his involvement. His insights into FDA regulatory matters is unparalleled,' says one impressed source."

Chambers USA 2016

"David Fox is a go-to attorney for clients bringing new products through review, as well as advising on related IP issues."

Chambers USA

"David is praised by clients for his 'unsurpassed knowledge' particularly in the fields of Hatch-Waxman and pharmaceutical life cycle management. He is also commended by observers for his 'technical expertise, knowledge, counsel and insight.'"

Chambers 2015

"David is the 'real deal' with 'extensive experience' advising on product lifecycle management for the pharmaceutical industry."

*Who's Who Legal Life Sciences
2015*

"We love the tremendous expertise that David Fox brings to our strategic product development initiatives."

Chambers 2013
