

## George A. O'Brien

Partner

Washington, D.C.

### Biography

George O'Brien works with innovative pharmaceutical and biotech companies on lifecycle management issues. He's probably best known for his substantial experience with orphan drug designation and exclusivity matters.

In particular, George helps clients avoid the pitfalls that can delay an orphan designation or award of orphan exclusivity, such as issues related to prevalence, orphan subsets, and clinical superiority. When clients must resolve a dispute with an agency over orphan issues, George's comprehensive knowledge of relevant precedent is a valuable tool.

George assists companies at all stages of product development to maximize their FDA regulatory exclusivities, including Hatch-Waxman, orphan drug, and pediatric exclusivities. Drafting citizen petitions is a key part of his practice, and he's collaborated with other organizations to create drafts on a wide range of issues, including bioequivalence and approval requirements for generic products, the operation of 180-day exclusivity, therapeutic equivalence issues, and new chemical entity exclusivity.

George recently served on the Drugs & Biologics Committee of the Food and Drug Law Institute. He also has spoken on orphan drug issues at FDLI conferences



### Phone

+1 202 637 5497

### Fax

+1 202 637 5910

### Email

[george.obrien@hoganlovells.com](mailto:george.obrien@hoganlovells.com)

---

### Practices

Pharmaceuticals and Biotechnology  
Regulatory

---

### Industries

Life Sciences and Health Care

---

### Areas of focus

Product Development and Approval  
Regulatory Exclusivities, Hatch-  
Waxman, and Similar Statutes  
Pharmaceuticals and Biotechnology  
Cell, Tissue, and Gene Therapies

---

and elsewhere.

## Representative experience

Submitted citizen petition convincing FDA to recognize five-year "new chemical entity" exclusivity for certain fixed-dose combination products.

Represented Depomed, Inc. in regulatory proceedings and federal litigation regarding orphan drug designation and exclusivity.

## Awards and rankings

- Rising Stars, Food & Drugs, *Washington, D.C. Super Lawyers*, 2018
- Healthcare: Life Sciences, Recommended, *Legal 500 US*, 2020

## Latest thinking and events

- News
  - New Orange & Purple Book laws increase transparency of patent information for drugs, biologics
- News
  - Labeling carve-out does not shield generic drug makers from induced infringement claims, CAFC rules
- Insights
  - "Misleading" to suggest a biosimilar is inferior, FDA draft guidance warns
- Insights
  - FDA issues draft guidance regarding "sameness" for Orphan Drug gene therapies
- Insights
  - Spending bill advances FDA biosimilars policy
- Press Releases
  - Hogan Lovells Celebrates the New Year with 29 Promotions to Partner and 56 Promotions to

## Education and admissions

### Education

J.D., University of Maryland, Francis King Carey School of Law, magna cum laude, Order of the Coif, 2008

A.B., Dartmouth College, cum laude, 1995

---

### Bar admissions and qualifications

District of Columbia

Maryland

---

Counsel