

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 and elsewhere.

Representative experience



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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

Education and admissions

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
 - Eleventh Circuit decision could significantly expand scope of orphan exclusivity
- News
 - FDA finalizes guidance on Orphan Drug "sameness" of gene therapies
- News
 - Biden signs bill limiting new drug exclusivity awards to innovations in active moiety
- 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

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
