Hogan Lovells

Orphan Drugs

Developing Drugs and Biologics to Treat Rare Diseases

We have a proven track record of helping clients obtain and benefit from orphan drug designation and exclusivity. Our landmark victory in the *Depomed* case changed the regulatory landscape, but equally important are the many behind the scenes wins that help clients big and small bring important drugs to market for small patient populations.

Nobody knows the detailed law and regulations or hard-to-find FDA precedents better, or puts them to use more creatively or successfully – always with an eye toward practical solutions and meeting business imperatives.

Representative experience

Identified and justified an appropriate "orphan subset" of a larger, non-orphan disease or condition.

Developed data and information demonstrating prevalence below 200,000 people in the United States for a given disease or condition.

Selected the appropriate disease for purposes of orphan designation.

Combined scientific, policy, and legal arguments to overcome FDA resistance to designation.

Contacts

Philip Katz,
Washington, D.C.

Hein van den Bos,
Amsterdam

Obtained a meeting with OOPD to argue for designation that FDA initially denied, and followed up with a revised request that led to designation.

Identified and enlisted an expert epidemiologist to help persuade FDA to grant designation, reversing a denial based on prevalence.

Strategized with clients on labeling and product lifecycle changes to maximize the benefits of orphan exclusivity.

Helped identify and take advantage of opportunities to accelerate a development program to prevail in an orphan "horse race."

Counseled on taking full advantage of the benefits of the Orphan Drug Act, including tax cuts and exemptions from statutory fees and pediatric assessments.

Successfully challenged agency approach that would have undermined exclusivity as applied to biosimilars.

Successfully responded to FDA inquiries about possible revocation of orphan designation or exclusivity.

Drafted client comments on proposed revisions to orphan drug regulations.

Provided strategic analysis and advice on orphan designation and exclusivity issues in product acquisitions.

Drafted and submitted petitions and comments regarding eligibility for orphan designation, scope of orphan exclusivity, labeling carve-outs of orphan-protected indications.

Successfully sued FDA to grant orphan exclusivity, creating landmark decision relied on by others and leading to changes to statute and regulations.