WHAT IS THE ORPHAN DRUG ACT?

The Orphan Drug Act (ODA) of 1983 is a federal law that incentivizes biopharmaceutical companies to develop drugs and biologics, known as “orphan drugs,” for individuals with rare diseases.

HOW DOES THE ORPHAN DRUG ACT WORK?

There are 4 INCENTIVES in the law that encourage biopharmaceutical companies to develop orphan drugs.

- **7 YEARS OF EXCLUSIVITY** that prevent competitors from selling the same product labeled for the orphan indication.
- **$18 MILLION** in FDA research grant funding.
- **$2.5 MILLION** in FDA user fees waived.
- **25% TAX CREDIT** for qualified clinical testing expenses incurred in clinical trials.

THE ORPHAN DRUG ACT HAS BEEN SUCCESSFUL but more than 90% of rare diseases are still without any FDA-approved treatment.


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