WHAT IS THE ORPHAN DRUG ACT?

NORD® RARE INSIGHTS®

1983

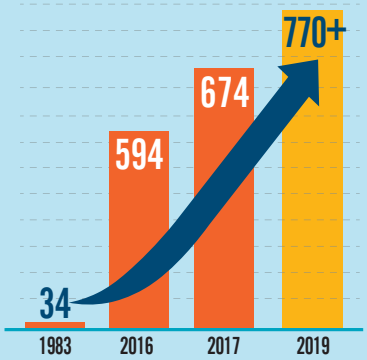
The Orphan Drug Act (ODA) of 1983 is a federal law that incentivizes biopharmaceutical companies to develop drugs and biologics, known as "orphan drugs," for individuals with **rare diseases.**

A RARE DISEASE IS ANY CONDITION AFFECTING FEWER THAN **200,000** AMERICANS

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
- **25% TAX CREDIT** for qualified clinical testing expenses incurred in clinical trials
- **~$18 MILLION** in FDA research grant funding
- **~$2.5 MILLION** FDA user fees waived



(# of approved orphan indications)

THE ORPHAN DRUG ACT HAS BEEN SUCCESSFUL

BUT MORE THAN 90%

of rare diseases are still without any FDA-approved treatment.

Source: FDA Orphan Drug Database; Drugs@FDA Database, FDA websites, IQVIA Institute, Sep 2018 for Human Data Science. Note: The graphic was created using a curated list of indications and approvals based on the FDA Orphan Drug Database. Includes drug approvals through March 2019. IQVIA Institute for Human Data Science. Orphan Drugs in the United States: Exclusivity, Pricing and Treated Populations. 2018 Dec. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-exclusivity-pricing-and-treated-populations.pdf?_=1548445322680.

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