NORD® RARE INSIGHTS™

WHAT IS THE ORPHAN DRUG ACT?

1983

The Orphan Drug Act (ODA) of 1983 is a federal law that incentivize 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?

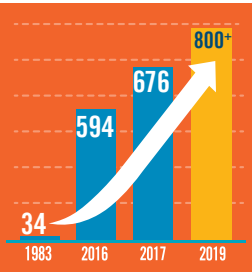
There are **4** **INCENTIVES** in the law that encourage biopharmaceutical companies to develop orphan drugs.

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



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. **Learn more at: rarediseases.org.**

NORD® National Organization for Rare Disorders