

# 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**.

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

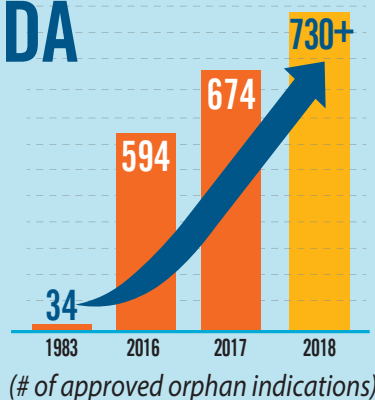
## HOW DOES THE ORPHAN DRUG ACT WORK?

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
- 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

### HAS THE ODA WORKED?

**YES!**



### BUT APPROXIMATELY

**95%** of rare diseases are still without any FDA-approved treatment.

**PLEASE SUPPORT THE ORPHAN DRUG ACT!**

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 Aug 2018. ©2018 NORD. All rights reserved. NORD® and RareInsights® are registered trademarks of The National Organization for Rare Disorders. NORD is a 501(c)(3) charity organization. For more information, visit: [rarediseases.org](http://rarediseases.org). NRD-1159