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
- 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. NRD-1159