RESTORING THE ORPHAN DRUG TAX CREDIT

CALIFORNIA LIFE SCIENCES

MAINTAINING PROGRESS FOR CALIFORNIANS WITH RARE DISEASE

Congress should pass *Cameron's Law* (H.R.1414) and include the restoration of the Orphan Drug Tax Credit in any tax reform package.

CRITICAL DEVELOPMENT INCENTIVES FOR THOSE WHO NEED THEM MOST

Research and development for rare diseases is highly risky and scientifically complex. Rare diseases have small patient populations, which makes developing drugs to treat them inherently more difficult and costly than those for common medical conditions. Because of these challenges it takes nearly 4 years longer to develop an orphan drug compared with medicines to treat more common conditions. In the absence of sufficient incentives to encourage their development, these medicines would cease to exist.

SUCCESS OF THE ODA

Since the enactment of the ODA **more than 600 orphan drugs** have been approved in the U.S. compared with just 10 in the decade before passage.

CHALLENGES IN ORPHAN DRUG DEVELOPMENT

- Small patient population
- Complex scientific challenges of the disease
- Difficulties diagnosing patients and recruiting for clinical trials

Recognizing that rare diseases have historically attracted minimal attention, Congress established the ***Orphan Drug Act* (ODA)** in 1983, which created the **Orphan Drug Tax Credit (ODTC)** to create incentives for the advancement of treatments for rare diseases.

A MISGUIDED CUT

The TCJA cut incentives for orphan drug development in half.

THE RESOUNDING SUCCESS OF THE ODTC

The ODTC has encouraged investment into the research and development of treatments that may not otherwise be seen as economically viable due to a disease's relatively low incidence rate. Importantly, it can help to offset the cost of developing and testing orphan therapies as they move through the clinical trial process. This long-standing incentive is particularly important for smaller companies focused exclusively on rare diseases.

Despite the success of the tax credit, the 2017 *Tax Cut and Jobs Act* (TCJA) reduced the total amount of the ODTC from 50% to 25% for qualified clinical testing expenses.

RESTORING THE ODTC

Cameron's Law is a legislative solution that would return the ODTC to its original level by **increasing the current rate of the tax credit for clinical testing expenses for rare diseases or conditions from 25% to 50%.** As Congress considers tax policy, it should restore the Orphan Drug Tax Credit to its pre-2017 level of 50%.

HIGH UNMET NEED



More than 95% of rare diseases lack an FDA approved therapy.