RDLA Policy Primer:
Priority Review Voucher (PRV)

Background

The priority review voucher (PRV) program was expanded to include drugs that treat rare pediatric diseases in the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012. The purpose of the PRV is to expedite the development and promotion of drugs in the rare pediatric disease, tropical disease, and medical countermeasure fields.

Developing drugs for rare pediatric diseases is particularly challenging due to the small populations affected, difficulties associated with conducting clinical trials for children, delays in diagnosis and more. A majority of PRVs have gone to rare pediatric disease drugs, meaning the program has a large impact on the rare disease community. The PRV program expired on December 20, 2024.

About the PRV Program

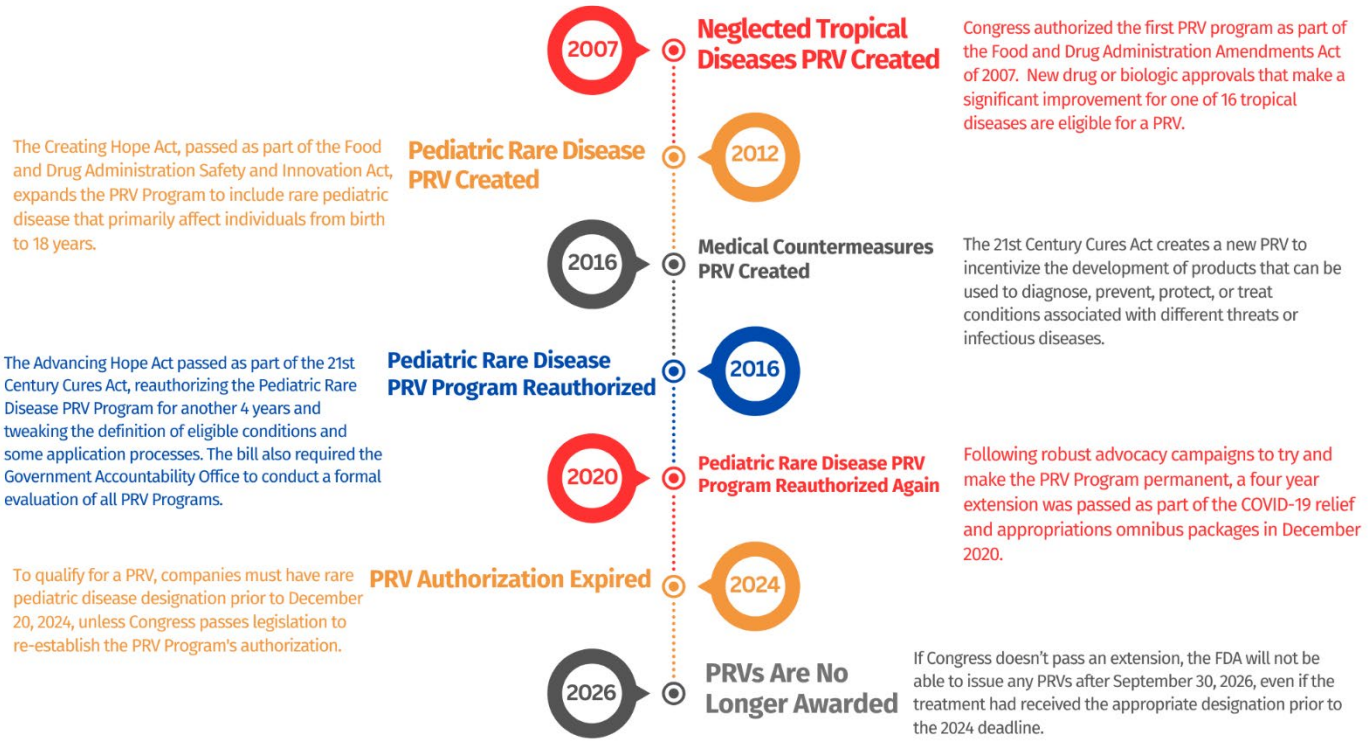
The PRV program incentivizes pharmaceutical companies to develop a rare pediatric disease treatment. Before a treatment is approved, the company can obtain Rare Pediatric designation from the FDA. To be eligible, the drug must be eligible for priority review, and it must be the first approval for the drug's active ingredient.

After an eligible treatment is approved by the FDA, the company is issued a PRV that can be used to obtain priority review for a treatment that wouldn't otherwise qualify. Priority review means a treatment is generally reviewed by the FDA within 6-months rather than the standard 10-month period.

Once issued by the FDA, PRVs can be used by the company on a future treatment that wouldn't otherwise be eligible for priority review or it can be sold to another company, generating revenue for the seller. The revenue that they generate from selling a PRV is part of the incentive for companies to invest in developing treatments for rare pediatric conditions. Companies purchase PRVs so that they can get treatments on the market faster than the typical 10-month review period.

Timeline

RDLA
Rare Disease Legislative Advocates
POWERED BY THE EVERYLIFE FOUNDATION



Resources

https://www.raps.org/news-and-articles/news-articles/2017/12/regulatory-explainer-everything-you-need-to-know
https://www.gao.gov/assets/gao-20-251.pdf
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