Cosponsor the Creating Hope Reauthorization Act, S. 4010/H.R. 4439

This bill will permanently authorize the Pediatric Priority Review Voucher (PRV) program. It will allow further opportunity to spur innovation in rare and neglected diseases that disproportionately impact children.

Please contact Sara_Maskornick@help.senate.gov or Amy_Pellegrino@aging.senate.gov for more information or to cosponsor this legislation.

Background

- In 2012, the Food and Drug Administration Safety and Innovation Act created the PRV program based on the Creating Hope Act.
- This program established an incentive for pharmaceutical companies to develop treatments for rare pediatric diseases by providing them with a priority review voucher that entitles the company to receive a 6-month review that would normally be reviewed under FDA’s standard 10-month review period.

Why Is the Priority Review Voucher Program Critical?

- An estimated 30 million Americans have a rare disease, with 70% of those disorders beginning in childhood.
- Private companies seldom pursue new therapies for rare diseases because it requires making an investment in products that will likely not recoup the high costs associated with the research, development, marketing and distribution of the treatment.
- Developing treatments for children is especially challenging due to the difficulties associated with conducting clinical trials.
- The Priority Review Voucher provides critical incentives to rare disorder product developers.

Priority Review Voucher Program Success

- New drugs that received vouchers were more likely to advance in clinical trials compared to adult rare disease drugs.
- The PRV program comes at no cost to taxpayers.
- The drug trial process was quicker overall under the PRV program.
- The PRV program has resulted in 22 therapies for children with rare diseases.
- The PRV program created over one billion dollars of incentives for companies to develop rare pediatric disease drugs with no cost to consumers or taxpayers.
- 19 PRVs were awarded between February 2014 to September 2019.
- Of the 19 vouchers, twelve were sold for amounts between $67.5 and $350 million, and 5 vouchers were held by the originating companies.