

Opening Statement
Chairwoman Anna G. Eshoo
Subcommittee on Health
Committee on Energy and Commerce
Markup of 38 Bills
September 9, 2020

I request recognition to strike the last word.

The *Creating Hope Reauthorization Act* sponsored by Representative G.K. Butterfield helps children access pediatric cancer drugs.

Pediatric cancer is the number one disease killer of American children, but pharmaceutical companies often avoid developing pediatric cancer drugs because of the small market and the high risks associated with studying and testing drugs for children.

The *Creating Hope Act* provides incentives for the research and development of pediatric cancer drugs by providing the developers with the valuable Priority Review Vouchers which allow the recipient to speed up the FDA review of any one of its new drug products.

Since its passage the GAO studied the pediatric priority review vouchers and found that pharmaceutical developers said Priority Review Vouchers were a factor in drug development decisions.

In addition, as I mentioned at the hearing, Dr. Crystal Mackall of the Stanford Center for Cancer Cell Therapy said that, I quote,

“The voucher program has been remarkably impactful for childhood cancers. Before the program, I used to go with my hat in hand to beg investors to consider a potential drug. Now people take a second look and are interested in developing drugs.

A bean counter may be disappointed by the sheer numbers of approved pediatric drugs, but that disregards the lengthy drug development cycle. It’s more important to look at the impact of the approved drug, including 3 new immunotherapies for children developed after the voucher program, including gene therapy and for leukemia and neuroblastoma.

We’re just getting started on this new way of thinking about children’s drugs. The voucher program required a culture change around how to think of the pediatric drug business model, which in the drug development world could take a while.”

As Dr. Mackall said, this program seeks to shift decision-making early in the lengthy drug development cycle. That’s why I support a permanent reauthorization of the program. A guarantee that the vouchers will continue helps investors better weigh the benefits of pursuing a pediatric cancer drug.

However, a lengthy reauthorization of 4 years as offered in the AINS will also be beneficial and I appreciate Chairman Pallone's willingness to negotiate despite his concerns with the program. I urge my colleagues to support this bill.