

FOR IMMEDIATE RELEASE
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The Voice of Children with Cancer

Breaking News: The Senate overwhelmingly passed the *Research to Accelerate Cures and Equity for Children Act* - known as the RACE Act - today as part of a larger FDA user fees bill. The legislation now heads to the president's desk for signage into law!

The FDA Reauthorization Act is a five-year reauthorization of user fee programs, which fund the agency's drug and medical device reviews. The current user fee program is set to expire September 30th.

Today, the childhood cancer community celebrates this hard-fought achievement. RACE Act provisions hail from a blueprint report that grew out of a working group of the Alliance for Childhood Cancer and the Coalition Against Childhood Cancer in 2015-2016. For the past year, childhood cancer stakeholders - including the Children's Cause - have been involved in intensive bipartisan, bicameral negotiations with Congressional champions to make these recommendations a reality.

This legislation calls for patients to be part of the discussion with FDA about what drugs should be developed for kids. Children's Cause will continue to be at the table speaking up for our kids.

More on the RACE Act: The small population of children with cancer provides little market incentive for the biopharmaceutical industry to develop new pediatric oncology drugs. Childhood cancer remains the leading cause of disease-related death in our children, and new and better therapies are sorely needed for children battling cancer.

Fifteen years ago, Congress passed a pair of laws - the *Best Pharmaceuticals for Children Act* (BPCA) and the *Pediatric Research Equity Act* (PREA) - that provide critically important information on the safe and effective use of medications in the pediatric population. **While BPCA and PREA have yielded important new safety and labeling**

information for other children's diseases, the laws have had a very modest impact on childhood cancer. In fact, exceptions carved out have resulted in PREA having virtually *no effect* in stimulating more treatments for childhood cancer.

The *RACE Act* will eliminate those exemptions and improve opportunities for more studies in childhood cancer by:

- Requiring that companies developing cancer drugs do PREA studies of their drugs in children when the molecular target of their drug is relevant to a children's cancer; and
 - Ending the exemption of PREA obligations for cancer drugs with orphan designations if the molecular target of their drug is relevant to a children's cancer.
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The Children's Cause for Cancer Advocacy works to ensure the needs and perspectives of children with cancer, their families and survivors are integrated into federal health care, research and cancer policy discussion. Cancer remains the leading disease-killer of children, and those who do survive experience serious long-term and late effects on their health and well-being. This year, 13,000 children under the age of 15 will be diagnosed with cancer. Across the nation, there are almost 500,000 childhood cancer survivors.