



September xx, 2019

Representative G.K. Butterfield
Co-Chairman
Childhood Cancer Caucus

Representative Michael McCaul
Co-Chairman/Founder
Childhood Cancer Caucus

Dear Representatives Butterfield and McCaul:

On behalf of The Alliance for Childhood Cancer, we are writing to offer our endorsement of the Creating Hope Act Reauthorization Act of 2019, H.R 4439. Thank you for your continued leadership in the fight against childhood cancer.

As you know, more children are lost to cancer in the U.S. than any other disease. Before they turn 20, about 1 in 285 children in the U.S. will have cancer. However, there are very few cancer treatments that are specifically indicated for pediatric cancer. In addition, due to the lack of child-specific treatment options, survivors of childhood cancer often suffer long term health consequences due to use of harsh treatments intended for adult patients.

While recent decades have seen dozens of new Food and Drug Administration (FDA)-approved cancer therapies, only a handful treatments for childhood cancers have been approved over the same period. Despite the significant unmet medical need, pharmaceutical companies have been reluctant to develop drugs for pediatric cancer, since the high costs associated with their research, development, marketing, and distribution are unlikely to be recouped following approval.

The Creating Hope Act, originally passed in 2012 and reauthorized through 2020, expanded the FDA priority review voucher program to incentivize pharmaceutical manufacturers to invest in drugs with indications for rare pediatric diseases. Under this program, a qualifying rare pediatric drug approval earns a manufacturer a voucher that guarantees them access to the FDA's priority review system for any subsequent drug review. Whether a company chooses to use this voucher themselves or sell the voucher to another manufacturer, this program provides a helpful new incentive for increased investment in developing treatments for pediatric rare diseases like cancer. Through this program, the FDA has awarded vouchers for two pediatric cancer drugs, dinutuximab (for high risk neuroblastoma) and CAR T-cell therapy tisagenlecleucel (for relapsed acute lymphoblastic leukemia). These drugs offer new hope for children with cancer.

The Creating Hope Act Reauthorization Act of 2019 would permanently reauthorize this important program that expands treatment options for children with cancer and their families and continues to advance the research that brings us closer to curing childhood cancers.

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Thank you for your leadership on behalf of children with cancer. We look forward to working with you enact the Creating Hope Act Reauthorization Act of 2019.

Sincerely,

The Alliance for Childhood Cancer