



American Cancer Society
Cancer Action Network
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March 29, 2017

Senator Marco Rubio
U.S. Senate
Washington, DC 20510

Senator Michael Bennet
U.S. Senate
Washington, DC 20510

Representative Michael McCaul
U.S. House of Representatives
Washington, DC 20515

Representative G.K. Butterfield
U.S. House of Representatives
Washington, DC 20515

Re: Research to Accelerate Cures and Equity (RACE) for Children Act

Dear Senator Rubio, Senator Bennet, Representative McCaul and Representative Butterfield:

On behalf of the American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, thank you for introducing S. 456/H.R. 1231, the Research to Accelerate Cures and Equity (RACE) for Children Act, and we are pleased to support it. This important bill will encourage drug research for children with cancer, which we hope will lead to better outcomes for pediatric patients. ACS CAN is committed to policy solutions that improve outcomes for all cancer patients.

We support the modifications your legislation would make to the Pediatric Research Equity Act (PREA) and the Best Pharmaceuticals for Children Act (BPCA). While PREA was intended to encourage manufacturers to study the effects of drugs in childhood diseases, it has not been successful in driving pediatric studies for therapeutic cancer drugs. PREA requirements for adult drugs do not apply to orphan drugs, and a large majority of all cancer drugs developed are classified as orphan. Drugs for some of the most common cancers, such as prostate, breast or colorectal cancer are less likely to receive orphan designation, but PREA requirements only apply to childhood research for the same indication as for adults, and children do not experience these cancers. The result is that PREA requirements have not been triggered for any cancer therapeutics.

Your bill recognizes that cancer therapeutics are increasingly targeted at specific molecular pathways that are often shared across different types of cancer, and therefore targeted drugs may have benefits in the pediatric population for cancers that are different than the cancer indication

in adults. In short, this bill attempts to update a longstanding policy based on our latest scientific understanding of cancer. By ensuring adult cancer drugs with the same molecular targets as pediatric cancers are subject to PREA requirements, the RACE Act will encourage new research and development in childhood cancer.

While we endorse the RACE for Children Act, we want to emphasize that proper implementation will be key to successfully achieving the goals of the legislation. Relative to adults, cancer in children is rare, meaning that the population of children available for clinical trials is small. The number of children diagnosed each year for any individual childhood cancer may range from as small as a few dozen up to a couple thousand, so a failure to appropriately select and prioritize required studies could result in multiple studies competing for the same small pool of patients, jeopardizing the ability to complete research in a timely manner. The legislation calls for guidance to be issued that would detail the process for prioritization and the types of molecular pathways subject to PREA studies. We believe that it is critical that this guidance be developed with broad stakeholder input, be based on sound science, and provide very clear criteria for the selection and prioritization process of agents newly subject to PREA requirements.

Outside of oncology, PREA and BPCA have worked in concert, and historically it has been possible for studies required by PREA to also be included in voluntary BPCA written request agreements. We would expect that if this legislation were to pass, it would likewise be possible for the BPCA incentives to continue to be available to oncology agents newly subject to PREA.

We appreciate the significant efforts that went into drafting the RACE for Children Act. As discussions of this legislation continue, we look forward to further dialogue about ways to make BPCA and PREA work better for children with cancer. If you have any questions, please feel free to contact me or have your staff contact Rosalie Abbott Rosalie.abbot@cancer.org or 202-585-3261. We look forward to working with you to improve the lives of children with cancer.

Sincerely,



Christopher W. Hansen
President
American Cancer Society Cancer Action Network