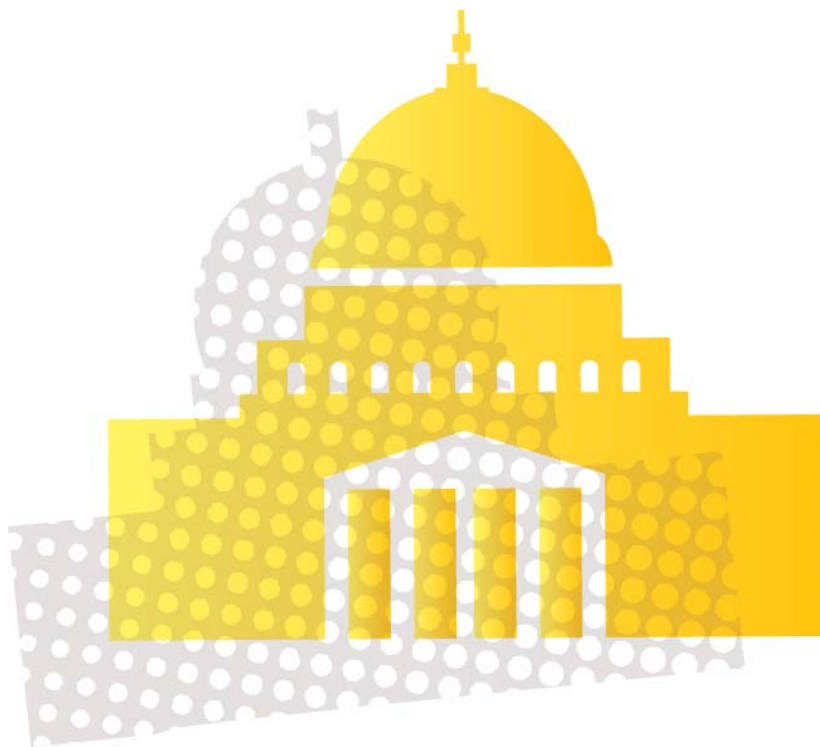


# PEDIATRIC CANCER LEGISLATIVE YEARBOOK 2017



Edited by:  
KIDS **V** CANCER

The Pediatric Cancer Yearbook 2017 was compiled and published by Kids v Cancer ([www.kidsvcancer.org](http://www.kidsvcancer.org)). All efforts were made to contact the lead advocates of each legislative initiative.

If you would like your federal legislative initiative to be included in future Pediatric Cancer Yearbooks, please contact Elena Gerasimov at [elena@kidsvcancer.org](mailto:elena@kidsvcancer.org).

If you would like to be on the mailing lists of all legislative efforts included in the Pediatric Cancer Legislative Year Book 2018, please sign up here:  
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## OVERVIEW: LEGISLATIVE ACCOMPLISHMENTS IN 2017

***We, the pediatric cancer community, have had a great year.***

***CONGRESS PASSED THE RACE FOR CHILDREN ACT:*** In August 2017, Congress passed The RACE for Children Act to require drug companies developing cancer targeted therapies for adults to also develop those drugs for children with cancer. We thank House Energy and Commerce Chair Greg Walden and Ranking Member Frank Pallone. We also thank Senate Health, Education, Labor and Pensions Chair Lamar Alexander and Ranking Member Patty Murray. We thank our champions: Sen. Michael Bennet, Sen. Marco Rubio, Rep. Michael McCaul, Rep. G.K. Butterfield.

***CONGRESS INCLUDED PEDIATRIC CANCERS IN THE DOD CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (DOD CDMRP):*** In 2017, Congress included in The DOD CDMRP Peer Review Cancer Research Program funding for: cancers in children, adolescents and young adults; pediatric brain tumors and brain cancers; and neuroblastoma. We thank Senate Appropriations Chair Thad Cochran and Ranking Member Dick Durbin, and House Appropriations Defense Subcommittee Chair Kay Granger and Ranking Member Pete Visclosky. We also thank our champions: Rep. Michael McCaul, Rep. Scott Peters, Rep. Sam Grave, Rep. Matt Gaetz.

***CONGRESS FULLY APPROPRIATED THE GABRIELLA MILLER KIDS FIRST RESEARCH ACT:*** In 2017 and 2016 Congress appropriated \$12.6 million each year pursuant to the Gabriella Miller Kids First Research Act. We thank Senate Chairman of the Committee on Appropriations Subcommittee on the Departments of Labor, Health and Human Services Blunt and Ranking Member Murray. We thank Chair of the House Appropriations Subcommittee on Labor, Health and Human Services, Education Tom Cole and Ranking Member Rosa DeLauro. We also thank our champions: Rep. Paul Cook and Rep. Ken Calvert.

***THE CREATING HOPE ACT PEDIATRIC PRIORITY REVIEW VOUCHER PROGRAM CREATED NEW VOUCHERS:*** In 2017, the FDA awarded five rare pediatric priority review vouchers, bringing the total number of vouchers for rare pediatric diseases to 13, including the second voucher for a pediatric cancer drug. As part of the 21<sup>st</sup> Century Cures Act, Congress reauthorized the Creating Hope Act pediatric priority review voucher program in December 2016. We thank House Energy and Commerce Committee Chair Greg Walden and Ranking Member Frank Pallone. We also thank Senate Health, Education, Labor and Pensions Chair Lamar Alexander and Ranking Member Patty Murray. We also thank our champions: Sen. Johnny Isakson, Sen. Bob Casey, Rep. Michael McCaul, Rep. G.K. Butterfield.

## FUTURE LEGISLATIVE AGENDA FOR 2018

**PASSAGE OF THE CHILDHOOD CANCER STAR ACT:** Advocates will ask Congress to pass the Childhood Cancer STAR Act. In December 2016, the House of Representatives passed the Childhood Cancer STAR Act by unanimous consent. However, the Senate did not pass it by the end of the 114<sup>th</sup> Congress. The Childhood Cancer STAR Act was reintroduced in House and Senate in the 115<sup>th</sup> Congress. There are over 340 cosponsors of the Act. (Rep. Michael McCaul, Rep. Jackie Speier, Rep. G.K. Butterfield, Rep. Mike Kelly, Sen. Jack Reed, Sen. Shelly Moore Capito)

**FULL APPROPRIATIONS OF THE GABRIELLA MILLER KIDS FIRST RESEARCH ACT:** Advocates will ask Congress to fully appropriate \$12.6 million for the Act. (Sen Roy Blunt, Rep. Tom Cole)

**CONTINUED INCLUSION OF PEDIATRIC CANCERS IN THE DOD CDMRP AND A NEW STAND-ALONE PEDIATRIC CANCER PROGRAM:** Advocates will ask Congress to continue funding for: (1) cancers in children, adolescents and young adults; (2) pediatric brain tumors and brain cancers; and (3) neuroblastoma. Advocates will also ask for a stand-alone program. (Rep. Michael McCaul, Rep. Scott Peters, Rep. Sam Graves)

**PASSAGE OF THE KIDS FIRST RESEARCH ACT 2.0:** Advocates will ask Congress to pass The Kids First Research Act 2.0 (Rep. Barbara Comstock, Rep. Harper)

**PASSAGE OF THE DEFERMENT FOR ACTIVE CANCER TREATMENT ACT:** Advocates will ask Congress to pass the Deferment for Active Cancer Treatment Act. (Rep. Ileana Ros-Lehtinen, Rep. Ed Perlmutter)

**INTRODUCTION AND PASSAGE OF THE STAMP OUT CHILDHOOD CANCER ACT:** Advocates will seek to introduce and pass the Stamp Out Childhood Cancer Act.

**PASSAGE OF THE HOUSE RESOLUTION FOR DIFFUSE INTRINSIC PONTINE GLIOMA:** Advocates will ask the House of Representatives to pass the House Resolution for Diffuse Intrinsic Pontine Glioma. (Rep. Steve Knight, Rep. Jackie Speier)

**BILLS & AUTHORIZATIONS PASSED IN 2017**

## **RACE FOR CHILDREN ACT OF 2017**

### **RESEARCH TO ACCELERATE CURES AND EQUITY FOR CHILDREN ACT (Title V of FDA Reauthorization Act, H.R. 2430)**

The RACE for Children Act was passed into law as Title V of the FDA Reauthorization Act to amend the Pediatric Research Equity Act (PREA) (21 U.S. Code 355c).

#### What is the problem/opportunity:

There are 900 drugs in the adult cancer pipeline but few of them have been studied for children with cancer. Those drugs that are studied in children pursuant to other programs are often studied years and even decades after they are developed for adults. While the Pediatric Research Equity Act requires companies to develop their adult drugs for children as well, PREA has not been applied to cancer because kids often have cancers that arise in different organs than adult cancers. However, cancer drug development is now guided by molecular targets that are often present in both adult and pediatric cancers.

The RACE for Children Act updates the Pediatric Research Equity Act (PREA, 21 U.S.C. 355c).

The RACE for Children Act of 2017 requires companies developing targeted cancer drugs for adults to also develop those drugs for children with cancer. The RACE for Children Act expands PREA so that the PREA's pediatric studies will be required when the molecular targets of the drugs in development are relevant to children's cancers. In addition, the RACE for Children Act ends an exemption from PREA requirements for cancer drugs that have orphan status.

#### 2017 Accomplishments:

**On August 18, 2017, The RACE for Children Act was passed into law as part of the FDA Reauthorization Act, Title V. The RACE for Children Act amends the Pediatric Research Equity Act (21 U.S.C. 355c).**

#### Next Steps:

Within 365 days of enactment of the FDA Reauthorization Act, FDA is required to hold a public meeting to solicit feedback from physicians and researchers (including pediatric oncologists and rare disease specialists), patients, and other stakeholders to provide input on development of a guidance.

Within two years of enactment of the FDA Reauthorization Act, FDA is required to publish a guidance.

Within three years of enactment of the FDA Reauthorization Act or a year after the FDA publishes the guidance, whichever is earlier, the requirements of the RACE for Children Act will be enforced.

For more information, please contact:

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## **DOD CDRMP FUNDING**

### **FOR CANCERS IN: YOUNG ADULTS, ADOLESCENTS AND CHILDREN NEUROBLASTOMA PEDIATRIC BRAIN TUMORS AND BRAIN CANCER**

#### What is the problem/opportunity:

The Department of Defense (DoD) has an approximately \$1 billion medical research program through the Congressionally Directed Medical Research Program (CDMRP). Historically, this program has appropriated \$300 million for breast, prostate, ovarian, lung and other cancers, with the average age of diagnosis for these cancers being 66 years old.

Eight six percent of the active military are under the age of 39 and more than 90% of the active military have families. As preponderance of active military and their families fall into the age range categorized by the NIH as Adolescent and Young Adults (AYA, ages 15-39) or pediatrics (0-18), the DoD Congressionally Directed Medical Research Program should fund research for cancers prevalent in adolescents, young adults and children.

#### 2017 Accomplishments:

In 2017, Congress passed the FY17 Omnibus Appropriations Act, that includes a \$10 million increase for the Department of Defense (DoD) Peer-Reviewed Cancer Research Program (PRCRP), bringing the funding level to \$60 million. The community successfully secured the continued inclusion of neuroblastoma and pediatric brain tumors and added adult brain cancer. Also, for the first time children, adolescents and young adult cancer are eligible categories for funding under the PRCRP, which is a part of the Congressionally Directed Medical Research Programs.

The pediatric cancer community also focused its efforts this year on making sure researchers within the brain cancer, pediatric and AYA community were made aware of the opportunity to apply for PRCRP for funding.

#### Next Steps:

Pediatric cancer advocates will ask that current eligible categories of cancer research within PRCRP continue to include cancers in children, AYA, neuroblastoma, brain cancer and pediatric brain tumors. Including these categories in the PRCRP program has no cost associated with it.

Additionally, we ask that the Senate language, which funds the PRCRP program at \$60 million, be included in the final version of the appropriations bill.

We are preparing for the creation of a \$30 million standalone peer-reviewed Adolescent, Young Adult, and Pediatric Cancer Research Program (also known as DoD Funding for AYA and Pediatrics).

Given that that cancer is the #1 disease killer in AYA and children, we believe the DoD medical research program should also fund a standalone research for cancers prevalent in adolescents and young adults and children.

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## **GABRIELLA MILLER KIDS FIRST ACT (HR 2019; Pub.L. 113–94)**

### What is the problem/opportunity:

Pediatric cancer receives inadequate funding by the National Institutes of Health (NIH).

Gabriella Miller was a girl who died of cancer on October 26, 2013 at the age of 10. While she was ill, she was an activist and raised support for research. In *The Truth 365* documentary, Gabriella was asked what she'd like to tell Congress about research on pediatric cancer. She answered that there needed to be "less talking, more doing... We need action." When House Majority Leader Eric Cantor saw this video, he decided to name the bill in her honor.

In 2014, The Gabriella Miller Kids First Research Act was signed into law, authorizing through the NIH a pediatric research fund, Gabriella Miller Kids First Research Program, of \$126 million over 10 years.

### 2017 Accomplishments:

Congress appropriated \$12.6 million in authorized funds pursuant to the Gabriella Miller Kids First Research Act.

### Next Steps:

Advocates will again ask Congress to fully fund The Gabriella Miller Kids First Research Act for FY2018, the program's 4th year. Advocates will ask Congress to authorize the funds that were appropriated under the Gabriella Miller Kids First Research Act for each of the 10 years of the program.

In addition, advocates are working with the NIH to ensure that the research funds from the Gabriella Miller Kids First Act are dedicated specifically to pediatric cancer.

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**BILLS & APPROPRIATIONS ON 2018 LEGISLATIVE AGENDA**

## CHILDHOOD CANCER STAR ACT OF 2017 (S 292, HR 820)

### (CHILDHOOD CANCER SURVIVORSHIP, TREATMENT, ACCESS, AND RESEARCH ACT)

#### What is the problem/opportunity:

The Childhood Cancer STAR Act would expand opportunities for childhood cancer research, improve efforts to identify and track childhood cancer incidence, and enhance the quality of life for childhood cancer survivors.

*Expanding Opportunities for Childhood Cancer Research:* The Childhood Cancer STAR Act would authorize the National Cancer Institute (NCI) to expand existing efforts to collect biospecimens for childhood cancer patients enrolled in NCI-sponsored clinical trials to maintain relevant clinical, biological, and demographic information on all children, adolescents, and young adults with cancer.

*Improving Childhood Cancer Surveillance:* Building upon previous efforts, this bill would authorize grants to state cancer registries to identify and track incidence of pediatric, adolescent and young adult cancers. This funding would be used to identify and train reporters of childhood cancer cases, secure infrastructure to ensure early reporting and capture of childhood cancer cases, and support the submission of cases into a national childhood cancer registry.

*Improving Quality of Life for Childhood Cancer Survivors:* As many as two-thirds of cancer survivors suffer from late effects of the disease or treatment, including secondary cancers and organ damage. This legislation would support research on the late effects of childhood cancers, including a study on insurance coverage and payment of care for childhood cancer survivors; improve collaboration among providers so that doctors are better able to care for this population as they age; and establish a new pilot program to begin to explore innovative models of care for childhood cancer survivors.

*Ensuring Pediatric Expertise at the National Institutes of Health (NIH):* The Childhood Cancer STAR Act would require the inclusion of at least one pediatric oncologist on the National Cancer Advisory Board and would improve childhood health reporting requirements to include pediatric cancer.

#### 2017 Accomplishments:

In December 2016, the House passed the STAR Act with unanimous consent with 270 cosponsors. However, the Senate did not vote on the STAR Act before the conclusion of the 114<sup>th</sup> Congress. In 2017, the House of Representatives and the Senate reintroduced The STAR Act. The STAR Act has over 340 cosponsors in the House and Senate.

Next Steps:

Advocates will ask the Senate and House of Representatives to pass the STAR Act into law.

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## **KIDS FIRST RESEARCH ACT 2.0 (HR 2008)**

### What is the problem/opportunity:

Additional funding is needed to fund research for childhood cancers and other disorders that strike our nation's children.

The Kids First Research Act 2.0 would redirect approximately \$320 million in existing, reserved and unused government funds from the Presidential Election Campaign Fund to the Gabriella Miller Kids First Pediatric research program at the NIH. Under the direction of the NIH, the funds would be used to develop a comprehensive shared data resource for scientists researching hundreds of different pediatric cancers and structural birth defects and would support the development of computational tools to analyze these large, complex genomic and clinical datasets.

### 2017 Accomplishments of the Kids First Research Act 2.0:

The Kids First Research Act 2.0 was introduced in the House in April 2017.

### 2017 Accomplishments of the Kids First Research Act of 2014

Supported with funding from the original Gabriella Miller Kids First Research Act, a data resource center has been established in collaboration with six partner organizations. The Center for Data Driven Discovery in Biomedicine at Children's Hospital of Philadelphia (CHOP) will lead a new, collaborative effort funded by the National Institutes of Health Common Fund to discover the causes of pediatric cancer and structural birth defects through big data. The Center will be known as the Kids First Pediatric Data Resource Center (DRC). Investigators will create a centralized, cloud-based database and discovery portal of well-curated clinical and genetic sequence data from dozens of childhood cancer and structural birth defects cohorts, comprising thousands of patients and their families.

### Next Steps:

Advocates will ask that Congress pass The Kids First Research Act 2.0.

### For more information, please contact:

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## DEFERMENT FOR ACTIVE CANCER TREATMENT ACT (HR 2976)

### What is the problem/opportunity:

In the last 10 years, nearly 70% of all college graduates have funded their education through student loans. The national delinquency rate on these loans is 11.2%. Delinquency is particularly a challenge for students in active cancer treatment.

Each year, more than 70,000 Americans ages 15 to 39 are diagnosed with cancer. Many adolescents and young adults diagnosed with cancer face the risk of delinquency on their student loans when treatment interferes with their ability to work or attend school.

The Deferment for Active Cancer Treatment Act will enable students who are diagnosed with cancer and who are actively receiving treatment to defer payments on public student loans without interest accruing and compounding during the deferment period. This bill does not seek to change the terms of the public loan agreement between lender and borrower beyond placing a pause in repayments while cancer treatment is underway.

### 2017 Accomplishments:

The Deferment for Active Cancer Treatment Act was introduced in the House in June 2017.

### Next Steps:

Advocates will ask Congress to pass the Act into law.

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## STAMP OUT CHILDHOOD CANCER ACT

### What is the problem/opportunity?

During the entire history of the FDA, only four drugs have been approved specifically for children's cancers. Today, childhood cancer research remains underfunded even though it is this nation's number one cause of death by disease for our children.

The Stamp Out Childhood Cancer Act is intended to help generate additional research funds for childhood, adolescent and young adult cancers. It will supplement National Cancer Institute funding for childhood cancer research without increasing taxes.

The proposed bill would introduce a postage stamp similar to the one that is now being used to generate research funds for breast cancer. Since 1998, more than 1 billion stamps have been sold, raising \$84.7 million for breast cancer research from sales of the Breast Cancer Research Stamp. The Stamp Out Childhood Cancer Act would have Congress direct the U.S. Postal Service to issue a stamp to be sold to the public in the same manner and denomination as the Breast Cancer Research Stamp and distribute funds in a similar manner. 70% of the proceeds from the sale of the Childhood Cancer Research Stamp would be directed to the National Cancer Institute to be used for childhood cancer research funding, and 30% of the proceeds would be directed to the Peer-Reviewed Young Adult, Adolescent, and Pediatric Cancer Research Program within the Department of Defense CDMRP.

### Next Steps:

Advocates will solicit House of Representatives early in 2018 to get the bipartisan Stamp Out Childhood Cancer Act sponsored and introduced. Once the bill has its sponsors, actions will be taken by interested advocates to get cosponsors for the bill and have it passed through the required committees and then have it voted on and approved by Congress.

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**RESOLUTIONS ON 2018 LEGISLATIVE AGENDA**

## **HOUSE RESOLUTION FOR DIPG (H. Res. 69)**

### What is the problem/opportunity:

Diffuse intrinsic pontine glioma (DIPG), a children's brain cancer, has a terminal prognosis.

The DIPG Awareness Resolution, H. Res. 69, addresses the inadequacy of research funding for DIPG and asks that pediatric and high-risk cancers have a more elevated consideration for research grant funding both with government and private sectors. Specifically, it asks the National Institutes of Health to elevate the consideration of mortality rate and years of life lost in the grant decision-making process. The Resolution would also establish a national "DIPG Awareness Day" on May 17 to raise awareness of the disease.

In addition, The Michael Mosier Defeat DIPG Foundation's "Across the Map" project is petitioning for every state to issue a proclamation also designating May 17 as DIPG Awareness Day.

### 2017 Accomplishments:

In 2017, the House of Representatives introduced The DIPG Awareness Resolution (H.Res. 69).

As of 2017, there were 21 U.S. states that have proclaimed May 17 to be Awareness Day for DIPG.

### Next Steps:

Advocates will ask the House to pass H.Res. 69

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**BILLS PASSED IN 2017 THAT ARE NOT PEDIATRIC CANCER-SPECIFIC**

## **FDA REAUTHORIZATION ACT OF 2017: GUIDANCE FOR INDUSTRY ON ACCESS TO INVESTIGATIONAL DRUGS**

The FDA Reauthorization Act of 2017 calls for the FDA to convene a public meeting within 270 days of its enactment to discuss clinical trial inclusion and exclusion criteria in preparation for the FDA to draft guidance on patients' access to investigational drugs. The guidance is to include the assessment of the impact of exclusion criteria on the enrollment in clinical trials of specific populations, including infants and children. Finally, it specifically mentions that data from expanded access trials may be used by the FDA to support safety and effectiveness of a drug.

The Act mandates FDA to examine whether the new form and guidance on expanded access (compassionate use) revised in June 2016 have reduced application burden and improved access for individual patients seeking compassionate use, and what barriers to such access remain. In addition, within a year, FDA is to issue regulations or a guidance to streamline the Institutional Review Board review of compassionate use requests, which will include a provision making it possible for just one member of an IRB to review such requests.