

## [Childhood Cancer STAR Act \(HR 820 / S 292, 115th Congress\)](#)

Amends a series of sections throughout the Public Health Service Act to improve the treatment and understanding of pediatric cancers and late effects for survivors and their families.

Updated last **December 20, 2017**  
for the 02/02/2017 versions of HR 820 and S 292.

### WHAT IT DOES

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[HR 820](#) and [S 292](#) are identical bills proposing the “Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act of 2017” (here, “childhood cancer” includes cancer in children, adolescents, and young adults. )The act is comprised of two main titles addressing the maximization of 1) childhood cancer research and 2) the delivery of care for childhood cancer survivors.

Portions of this act amend sections of the [Public Health Service Act](#) to improve childhood cancer research and [survivorship](#) by stipulating \$150 million funding over five years for [surveillance](#) and collection of childhood cancer [biospecimens](#), survivor monitoring and assistance programs, and the development of expertise in clinical and administrative positions. This act has the following amendments and stipulations:

#### Section 101 — Children’s Cancer Biorepositories and Biospecimen Research

This section amends section 417E of the Public Health Service Act ([42 U.S.C. 285a-11](#)), establishing and funding Department of Health and Human Services (HHS) and National Institute of Health (NIH) efforts to facilitate and expand opportunities for research regarding the treatment and prevention of childhood cancers, with respect to the following:

- Awards, Use of Funds, and Criteria for Applicants – Provide approximately \$30 million annual (FY 2018 through 2022) in funding and an application process to support:
  - Collection and secured storage of biospecimens, clinical data, and demographic data voluntarily provided by patients diagnosed with the country’s hardest to treat childhood cancers; and
  - Integration of the biospecimens and data into a publicly available and searchable database to be used by researchers and physicians for research regarding the cause of these cancers, why relapse occurs, and the effects of known cancer treatments.
- Single Point of Access; Standard Data; Guidelines and Oversight; and Coordination of Biospecimens and Data – Specifying expectations regarding the format and storage of biospecimens and patient data:
  - Single Point of Access – HHS will ensure that awarded biorepository datasets are electronically available.
  - Standard Data – HHS will determine a standardization scheme for all awarded biorepository datasets.
  - Guidelines and Oversight – HHS will determine responsible development and maintenance of awarded biorepositories.
- Reports – mandates the HHS to submit a report to Congress within four years regarding:
  - Number of data collected and requested resulting from the Childhood Cancer STAR Act;
  - Barriers and complications in the collection or access of data; and
  - Recommendations for the improvement of provisions under the Childhood Cancer STAR Act.

#### Section 102 — Improving Childhood Cancer Surveillance

Section 102 of this act amends section 399E-1 of the Public Health Service Act ([42 U.S.C. 280e-3a](#)), to provide funding for State cancer registries for the identification and tracking of childhood cancers, which would eventually be incorporated into a national registry. Such funding may be used for:

- Identification, recruitment, and training of patient data sources (e.g., medical facilities);
- Procedures and infrastructure for quick and easy inclusion of data in State cancer registries by electronic reporting;
- The submission of anonymized biospecimen, clinical, and demographic data to the Center for Disease Control's (CDC) [national registry](#); and/or
- Monitoring the long-term treatment side effects, or [late effects](#), experienced by childhood cancer survivors (e.g., secondary cancers or organ damage).

Section 111 — Inclusion of at Least One Pediatric Oncologist on the [National Cancer Advisory Board](#)

Section 112 — Sense of Congress Regarding Pediatric Expertise at the National Cancer Institute

The first section ([Section 111](#)) under this subtitle amends Clause (iii) of section 406(h)(2)(A) of the Public Health Service Act ([42 U.S.C. 284a\(h\)\(2\)\(A\)](#)), which determines the establishment; membership; compensation; and terms of office for advisors to the national research institutes, to ensure at least one member of the National Cancer Advisory Board has professional experience in pediatric oncology. Similarly the second section ([Section 112](#)) mandates the NCI to include pediatric oncologists in “all applicable study sections, committees, advisory groups, and panels”.

Section 121 — Reporting on Childhood Cancer Research Projects

This section amends section 409D(c)(3) of the Public Health Service Act ([42 U.S.C. 284h\(c\)\(3\)](#)) to require an annual report from the NIH Director to Congress and the public on childhood cancer research projects supported by the NIH.

Section 201 — Cancer Survivorship Programs

This section adds the following sections after section 399N of the Public Health Service Act ([42 U.S.C. 280g-2](#)).

- Section 399N-1. Pilot Programs to Explore Model Systems of Care for Pediatric Cancer Survivors. – authorizes HHS to fund pilot programs at a variety of medical facilities that develop, study, or evaluate systems of monitoring and caring for childhood cancer survivors to provide them with more holistic, lifelong care beyond cancer treatment.
- Section 399N-2. Workforce Development Collaborative on Medical and Psychosocial Care for Childhood Cancer Survivors. – establishes a convening of cross-specialty, multidisciplinary professionals to cultivate and share best practices for medical and psychosocial services.

Section 202 — Grants to Improve Care for Pediatric Cancer Survivors

This section retitles and amends section 417E of the Public Health Service Act ([42 U.S.C. 285a-11](#)), “Research and Awareness”, which established and funds research on the treatment and prevention of pediatric cancers, to now include “Survivorship”.

1. Research on Causes of Health Disparities in Pediatric Cancer Survivorship – authorizes the NIH to fund research on childhood cancer survivorship to examine aspects like treatment outcomes, barriers to care, and the physiological and psychological needs of underserved populations.
2. Research on Late Effects and Follow-up Care for Pediatric Cancer Survivors – authorizes the NIH to conduct or support research on cancer late effects, including studies on:
  - The molecular factors affecting long-term complications;
  - Models to predict survivors with the highest risk of long-term complications;
  - Targeted interventions to treat or avoid late effects of cancer treatment; and
  - Transitions in care and the competent training for providers to administer and examine various forms of follow-up care for cost-effectiveness.

Section 203 — Comprehensive Long-term Follow-up Services for Pediatric Cancer Survivors

This section authorizes HHS to establish a task force of wide-ranging medical expertise to create standards and metrics for high-quality childhood cancer survivor care.

#### Section 204 — Survivorship Demonstration Project

This section directs HHS to initiate a three-year demonstration project that spans a variety of sites across the country and is designed to improve childhood cancer survivor care. Activities carried out under the demonstration project may include:

- Efficient care coordination and patient data sharing by multidisciplinary provider teams;
- Improvement of cancer survivor monitoring programs; and
- Development of peer support and mentoring programs to assist cancer survivors and their families.

Survivorship Demonstration Projects will be reviewed by the [US Government Accountability Office](#) (GAO) and a report will be submitted to Congress to provide an assessment of the efficacy of the Project's effect on the cost-effectiveness of services provided to survivors.

#### Section 211 — Report by the Comptroller General

This final section directs GAO to issue a report to Congress detailing barriers faced by childhood cancer survivors to receiving and paying for medical care throughout their lifetime, and relevant solutions. Specifically, the report will consider potential barriers like:

- Deficient education of patients, providers, and other parties regarding late effects and appropriate care;
- Inadequate payment codes for necessary services; and
- Lack of access to care, including palliative care.

#### RELEVANT SCIENCE

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##### Biospecimen Collection and Storage

Sections 101 and 102 of this bill call for the funding of biospecimen collection for the purpose of studying the causes and treatment of childhood cancers. Biospecimens are voluntarily collected samples of [DNA, cells, tissues](#) (e.g., a [tumor](#)), blood, [gametes](#), and/or waste emissions (including sweat, hair, and shed skin cells.) Biospecimens [enable scientists](#) to study the molecular and cellular characteristics of different types of cancer. For instance, by sequencing the DNA of a tumor and comparing it to normal tissue, researchers can begin to identify cancer-promoting genetic changes. The methods and techniques of biospecimen collection and storage can greatly affect the quality of research derived. Here, quality is a function of how little the biospecimen is altered at a molecular and cellular level by the collection and storage processes. While this bill allocates funding for the improvement of biospecimen collection, the NCI has published [best practices](#) for biospecimen collection, storage, and research to ensure quality research as well as the privacy and autonomy of the patients whose biospecimens are collected.

##### Late effects of Childhood Cancers

Health complications experienced by cancer survivors as a result of the cancer or its treatment are known as late effects. According to [research](#) from St. Jude Children's Research Hospital, more than 95% of childhood cancer survivors will have a significant health-related issue by the time they are 45 years of age in the form of a late effect. Late effects, sometimes fatal, can affect [a wide variety of bodily functions](#).

According to the [NCI](#), childhood cancer late effects are often caused by the treatment that the patient receives, which can have unintended effects on other parts of the body besides the cancer:

- [Chemotherapy](#) - can cause cancer cells (and normal cells) to stop growing and/or die through a variety of mechanisms, but often

works by damaging DNA;

- [Radiation therapy](#) - damages DNA in cancer (and normal) cells, causing the cells to stop dividing and/or die;
- Surgery - surgery goals are balanced between removing as much of the tumor as possible and limiting damage to the surrounding normal tissue; and
- [Stem cell transplant](#) - replenishes blood stem cells wiped out by high doses of radiation or chemotherapy, but can cause [side effects](#).

The [late effects of childhood cancers](#) can be especially damaging due to their effect on the development of the child or adolescent. [Areas of particular concern](#) for childhood and adolescent cancer survivors include:

- [Secondary cancers](#) - new cancers that can arise months or years after treatment, often as a result of DNA damage to normal tissue caused by treatment.
- Growth and Fitness - endocrine defects, sometimes caused by treatment or the tumor itself, can stunt bone and muscle growth, organ fitness, metabolism, and strength.
- Sexual Development - in addition to affecting a patient's reproductive health, chemo and radiation therapies, as well as cancers of the reproductive organs, can also delay or severely impair puberty.
- Brain Development and Behavioral Maturity - brain and blood cancers, and their treatment, tend to have the greatest effect on the survivor's brain development and behavioral maturity. Nevertheless, radiation treatments of all cancers have a great effect on children's brains as they are vulnerable during early development. Negative effects on survivors' brain development and behavior maturity can include:
  - learning disabilities;
  - problems with memory and attention;
  - poor eye-hand coordination;
  - delayed development; and
  - delayed schooling.

### [Psychosocial Effects of Childhood Cancer](#)

Provisions under sections 201 and 202 stipulate programs and research to address the psychosocial effects of childhood cancer experienced by patients and their families. While the stress of childhood cancer can have negative effects on a patient's adherence to their treatment regimen by impairing cognition and weakening motivation, stress can also present problems for patients and families. Families of children with cancer have shown signs of post-traumatic stress disorder and psychological problems (such as depression and anxiety) are often accompanied by physical problems like loss of appetite, sleeplessness, and fatigue.

## BACKGROUND

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### Congressional Findings on Childhood Cancer

Included in the prelude of this bill were a series of Congressional Findings detailing the current state of childhood cancer in the US.

### Childhood Cancer Research Relative to Adult Cancer Research Funding

Childhood Cancer Advocacy Groups, such as St. Baldrick's, have provided [reports](#) raising concerns about the relative disproportion of funding allocated for the research and treatment of childhood cancers compared to adult cancers. In particular, of the taxpayer funding for cancer research at the National Cancer Institute, only 4% is awarded to pediatric studies. For more context, in the NCI [budget](#) for 2015, Prostate cancer receives more research funding from NCI than all childhood cancers combined.

### National Cancer Institute Research Programs for Childhood Cancer Care

Despite the relative disproportion cited between [NCI](#) funding for childhood cancer research and development, the NCI hosts [several](#)

[programs](#) focused on the advancement of childhood cancer care including study and trial groups, consortia, and programs.

#### The Unique Financial Burdens of Childhood Cancer

During the summer of 2017, a children's advocacy group, Children's Cause Cancer Advocacy, published its [key findings](#) and a [report](#) regarding the specific financial burdens for patients, survivors, and families with childhood cancer. Findings from both sources include: nearly 20% of child cancer patients already live in poverty prior to diagnosis; 10-15% of families enter poverty after their child's diagnosis; over 60% of families report financial hardships due to the costs of their child's care; 87% report great difficulty maintaining their regular employment, losing over 40% of their annual income; and about 44% report allocating over 20 hours a week, on average, to facilitate their child's care.

#### Childhood Cancer Mortality

As indicated in this bill's [Congressional Findings](#) cancer is the number one cause of death by disease for children under the age of fourteen. Further, a [summary of facts](#) related to the mortality of childhood cancers was created by the advocacy group, the Coalition Against Childhood Cancer.

#### The Gabriella Miller Kids First Pediatric Research Program

The [Gabriella Miller Kids First Pediatric Research Program](#) is one of thirty one [Common Fund Programs](#) at the NIH and the focus of Section 101 in this bill . Funding under this program is stipulated for the research and improvement of biospecimen and genetic data analysis of the causes childhood cancer and the success of current treatments.

#### ENDORSEMENTS & OPPOSITION

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##### Endorsements

- Chairman [Michael McCaul \(R-TX\)](#) and co-founder of the [Childhood Cancer Caucus](#), the sponsor of this bill in the House, [stated](#): "...this tragedy [of childhood cancer] continues to be a far too frequent occurrence for children across the nation. That is why we need to move legislation like the STAR Act through Congress this year, and prevent the worst outcomes from becoming a reality."
- Senator [Jack Reed \(D-RI\)](#), sponsor of this bill in the Senate, [stated](#): "The Childhood Cancer STAR Act will bring needed assistance to children with cancer and their families by expanding opportunities for research on childhood cancer and providing new strategies to help survivors overcome late health effects, such as secondary cancers."
- A joint statement of support from sponsors McCaul and Reed can be found [here](#).

##### Opposition

At present, there has not been any publicly reported endorsement of or opposition to this bill.

#### STATUS

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HR 820 was introduced in the House on February 2, 2017, and referred to the [Subcommittee on Health](#) by the [Committee on Energy and Commerce](#) on February 3, 2017.

S 292 was introduced in the Senate on February 2, 2017, and referred to the [Committee on Health, Education, Labor, and Pensions](#).

#### RELATED POLICIES

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## The Hematological Cancer Research Investment and Education Act

The Hematological Cancer Research Investment and Education Act of 2002 ([42 U.S. Code § 285a-10](#)), referenced in [section 201](#) of this bill, amended the Public Health Service Act to fund NCI research and education programs focused on blood cancers.

## National Cancer Moonshot Initiative and Task Force

In January of 2016, under President Obama, the [National Cancer Moonshot Initiative](#) ([SciPol brief Available](#)) was created to direct over \$1 billion provided by the [21st Century Cures Act](#) ([SciPol brief Available](#)) to identify new ways to prevent, diagnose, and treat cancer. Within this new initiative, funding for the study of new childhood cancer treatments was stipulated.

## Proclamation of National Childhood Cancer Awareness Month

On September 1st, 2016, the Executive Office of the President under Barack Obama issued a [proclamation](#) stipulating September as National Childhood Cancer Awareness Month to bring attention to the stories of childhood cancer patients, survivors, and their families.

[HR 1121](#), 115th Congress - Pre-Existing Conditions Protection Act of 2017 and

[HR 628](#), 115th Congress - Guaranteed Health Coverage for Pre-Existing Conditions Act of 2017

These related bills, introduced in February and January of 2017, would prevent the exclusion and discrimination of individuals with pre-existing health conditions from obtaining insurance, in the event the Patient Protection and Affordable Care Act is repealed ([SciPol brief Available](#)).

[S 463](#) and [HR 1834](#), 115th Congress - Cancer Care Payment Reform Act of 2017

These identical bills introduced at the end of February 2017 in the House and Senate amends [title XVIII](#) of the Social Security Act, which deals with the provision of Medicare. This amendment provides funding to the Centers for Medicare and Medicaid Services to establish an Oncology Medical Home Demonstration Project, which would fund and monitors efforts to coordinate patient oncology care.

[S 456](#) and [HR 1231](#), 115th Congress - RACE for Children Act

These identical bills, introduced at the end of February 2017 in the House and Senate amends the [Federal Food, Drug, and Cosmetic Act](#) to fund, monitor, and incentivize the development of new and timely drug treatments for childhood cancers.

[HR 2008](#), 115th Congress - Kids First Research Act 2.0

This bill, introduced in April of 2017 in the House proposes to increase funding for the treatment of childhood diseases, by amending the [Internal Revenue Code](#) to eliminate taxpayer financing of presidential election campaigns and reallocate the funds to the NIH's Pediatric Research Fund.

## White House Press Release Regarding Patients with Preexisting Conditions

On May 2, 2017, the White House Office of the Press Secretary provided a statement for immediate release that directed attention to [a Wall Street Journal editorial](#) written by the newspaper's Editorial Board explaining how the House's Patient Protection and Affordable Care Act replacement, the American Health Care Act, would better serve patients with preexisting conditions, including survivors of childhood cancers facing late effects.

**POLICY HISTORY**

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Largely identical versions of this bill ([HR 3381](#) and [S 1883](#), 114th Congress) were introduced in July 2015. As with the current bill, the 114th House of Representatives referred HR 3381 to the Committee on Energy and Commerce, then Subcommittee on Health, and finally passed and sent an [amended version](#) to the Senate in December of 2016. The amended version was identical to HR 820.

**SPONSORS**

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HR 820

Sponsor: [Representative Michael T. McCaul](#) (R-TX-10)

[Cosponsors:](#)

- 152 Democrats
- 108 Republicans

S 292

Sponsor: [Senator Jack Reed](#) (D-RI)

[Cosponsors:](#)

- 10 Republicans
- 9 Democrats
- 1 Independent

**PRIMARY AUTHOR**

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**RECOMMENDED CITATION**

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Duke SciPol, "Childhood Cancer STAR Act (HR 820 / S 292, 115th Congress)" available at <http://scipol.duke.edu/content/childhood-cancer-star-act-hr-820-s-292-115th-congress> (04/04/2018).