

113TH CONGRESS  
1ST SESSION

# S. 1251

To establish programs with respect to childhood, adolescent, and young adult cancer.

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## IN THE SENATE OF THE UNITED STATES

JUNE 27, 2013

Mr. REED (for himself, Mrs. FISCHER, Mr. MENENDEZ, Mr. CASEY, Mr. FRANKEN, and Ms. KLOBUCHAR) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To establish programs with respect to childhood, adolescent, and young adult cancer.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Caroline Pryce Walker  
5 Conquer Childhood Cancer Reauthorization Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) Every year, 13,500 children in the United  
9 States are diagnosed with cancer.

1           (2) While the cure rates for some childhood  
2           cancers are now over 80 percent, the survival rates  
3           for many types of cancers in children remain ex-  
4           tremely low.

5           (3) According to the Centers for Disease Con-  
6           trol and Prevention, cancer continues to be the lead-  
7           ing cause of death by disease in children and adoles-  
8           cents under the age of 14.

9           (4) There are currently more than 360,000  
10          childhood cancer survivors living in the United  
11          States.

12          (5) As many as two-thirds of childhood cancer  
13          survivors experience at least one long-term health ef-  
14          fect of their cancer treatment, including secondary  
15          malignancies, cardiopulmonary damage, physical and  
16          intellectual developmental impairments, endocrine  
17          disorders, and others.

18          (6) Collection of biospecimens and clinical and  
19          demographic data on the maximum possible number  
20          of children with cancer in the United States is nec-  
21          essary to improve childhood cancer treatments and  
22          cures. Currently biospecimens and some demo-  
23          graphic data are collected for less than half of chil-  
24          dren with cancer.

1 **SEC. 3. COMPREHENSIVE CHILDREN’S CANCER BIOREPOSI-**  
2 **TORIES.**

3 (a) IN GENERAL.—Section 417E of the Public  
4 Health Service Act (42 U.S.C. 285a–11) is amended—

5 (1) by redesignating subsections (c) and (d) as  
6 subsections (k) and (l), respectively;

7 (2) by striking subsections (a) and (b) and in-  
8 serting the following:

9 “(a) COMPREHENSIVE CHILDREN’S CANCER BIO-  
10 REPOSITORIES.—The Secretary, acting through the Direc-  
11 tor of NIH, may make an award for a duration of at least  
12 5 years to an entity or entities described in subsection (d)  
13 to build upon existing initiatives to collect biospecimens  
14 and clinical and demographic information for at least 90  
15 percent of all children, adolescents, and young adults with  
16 cancer in 1 or more Comprehensive Children’s Cancer Bio-  
17 repositories to achieve a better understanding of the cause  
18 of such cancers and the effects of treatments for such can-  
19 cers.

20 “(b) USE OF FUNDS.—Amounts received under the  
21 award under subsection (a) may be used to carry out the  
22 following:

23 “(1) Prospectively acquire, preserve, and store  
24 high quality, donated biospecimens and associated  
25 clinical and demographic information on children,

1 adolescents, and young adults diagnosed with cancer  
2 in the United States.

3 “(2) Maintain a secure searchable database on  
4 stored biospecimens and associated clinical and de-  
5 mographic data from children, adolescents, and  
6 young adults with cancer for the conduct of research  
7 by scientists and qualified health care professionals.

8 “(3) Establish procedures for evaluating appli-  
9 cations for access to such biospecimens and clinical  
10 and demographic data from researchers and other  
11 qualified health care professionals.

12 “(4) Make available and distribute biospecimens  
13 and clinical and demographic data from children,  
14 adolescents, and young adults with cancer to re-  
15 searchers and qualified health care professionals for  
16 peer-reviewed research at a minimal cost.

17 “(c) NO REQUIREMENT.—No child, adolescent, or  
18 young adult with cancer shall be required to contribute  
19 a specimen to a Biorepository or share clinical or demo-  
20 graphic data.

21 “(d) APPLICATION; CONSIDERATIONS.—

22 “(1) APPLICATION.—To be eligible to receive an  
23 award under subsection (a) an entity shall submit an  
24 application to the Secretary at such a time, in such

1 a manner, and containing such information as the  
2 Secretary may reasonably require.

3 “(2) CONSIDERATIONS.—In evaluating the ap-  
4 plications in paragraph (1), the Secretary shall con-  
5 sider the existing infrastructure of the entity that  
6 would allow for the timely capture of biospecimens  
7 and related clinical and demographic information for  
8 children, adolescents, and young adults with cancer.

9 “(e) PRIVACY PROTECTIONS; CONSENT.—

10 “(1) IN GENERAL.—The Secretary may not  
11 make an award under subsection (a) to an entity un-  
12 less the Secretary ensures that such entity—

13 “(A) collects biospecimens and associated  
14 clinical and demographic information from chil-  
15 dren with appropriate permission from parents  
16 or legal guardians in accordance with Federal  
17 and State law; and

18 “(B) adheres to strict confidentiality to  
19 protect the identity and privacy of patients in  
20 accordance with Federal and State law.

21 “(2) CONSENT.—The Secretary shall establish  
22 an appropriate process for achieving consent from  
23 the patient, parent, or legal guardian.

24 “(f) SINGLE POINT OF ACCESS; STANDARD DATA;  
25 GUIDELINES AND OVERSIGHT.—

1           “(1) SINGLE POINT OF ACCESS.—The Secretary  
2 shall ensure that a Biorepository established under  
3 subsection (a) has electronically searchable data for  
4 use by researchers and other qualified health care  
5 professionals in the manner and to the extent de-  
6 fined by the Secretary.

7           “(2) STANDARD DATA.—The Secretary shall re-  
8 quire all recipients of an award under this section to  
9 make available a standard dataset for the purposes  
10 of paragraph (1) in a standard electronic format  
11 that enables researchers and qualified health care  
12 professionals to search.

13           “(3) GUIDELINES AND OVERSIGHT.—The Sec-  
14 retary shall develop and disseminate appropriate  
15 guidelines for the development and maintenance of  
16 the biorepositories authorized under this section, in-  
17 cluding appropriate oversight.

18           “(g) DEFINITIONS.—

19           “(1) AWARD.—The term ‘award’ includes a  
20 grant, contract, cooperative agreement, or other  
21 mechanism determined by the Secretary.

22           “(2) BIOSPECIMEN.—The term ‘biospecimen’  
23 includes—

24                   “(A) solid tumor tissue or bone marrow;

25                   “(B) normal or control tissue;

1           “(C) blood/plasma;  
2           “(D) DNA and RNA extractions;  
3           “(E) familial DNA; and  
4           “(F) any other sample required by the Sec-  
5           retary.

6           “(3) CLINICAL AND DEMOGRAPHIC INFORMA-  
7           TION.—The term ‘clinical and demographic informa-  
8           tion’ shall include—

9           “(A) date of diagnosis;  
10          “(B) age at diagnosis;  
11          “(C) patient’s gender, race and ethnicity;  
12          “(D) extent of disease at enrollment;  
13          “(E) site of metastases;  
14          “(F) location of primary tumor coded;  
15          “(G) histologic diagnosis;  
16          “(H) tumor marker data when available;  
17          “(I) treatment and outcome data;  
18          “(J) information related to specimen qual-  
19          ity; and  
20          “(K) any other information required by the  
21          Secretary.

22          “(h) COORDINATION.—The Secretary shall ensure  
23          that clinical and demographic information collected in ac-  
24          cordance with this section is collected in coordination with  
25          the information collected under section 399E–1.

1       “(i) PROHIBITION ON USE OF FUNDS.—Funds made  
2 available under this section shall not be used to acquire,  
3 preserve, or maintain a biospecimen collected from a pa-  
4 tient if such activity is already covered by funds available  
5 from the National Cancer Institute for such purpose.

6       “(j) REPORT.—Not later than 4 years after the date  
7 of enactment of the Caroline Pryce Walker Conquer Child-  
8 hood Cancer Reauthorization Act, the Secretary shall sub-  
9 mit to Congress a report on—

10           “(1) the number of biospecimens and cor-  
11 responding clinical demographic data collected  
12 through the Comprehensive Children’s Cancer Bio-  
13 repositories established under subsection (a);

14           “(2) the number of biospecimens and cor-  
15 responding clinical demographic data requested for  
16 use by researchers;

17           “(3) any barriers to the collection of biospeci-  
18 mens and corresponding clinical demographic data;

19           “(4) any barriers experienced by researchers or  
20 health care professionals in accessing the biospeci-  
21 mens and corresponding clinical demographic data  
22 necessary for use in research; and

23           “(5) any recommendations with respect to im-  
24 proving the Comprehensive Children’s Cancer Bio-  
25 repository program under this section.”; and

1           (3) in subsection (1), as so redesignated, by  
2           striking the first sentence and inserting the fol-  
3           lowing: “For purposes of carrying out this section  
4           and section 399E–1, there are authorized to be ap-  
5           propriated such sums as may be necessary for each  
6           of fiscal years 2014 through 2018.”.

7           (b) IMPROVING CHILDHOOD CANCER SURVEIL-  
8 LANCE.—Section 399E–1 of the Public Health Service Act  
9 (42 U.S.C. 280e–3a) is amended—

10           (1) by redesignating subsection (b) as sub-  
11           section (d); and

12           (2) by striking subsection (a) and inserting the  
13           following:

14           “(a) IN GENERAL.—The Secretary, acting through  
15           the Director of the Centers for Disease Control and Pre-  
16           vention, shall award grants to State cancer registries to  
17           enhance and expand infrastructure to track the epidemi-  
18           ology of cancer in children, adolescents, and young adults.  
19           Such registries shall be updated to include each occurrence  
20           of such cancers within a period of time designated by the  
21           Secretary.

22           “(b) ACTIVITIES.—The grants described in sub-  
23           section (a) may be used for—

1           “(1) identifying, recruiting, and training all po-  
2           tential sources for reporting childhood, adolescent,  
3           and young adult cancer cases;

4           “(2) developing procedures to implement early  
5           inclusion of childhood, adolescent, and young adult  
6           cancer cases on State cancer registries through the  
7           use of electronic reporting;

8           “(3) purchasing infrastructure to support the  
9           early inclusion of childhood, adolescent, and young  
10          adult cancer cases on such registries;

11          “(4) submitting deidentified data to the Centers  
12          for Disease Control and Prevention for inclusion in  
13          a national database of childhood, adolescent, and  
14          young adult cancers; and

15          “(5) tracking the late effects of childhood, ado-  
16          lescent, and young adult cancers.

17          “(c) COORDINATION.—The Secretary shall ensure  
18          that information collected through State cancer registries  
19          under this section is collected in coordination with clinical  
20          and demographic information collected under section  
21          417E.”.

1 **SEC. 4. REPORT TO IMPROVE DEVELOPMENT OF NEW**  
2 **DRUGS AND BIOLOGIC PRODUCTS TO TREAT**  
3 **CHILDHOOD CANCERS.**

4 (a) IN GENERAL.—Not later than 2 years after the  
5 date of enactment of this Act, the Comptroller General  
6 of the United States shall report to Congress on barriers  
7 to studying oncologic therapies in pediatric populations  
8 under section 505B of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 355c).

10 (b) CONTENT.—The report under subsection (a) shall  
11 include—

12 (1) an assessment of the feasibility of requiring  
13 studies for a pediatric oncologic indication under  
14 section 505B of the Federal Food, Drug, and Cos-  
15 metic Act (21 U.S.C. 355c) if the therapeutic target  
16 of a drug or biologic product for an adult oncologic  
17 indication is highly relevant to any pediatric cancer  
18 to which it could apply;

19 (2) recommendations to overcome any barriers  
20 identified in the report on how to improve research,  
21 development and access to new oncologic therapies  
22 for use in pediatric patients; and

23 (3) an assessment of the potential impact of al-  
24 tering the exemption under subsection (k) of such  
25 section 505B.

1           (c) STAKEHOLDER INPUT.—The report under sub-  
2 section (a) shall be developed with input from relevant  
3 stakeholders.

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