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113TH CONGRESS
1ST SESSION

H. R. 2607

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 2013

Mr. VAN HOLLEN (for himself, Mr. MCCAUL, Mr. UPTON, Ms. SPEIER, Mr. REICHERT, Ms. CASTOR of Florida, Mr. KING of New York, Mr. WAXMAN, and Mr. HARPER) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act''.

SEC. 2. FINDINGS.

Congress finds as follows:

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

(2) While the cure rates for some childhood cancers are now over 80 percent, the survival rates for many types of cancers in children remain extremely low.

(3) According to the Centers for Disease Control and Prevention, cancer continues to be the leading cause of death by disease in children and adolescents under the age of 14.

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

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

(6) Collection of biospecimens and clinical and demographic data on the maximum possible number of children with cancer in the United States is necessary to improve childhood cancer treatments and cures. Currently biospecimens and some demographic data are collected for less than half of children with cancer.

SEC. 3. COMPREHENSIVE CHILDREN'S CANCER BIOREPOSITORIES.

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

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

(2) by striking subsections (a) and (b) and inserting the following:

''(a) COMPREHENSIVE CHILDREN'S CANCER BIOREPOSITORIES.—The Secretary, acting through the Director of NIH, may make an award for a duration of at least 5 years to an entity or entities described in subsection (d) to build upon existing initiatives to collect biospecimens and clinical and demographic information for at least 90 percent of all children, adolescents, and young adults with cancer in 1 or more Comprehensive Children's Cancer Biorepositories to achieve a better understanding of the cause of such cancers and the effects of treatments for such cancers.

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

''(1) Prospectively acquire, preserve, and store high-quality, donated biospecimens and associated clinical and demographic information on children,

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

''(2) Maintain a secure searchable database on stored biospecimens and associated clinical and demographic data from children, adolescents, and young adults with cancer for the conduct of research by scientists and qualified health care professionals.

''(3) Establish procedures for evaluating applications for access to such biospecimens and clinical and demographic data from researchers and other qualified health care professionals.

''(4) Make available and distribute biospecimens and clinical and demographic data from children, adolescents, and young adults with cancer to researchers and qualified health care professionals for peer-reviewed research at a minimal cost.

''(c) NO REQUIREMENT.—No child, adolescent, or young adult with cancer shall be required to contribute a specimen to a Biorepository or share clinical or demographic data.

''(d) APPLICATION; CONSIDERATIONS.—

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

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

''(2) CONSIDERATIONS.—In evaluating the applications in paragraph (1), the Secretary shall consider the existing infrastructure of the entity that would allow for the timely capture of biospecimens and related clinical and demographic information for children, adolescents, and young adults with cancer.

''(e) PRIVACY PROTECTIONS; CONSENT.—

''(1) IN GENERAL.—The Secretary may not make an award under subsection (a) to an entity unless the Secretary ensures that such entity—

''(A) collects biospecimens and associated clinical and demographic information from children with appropriate permission from parents or legal guardians in accordance with Federal and State law; and

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

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

''(f) SINGLE POINT OF ACCESS; STANDARD DATA; GUIDELINES AND OVERSIGHT.—

''(1) SINGLE POINT OF ACCESS.—The Secretary shall ensure that a Biorepository established under subsection (a) has electronically searchable data for use by researchers and other qualified health care professionals in the manner and to the extent defined by the Secretary.

''(2) STANDARD DATA.—The Secretary shall require all recipients of an award under this section to make available a standard dataset for the purposes of paragraph (1) in a standard electronic format that enables researchers and qualified health care professionals to search.

''(3) GUIDELINES AND OVERSIGHT.—The Secretary shall develop and disseminate appropriate guidelines for the development and maintenance of the biorepositories authorized under this section, including appropriate oversight.

''(g) DEFINITIONS.—

''(1) AWARD.—The term 'award' includes a grant, contract, cooperative agreement, or other mechanism determined by the Secretary.

''(2) BIOSPECIMEN.—The term 'biospecimen' includes—

''(A) solid tumor tissue or bone marrow;

''(B) normal or control tissue;

"(C) blood/plasma;

"(D) DNA and RNA extractions;

"(E) familial DNA; and

"(F) any other sample required by the Secretary.

"(3) CLINICAL AND DEMOGRAPHIC INFORMATION.—The term 'clinical and demographic information' shall include—

"(A) date of diagnosis;

"(B) age at diagnosis;

"(C) patient's gender, race and ethnicity;

"(D) extent of disease at enrollment;

"(E) site of metastases;

"(F) location of primary tumor coded;

"(G) histologic diagnosis;

"(H) tumor marker data when available;

"(I) treatment and outcome data;

"(J) information related to specimen quality; and

"(K) any other information required by the Secretary.

"(h) COORDINATION.—The Secretary shall ensure that clinical and demographic information collected in accordance with this section is collected in coordination with the information collected under section 399E–1.

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

''(j) REPORT.—Not later than 4 years after the date of enactment of the Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act, the Secretary shall submit to Congress a report on—

''(1) the number of biospecimens and corresponding clinical demographic data collected through the Comprehensive Children's Cancer Biorepositories established under subsection (a);

''(2) the number of biospecimens and corresponding clinical demographic data requested for use by researchers;

''(3) any barriers to the collection of biospecimens and corresponding clinical demographic data;

''(4) any barriers experienced by researchers or health care professionals in accessing the biospecimens and corresponding clinical demographic data necessary for use in research; and

''(5) any recommendations with respect to improving the Comprehensive Children's Cancer Biorepository program under this section.''; and

(3) in subsection (l), as so redesignated—

(A) by striking ''$30,000,000'' and inserting ''$10,000,000''; and

(B) by striking ''2013'' and inserting ''2018''.

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

(1) by redesignating subsection (b) as subsection (d); and

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

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants to State cancer registries to enhance and expand infrastructure to track the epidemiology of cancer in children, adolescents, and young adults. Such registries shall be updated to include each occurrence of such cancers within a period of time designated by the Secretary.

''(b) ACTIVITIES.—The grants described in subsection (a) may be used for—

''(1) identifying, recruiting, and training all potential sources for reporting childhood, adolescent, and young adult cancer cases;

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

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

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

''(5) tracking the late effects of childhood, adolescent, and young adult cancers.

''(c) COORDINATION.—The Secretary shall ensure that information collected through State cancer registries under this section is collected in coordination with clinical and demographic information collected under section 417E.''.

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

(a) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall report to Congress on barriers to studying oncologic therapies in pediatric populations

under section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c).

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

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

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

(3) an assessment of the potential impact of altering the exemption under subsection (k) of such section 505B.

(c) STAKEHOLDER INPUT.—The report under subsection (a) shall be developed with input from relevant stakeholders.

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