Calendar No. 342

115TH CONGRESS
2D SESSION

S. 292

To maximize discovery, and accelerate development and availability, of promising childhood cancer treatments, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 2, 2017

Mr. REED (for himself, Mrs. CAPITO, Mr. VAN HOLLEN, Mr. ISAKSON, Mr. BLUNT, Mrs. SHAHEEN, Mr. RUBIO, Mrs. GILLIBRAND, Mr. BOOKER, Ms. COLLINS, Mr. KING, Mr. COONS, Mr. PERDUE, Mr. GRASSLEY, Ms. STABENOW, Mr. KENNEDY, Mr. WHITEHOUSE, Mr. CASSIDY, Mr. BLUMENTHAL, Mr. YOUNG, Mr. CASEY, Mr. MANCHIN, Mrs. ERNST, Mr. NELSON, Mr. PORTMAN, Mrs. FISCHER, Mr. FRANKEN, Mr. BROWN, Mr. HATCH, Mr. PETERS, Ms. MURKOWSKI, Ms. DUCKWORTH, Mr. MARKEY, Mr. HELLER, Ms. KLOBUCHAR, Mr. WICKER, Mr. MERKLEY, Mr. DONNELLY, Mrs. FEINSTEIN, Mr. SCHUMER, Mr. BENNET, Mr. LEAHY, Mr. KAINE, Ms. SMITH, Mr. TILLIS, Ms. CORTEZ MASTO, Mr. SANDERS, Mr. CARDIN, and Ms. BALDWIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

MARCH 12, 2018

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To maximize discovery, and accelerate development and availability, of promising childhood cancer treatments, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2017'' or the ''Childhood Cancer STAR Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Each year in the United States there are an estimated 15,780 children between birth and the age of 19 diagnosed with cancer. Approximately 1 in 285 children in the United States will be diagnosed with cancer before their 20th birthday.

(2) In 1960, only 4 percent of children with cancer survived more than 5 years, but today, cure rates have increased to over 80 percent for children and adolescents under age 20.

(3) 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.

(4) 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.

(5) By 2020, the population of childhood cancers survivors is expected to be 500,000 individuals.

(6) As many as two-thirds of childhood cancer survivors are likely to experience at least one late effect of treatment, with as many as one-fourth experiencing a late effect that is serious or life-threatening. Common late effects of childhood cancer are

neurocognitive, psychological, cardiopulmonary, endocrine, and musculoskeletal effects, secondary malignancies, and early death.

(7) As a result of disparities in the delivery of cancer care, minority, low-income, and other medically underserved children are more likely to be diagnosed with late stage disease, experience poorer treatment outcomes, have shorter survival time with less quality of life, and experience a substantially greater likelihood of cancer death.

(8) Collection of biospecimens, along with clinical and outcome data, on children and adolescents with cancer in the United States is necessary to improve childhood and adolescent cancer treatments and cures. Currently biospecimens, and clinical and outcome data, are collected for less than half of children in the United States with cancer.

(9) The late effects of cancer treatment may change as therapies evolve, which means that the monitoring and care of cancer survivors may need to be modified on a routine basis.

(10) Despite the intense stress caused by childhood cancer, there is a lack of standardized and coordinated psychosocial care for the children and

their families, from the date of diagnosis through treatment and survivorship.

(11) The National Academy of Medicine, in its report on cancer survivorship entitled ''Childhood Cancer Survivorship: Improving Care and Quality of Life'', states that an organized system of care and a method of care for pediatric cancer survivors is needed.

(12) Focused and well-designed research and pilot health delivery programs can answer questions about the optimal ways to provide health care, follow-up monitoring services, and survivorship care to those diagnosed with childhood cancer and contribute to improvements in the quality of care and quality of life of those individuals through adulthood.

(13) The National Institutes of Health, including the National Cancer Institute, invest approximately half of their annual appropriations to support basic research that serves as the foundation for translational and clinical research for all diseases and conditions, with the potential to lead to breakthroughs for children with cancer. Virtually all progress against cancer—in both children and

adults—has been founded in basic research, often in areas not directly related to the disease.

(14) The National Cancer Institute supports a number of key research programs specifically to advance childhood cancer care, including precision medicine clinical trials for children with cancer, the Children's Oncology Group (part of the National Clinical Trials Network of the National Cancer Institute), the Pediatric Preclinical Testing Consortium, the Pediatric Brain Tumor Consortium, the Childhood Cancer Survivor Study, the Therapeutically Applicable Research to Generate Effective Treatments program and related pediatric cancer genomics research (including the Pediatric MATCH Precision Medicine trial), and the Pediatric Oncology Branch (part of the intramural program of the National Cancer Institute, whose mission is to develop new treatments for pediatric cancer).

TITLE I—MAXIMIZING RESEARCH THROUGH DISCOVERY

Subtitle A—Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act

SEC. 101. CHILDREN'S CANCER BIOREPOSITORIES AND BIOSPECIMEN RESEARCH.

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

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

"(a) CHILDREN'S CANCER BIOREPOSITORIES.—

"(1) AWARD.—The Secretary, acting through the Director of NIH, may make awards to an entity or entities described in paragraph (4) to build upon existing initiatives to collect biospecimens and clinical and demographic information with a goal of collection for the vast majority of all children, adolescents, and young adults with selected cancer subtypes (and their recurrences) for which current treatments are least effective, through one or more biospecimen research efforts designed to achieve a better understanding of the cause of such cancers

(and their recurrences) and the effects of treatments for such cancers.

''(2) USE OF FUNDS.—Amounts received under an award under paragraph (1) may be used to carry out the following:

''(A) 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, focusing on children and adolescents enrolled in clinical trials for whom current treatments are least effective. Activities under this subparagraph may include storage of biospecimens and associated clinical and demographic data at biorepositories supported by the National Cancer Institute, such as the Children's Oncology Group Biorepository and the Pediatric Cooperative Human Tissue Network as well as through biorepositories established as appropriate to support the scientific needs of future research efforts.

''(B) Make such information publicly available, including the repositories described in subparagraph (A).

"(C) 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.

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

"(E) 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.

"(3) NO REQUIREMENT.—No child, adolescent, or young adult with cancer shall be required under this subsection to contribute a specimen to a biorepository or share clinical or demographic data.

"(4) APPLICATION; CONSIDERATIONS.—

"(A) APPLICATION.—To be eligible to receive an award under paragraph (1) an entity shall submit an application to the Secretary at

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

"(B) CONSIDERATIONS.—In evaluating the applications in subparagraph (A), 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.

"(5) PRIVACY PROTECTIONS; CONSENT.—

"(A) IN GENERAL.—The Secretary may not make an award under paragraph (1) to an entity unless the Secretary ensures that such entity—

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

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

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

"(6) SINGLE POINT OF ACCESS; STANDARD DATA; GUIDELINES AND OVERSIGHT.—

"(A) SINGLE POINT OF ACCESS.—The Secretary shall ensure that each biorepository supported under paragraph (1) 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.

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

"(C) GUIDELINES AND OVERSIGHT.—The Secretary shall develop and disseminate appropriate guidelines for the development and maintenance of the biorepositories supported under this subsection, including appropriate oversight.

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

"(8) PROHIBITION ON USE OF FUNDS.—Funds made available to carry out this subsection 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.

"(9) REPORT.—Not later than 4 years after the date of enactment of the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2017, the Secretary shall submit to Congress a report on—

"(A) the number of biospecimens and corresponding clinical demographic data collected through the biospecimen research efforts supported under paragraph (1);

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

"(C) any barriers to the collection of biospecimens and corresponding clinical demographic data;

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

‘‘(E) any recommendations with respect to improving the biospecimen and biorepository research efforts under this subsection.

‘‘(10) DEFINITIONS.—For purposes of this subsection:

‘‘(A) AWARD.—The term ‘award’ includes a grant, contract, cooperative agreement, or other transaction determined by the Secretary.

‘‘(B) BIOSPECIMEN.—The term ‘biospecimen’ includes—

‘‘(i) solid tumor tissue or bone marrow;

‘‘(ii) normal or control tissue;

‘‘(iii) blood and plasma;

‘‘(iv) DNA and RNA extractions;

‘‘(v) familial DNA; and

‘‘(vi) any other sample required by the Secretary.

‘‘(C) CLINICAL AND DEMOGRAPHIC INFORMATION.—The term ‘clinical and demographic information’ includes—

''(i) date of diagnosis;

''(ii) age at diagnosis;

''(iii) the patient's gender, race, ethnicity, and environmental exposures;

''(iv) extent of disease at enrollment;

''(v) site of metastases;

''(vi) location of primary tumor coded;

''(vii) histologic diagnosis;

''(viii) tumor marker data when available;

''(ix) treatment and outcome data;

''(x) information related to specimen quality; and

''(xi) any other information required by the Secretary.''; and

(2) in subsection (d)—

(A) by striking ''and section 399E–1'' and inserting ''and sections 317U, 399E–1, 417H, and 417H–1'';

(B) by striking ''2009 through 2013'' and inserting ''2018 through 2022''; and

(C) by striking ''such purpose'' and inserting ''such purposes''.

SEC. 102. 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, may make awards to State cancer registries to enhance and expand infrastructure to track the epidemiology of cancer in children, adolescents, and young adults. Such registries may 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(a), as appropriate.''.

Subtitle B—Pediatric Expertise at NIH

SEC. 111. INCLUSION OF AT LEAST ONE PEDIATRIC ONCOLOGIST ON THE NATIONAL CANCER ADVISORY BOARD.

Clause (iii) of section 406(h)(2)(A) of the Public Health Service Act (42 U.S.C. 284a(h)(2)(A)) is amended to read as follows:

''(iii) of the members appointed to the Board—

''(I) not less than 5 members shall be individuals knowledgeable in environmental carcino-

genesis (including carcinogenesis involving occupational and dietary factors); and

''(II) not less than one member shall be an individual knowledgeable in pediatric oncology;''.

SEC. 112. SENSE OF CONGRESS REGARDING PEDIATRIC EXPERTISE AT THE NATIONAL CANCER INSTITUTE.

It is the sense of Congress that the Director of the National Cancer Institute should ensure that all applicable study sections, committees, advisory groups, and panels at the National Cancer Institute include one or more qualified pediatric oncologists, as appropriate.

Subtitle C—NIH Report on Childhood Cancer Activities

SEC. 121. REPORTING ON CHILDHOOD CANCER RESEARCH PROJECTS.

Section 409D(c)(3) of the Public Health Service Act (42 U.S.C. 284h(c)(3)) is amended by—

(1) striking ''public on'' and inserting ''public on—

''(A)'';

(2) striking the period at the end and inserting ''; and''; and

(3) inserting at the end the following:

''(B) childhood cancer research projects conducted or supported by the National Institutes of Health.''.

TITLE II—MAXIMIZING DELIVERY: CARE, QUALITY OF LIFE, SURVIVORSHIP, AND CAREGIVER SUPPORT

Subtitle A—Childhood Cancer Survivors' Quality of Life Act

SEC. 201. CANCER SURVIVORSHIP PROGRAMS.

(a) CANCER SURVIVORSHIP PROGRAMS.—The Public Health Service Act is amended by inserting after section 399N of such Act (42 U.S.C. 280g–2) the following:

''SEC. 399N–1. PILOT PROGRAMS TO EXPLORE MODEL SYSTEMS OF CARE FOR PEDIATRIC CANCER SURVIVORS.

''(a) IN GENERAL.—Not later than 1 year after the date of enactment of the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2017, the Secretary may make awards to eligible entities to establish pilot programs to develop, study, or evaluate model systems for monitoring and caring for childhood cancer survivors throughout their lifespan, including evaluation of shared care and medical home and clinic based models for transition to adult care.

''(b) ELIGIBLE ENTITIES.—In this section, the term 'eligible entity' means—

''(1) a medical school;

''(2) a children's hospital;

''(3) a cancer center;

''(4) a community-based medical facility; or

''(5) any other entity with significant experience and expertise in treating survivors of childhood cancers.

''(c) USE OF FUNDS.—The Secretary may make an award under this section to an eligible entity only if the entity agrees—

''(1) to use the award to establish a pilot program to develop, study, or evaluate one or more model systems for monitoring and caring for cancer survivors; and

''(2) in developing, studying, and evaluating such systems, to give special emphasis to—

''(A) design of protocols for different models of follow-up care, monitoring, and other survivorship programs (including peer support and mentoring programs);

''(B) development of various models for providing multidisciplinary care;

"(C) dissemination of information and the provision of training to health care providers about how to provide linguistically and culturally competent follow-up care and monitoring to cancer survivors and their families;

"(D) development of psychosocial interventions and support programs to improve the quality of life of cancer survivors and their families;

"(E) design of systems for the effective transfer of treatment information and care summaries from cancer care providers to other health care providers (including risk factors and a plan for recommended follow-up care);

"(F) dissemination of the information and programs described in subparagraphs (A) through (E) to other health care providers (including primary care physicians and internists) and to cancer survivors and their families, where appropriate; and

"(G) development of initiatives that promote the coordination and effective transition of care between cancer care providers, primary care physicians, and mental health professionals.

"SEC. 399N–2. WORKFORCE DEVELOPMENT COLLABORATIVE ON MEDICAL AND PSYCHOSOCIAL CARE FOR CHILDHOOD CANCER SURVIVORS.

"(a) IN GENERAL.—The Secretary shall, not later than 1 year after the date of enactment of the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2017, convene a Workforce Development Collaborative on Medical and Psychosocial Care for Pediatric Cancer Survivors (referred to in this section as the 'Collaborative'). The Collaborative shall be a cross-specialty, multidisciplinary group composed of educators, consumer and family advocates, and providers of psychosocial and biomedical health services.

"(b) GOALS AND REPORTS.—The Collaborative shall submit to the Secretary a report establishing a plan to meet the following objectives for medical and psychosocial care workforce development:

"(1) Identifying, refining, and broadly disseminating to health care educators information about workforce competencies, models, and curricula relevant to providing medical and psychosocial services to persons surviving pediatric cancers.

"(2) Adapting curricula for continuing education of the existing workforce using efficient workplace-based learning approaches.

''(3) Developing the skills of faculty and other trainers in teaching psychosocial health care using evidence-based teaching strategies.

''(4) Strengthening the emphasis on psychosocial health care in educational accreditation standards and professional licensing and certification exams by recommending revisions to the relevant oversight organizations.

''(5) Evaluating the effectiveness of patient navigators in pediatric cancer survivorship care.

''(6) Evaluating the effectiveness of peer support programs in the psychosocial care of pediatric cancer patients and survivors.''.

(b) TECHNICAL AMENDMENT.—

(1) IN GENERAL.—Section 3 of the Hematological Cancer Research Investment and Education Act of 2002 (Public Law 107–172; 116 Stat. 541) is amended by striking ''section 419C'' and inserting ''section 417C''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect as if included in section 3 of the Hematological Cancer Research Investment and Education Act of 2002 (Public Law 107–172; 116 Stat. 541).

SEC. 202. GRANTS TO IMPROVE CARE FOR PEDIATRIC CANCER SURVIVORS.

(a) IN GENERAL.—Section 417E of the Public Health Service Act (42 U.S.C. 285a–11), as amended by section 101, is further amended—

(1) in the section heading, by striking "**RESEARCH AND AWARENESS**" and inserting "**RESEARCH, AWARENESS, AND SURVIVORSHIP**"; and

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

"(b) IMPROVING CARE FOR PEDIATRIC CANCER SURVIVORS.—

"(1) RESEARCH ON CAUSES OF HEALTH DISPARITIES IN PEDIATRIC CANCER SURVIVORSHIP.—

"(A) RESEARCH AWARDS.—The Director of NIH, in coordination with ongoing research activities, may conduct or support pediatric cancer survivorship research including in any of the following areas:

"(i) Needs and outcomes of pediatric cancer survivors within minority or other medically underserved populations.

"(ii) Health disparities in pediatric cancer survivorship outcomes within minor-

ity or other medically underserved populations.

"(iii) Barriers that pediatric cancer survivors within minority or other medically underserved populations face in receiving follow-up care.

"(iv) Familial, socioeconomic, and other environmental factors and the impact of such factors on treatment outcomes and survivorship.

"(B) BALANCED APPROACH.—In conducting or supporting research under subparagraph (A)(i) on pediatric cancer survivors within minority or other medically underserved populations, the Director of NIH shall ensure that such research addresses both the physical and the psychological needs of such survivors, as appropriate.

"(2) RESEARCH ON LATE EFFECTS AND FOLLOW-UP CARE FOR PEDIATRIC CANCER SURVIVORS.—The Director of NIH, in coordination with ongoing research activities, may conduct or support research on follow-up care for pediatric cancer survivors, including in any of the following areas:

~~"(A) The development of indicators used for long-term patient tracking and analysis of the late effects of cancer treatment for pediatric cancer survivors.~~

~~"(B) The identification of risk factors associated with the late effects of cancer treatment.~~

~~"(C) The identification of predictors of adverse neurocognitive and psychosocial outcomes.~~

~~"(D) The identification of the molecular underpinnings of long-term complications.~~

~~"(E) The development of risk prediction models to identify those at highest risk of long-term complications.~~

~~"(F) Initiatives to protect cancer survivors from the late effects of cancer treatment, by developing targeted interventions to reduce the burden of morbidity borne by cancer survivors.~~

~~"(G) Transitions in care for pediatric cancer survivors.~~

~~"(H) Training of professionals to provide linguistically and culturally competent follow-up care to pediatric cancer survivors.~~

~~"(I) Different models of follow-up care.~~

''(J) Examining the cost-effectiveness of the different models of follow-up care.''.

SEC. 203. COMPREHENSIVE LONG-TERM FOLLOW-UP SERVICES FOR PEDIATRIC CANCER SURVIVORS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317T the following:

''SEC. 317U. STANDARDS FOR COMPREHENSIVE LONG-TERM CARE FOR PEDIATRIC CANCER SURVIVORS THROUGH THE LIFESPAN.

''The Secretary may establish a task force to develop and test standards, outcomes, and metrics for high-quality childhood cancer survivorship care in consultation with a full spectrum of representation of experts in late effects of disease and treatment of childhood cancers, including—

''(1) oncologists who treat children and adolescents;

''(2) oncologists who treat adults;

''(3) primary care providers engaged in survivorship care;

''(4) survivors of childhood cancer;

''(5) parents of children who have been diagnosed with and treated for cancer and parents of long-term survivors;

''(6) professionals who are engaged in the development of clinical practice guidelines;

''(7) nurses and social workers;

''(8) mental health professionals;

''(9) allied health professionals, including physical therapists and occupational therapists;

''(10) experts in health care quality measurement and improvement; and

''(11) others, as the Secretary determines appropriate.''.

SEC. 204. SURVIVORSHIP DEMONSTRATION PROJECT.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') may carry out a demonstration project over a 3-year period, designed to improve the quality and efficiency of care provided to childhood cancer survivors throughout their lifespan, through improved care coordination as survivors transitions to adult care.

(b) SELECTION OF DEMONSTRATION SITES.—

(1) MAXIMUM NUMBER OF SITES.—The maximum number of sites at which the demonstration project under subsection (a) is carried out may not exceed 10.

(2) DIVERSITY OF SITES.—In selecting entities to participate in the demonstration project, the Secretary may, to the extent practicable, include in such selection—

(A) small-, medium-, and large-sized sites; and

(B) sites located in different geographic areas.

(c) ACTIVITIES UNDER DEMONSTRATION PROJECT.—The activities conducted under the demonstration project under subsection (a) may, in addition to any other activity specified by the Secretary, include activities that seek to develop different models of care coordination, including transitions of care, follow-up care, monitoring, and other survivorship related programs that utilize a multidisciplinary, team based approach to care, including any of the following activities:

(1) Coordination of care and transitions of care between cancer care providers, primary care physicians, mental health professionals and any other relevant providers.

(2) Dissemination of information to, and training of, health care providers about linguistically and culturally competent follow-up care specific to cancer survivors.

(3) Development of monitoring programs for cancer survivors and their families.

(4) Incorporation of peer support and mentoring programs to improve the quality of life of cancer survivors.

(5) Designing systems and models for the effective transfer of treatment information and care summaries from cancer care providers to other health care providers (including risk factors and a care plan).

(6) Evaluation of functional status and incorporation of specific functional needs into the care planning process.

(7) Dissemination of the information on activities and programs conducted under this section to other health care providers (including primary care physicians) and to cancer survivors and their families, where appropriate.

(8) Other items determined by the Secretary.

(d) MEASURES.—The Secretary may use the following measures to assess the performance of each site:

(1) Patient care and patient/family satisfaction measures.

(2) Resource utilization measures.

(3) Adult survivorship measures, as appropriate.

(c) GAO REPORT.—The Comptroller General of the United States shall submit a report to Congress evaluating the success of the demonstration project. Such report shall include an assessment of the impact of the project upon the quality and cost-efficiency of services furnished to individuals under this title, including an assessment of the satisfaction of such individuals with respect to such services that were furnished under such project. Such report shall include recommendations regarding the possible expansion of the demonstration project.

Subtitle B—Coverage and Payment of High Quality Care

SEC. 211. REPORT BY THE COMPTROLLER GENERAL.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a review and submit recommendations to Congress on existing barriers to obtaining and paying for adequate medical care for survivors of childhood cancer.

(b) CONSIDERATIONS.—In carrying out the review and formulating recommendations under subsection (a), the Comptroller General shall—

(1) identify existing barriers to the availability of complete and coordinated survivorship care for

survivors of childhood cancer and to the availability of expert pediatric palliative care, including consideration of—

(A) understanding and education among patients, health care providers, regulators, and third-party payors;

(B) adequacy of payment codes to cover necessary survivorship services;

(C) access to necessary medical and other services for such survivors, including the services described in subsection (c); and

(D) lack of pediatric palliative care across all stages of illness and hospice services for patients approaching the end of life; and

(2) make recommendations to provide improved access and payment plans for childhood cancer survivorship programs and palliative care, including psychosocial services and coverage of such services.

(c) SERVICES DESCRIBED.—The services described in this subsection are the following:

(1) Coordinated multidisciplinary long-term follow-up care with access to appropriate pediatric subspecialists and adult subspecialists with specific expertise in survivorship, including subspecialists with expertise in oncology, radiation oncology, surgery,

cardiology, psychiatry or psychology, endocrinology, pulmonology, nephrology, dermatology, gynecology, and urology.

(2) Appropriate organ function testing (particularly screening for potential problems at much younger ages than usually indicated in the general population) and treatment, including—

(A) neuropsychological testing and mental health services;

(B) fertility testing and treatment;

(C) evaluation and treatment for endocrine disorders including growth hormone and testosterone replacement;

(D) diagnostic imaging to screen for late effects of treatment (including subsequent cancers), such as mammograms and magnetic resonance imaging testing to screen for possible breast cancer;

(E) screening for cardiac problems, such as echocardiograms;

(F) screening for osteoporosis with bone densitometry, including duel x-ray absorptiometry and monitoring 25-hydroxyvitamin D levels;

~~(G) dental coverage and necessary dental implants;~~

~~(H) hearing aids and other prosthetic devices; and~~

~~(I) screening for lung problems, such as pulmonary function testing.~~

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018" or the "Childhood Cancer STAR Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

TITLE I—MAXIMIZING RESEARCH THROUGH DISCOVERY

Subtitle A—Caroline Pryce Walker Conquer Childhood Cancer Reauthorization Act

SEC. 101. CHILDREN'S CANCER BIOREPOSITORIES AND BIOSPECIMEN RESEARCH.

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

*(1) in the section heading, by striking "**RESEARCH AND AWARENESS**" and inserting "**RESEARCH, AWARENESS, AND SURVIVORSHIP**";*

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

"(a) CHILDREN'S CANCER BIOREPOSITORIES.—

"(1) AWARD.—The Secretary, acting through the Director of NIH, may make awards to an entity or entities described in paragraph (4) to build upon existing research efforts to collect biospecimens and clinical and demographic information of children, adolescents, and young adults with selected cancer subtypes (and their recurrences) for which current treatments are least effective, in order to achieve a better understanding of the causes of such cancer subtypes (and

their recurrences), and the effects and outcomes of treatments for such cancers.

"(2) USE OF FUNDS.—Amounts received under an award under paragraph (1) may be used to carry out the following:

"(A) Collect 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, focusing on children, adolescents, and young adults with cancer enrolled in clinical trials for whom current treatments are least effective. Activities under this subparagraph may include storage of biospecimens and associated clinical and demographic data at existing biorepositories supported by the National Cancer Institute.

"(B) Maintain an interoperable, secure, and searchable database on stored biospecimens and associated clinical and demographic data from children, adolescents, and young adults with cancer for the purposes of research by scientists and qualified health care professionals.

"(C) Establish and implement procedures for evaluating applications for access to such bio-

specimens and clinical and demographic data from researchers and other qualified health care professionals.

"(D) Provide access to 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—

"(i) consistent with the procedures established pursuant to subparagraph (C);

"(ii) only to the extent permitted by applicable Federal and State law; and

"(iii) in a manner that protects personal privacy to the extent required by applicable Federal and State privacy law, at minimum.

"(3) NO REQUIREMENT.—No child, adolescent, or young adult with cancer shall be required under this subsection to contribute a specimen to a biorepository or share clinical or demographic data.

"(4) APPLICATION; CONSIDERATIONS.—

"(A) APPLICATION.—To be eligible to receive an award under paragraph (1) an entity shall submit an application to the Secretary at such a time, in such manner, and containing

such information as the Secretary may reasonably require.

"(B) CONSIDERATIONS.—In evaluating applications submitted under subparagraph (A), 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 for whom current treatments are least effective.

"(5) PRIVACY PROTECTIONS AND INFORMED CONSENT.—

"(A) IN GENERAL.—The Secretary may not make an award under paragraph (1) to an entity unless the Secretary ensures that such entity—

"(i) collects biospecimens and associated clinical and demographic information only from participants who have given their informed consent in accordance with Federal and State law; and

"(ii) protects personal privacy to the extent required by applicable Federal and State law, at minimum.

"(B) INFORMED CONSENT.—The Secretary shall ensure biospecimens and associated clinical and demographic information are collected with informed consent, as described in subparagraph (A)(i).

"(6) GUIDELINES AND OVERSIGHT.—The Secretary shall develop and disseminate appropriate guidelines for the development and maintenance of the biorepositories supported under this subsection, including appropriate oversight, to facilitate further research on select cancer subtypes (and their recurrences) in children, adolescents, and young adults with such cancers (and their recurrences).

"(7) COORDINATION.—To encourage the greatest possible efficiency and effectiveness of federally supported efforts with respect to the activities described in this subsection, the Secretary shall ensure the appropriate coordination of programs supported under this section with existing federally supported cancer registry programs and the activities under section 399E–1, as appropriate.

"(8) SUPPLEMENT NOT SUPPLANT.—Funds provided under this subsection shall be used to supplement, and not supplant, Federal and non-Federal

funds available for carrying out the activities described in this subsection.

"(9) REPORT.—Not later than 4 years after the date of enactment of the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018, the Secretary shall submit to Congress a report on—

"(A) the number of biospecimens and corresponding clinical demographic data collected through the biospecimen research efforts supported under paragraph (1);

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

"(C) barriers to the collection of biospecimens and corresponding clinical demographic data;

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

"(E) recommendations with respect to improving the biospecimen and biorepository research efforts under this subsection.

"(10) DEFINITIONS.—For purposes of this subsection:

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

"(B) BIOSPECIMEN.—The term 'biospecimen' includes—

"(i) solid tumor tissue or bone marrow;

"(ii) normal or control tissue;

"(iii) blood and plasma;

"(iv) DNA and RNA extractions;

"(v) familial DNA; and

"(vi) any other sample relevant to cancer research, as required by the Secretary.

"(C) CLINICAL AND DEMOGRAPHIC INFORMATION.—The term 'clinical and demographic information' includes—

"(i) date of diagnosis;

"(ii) age at diagnosis;

"(iii) the patient's sex, race, ethnicity, and environmental exposures;

"(iv) extent of disease at enrollment;

"(v) site of metastases;

"(vi) location of primary tumor coded;

"(vii) histologic diagnosis;

"(viii) tumor marker data when available;

"(ix) treatment and outcome data;

"(x) information related to specimen quality; and

"(xi) any other applicable information required by the Secretary."; and

(3) in subsection (c), by striking "(42 U.S.C. 202 note)".

SEC. 102. IMPROVING CHILDHOOD CANCER SURVEILLANCE.

(a) IN GENERAL.—Section 399E–1 of the Public Health Service Act (42 U.S.C. 280e–3a) is amended—

(1) in subsection (a)—

(A) by striking "shall award a grant" and inserting "may make awards to State cancer registries"; and

(B) by striking "track the epidemiology of pediatric cancer into a comprehensive nationwide registry of actual occurrences of pediatric cancer" and inserting "collect information to better understand the epidemiology of cancer in children, adolescents, and young adults"; and

(C) by striking the second sentence and inserting "Such registries may be updated to include each occurrence of such cancers within a period of time designated by the Secretary.";

(2) by redesignating subsection (b) as subsection (d);

(3) by inserting after subsection (a) the following:

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

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

"(2) developing practices to ensure early inclusion of childhood, adolescent, and young adult cancer cases in State cancer registries through the use of electronic reporting;

"(3) collecting and submitting deidentified data to the Centers for Disease Control and Prevention for inclusion in a national database that includes information on childhood, adolescent, and young adult cancers; and

"(4) improving State cancer registries and the database described in paragraph (3), as appropriate, including to support the early inclusion of childhood, adolescent, and young adult cancer cases.

"(c) COORDINATION.—To encourage the greatest possible efficiency and effectiveness of federally supported efforts with respect to the activities described in this section,

the Secretary shall ensure the appropriate coordination of programs supported under this section with other federally supported cancer registry programs and the activities under section 417E(a), as appropriate.''; and

(4) in subsection (d), as so redesignated, by striking ''registry established pursuant to subsection (a)'' and inserting ''activities described in this section''.

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 417E(d) of the Public Health Service Act (42 U.S.C. 285a–11(d)) is amended—

(1) by striking ''2009 through 2013'' and inserting ''2019 through 2023''; and

(2) by striking the second sentence.

Subtitle B—Pediatric Expertise at NIH

SEC. 111. INCLUSION OF AT LEAST ONE PEDIATRIC ONCOLOGIST ON THE NATIONAL CANCER ADVISORY BOARD.

Clause (iii) of section 406(h)(2)(A) of the Public Health Service Act (42 U.S.C. 284a(h)(2)(A)) is amended—

(1) by striking ''Board not less than five'' and inserting ''Board—

''(I) not less than 5'';

(2) by inserting ''and'' after the semicolon; and

(3) by adding at the end the following:

"(II) not less than one member shall be an individual knowledgeable in pediatric oncology;".

SEC. 112. SENSE OF CONGRESS REGARDING PEDIATRIC EXPERTISE AT THE NATIONAL CANCER INSTITUTE.

It is the sense of Congress that the Director of the National Cancer Institute should ensure that all applicable study sections, committees, advisory groups, and panels at the National Cancer Institute include one or more qualified pediatric oncologists, as appropriate.

Subtitle C—NIH Reporting on Childhood Cancer Activities

SEC. 121. REPORTING ON CHILDHOOD CANCER RESEARCH PROJECTS.

The Director of the National Institutes of Health shall ensure that childhood cancer research projects conducted or supported by the National Institutes of Health are included in appropriate reports to Congress, which may include the Pediatric Research Initiative report.

TITLE II—MAXIMIZING DELIVERY: CARE, QUALITY OF LIFE, SURVIVORSHIP, AND CAREGIVER SUPPORT

SEC. 201. CANCER SURVIVORSHIP PROGRAMS.

(a) PILOT PROGRAMS TO EXPLORE MODEL SYSTEMS OF CARE FOR PEDIATRIC CANCER SURVIVORS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") may make awards to eligible entities to establish pilot programs to develop, study, or evaluate model systems for monitoring and caring for childhood cancer survivors throughout their lifespan, including evaluation of models for transition to adult care and care coordination.

(2) AWARDS.—

(A) TYPES OF ENTITIES.—In making awards under this subsection, the Secretary shall, to the extent practicable, include—

(i) small, medium, and large-sized eligible entities; and

(ii) sites located in different geographic areas, including rural and urban areas.

(B) ELIGIBLE ENTITIES.—In this subsection, the term "eligible entity" means—

(i) a medical school;

(ii) a children's hospital;

(iii) a cancer center;

(iv) a community-based medical facility; or

(v) any other entity with significant experience and expertise in treating survivors of childhood cancers.

(3) USE OF FUNDS.—Funds awarded under this subsection may be used—

(A) to develop, study, or evaluate one or more models for monitoring and caring for cancer survivors; and

(B) in developing, studying, and evaluating such models, to give special emphasis to—

(i) design of models of follow-up care, monitoring, and other survivorship programs (including peer support and mentoring programs);

(ii) development of models for providing multidisciplinary care;

(iii) dissemination of information to health care providers about culturally and linguistically appropriate follow-up care for

cancer survivors and their families, as appropriate and practicable;

(iv) development of psychosocial and support programs to improve the quality of life of cancer survivors and their families, which may include peer support and mentoring programs;

(v) design of systems for the effective transfer of treatment information and care summaries from cancer care providers to other health care providers (including risk factors and a plan for recommended follow-up care);

(vi) dissemination of the information and programs described in clauses (i) through (v) to other health care providers (including primary care physicians and internists) and to cancer survivors and their families, where appropriate and in accordance with Federal and State law; and

(vii) development of initiatives that promote the coordination and effective transition of care between cancer care providers, primary care physicians, mental health professionals, and other health care profes-

sionals, as appropriate, including models that use a team-based or multi-disciplinary approach to care.

(b) WORKFORCE DEVELOPMENT FOR HEALTH CARE PROVIDERS ON MEDICAL AND PSYCHOSOCIAL CARE FOR CHILDHOOD CANCER SURVIVORS.—

(1) IN GENERAL.—The Secretary shall, not later than 1 year after the date of enactment of this Act, conduct a review of the activities of the Department of Health and Human Services related to workforce development for health care providers who treat pediatric cancer patients and survivors. Such review shall include—

(A) an assessment of the effectiveness of supportive psychosocial care services for pediatric cancer patients and survivors, including pediatric cancer survivorship care patient navigators and peer support programs;

(B) identification of existing models relevant to providing medical and psychosocial services to individuals surviving pediatric cancers, and programs related to training for health professionals who provide such services to individuals surviving pediatric cancers; and

(C) recommendations for improving the provision of psychosocial care for pediatric cancer survivors and patients.

(2) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and Committee on Energy and Commerce of the House of Representatives, a report concerning the findings and recommendations from the review conducted under paragraph (1).

SEC. 202. GRANTS TO IMPROVE CARE FOR PEDIATRIC CANCER SURVIVORS.

(a) IN GENERAL.—Section 417E of the Public Health Service Act (42 U.S.C. 285a–11), as amended by section 101, is further amended by striking subsection (b) and inserting the following:

"(b) IMPROVING CARE FOR PEDIATRIC CANCER SURVIVORS.—

"(1) RESEARCH ON PEDIATRIC CANCER SURVIVORSHIP.—The Director of NIH, in coordination with ongoing research activities, may continue to conduct or support pediatric cancer survivorship research including in any of the following areas:

"(A) Outcomes of pediatric cancer survivors, including within minority or other medi-

cally underserved populations and with respect to health disparities of such outcomes.

"(B) Barriers to follow-up care for pediatric cancer survivors, including within minority or other medically underserved populations.

"(C) The impact of relevant factors, which may include familial, socioeconomic, and other environmental factors, on treatment outcomes and survivorship.

"(D) The development of indicators used for long-term follow-up and analysis of the late effects of cancer treatment for pediatric cancer survivors.

"(E) The identification of, as applicable—

"(i) risk factors associated with the late effects of cancer treatment;

"(ii) predictors of adverse neurocognitive and psychosocial outcomes; and

"(iii) the molecular basis of long-term complications.

"(F) The development of targeted interventions to reduce the burden of morbidity borne by cancer survivors in order to protect such cancer survivors from the late effects of cancer.

"(2) BALANCED APPROACH.—In conducting or supporting research under paragraph (1)(A)(i) on pediatric cancer survivors within minority or other medically underserved populations, the Director of NIH shall ensure that such research addresses both the physical and the psychological needs of such survivors, as appropriate.".

SEC. 203. BEST PRACTICES FOR LONG-TERM FOLLOW-UP SERVICES FOR PEDIATRIC CANCER SURVIVORS.

The Secretary of Health and Human Services may facilitate the identification of best practices for childhood and adolescent cancer survivorship care, and, as appropriate, may consult with individuals who have expertise in late effects of disease and treatment of childhood and adolescent cancers, which may include—

(1) oncologists, which may include pediatric oncologists;

(2) primary care providers engaged in survivorship care;

(3) survivors of childhood and adolescent cancer;

(4) parents of children and adolescents who have been diagnosed with and treated for cancer and parents of long-term survivors;

(5) nurses and social workers;

(6) mental health professionals;

(7) allied health professionals, including physical therapists and occupational therapists; and

(8) others, as the Secretary determines appropriate.

SEC. 204. TECHNICAL AMENDMENT.

(a) IN GENERAL.—Section 3 of the Hematological Cancer Research Investment and Education Act of 2002 (Public Law 107–172; 116 Stat. 541) is amended by striking "section 419C" and inserting "section 417C".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect as if included in section 3 of the Hematological Cancer Research Investment and Education Act of 2002 (Public Law 107–172; 116 Stat. 541).

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A BILL

To maximize discovery, and accelerate development and availability, of promising childhood cancer treatments, and for other purposes.

MARCH 12, 2018

Reported with an amendment