AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.

S. 292

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

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 sub-

paragraph 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 biospecimens 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 professionals, 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 Depart-

ment 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 medically 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).