

STEM CELL THERAPEUTIC AND RESEARCH REAUTHORIZATION ACT OF 2015

SEPTEMBER 8, 2015.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 2820]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2820) to reauthorize the Stem Cell Therapeutic and Research Act of 2005, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

H.R. 2820, Stem Cell Therapeutic and Research Reauthorization Act of 2015, was introduced on June 18, 2015, by Rep. Chris Smith (R–NJ), Rep. Doris Matsui (D–CA), Rep. Chaka Fattah (D–PA), and Rep. David Jolly (R–FL), to reauthorize the Stem Cell Therapeutic and Research Act of 2005, and for other purposes.

BACKGROUND AND NEED FOR LEGISLATION

Bone marrow transplantation, a type of adult stem cell therapy, has been used for over 50 years to treat patients for a variety of blood-related diseases and conditions, such as leukemia, lymphoma, certain types of anemia, and inherited disorders of immunity and metabolism. Both bone marrow and umbilical cord blood contain hematopoietic stem cells. These cells have the capacity to multiply and differentiate into all types of blood cells. The hematopoietic stem cells found in cord blood can be used as an alternative to bone marrow transplantation in the treatment of patients for these various blood related diseases. It can be very difficult to find a bone marrow transplant match, and, as a result, cord blood may be used.

The calculated need for unrelated transplant has increased by 25 percent since 2005. Much of the reason is due to the expansion in the number of indications for transplant. The number of transplants for minority patients has increased from 253 in 2000 to 990 in 2014.

H.R. 2820 would reauthorize the National Marrow Donor Program and continue to support the national network of public cord blood banks. The bill also would provide health care professionals the ability to search for bone marrow and cord blood units through a single electronic point of access. The bill also would provide for a national system for recruiting potential bone marrow donors and coordinate the procurement of bone marrow and umbilical cord blood units for transplantation. H.R. 2820 would require the offering of patient and donor advocacy services; provide for public and professional education; and require the collection, analysis, and report of data on transplant outcomes.

The Committee also supports the ongoing work of the public cord blood banks participating in the National Cord Blood Inventory (NCBI) program. The Committee heard from one witness at the Subcommittee on Health hearing about the importance of allowing the definition of high quality cord blood units to evolve as physicians learn more about using cord blood units. Today, some cord blood units on the registry supported through NCBI subsidization may not be used because the transplant physician prefers using larger cord blood units because they believe that larger cord blood units lead to better patient outcomes. The Committee supports the efforts of the Advisory Council on Blood Stem Cell Transplantation to develop recommendations as to what constitutes a high-quality cord blood units. Depending on the recommendation of the Advisory Council on Blood Stem Cell Transplantation, the Committee urges the Health Resources and Services Administration to amend its existing contracts with the cord blood banks, or, if necessary, to conduct a new competition for the collection of high-quality, diverse cord blood units to increase access to unrelated blood stem cell transplants for patients.

HEARINGS

The Subcommittee on Health held a hearing on H.R. 2820 on June 25, 2015. The Subcommittee received testimony from:

- Joanne Kurtzberg, M.D., President, Cord Blood Association;
- Jeff Chell, M.D., Chief Executive Officer, National Marrow Donor Program;
- Patti Freemyer Martin, PhD, Director of Audiology and Speech Language Pathology, Arkansas Children's Hospital;
- Stephen W. Patrick, M.D., M.P.H., M.S., Assistant Professor of Pediatrics and Health Policy, Department of Pediatrics, Vanderbilt University School of Medicine; and
- Mishka Terplan, M.D., M.P.H., FACOG, Medical Director, Behavior Health System Baltimore.

COMMITTEE CONSIDERATION

On July 23, 2015, the Subcommittee on Health met in open markup session and forwarded H.R. 2820 to the full Committee, without amendment, by a voice vote. On July 29, 2015, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 2820 reported to the House, without amendment, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 2820 reported. A motion by Mr. Upton to order H.R. 2820 reported to the House, without amendment, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(1) of rule XIII of the House of Representatives, the goal of the legislation is to reauthorize the Stem Cell Therapeutic and Research Act of 2005, and for other purposes.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2820, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that

H.R. 2820 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, August 12, 2015.

Hon. FRED UPTON,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2820, the Stem Cell Therapeutic and Research Reauthorization Act of 2015.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lisa Ramirez-Branum.

Sincerely,

KEITH HALL.

Enclosure.

H.R. 2820—Stem Cell Therapeutic and Research Reauthorization Act of 2015

Summary: H.R. 2820 would reauthorize the National Cord Blood Inventory program and the C.W. Bill Young Cell Transplantation program. Those programs support efforts to collect and store blood from umbilical cords and to conduct research and facilitate transplants of bone marrow and blood from umbilical cords. In 2015, more than \$33 million was appropriated for these purposes.

Over the 2016–2020 period the bill would authorize the appropriation of \$23 million and \$30 million per year for the National Cord Blood Inventory program and the C.W. Bill Young Cell Transplantation program, respectively. CBO estimates that implementing the bill would cost \$220 million over the 2016–2020 period, assuming appropriation of the authorized amounts. Enacting H.R. 2820 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 2820 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary effects of H.R. 2820 are shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2016	2017	2018	2019	2020	2016–2020
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Authorization Level	53	53	53	53	53	265
Estimated Outlays	21	44	51	52	52	220

Basis of estimate: For this estimate, CBO assumes that H.R. 2820 will be enacted by the start of fiscal year 2016, that the Congress will appropriate the authorized amounts for each year, and that spending will follow historical patterns for the authorized programs.

Pay-As-You-Go considerations: None.

Intergovernmental and private-sector impact: H.R. 2820 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Lisa Ramirez-Branum; Impact on state, local, and tribal governments: J'nell Blanco Suchy; Impact on the private sector: Amy Petz.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 2820 would establish nor reauthorize a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 1725 specifically directs to be completed 0 rule makings within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 states that the legislation may be cited as the “Stem Cell Therapeutic and Research Reauthorization Act of 2015.”

Section 2. Amendments to the Stem Cell Therapeutic and Research Act of 2005

Section 2 would reauthorize the Cord Blood Inventory and the National Marrow Donor Program for fiscal years 2016 through 2020.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in *italic*, and existing law in which no change is proposed is shown in roman):

STEM CELL THERAPEUTIC AND RESEARCH ACT OF 2005

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SEC. 2. CORD BLOOD INVENTORY.

(a) **IN GENERAL.**—The Secretary of Health and Human Services shall enter into one-time contracts with qualified cord blood banks to assist in the collection and maintenance of the inventory goal of at least 150,000 new units of high-quality cord blood to be made available for transplantation through the C.W. Bill Young Cell Transplantation Program and to carry out the requirements of subsection (b).

(b) **REQUIREMENTS.**—The Secretary shall require each recipient of a contract under this section—

(1) to acquire, tissue-type, test, cryopreserve, and store donated units of cord blood acquired with the informed consent of the donor, as determined by the Secretary pursuant to section 379(c) of the Public Health Service Act, in a manner that complies with applicable Federal and State regulations;

(2) to encourage donation from a genetically diverse population;

(3) to make cord blood units that are collected pursuant to this section or otherwise and meet all applicable Federal standards available to transplant centers for transplantation;

(4) to make cord blood units that are collected, but not appropriate for clinical use, available for peer-reviewed research;

(5) to make data available, as required by the Secretary and consistent with section 379(d)(3) of the Public Health Service Act (42 U.S.C. 274k(d)(3)), as amended by this Act, in a standardized electronic format, as determined by the Secretary, for the C.W. Bill Young Cell Transplantation Program; and

(6) to submit data in a standardized electronic format for inclusion in the stem cell therapeutic outcomes database maintained under section 379A of the Public Health Service Act, as amended by this Act.

(c) RELATED CORD BLOOD DONORS.—

(1) IN GENERAL.—The Secretary shall establish a 3-year demonstration project under which qualified cord blood banks receiving a contract under this section may use a portion of the funding under such contract for the collection and storage of cord blood units for a family where a first-degree relative has been diagnosed with a condition that will benefit from transplantation (including selected blood disorders, malignancies, metabolic storage disorders, hemoglobinopathies, and congenital immunodeficiencies) at no cost to such family. Qualified cord blood banks collecting cord blood units under this paragraph shall comply with the requirements of paragraphs (1), (2), (3), and (5) of subsection (b).

(2) AVAILABILITY.—Qualified cord blood banks that are operating a program under paragraph (1) shall provide assurances that the cord blood units in such banks will be available for directed transplantation until such time that the cord blood unit is released for transplantation for a first-degree relative.

(3) INVENTORY.—Cord blood units collected through the program under this section shall not be counted toward the inventory goal under the C.W. Bill Young Cell Transplantation Program.

(4) REPORT.—Not later than 90 days after the date on which the project under paragraph (1) is terminated by the Secretary, the Secretary shall submit to Congress a report on the outcomes of the project that shall include the recommendations of the Secretary with respect to the continuation of such project.

(d) APPLICATION.—To seek to enter into a contract under this section, a qualified cord blood bank shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require. At a minimum, an application for a contract under this section shall include a requirement that the applicant—

(1) will participate in the C.W. Bill Young Cell Transplantation Program for a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section;

(2) will make cord blood units collected pursuant to this section available through the C.W. Bill Young Cell Transplantation Program in perpetuity or for such time as determined viable by the Secretary;

(3) will provide a plan to increase cord blood unit collections at collection sites that exist at the time of application, assist with the establishment of new collection sites, or contract with new collection sites;

(4) will annually provide to the Secretary a plan for, and demonstrate, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations; and

(5) if the Secretary determines through an assessment, or through petition by the applicant, that a cord blood bank is no longer operational or does not meet the requirements of section 379(d)(4) of the Public Health Service Act (as added by this Act) and as a result may not distribute the units, transfer the units collected pursuant to this section to another qualified

cord blood bank approved by the Secretary to ensure continued availability of cord blood units.

(e) DURATION OF CONTRACTS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the term of each contract entered into by the Secretary under this section shall be for a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section. The Secretary shall ensure that no Federal funds shall be obligated under any such contract after the date that is 5 years after the date on which the contract is entered into, except as provided in paragraphs (2) and (3).

(2) EXTENSIONS.—The Secretary may extend the period of funding under a contract under this section to exceed a period of 5 years if—

(A) the Secretary finds that the inventory goal described in subsection (a) has not yet been met;

(B) the Secretary does not receive an application for a contract under this section meeting the requirements under subsection (d) from any qualified cord blood bank that has not previously entered into a contract under this section; or

(C) the Secretary determines that the outstanding inventory need cannot be met by the qualified cord blood banks under contract under this section.

(3) EXTENSION ELIGIBILITY.—A qualified cord blood bank shall be eligible for a 5-year extension of a contract awarded under this section, as described in paragraph (2), provided that the qualified cord blood bank—

(A) demonstrates a superior ability to satisfy the requirements described in subsection (b) and achieves the overall goals for which the contract was awarded;

(B) provides a plan for how the qualified cord blood bank will increase cord blood unit collections at collection sites that exist at the time of consideration for such extension of a contract, assist with the establishment of new collection sites, or contract with new collection sites; and

(C) annually provides to the Secretary a plan for, and demonstrates, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations.

(f) REGULATIONS.—The Secretary may promulgate regulations to carry out this section.

(g) DEFINITIONS.—In this section:

(1) The term “C.W. Bill Young Cell Transplantation Program” means the C.W. Bill Young Cell Transplantation Program under section 379 of the Public Health Service Act, as amended by this Act.

(2) The term “cord blood donor” means a mother who has delivered a baby and consents to donate the neonatal blood remaining in the placenta and umbilical cord after separation from the newborn baby.

(3) The term “cord blood unit” means the neonatal blood collected from the placenta and umbilical cord of a single newborn baby.

(4) The term “first-degree relative” means a sibling who is one meiosis away from a particular individual in a family.

(5) The term “qualified cord blood bank” has the meaning given to that term in section 379(d)(4) of the Public Health Service Act, as amended by this Act.

(6) The term “Secretary” means the Secretary of Health and Human Services.

(h) AUTHORIZATION OF APPROPRIATIONS.—

(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary to carry out the program under this section **[\$23,000,000 for each of fiscal years 2011 through 2014 and] \$20,000,000 for fiscal year 2015 and \$23,000,000 for each of fiscal years 2016 through 2020** .

(2) LIMITATION.—Not to exceed 5 percent of the amount appropriated under this section for each of fiscal years **[2011 through 2015] 2015 through 2020** may be used to carry out the demonstration project under subsection (c).

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PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART I—C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM

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SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this part, there are authorized to be appropriated \$30,000,000 for each of fiscal years **[2011 through 2014] 2016 through 2020** and \$33,000,000 for fiscal year 2015.

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