

Calendar No. 311

114TH CONGRESS
1ST SESSION**H. R. 2820**

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 9, 2015

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

DECEMBER 3, 2015

Reported by Mr. ALEXANDER, with an amendment

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

AN ACT

To reauthorize the Stem Cell Therapeutic and Research Act
of 2005, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Stem Cell Therapeutic
5 and Research Reauthorization Act of 2015”.

1 **SEC. 2. AMENDMENTS TO THE STEM CELL THERAPEUTIC**
 2 **AND RESEARCH ACT OF 2005.**

3 (a) **CORD BLOOD INVENTORY.**—Section 2 of the
 4 Stem Cell Therapeutic and Research Act of 2005 (42
 5 U.S.C. 274k note) is amended in subsection (h)—

6 (1) in paragraph (1)—

7 (A) by striking “\$23,000,000 for each of
 8 fiscal years 2011 through 2014 and”; and

9 (B) by inserting before the period at the
 10 end the following: “and \$23,000,000 for each of
 11 fiscal years 2016 through 2020”; and

12 (2) in paragraph (2), by striking “2011
 13 through 2015” and inserting “2015 through 2020”.

14 (b) **NATIONAL PROGRAM.**—Section 379B of the Pub-
 15 lic Health Service Act (42 U.S.C. 274m) is amended by
 16 striking “2011 through 2014” and inserting “2016
 17 through 2020”.

18 **SECTION 1. SHORT TITLE.**

19 *This Act may be cited as the “Stem Cell Therapeutic*
 20 *and Research Reauthorization Act of 2015”.*

21 **SEC. 2. REAUTHORIZATION OF THE C.W. BILL YOUNG CELL**
 22 **TRANSPLANTATION PROGRAM.**

23 (a) **IN GENERAL.**—Section 379(d)(2)(B) of the Public
 24 Health Service Act (42 U.S.C. 274k(d)(2)(B)) is amended—

25 (1) by striking “remote collection” and inserting
 26 “collection”; and

1 (2) by inserting “including remote collection,”
2 after “cord blood units,”.

3 (b) *AUTHORIZATION OF APPROPRIATIONS.*—Section
4 379B of the Public Health Service Act (42 U.S.C. 274m)
5 is amended—

6 (1) by striking “\$30,000,000 for each of fiscal
7 years 2011 through 2014 and”; and

8 (2) by inserting “and \$30,000,000 for each of fis-
9 cal years 2016 through 2020” before the period at the
10 end.

11 (c) *SECRETARY REVIEW ON STATE OF SCIENCE.*—The
12 Secretary of Health and Human Services, in consultation
13 with the Director of the National Institutes of Health, the
14 Commissioner of the Food and Drug Administration, and
15 the Administrator of the Health Resources and Services Ad-
16 ministration, including the Advisory Council on Blood
17 Stem Cell Transplantation established under section 379(a)
18 of the Public Health Service Act (42 U.S.C. 274k(a)), and
19 other stakeholders, where appropriate given relevant exper-
20 tise, shall conduct a review of the state of the science of
21 using adult stem cells and birthing tissues to develop new
22 types of therapies for patients, for the purpose of consid-
23 ering the potential inclusion of such new types of therapies
24 in the C.W. Bill Young Cell Transplantation Program (es-
25 tablished under such section 379) in addition to the con-

1 *tinuation of ongoing activities. Not later than June 30,*
 2 *2019, the Secretary shall submit to the Committee on*
 3 *Health, Education, Labor, and Pensions of the Senate and*
 4 *the Committee on Energy and Commerce of the House of*
 5 *Representatives recommendations on the appropriateness of*
 6 *such new types of therapies for inclusion in the C.W. Bill*
 7 *Young Cell Transplantation Program.*

8 **SEC. 3. CORD BLOOD INVENTORY.**

9 *Section 2 of the Stem Cell Therapeutic and Research*
 10 *Act of 2005 (42 U.S.C. 274k note) is amended—*

11 *(1) in subsection (a), by striking “one-time”;*

12 *(2) by striking subsection (c);*

13 *(3) by redesignating subsections (d) through (h)*
 14 *as subsections (c) through (g), respectively;*

15 *(4) in subsection (d) (as so redesignated)—*

16 *(A) in paragraph (1), by striking “para-*
 17 *graphs (2) and (3)” and inserting “paragraphs*
 18 *(2), (3), and (4)”;*

19 *(B) in paragraph (2)(B), by striking “sub-*
 20 *section (d)” and inserting “subsection (c)”;* and

21 *(C) by adding at the end the following:*

22 *“(4) CONSIDERATION OF BEST SCIENCE.—The*
 23 *Secretary shall take into consideration the best sci-*
 24 *entific information available in order to maximize the*
 25 *number of cord blood units available for transplant*

1 *when entering into contracts under this section, or*
2 *when extending a period of funding under such a con-*
3 *tract under paragraph (2).*

4 *“(5) CONSIDERATION OF BANKED UNITS OF CORD*
5 *BLOOD.—In extending contracts pursuant to para-*
6 *graph (3), and determining new allocation amounts*
7 *for the next contract period or contract extension for*
8 *such cord blood bank, the Secretary shall take into ac-*
9 *count the number of cord blood units banked in the*
10 *National Cord Blood Inventory by a cord blood bank*
11 *during the previous contract period, in addition to*
12 *consideration of the ability of such cord blood bank to*
13 *increase the collection and maintenance of additional,*
14 *genetically diverse cord blood units.”;*

15 *(5) in subsection (f) (as so redesignated)—*

16 *(A) by striking paragraph (4); and*

17 *(B) by redesignating paragraphs (5) and*
18 *(6) as paragraphs (4) and (5), respectively; and*

19 *(6) in subsection (g) (as so redesignated)—*

20 *(A) in paragraph (1)—*

21 *(i) by striking “\$23,000,000 for each of*
22 *fiscal years 2011 through 2014 and”;* and

23 *(ii) by inserting “and \$23,000,000 for*
24 *each of fiscal years 2016 through 2020” be-*
25 *fore the period at the end; and*

1 *(B) by striking paragraph (2).*

2 **SEC. 4. DETERMINATION ON THE DEFINITION OF HUMAN**

3 **ORGAN.**

4 *Not later than one year after the date of enactment*
5 *of this Act, the Secretary of Health and Human Services*
6 *shall issue determinations with respect to the inclusion of*
7 *peripheral blood stem cells and umbilical cord blood in the*
8 *definition of human organ.*

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