

111TH CONGRESS
2^D SESSION

H. R. 6083

To amend the Stem Cell Therapeutic and Research Act of 2005.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 10, 2010

Mr. SMITH of New Jersey (for himself, Mr. DAVIS of Alabama, Mr. PITTS, Mr. LIPINSKI, and Mr. FATTAH) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Stem Cell Therapeutic and Research Act of 2005.

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 2010”.

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

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

1 (1) in subsection (a), by inserting “at least” be-
2 fore “150,000”;

3 (2) in subsection (c)(3), by inserting “at least”
4 before “150,000”;

5 (3) in subsection (d)—

6 (A) in paragraph (2), by striking “; and”
7 and inserting “;”;

8 (B) by redesignating paragraph (3) as
9 paragraph (5); and

10 (C) by inserting after paragraph (2) the
11 following:

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

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

21 (4) in subsection (e)—

22 (A) in paragraph (1)—

23 (i) by striking “10 years” and insert-
24 ing “a period of at least 10 years begin-
25 ning on the last date on which the recipi-

1 ent of a contract under this section re-
2 ceives Federal funds under this section”;
3 and

4 (ii) by striking the second sentence
5 and inserting “The Secretary shall ensure
6 that no Federal funds shall be obligated
7 under any such contract after the date
8 that is 5 years after the date on which the
9 contract is entered into, except as provided
10 in paragraphs (2) and (3).”;

11 (B) in paragraph (2)—

12 (i) in the matter preceding subpara-
13 graph (A)—

14 (I) by striking “Subject to para-
15 graph (1)(B), the” and inserting
16 “The”; and

17 (II) by striking “3” and inserting
18 “5”;

19 (ii) in subparagraph (A)—

20 (I) by inserting “at least” before
21 “150,000”; and

22 (II) by striking “; and” and in-
23 serting “;”;

24 (iii) in subparagraph (B)—

1 (I) by inserting “meeting the re-
2 quirements under subsection (d)”
3 after “receive an application for a
4 contract under this section”; and

5 (II) by striking “or the Sec-
6 retary” and all that follows through
7 the period at the end and inserting “;
8 or”; and

9 (iv) by adding at the end the fol-
10 lowing:

11 “(C) the Secretary determines that the
12 outstanding inventory need cannot be met by
13 the qualified cord blood banks under contract
14 under this section.”; and

15 (C) by striking paragraph (3) and insert-
16 ing the following:

17 “(3) EXTENSION ELIGIBILITY.—A qualified
18 cord blood bank shall be eligible for a 5-year exten-
19 sion of a contract awarded under this section, as de-
20 scribed in paragraph (2), provided that the qualified
21 cord blood bank—

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

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

8 “(C) annually provides to the Secretary a
9 plan for, and demonstrates, ongoing measurable
10 progress toward achieving self-sufficiency of
11 cord blood unit collection and banking oper-
12 ations.”;

13 (5) in subsection (g)(4), by striking “or par-
14 ent”; and

15 (6) in subsection (h)—

16 (A) by striking paragraph (2) and insert-
17 ing the following:

18 “(2) AUTHORIZATION OF APPROPRIATIONS.—
19 There are authorized to be appropriated to the Sec-
20 retary to carry out the program under this section
21 \$23,000,000 for each of fiscal years 2011 through
22 2014 and \$20,000,000 for fiscal year 2015. Such
23 funds so appropriated shall remain available until
24 expended.”; and

1 (B) in paragraph (3), by striking “in each
2 of fiscal years 2007 through 2009” and insert-
3 ing “for fiscal years 2011 through 2015”.

4 (b) NATIONAL PROGRAM.—Section 379 of the Public
5 Health Service Act (42 U.S.C. 274k) is amended—

6 (1) by striking subsection (a)(6) and inserting
7 the following:

8 “(6) The Secretary, acting through the Advi-
9 sory Council, shall submit to Congress an annual re-
10 port on the activities carried out under this sec-
11 tion.”;

12 (2) by striking subsection (d)(2)(D) and insert-
13 ing the following:

14 “(D) support studies and demonstration
15 and outreach projects for the purpose of in-
16 creasing cord blood unit donation and collection
17 from a genetically diverse population, including
18 exploring novel approaches or incentives, such
19 as remote or other innovative technological ad-
20 vances that could be used to collect cord blood
21 units, to expand the number of cord blood unit
22 collection sites partnering with cord blood
23 banks that receive a contract under the Na-
24 tional Cord Blood Bank Inventory program

1 under section 2 of the Stem Cell Therapeutic
2 and Research Act of 2005;” and

3 (3) by striking subsection (f)(5)(A) and insert-
4 ing the following:

5 “(A) require the establishment of a system
6 of strict confidentiality to protect the identity
7 and privacy of patients and donors in accord-
8 ance with Federal and State law; and”.

9 (c) AUTHORIZATION OF APPROPRIATIONS.—Section
10 379B of the Public Health Service Act (42 U.S.C. 274m)
11 is amended by striking “\$34,000,000” and all that follows
12 through the period at the end, and inserting “\$30,000,000
13 for each of fiscal years 2011 through 2014 and
14 \$33,000,000 for fiscal year 2015. Such funds so appro-
15 priated shall remain available until expended.”.

16 (d) REPORT ON CORD BLOOD UNIT DONATION AND
17 COLLECTION.—

18 (1) IN GENERAL.—Not later than 1 year after
19 the date of enactment of this Act, the Comptroller
20 General of the United States shall submit to the
21 Committee on Health, Education, Labor, and Pen-
22 sions and the Committee on Appropriations of the
23 Senate, the Committee on Energy and Commerce
24 and the Committee on Appropriations of the House
25 of Representatives, and the Secretary of Health and

1 Human Services a report reviewing studies, dem-
2 onstration programs, and outreach efforts for the
3 purpose of increasing cord blood unit donation and
4 collection for the National Cord Blood Inventory to
5 ensure a high-quality and genetically diverse inven-
6 tory of cord blood units.

7 (2) CONTENTS.—The report described in para-
8 graph (1) shall include a review of such studies,
9 demonstration programs, and outreach efforts under
10 section 2 of the Stem Cell Therapeutic and Research
11 Act of 2005 (42 U.S.C. 274k note) (as amended by
12 this Act) and section 379 of the Public Health Serv-
13 ice Act (42 U.S.C. 274k) (as amended by this Act),
14 including—

15 (A) a description of the challenges and
16 barriers to expanding the number of cord blood
17 unit collection sites, including cost, the impact
18 of regulatory and administrative requirements,
19 and the capacity of cord blood banks to main-
20 tain high-quality units;

21 (B) remote or other innovative techno-
22 logical advances that could be used to collect
23 cord blood units;

24 (C) appropriate methods for improving
25 provider education about collecting cord blood

1 units for the national inventory and participa-
2 tion in such collection activities;

3 (D) estimates of the number of cord blood
4 unit collection sites necessary to meet the out-
5 standing national inventory need and the char-
6 acteristics of such collection sites that would
7 help increase the genetic diversity and enhance
8 the quality of cord blood units collected;

9 (E) best practices for establishing and sus-
10 taining partnerships for cord blood unit collec-
11 tion at medical facilities with a high number of
12 minority births;

13 (F) potential and proven incentives to en-
14 courage hospitals to become cord blood unit col-
15 lection sites and partner with cord blood banks
16 participating in the National Cord Blood Inven-
17 tory under section 2 of the Stem Cell Thera-
18 peutic and Research Act of 2005 and to assist
19 cord blood banks in expanding the number of
20 cord blood unit collection sites with which such
21 cord blood banks partner; and

22 (G) recommendations about methods cord
23 blood banks and collection sites could use to
24 lower costs and improve efficiency of cord blood

- 1 unit collection without decreasing the quality of
- 2 the cord blood units collected.

