

111TH CONGRESS  
2D SESSION

# S. 3751

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

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IN THE SENATE OF THE UNITED STATES

AUGUST 5, 2010

Mr. HATCH (for himself, Mr. DODD, Mr. BURR, Mr. REED, Mr. ENSIGN, and Mr. FRANKEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## 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-

ent of a contract under this section receives Federal funds under this section”;  
and

(ii) by striking the second sentence and inserting “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).”;

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A)—

(I) by striking “Subject to paragraph (1)(B), the” and inserting “The”; and

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

(ii) in subparagraph (A)—

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

(II) by striking “; and” and inserting “;”;

(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.

