

109TH CONGRESS
1ST SESSION

S. 681

To amend the Public Health Service Act to establish a National Cord Blood Stem Cell Bank Network to prepare, store, and distribute human umbilical cord blood stem cells for the treatment of patients and to support peer-reviewed research using such cells.

IN THE SENATE OF THE UNITED STATES

MARCH 17, 2005

Mr. HATCH (for himself, Mr. DODD, Mr. BROWNBACK, Mr. HARKIN, and Mr. SPECTER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to establish a National Cord Blood Stem Cell Bank Network to prepare, store, and distribute human umbilical cord blood stem cells for the treatment of patients and to support peer-reviewed research using such cells.

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 “Cord Blood Stem Cell
5 Act of 2005”.

1 **SEC. 2. NATIONAL CORD BLOOD STEM CELL BANK NET-**
2 **WORK.**

3 Part H of title III of the Public Health Service Act
4 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
5 tion 376 the following:

6 **“SEC. 376A. NATIONAL CORD BLOOD STEM CELL BANK NET-**
7 **WORK.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) ADMINISTRATOR.—The term ‘Adminis-
10 trator’ means the Administrator of the Health Re-
11 sources and Services Administration.

12 “(2) CORD BLOOD UNIT.—The term ‘cord blood
13 unit’ means the blood collected from a single pla-
14 centa and umbilical cord.

15 “(3) DONOR.—The term ‘donor’ means a moth-
16 er who has delivered a baby and consents to donate
17 the newborn’s blood remaining in the placenta and
18 umbilical cord.

19 “(4) DONOR BANK.—The term ‘donor bank’
20 means a qualified cord blood stem cell bank that en-
21 ters into a contract with the Secretary under sub-
22 section (b)(1).

23 “(5) HUMAN CORD BLOOD STEM CELLS.—The
24 term ‘human cord blood stem cells’ means
25 hematopoietic stem cells and any other stem cells
26 contained in the neonatal blood collected imme-

1 diately after the birth from the separated placenta
2 and umbilical cord.

3 “(6) NATIONAL CORD BLOOD STEM CELL
4 BANK NETWORK.—The term ‘National Cord Blood
5 Stem Cell Bank Network’ means a network of quali-
6 fied cord blood stem cell banks established under
7 subsection (b).

8 “(b) NATIONAL CORD BLOOD STEM CELL BANK
9 NETWORK.—

10 “(1) IN GENERAL.—The Secretary, acting
11 through the Administrator, shall enter into contracts
12 with qualified cord blood stem cell banks to assist in
13 the establishment, provision, and maintenance of a
14 National Cord Blood Stem Cell Bank Network that
15 contains at least 150,000 units of human cord blood
16 stem cells.

17 “(2) PURPOSE OF DONOR BANKS.—It is the
18 purpose of the donor banks that are a part of the
19 Network to—

20 “(A) acquire, tissue-type, test,
21 cryopreserve, and store donated units of human
22 cord blood acquired with the informed consent
23 of the donor, in a manner that complies with
24 applicable Federal regulations;

1 “(B) make cord blood units collected under
2 this section, or otherwise, available to trans-
3 plant centers for stem cell transplantation; and

4 “(C) allocate up to 10 percent of the cord
5 blood inventory each year for peer-reviewed re-
6 search.

7 “(3) ELIGIBILITY OF DONOR BANKS.—A cord
8 blood stem cell bank shall be eligible to be a donor
9 bank if such a bank—

10 “(A) has obtained all applicable Federal
11 and State licenses, certifications, registrations
12 (including registration with the Food and Drug
13 Administration), and other authorizations re-
14 quired to operate and maintain a cord blood
15 stem cell bank;

16 “(B) has implemented donor screening and
17 cord blood collection practices adequate to pro-
18 tect both donors and transplant recipients and
19 to prevent transmission of potentially harmful
20 infections and other diseases;

21 “(C) has established a system of strict con-
22 fidentiality to protect the identity and privacy
23 of patients and donors in accordance with exist-
24 ing Federal and State law, and consistent with
25 the regulations promulgated under section

1 264(c) of the Health Insurance Portability and
2 Accountability Act of 1996 for the release of
3 the identity of donors, recipients, or identifiable
4 records;

5 “(D) has established a system for encour-
6 aging donation by an ethnically diverse group of
7 donors;

8 “(E) has developed adequate systems for
9 communication with other cord blood stem cell
10 banks, transplant centers, and physicians with
11 respect to the request, release, and distribution
12 of cord blood units nationally, and has devel-
13 oped such systems, consistent with the regula-
14 tions promulgated under section 264(c) of the
15 Health Insurance Portability and Accountability
16 Act of 1996, to track recipients’ clinical out-
17 comes for distributed units; and

18 “(F) has developed a system for educating
19 the public, including patient advocacy organiza-
20 tions, about the benefits of donating and uti-
21 lizing cord blood stem cells in appropriate cir-
22 cumstances.

23 “(c) ADMINISTRATION OF THE NETWORK.—

24 “(1) BOARD OF DIRECTORS.—

1 “(A) IN GENERAL.—The Secretary shall
2 provide for the establishment of a Board of Di-
3 rectors, including a chairperson, who shall ad-
4 minister the National Cord Blood Stem Cell
5 Network, including establishing a national cord
6 blood stem cell registry within the Network and
7 coordinating the donor banks in the Network.

8 “(B) COMPOSITION.—

9 “(i) IN GENERAL.—The Board of Di-
10 rectors shall be composed of members to
11 be appointed by the Secretary who shall
12 serve 3-year terms, and shall include rep-
13 resentatives from—

14 “(I) cord blood stem cell trans-
15 plant centers;

16 “(II) physicians from partici-
17 pating birthing hospitals;

18 “(III) the cord blood stem cell re-
19 search community;

20 “(IV) recipients of cord blood
21 stem cell transplants;

22 “(V) patients or family members
23 of a patient who has requested the as-
24 sistance of the national cord blood

1 stem cell registry in searching for
2 donor cord blood;

3 “(VI) individuals with expertise
4 in the social sciences;

5 “(VII) members of the general
6 public;

7 “(VIII) the Health Resources
8 and Services Administration, who
9 shall serve as a nonvoting member;
10 and

11 “(IX) the network donor banks.

12 “(ii) TERMS OF SERVICE.—Each
13 member appointed under clause (i) may
14 serve up to 2 consecutive 3-year terms, ex-
15 cept that this clause shall not apply to the
16 member appointed under subclause (VIII)
17 of clause (i).

18 “(C) CONTINUITY.—In order to ensure the
19 continuity of the Board of Directors, the Board
20 shall be appointed so that each year the terms
21 of approximately $\frac{1}{3}$ of the Board members ex-
22 pire. A member of the Board may continue to
23 serve after the expiration of the term of such a
24 member until a successor is appointed.

1 “(2) NATIONAL CORD BLOOD STEM CELL REG-
2 ISTRY.—

3 “(A) IN GENERAL.—The Secretary, acting
4 through the Administrator, shall establish as
5 part of the Network a National Cord Blood
6 Stem Cell Registry. The Registry shall—

7 “(i) operate a system for identifying,
8 acquiring, and distributing donated units
9 of cord blood that are suitably matched to
10 candidate patients;

11 “(ii) provide transplant physicians
12 and other appropriate health care profes-
13 sionals the ability to search the entire reg-
14 istry for a suitable donor match for pa-
15 tients; and

16 “(iii) maintain a database to docu-
17 ment the collection, storage, distribution,
18 and clinical outcomes related to the Net-
19 work.

20 “(B) DATABASE.—The database main-
21 tained under subparagraph (A)(iii) shall be op-
22 erated according to standards of consent, dis-
23 closure, and confidentiality, including those ap-
24 plicable under the regulations promulgated
25 under section 264(e) of the Health Insurance

1 Portability and Accountability Act of 1996. The
2 Administrator, using the database, shall report
3 to the Secretary on a periodic basis regarding
4 the safety, efficacy, and cost-effectiveness of the
5 clinical, research, and educational activities of
6 the Network. The Secretary shall make such in-
7 formation available to the public.

8 “(3) NETWORK STANDARDS.—The Board of Di-
9 rectors shall ensure that—

10 “(A) the donor banks within the National
11 Cord Blood Stem Cell Bank Network meet the
12 requirements of subsection (b)(3); and

13 “(B) the National Cord Blood Stem Cell
14 Bank Network is geographically distributed
15 throughout the United States.

16 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
17 carry out this section, there are authorized to be appro-
18 priated, \$15,000,000 for fiscal year 2006, and such sums
19 as may be necessary for each of fiscal years 2007 through
20 2010.”.

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