

108TH CONGRESS
1ST SESSION

H. R. 2852

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 HOUSE OF REPRESENTATIVES

JULY 24, 2003

Mr. SMITH of New Jersey (for himself, Mr. BURR, Mr. DAVIS of Alabama, Mr. TOWNS, Mr. DOOLITTLE, Mr. TOOMEY, Mr. FALEOMAVAEGA, Mr. WELDON of Florida, and Mrs. MYRICK) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 2003” .

1 **SEC. 2. FINDINGS.**

2 The Congress makes the following findings:

3 (1) Research sponsored by the National Insti-
4 tutes of Health and conducted in full compliance
5 with applicable Food and Drug Administration regu-
6 lations has demonstrated the feasibility of using cord
7 blood for clinical applications. Stem cells, obtained
8 from the blood contained in the delivered placenta
9 and umbilical cord and donated by the mother, can
10 be used for bone marrow reconstitution by trans-
11 plantation to recipients with certain malignancies
12 (such as leukemia and lymphoma), genetic disorders
13 (such as sickle cell anemia), and acquired diseases.

14 (2) The placenta, umbilical cord, and the neo-
15 natal blood they contain are normally discarded
16 after childbirth. This residual neonatal blood, termed
17 cord blood, is a source of stem cells that can be col-
18 lected as donor tissue without risk to the donor and
19 can be preserved through freezing for many years
20 and be made immediately available for transplan-
21 tation in routine or emergency clinical situations. It
22 can also be used for scientific research involving its
23 stem cells.

24 (3) Advantages of cord blood stem cell trans-
25 plants relative to bone marrow transplants include
26 the reduction of risks to the donor, availability of

1 donor cell units in days rather than months, and
2 lower risk of transplant complications, including
3 graft versus host disease and latent virus infections
4 (such as Epstein-Barr virus or Cytomegalovirus).

5 (4) In conventional bone marrow transplan-
6 tation, matched siblings are the preferred donors,
7 but only 30 percent of patients have a matched sib-
8 ling. When no sibling match is found, a search is ini-
9 tiated for an unrelated donor.

10 (5) Finding a fully matched unrelated donor op-
11 timizes the chances of successful bone marrow trans-
12 plantation. In conventional bone marrow transplan-
13 tation, patients of ethnic minorities generally have
14 difficulty finding fully matched donors, leaving par-
15 tially matched transplants as their only transplant
16 option. Partially matched bone marrow transplan-
17 tation leads to a disproportionately high rate of com-
18 plications, including graft versus host disease and
19 mortality.

20 (6) Cord blood stem cell banks would provide
21 increased genetic diversity in the supply of donors
22 and increase the opportunity to identify fully
23 matched and partially matched transplant units for
24 qualified candidates. Cord blood stem cell trans-
25 plants using partially matched units reduce the risk

1 of graft versus host disease with its attending mor-
2 bidity and mortality as compared to conventional
3 bone marrow transplantation.

4 (7) Identifying and delivering an unrelated bone
5 marrow donor from among the several millions in
6 the National registry typically requires many
7 months, sometimes more than 1 year. An inventory
8 of 150,000 cord blood stem cell units, that takes
9 into account the ethnic diversity of the country,
10 would help provide appropriate matches for at least
11 90 percent of those seeking matched cord blood stem
12 cell transplants, within days of a formal request.

13 (8) Matched donors are more likely within the
14 same ethnic group as the patient's. Some genetic
15 conditions are also more prevalent in members of
16 particular ethnic groups, such as Sickle Cell Anemia,
17 a disease that occurs in one out of 500 African-
18 American newborns. From early infancy, patients
19 with Sickle Cell Anemia have a high risk of severe
20 or fatal bacterial blood infections. Many patients de-
21 velop painful crises beginning in infancy and occur-
22 ring up to 20 times per year. Children with recur-
23 rent crises, chest syndrome or strokes, are at great
24 risk of dying before the age of 20 years. The median
25 life-span of a patient with Sickle Cell Disease is 42

1 years, but patients with severe disease in childhood
2 rarely live beyond 20 years. Cord blood stem cell
3 transplantation has cured patients with Sickle Cell
4 Anemia: 80 percent of children transplanted with re-
5 lated cord blood to correct Sickle Cell Anemia or
6 thalassemia were cured in a recently published
7 study. The earlier in the course of severe disease,
8 the transplant is performed, the better the outcomes.
9 Unrelated cord blood transplants are especially bene-
10 ficial for African American and other ethnic minor-
11 ity patients because cord blood does not have to
12 match as closely as bone marrow. For this reason,
13 an African American patient is much more likely to
14 find a suitable unrelated cord blood donor as com-
15 pared to a matched bone marrow donor. With an
16 ethnically balanced national cord blood bank of at
17 least 150,000 units, some 90 percent of African
18 American patients who suffer from Sickle Cell Ane-
19 mia or other conditions requiring bone marrow re-
20 placement would be able to find appropriately
21 matched cord blood stem cells for successful treat-
22 ment.

23 (9) Since its inception in 1987, the National
24 Marrow Donor Program has facilitated 17,000 bone
25 marrow transplants. Cord blood transplantation

1 complements conventional bone marrow transplan-
2 tation by providing appropriately matched units to
3 patients, especially those of non-caucasoid ethnicity,
4 who have a much lower probability of finding an
5 adequate match through the National Marrow Donor
6 Program. Cord blood is one of the sources of stem
7 cells used in transplantation, however, its collection,
8 preparation, storage and dissemination require spe-
9 cific systems and expertise.

10 (10) Radiation exposure, from accidents or hos-
11 tile actions could cause bone marrow failure in a
12 portion of those exposed, requiring treatment includ-
13 ing bone marrow reconstitution. In these cases the
14 rapid availability of cryopreserved cord blood stem
15 cell units may be important. Years later, those ex-
16 posed would incur an increased risk of leukemia
17 or lymphoma, which might also require stem cell
18 transplantation.

19 (11) Recent scientific developments suggest
20 that further research on cord blood stem cells may
21 lead to a greater understanding of certain chronic
22 diseases. This research might improve therapies for,
23 and possibly cure, debilitating diseases such as Par-
24 kinson's disease, insulin-dependent diabetes, heart
25 disease, and certain types of cancer. These diseases

1 cause a disproportionately large share of chronic dis-
2 abilities and account for a large portion of health
3 care expenditures in the United States.

4 **SEC. 3. NATIONAL CORD BLOOD STEM CELL BANK NET-**
5 **WORK.**

6 Part H of title III of the Public Health Service Act
7 (42 U.S.C. 273 et seq.) is amended by inserting after sec-
8 tion 376 the following:

9 **“SEC. 376A. NATIONAL CORD BLOOD STEM CELL BANK NET-**
10 **WORK.**

11 “(a) DEFINITIONS.—In this section:

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

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

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

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

1 “(5) HUMAN CORD BLOOD STEM CELLS.—The
2 term ‘human cord blood stem cells’ means
3 hematopoietic stem cells and any other stem cells
4 contained in the neonatal blood collected imme-
5 diately after the birth from the separated placenta
6 and umbilical cord.

7 “(6) NATIONAL CORD BLOOD STEM CELL BANK
8 NETWORK.—The term ‘National Cord Blood Stem
9 Cell Bank Network’ means a network of qualified
10 cord blood stem cell banks established under sub-
11 section (b).

12 “(b) NATIONAL CORD BLOOD STEM CELL BANK
13 NETWORK.—

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

21 “(2) PURPOSE OF DONOR BANKS.—It is the
22 purpose of the donor banks that are a part of the
23 Network to—

24 “(A) acquire, tissue-type, test,
25 cryopreserve, and store donated units of human

1 cord blood acquired with the informed consent
2 of the donor, in a manner that complies with
3 applicable Federal regulations;

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

7 “(C) allocate up to 10 percent of the cord
8 blood inventory each year for peer-reviewed re-
9 search.

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

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

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

24 “(C) has established a system of strict con-
25 fidentiality to protect the identity and privacy

1 of patients and donors in accordance with exist-
2 ing Federal and State law, and consistent with
3 the regulations promulgated under section
4 264(c) of the Health Insurance Portability and
5 Accountability Act of 1996 for the release of
6 the identity of donors, recipients, or identifiable
7 records;

8 “(D) has established a system for encour-
9 aging donation by an ethnically diverse group of
10 donors;

11 “(E) has developed adequate systems for
12 communication with other cord blood stem cell
13 banks, transplant centers, and physicians with
14 respect to the request, release, and distribution
15 of cord blood units nationally and has developed
16 such systems, consistent with the regulations
17 promulgated under section 264(c) of the Health
18 Insurance Portability and Accountability Act of
19 1996, to track recipients’ clinical outcomes for
20 distributed units; and

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

1 “(c) ADMINISTRATION OF THE NETWORK.—

2 “(1) BOARD OF DIRECTORS.—

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

11 “(B) COMPOSITION.—

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

17 “(I) cord blood stem cell trans-
18 plant centers;

19 “(II) physicians from partici-
20 pating birthing hospitals;

21 “(III) the cord blood stem cell re-
22 search community;

23 “(IV) recipients of cord blood
24 stem cell transplants;

1 “(V) family members of a patient
2 of the National Cord Blood Stem Cell
3 Bank;

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

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

8 “(VIII) the Division of Stem Cell
9 Transplantation of the Health Re-
10 sources and Services Administration,
11 who shall serve as nonvoting member;
12 and

13 “(IX) the network donor banks.

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

20 “(C) CONTINUITY.—In order to ensure the
21 continuity of the Board of Directors, the Board
22 shall be appointed so that each year the terms
23 of approximately 1/3 of the Board members ex-
24 pire. A member of the Board may continue to

1 serve after the expiration of the term of such a
2 member until a successor is appointed.

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

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

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

13 “(ii) provide transplant physicians
14 and other appropriate health care profes-
15 sionals a website function that enables
16 searching the entire registry for suitable
17 donor matches for patients, and requesting
18 specific cord blood units; and

19 “(iii) maintain a database to docu-
20 ment the collection, storage, distribution,
21 and transplantation of cord blood units
22 and the clinical outcomes of all
23 transplantations related to the Network.

24 “(B) DATABASE.—The database main-
25 tained under subparagraph (A)(iii) shall be op-

1 erated according to standards of consent, dis-
2 closure, and confidentiality, including those ap-
3 plicable under the regulations promulgated
4 under section 264(e) of the Health Insurance
5 Portability and Accountability Act of 1996. The
6 Administrator, using the database, shall report
7 to the Secretary on a periodic basis regarding
8 the safety, efficacy, and cost-effectiveness of the
9 clinical, research, and educational activities of
10 the Network. The Secretary shall make such in-
11 formation available to the public.

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

14 “(A) the donor banks within the National
15 Cord Blood Stem Cell Bank Network meet the
16 requirements of subsection (b)(3) on a con-
17 tinuing basis; and

18 “(B) the National Cord Blood Stem Cell
19 Bank Network and their birthing hospital col-
20 lection sites be geographically distributed
21 throughout the United States.

22 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
23 purpose of carrying out this section, there are authorized
24 to be appropriated \$15,000,000 for fiscal year 2004, and
25 \$30,000,000 for fiscal year 2005 and such sums as may

1 be necessary for each of fiscal years 2006 through 2008
2 or until the 150,000 unit inventory is successfully ac-
3 quired.”.

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