

109TH CONGRESS  
1ST SESSION

# H. R. 596

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.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 2, 2005

Mr. SMITH of New Jersey (for himself, Mr. DAVIS of Alabama, Mrs. MYRICK, Mr. TOWNS, Mr. NORWOOD, Mrs. CHRISTENSEN, Mr. WAMP, Mr. CUMMINGS, Mr. BURGESS, Ms. MILLENDER-McDONALD, Mrs. JO ANN DAVIS of Virginia, Ms. ESHOO, Mr. LEWIS of Kentucky, Mr. RYUN of Kansas, Mr. MARSHALL, Mr. KENNEDY of Minnesota, Mr. RANGEL, Mr. WELDON of Florida, and Mr. BARTLETT of Maryland) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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,*

1 **SECTION 1. SHORT TITLE.**

2       This Act may be cited as “Cord Blood Stem Cell Act  
3 of 2005”.

4 **SEC. 2. FINDINGS.**

5       The Congress makes the following findings:

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

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

1 cover a potential to treat a wide variety of diseases  
2 not yet attempted.

3 (3) Advantages of cord blood stem cell trans-  
4 plants include no risk to the donor, and reduced risk  
5 of certain transplant complications, including graft  
6 versus host disease and latent virus infections (such  
7 as Epstein-Barr virus or cytomegalovirus) and im-  
8 mediate availability of cord blood stem cell units,  
9 whenever needed.

10 (4) Cord blood gives all patients a chance for  
11 a transplant, regardless of their ethnic background.  
12 An ethnically diverse inventory of 150,000 cord  
13 blood stem cell units would help provide appropriate  
14 matches for 80 to 90 percent of patients seeking  
15 matched cord blood stem cell transplants.

16 (5) Some genetic conditions are more prevalent  
17 in members of particular ethnic groups, such as  
18 sickle cell anemia, a disease that occurs in one out  
19 of 500 African-American newborns. From early in-  
20 fancy, patients with sickle cell anemia have a high  
21 risk of severe or fatal bacterial blood infections.  
22 Many patients develop painful crises beginning in in-  
23 fancy and occurring up to 20 times per year. Chil-  
24 dren with recurrent crises, chest syndrome or  
25 strokes, are at great risk of dying before the age of

1       20 years. The median life-span of a patient with  
2       sickle cell disease is 42 years, but patients with se-  
3       vere disease in childhood rarely live beyond 20 years.  
4       Cord blood stem cell transplantation has cured pa-  
5       tients with sickle cell anemia: 80 percent of children  
6       transplanted with related cord blood to correct sickle  
7       cell anemia or thalassemia were cured in a recently  
8       published study. The earlier in the course of severe  
9       disease, the transplant is performed, the better the  
10      outcomes. Unrelated cord blood transplants are es-  
11      pecially beneficial for African-American and other  
12      ethnic minority patients because cord blood does not  
13      have to match as closely as bone marrow. With an  
14      ethnically balanced national cord blood stem cell net-  
15      work of at least 150,000 units, some 80 to 90 per-  
16      cent of African American patients who suffer from  
17      sickle cell anemia or other conditions requiring bone  
18      marrow replacement would be able to find appro-  
19      priately matched cord blood stem cells for successful  
20      treatment.

21           (6) Cord blood is an alternate to bone marrow  
22      as a source of stem cells for transplantation. Cord  
23      blood banks, therefore, serve the same kinds of pa-  
24      tients as marrow donor registries. However, its col-

1       lection, processing, storage and selection for trans-  
2       plant require unique systems and expertise.

3           (7) Radiation exposure, from accidents or hos-  
4       tile actions, could cause bone marrow failure in a  
5       portion of those exposed and require treatment, in-  
6       cluding bone marrow reconstitution. In these cases  
7       the rapid availability of frozen cord blood stem cell  
8       units may be an important resource to help rescue  
9       the victims years later, those who were exposed and  
10      survived may incur an increased risk of leukemia or  
11      lymphoma, which might also require stem cell trans-  
12      plantation.

13          (8) Recent scientific developments suggest that  
14      further research on cord blood stem cells may lead  
15      to a greater understanding of certain chronic dis-  
16      eases. This research might improve therapies for,  
17      and possibly cure, debilitating diseases such as Par-  
18      kinson's disease, insulin-dependent diabetes, heart  
19      disease, and certain types of cancer. These diseases  
20      cause a disproportionately large share of chronic dis-  
21      abilities and account for a large portion of health  
22      care expenditures in the United States.

1 **SEC. 3. 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 BANK  
4 NETWORK.—The term ‘National Cord Blood Stem  
5 Cell Bank Network’ means a network of qualified  
6 cord blood stem cell banks established under sub-  
7 section (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 Network of Cord Blood Stem Cell Banks  
15 that contains at least 150,000 units of human cord  
16 blood 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 developed  
13          such systems, consistent with the regulations  
14          promulgated under section 264(c) of the Health  
15          Insurance Portability and Accountability Act of  
16          1996, to track recipients’ clinical outcomes for  
17          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 Bank Network, including establishing a na-  
6 tional cord blood stem cell registry within the  
7 Network and coordinating the donor banks in  
8 the Network.

9           “(B) COMPOSITION.—

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

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

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

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

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

23           “(V) family members of a patient  
24 of the National Cord Blood Stem Cell  
25 Bank;

1 “(VI) individuals with expertise  
2 in the social sciences;

3 “(VII) members of the general  
4 public;

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

10 “(IX) the network donor banks.

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

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

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

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

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

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

15                  “(iii) maintain a database to docu-  
16                  ment the collection, storage, distribution,  
17                  and transplantation of cord blood units  
18                  and the clinical outcomes of all  
19                  transplantations related to the Network.

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(c) 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) on a con-  
13 tinuing basis; and

14 “(B) the National Cord Blood Stem Cell  
15 Bank Network and their birthing hospital col-  
16 lection sites be geographically distributed  
17 throughout the United States.

18 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the  
19 purpose of carrying out this section, there are authorized  
20 to be appropriated \$15,000,000 for fiscal year 2006, and  
21 \$30,000,000 for fiscal year 2007 and such sums as may  
22 be necessary for each of fiscal years 2008 through 2010  
23 or until the 150,000 unit inventory is successfully ac-  
24 quired.”.

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