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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Cord Blood Stem Cell Act of 2003'' .

SEC. 2. FINDINGS.

The Congress makes the following findings:

(1) Research sponsored by the National Institutes of Health and conducted in full compliance with applicable Food and Drug Administration regulations has demonstrated the feasibility of using cord blood for clinical applications. Stem cells, obtained from the blood contained in the delivered placenta and umbilical cord and donated by the mother, can be used for bone marrow reconstitution by transplantation to recipients with certain malignancies (such as leukemia and lymphoma), genetic disorders (such as sickle cell anemia), and acquired diseases.

(2) The placenta, umbilical cord, and the neonatal blood they contain are normally discarded after childbirth. This residual neonatal blood, termed cord blood, is a source of stem cells that can be collected as donor tissue without risk to the donor and can be preserved through freezing for many years and be made immediately available for transplantation in routine or emergency clinical situations. It can also be used for scientific research involving its stem cells.

(3) Advantages of cord blood stem cell transplants relative to bone marrow transplants include the reduction of risks to the donor, availability of

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

(4) In conventional bone marrow transplantation, matched siblings are the preferred donors, but only 30 percent of patients have a matched sibling. When no sibling match is found, a search is initiated for an unrelated donor.

(5) Finding a fully matched unrelated donor optimizes the chances of successful bone marrow transplantation. In conventional bone marrow transplantation, patients of ethnic minorities generally have difficulty finding fully matched donors, leaving partially matched transplants as their only transplant option. Partially matched bone marrow transplantation leads to a disproportionately high rate of complications, including graft versus host disease and mortality.

(6) Cord blood stem cell banks would provide increased genetic diversity in the supply of donors and increase the opportunity to identify fully matched and partially matched transplant units for qualified candidates. Cord blood stem cell transplants using partially matched units reduce the risk

of graft versus host disease with its attending morbidity and mortality as compared to conventional bone marrow transplantation.

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

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

years, but patients with severe disease in childhood rarely live beyond 20 years. Cord blood stem cell transplantation has cured patients with Sickle Cell Anemia: 80 percent of children transplanted with related cord blood to correct Sickle Cell Anemia or thalassemia were cured in a recently published study. The earlier in the course of severe disease, the transplant is performed, the better the outcomes. Unrelated cord blood transplants are especially beneficial for African American and other ethnic minority patients because cord blood does not have to match as closely as bone marrow. For this reason, an African American patient is much more likely to find a suitable unrelated cord blood donor as compared to a matched bone marrow donor. With an ethnically balanced national cord blood bank of at least 150,000 units, some 90 percent of African American patients who suffer from Sickle Cell Anemia or other conditions requiring bone marrow replacement would be able to find appropriately matched cord blood stem cells for successful treatment.

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

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

(10) Radiation exposure, from accidents or hostile actions could cause bone marrow failure in a portion of those exposed, requiring treatment including bone marrow reconstitution. In these cases the rapid availability of cryopreserved cord blood stem cell units may be important. Years later, those exposed would incur an increased risk of leukemia orlymphoma, which might also require stem cell transplantation.

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

cause a disproportionately large share of chronic disabilities and account for a large portion of health care expenditures in the United States.

SEC. 3. NATIONAL CORD BLOOD STEM CELL BANK NETWORK.

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

"SEC. 376A. NATIONAL CORD BLOOD STEM CELL BANK NETWORK.

''(a) DEFINITIONS.—In this section:

''(1) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Health Resources and Services Administration.

''(2) CORD BLOOD UNIT.—The term 'cord blood unit' means the blood collected from a single placenta and umbilical cord.

''(3) DONOR.—The term 'donor' means a mother who has delivered a baby and consents to donate the newborn's blood remaining in the placenta and umbilical cord.

''(4) DONOR BANK.—The term 'donor bank' means a qualified cord blood stem cell bank that enters into a contract with the Secretary under subsection (b)(1).

''(5) HUMAN CORD BLOOD STEM CELLS.—The term 'human cord blood stem cells' means hematopoietic stem cells and any other stem cells contained in the neonatal blood collected immediately after the birth from the separated placenta and umbilical cord.

''(6) NATIONAL CORD BLOOD STEM CELL BANK NETWORK.—The term 'National Cord Blood Stem Cell Bank Network' means a network of qualified cord blood stem cell banks established under subsection (b).

''(b) NATIONAL CORD BLOOD STEM CELL BANK NETWORK.—

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

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

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

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

"(B) make cord blood units collected under this section, or otherwise, available to transplant centers for stem cell transplantation; and

"(C) allocate up to 10 percent of the cord blood inventory each year for peer-reviewed research.

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

"(A) has obtained all applicable Federal and State licenses, certifications, registrations (including registration with the Food and Drug Administration), and other authorizations required to operate and maintain a cord blood stem cell bank;

"(B) has implemented donor screening and cord blood collection practices adequate to protect both donors and transplant recipients and to prevent transmission of potentially harmful infections and other diseases;

"(C) has established a system of strict confidentiality to protect the identity and privacy

of patients and donors in accordance with existing Federal and State law, and consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 for the release of the identity of donors, recipients, or identifiable records;

''(D) has established a system for encouraging donation by an ethnically diverse group of donors;

''(E) has developed adequate systems for communication with other cord blood stem cell banks, transplant centers, and physicians with respect to the request, release, and distribution of cord blood units nationally and has developed such systems, consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, to track recipients' clinical outcomes for distributed units; and

''(F) has developed a system for educating the public, including patient advocacy organizations, about the benefits of donating and utilizing cord blood stem cells in appropriate circumstances.

''(c) ADMINISTRATION OF THE NETWORK.—

''(1) BOARD OF DIRECTORS.—

''(A) IN GENERAL.—The Secretary shall provide for the establishment of a Board of Directors, including a chairperson, who shall administer the National Cord Blood Stem Cell Bank Network, including establishing a national cord blood stem cell registry within the Network and coordinating the donor banks in the Network.

''(B) COMPOSITION.—

''(i) IN GENERAL.—The Board of Directors shall be composed of members to be appointed by the Secretary who shall serve 3-year terms, and shall include representatives from—

''(I) cord blood stem cell transplant centers;

''(II) physicians from participating birthing hospitals;

''(III) the cord blood stem cell research community;

''(IV) recipients of cord blood stem cell transplants;

''(V) family members of a patient of the National Cord Blood Stem Cell Bank;

''(VI) individuals with expertise in the social sciences;

''(VII) members of the general public;

''(VIII) the Division of Stem Cell Transplantation of the Health Resources and Services Administration, who shall serve as nonvoting member; and

''(IX) the network donor banks.

''(ii) TERMS OF SERVICE.—Each member appointed under clause (i) may serve up to 2 consecutive 3-year terms, except that this clause shall not apply to the members appointed under subclauses (VIII) and (IX) of clause (i).

''(C) CONTINUITY.—In order to ensure the continuity of the Board of Directors, the Board shall be appointed so that each year the terms of approximately 1/3 of the Board members expire. A member of the Board may continue to

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

''(2) NATIONAL CORD BLOOD STEM CELL REGISTRY.—

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

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

''(ii) provide transplant physicians and other appropriate health care professionals a website function that enables searching the entire registry for suitable donor matches for patients, and requesting specific cord blood units; and

''(iii) maintain a database to document the collection, storage, distribution, and transplantation of cord blood units and the clinical outcomes of all transplantations related to the Network.

''(B) DATABASE.—The database maintained under subparagraph (A)(iii) shall be op-

erated according to standards of consent, disclosure, and confidentiality, including those applicable under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. The Administrator, using the database, shall report to the Secretary on a periodic basis regarding the safety, efficacy, and cost-effectiveness of the clinical, research, and educational activities of the Network. The Secretary shall make such information available to the public.

''(3) NETWORK STANDARDS.—The Board of Directors shall ensure that—

''(A) the donor banks within the National Cord Blood Stem Cell Bank Network meet the requirements of subsection (b)(3) on a continuing basis; and

''(B) the National Cord Blood Stem Cell Bank Network and their birthing hospital collection sites be geographically distributed throughout the United States.

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

be necessary for each of fiscal years 2006 through 2008 or until the 150,000 unit inventory is successfully acquired.''.

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