

Calendar No. 256

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

**H. R. 2520**

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IN THE SENATE OF THE UNITED STATES

MAY 26, 2005

Received

OCTOBER 24, 2005

Read twice and placed on the calendar

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**AN ACT**

To provide for the collection and maintenance of human cord blood stem cells for the treatment of patients and research, and to amend the Public Health Service Act to authorize the C.W. Bill Young Cell Transplantation Program.

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 Act of 2005”.

1 **SEC. 2. CORD BLOOD INVENTORY.**

2 (a) IN GENERAL.—The Secretary of Health and  
3 Human Services shall enter into one-time contracts with  
4 qualified cord blood stem cell banks to assist in the collec-  
5 tion and maintenance of 150,000 units of high-quality  
6 human cord blood to be made available for transplantation  
7 through the C.W. Bill Young Cell Transplantation Pro-  
8 gram and to carry out the requirements of subsection (b).

9 (b) REQUIREMENTS.—The Secretary shall require  
10 each recipient of a contract under this section—

11 (1) to acquire, tissue-type, test, cryopreserve,  
12 and store donated units of human cord blood ac-  
13 quired with the informed consent of the donor in a  
14 manner that complies with applicable Federal and  
15 State regulations;

16 (2) to make cord blood units that are collected  
17 pursuant to this section or otherwise and meet all  
18 applicable Federal standards available to transplant  
19 centers for stem cell transplantation;

20 (3) to make cord blood units that are collected,  
21 but not appropriate for clinical use, available for  
22 peer-reviewed research;

23 (4) to submit data in a standardized format, as  
24 required by the Secretary, for the C.W. Bill Young  
25 Cell Transplantation Program; and

1           (5) to submit data for inclusion in the stem cell  
2           therapeutic outcomes database maintained under  
3           section 379A of the Public Health Service Act, as  
4           amended by this Act.

5           (c) APPLICATION.—To seek to enter into a contract  
6           under this section, a qualified cord blood stem cell bank  
7           shall submit an application to the Secretary at such time,  
8           in such manner, and containing such information as the  
9           Secretary may reasonably require. At a minimum, an ap-  
10          plication for a contract under this section shall include an  
11          assurance that the applicant—

12           (1) will participate in the C.W. Bill Young Cell  
13          Transplantation Program for a period of at least 10  
14          years; and

15           (2) in the event of abandonment of this activity  
16          prior to the expiration of such period, will transfer  
17          the units collected pursuant to this section to an-  
18          other qualified cord blood stem cell bank approved  
19          by the Secretary to ensure continued availability of  
20          cord blood units.

21          (d) DURATION OF CONTRACTS.—

22           (1) IN GENERAL.—The Secretary may not enter  
23          into any contract under this section for a period  
24          that—

25           (A) exceeds 3 years; or

1 (B) ends after September 30, 2010.

2 (2) EXTENSIONS.—Subject to paragraph  
3 (1)(B), the Secretary may extend the period of a  
4 contract under this section to exceed a period of 3  
5 years if—

6 (A) the Secretary finds that 150,000 units  
7 of high-quality human cord blood have not yet  
8 been collected pursuant to this section; and

9 (B) the Secretary does not receive an ap-  
10 plication for a contract under this section from  
11 any qualified cord blood stem cell bank that has  
12 not previously entered into a contract under  
13 this section or the Secretary determines that  
14 the outstanding inventory need cannot be met  
15 by the one or more qualified cord blood stem  
16 cell banks that have submitted an application  
17 for a contract under this section.

18 (e) REGULATIONS.—The Secretary may promulgate  
19 regulations to carry out this section.

20 (f) DEFINITIONS.—In this section:

21 (1) The term “C.W. Bill Young Cell Transplan-  
22 tation Program” means the C.W. Bill Young Cell  
23 Transplantation Program under section 379 of the  
24 Public Health Service Act, as amended by this Act.

1           (2) The term “cord blood donor” means a  
2           mother who has delivered a baby and consents to do-  
3           nate the neonatal blood remaining in the placenta  
4           and umbilical cord after separation from the new-  
5           born baby.

6           (3) The term “human cord blood unit” means  
7           the neonatal blood collected from the placenta and  
8           umbilical cord.

9           (4) The term “qualified cord blood stem cell  
10          bank” has the meaning given to that term in section  
11          379(b) of the Public Health Service Act, as amended  
12          by this Act.

13          (5) The term “Secretary” means the Secretary  
14          of Health and Human Services.

15          (g) AUTHORIZATION OF APPROPRIATIONS.—

16           (1) FISCAL YEAR 2006.—Any amounts appro-  
17           priated to the Secretary for fiscal year 2004 or 2005  
18           for the purpose of assisting in the collection or  
19           maintenance of human cord blood shall remain avail-  
20           able to the Secretary until the end of fiscal year  
21           2006 for the purpose of carrying out this section.

22           (2) SUBSEQUENT FISCAL YEARS.—There are  
23           authorized to be appropriated to the Secretary  
24           \$15,000,000 for each of fiscal years 2007, 2008,  
25           2009, and 2010 to carry out this section. Amounts



1 major functions of the Program described in  
2 paragraphs (1) and (2) of subsection (b) if  
3 deemed necessary by the Secretary to operate  
4 an effective and efficient system. The Secretary  
5 shall conduct a separate competition for the ini-  
6 tial establishment of the cord blood functions of  
7 the Program. The Program shall be under the  
8 general supervision of the Secretary. The Sec-  
9 retary shall establish an Advisory Council to ad-  
10 vise, assist, consult with, and make rec-  
11 ommendations to the Secretary on matters re-  
12 lated to the activities carried out by the Pro-  
13 gram. The members of the Advisory Council  
14 shall be appointed in accordance with the fol-  
15 lowing:”;

16 (B) in paragraph (1), by striking “except  
17 that” and all that follows and inserting “except  
18 that—

19 “(A) such limitations shall not apply to the  
20 Chair of the Advisory Council (or the Chair-  
21 elect) or to the member of the Advisory Council  
22 who most recently served as the Chair; and

23 “(B) 1 additional consecutive 2-year term  
24 may be served by any member of the Advisory  
25 Council who has no employment, governance, or

1 financial affiliation with any donor center, re-  
2 ruitment group, transplant center, or cord  
3 blood stem cell bank.”;

4 (C) by amending paragraph (4) to read as  
5 follows:

6 “(4) The membership of the Advisory Council—

7 (A) shall include as voting members a  
8 balanced number of representatives including  
9 representatives of marrow donor centers and  
10 marrow transplant centers, representatives of  
11 cord blood stem cell banks and participating  
12 birthing hospitals, recipients of a bone marrow  
13 transplant and cord blood transplants, persons  
14 who require such transplants, family members  
15 of such a recipient or family members of a pa-  
16 tient who has requested the assistance of the  
17 Program in searching for an unrelated donor of  
18 bone marrow or cord blood, persons with exper-  
19 tise in blood stem cell transplantation including  
20 cord blood, persons with expertise in typing,  
21 matching, and transplant outcome data anal-  
22 ysis, persons with expertise in the social  
23 sciences, and members of the general public;  
24 and

1           “(B) shall include as nonvoting members  
2           representatives from the Department of De-  
3           fense Marrow Donor Recruitment and Research  
4           Program operated by the Department of the  
5           Navy, the Division of Transplantation of the  
6           Health Resources and Services Administration,  
7           the Food and Drug Administration, and the  
8           National Institutes of Health.”; and

9           (D) by adding at the end the following:

10           “(5) Members of the Advisory Council shall be  
11           chosen so as to ensure objectivity and balance and  
12           reduce the potential for conflicts of interest. The  
13           Secretary shall establish bylaws and procedures—

14           “(A) to prohibit any member of the Advi-  
15           sory Council who has an employment, govern-  
16           ance, or financial affiliation with a donor cen-  
17           ter, recruitment group, transplant center, or  
18           cord blood stem cell bank from participating in  
19           any decision that materially affects the center,  
20           recruitment group, transplant center, or cord  
21           blood stem cell bank; and

22           “(B) to limit the number of members of  
23           the Advisory Council with any such affiliation.

24           “(6) The Secretary, acting through the Advi-  
25           sory Council, shall submit to the Congress—

1           “(A) an annual report on the activities car-  
2           ried out under this section; and

3           “(B) not later than 6 months after the  
4           date of the enactment of the Stem Cell Thera-  
5           peutic and Research Act of 2005, a report of  
6           recommendations on the scientific factors nec-  
7           essary to define a cord blood unit as a high-  
8           quality unit.”;

9           (3) by amending subsection (b) to read as fol-  
10          lows:

11          “(b) FUNCTIONS.—

12                 “(1) BONE MARROW FUNCTIONS.—With respect  
13                 to bone marrow, the Program shall—

14                         “(A) operate a system for listing, search-  
15                         ing, and facilitating the distribution of bone  
16                         marrow that is suitably matched to candidate  
17                         patients;

18                         “(B) carry out a program for the recruit-  
19                         ment of bone marrow donors in accordance with  
20                         subsection (c), including with respect to increas-  
21                         ing the representation of racial and ethnic mi-  
22                         nority groups (including persons of mixed an-  
23                         cestry) in the enrollment of the Program;

24                         “(C) maintain and expand medical emer-  
25                         gency contingency response capabilities in con-

1 cert with Federal programs for response to  
2 threats of use of terrorist or military weapons  
3 that can damage marrow, such as ionizing radi-  
4 ation or chemical agents containing mustard, so  
5 that the capability of supporting patients with  
6 marrow damage from disease can be used to  
7 support casualties with marrow damage;

8 “(D) carry out informational and edu-  
9 cational activities in accordance with subsection  
10 (c);

11 “(E) at least annually update information  
12 to account for changes in the status of individ-  
13 uals as potential donors of bone marrow;

14 “(F) provide for a system of patient advo-  
15 cacy through the office established under sub-  
16 section (d);

17 “(G) provide case management services for  
18 any potential donor of bone marrow to whom  
19 the Program has provided a notice that the po-  
20 tential donor may be suitably matched to a par-  
21 ticular patient (which services shall be provided  
22 through a mechanism other than the system of  
23 patient advocacy under subsection (d)), and  
24 conduct surveys of donors and potential donors  
25 to determine the extent of satisfaction with

1 such services and to identify ways in which the  
2 services can be improved;

3 “(H) with respect to searches for unrelated  
4 donors of bone marrow that are conducted  
5 through the system under subparagraph (A),  
6 collect, analyze, and publish data on the num-  
7 ber and percentage of patients at each of the  
8 various stages of the search process, including  
9 data regarding the furthest stage reached, the  
10 number and percentage of patients who are un-  
11 able to complete the search process, and the  
12 reasons underlying such circumstances;

13 “(I) support studies and demonstration  
14 and outreach projects for the purpose of in-  
15 creasing the number of individuals who are will-  
16 ing to be marrow donors to ensure a genetically  
17 diverse donor pool;

18 “(J) conduct and support research to im-  
19 prove the availability, efficiency, safety, and  
20 cost of transplants from unrelated donors and  
21 the effectiveness of Program operations; and

22 “(K) assist qualified cord blood stem cell  
23 banks in the Program in accordance with para-  
24 graph (3).

1 Subsections (c) through (e) apply with respect to  
2 each entity awarded a contract under this section  
3 with respect to bone marrow.

4 “(2) CORD BLOOD FUNCTIONS.—With respect  
5 to cord blood, the Program shall—

6 “(A) operate a system for identifying,  
7 matching, and facilitating the distribution of  
8 donated cord blood units that are suitably  
9 matched to candidate patients and meet all ap-  
10 plicable Federal and State regulations (includ-  
11 ing informed consent and Food and Drug Ad-  
12 ministration regulations) from a qualified cord  
13 blood stem cell bank;

14 “(B) allow transplant physicians, other ap-  
15 propriate health care professionals, and patients  
16 to search by means of electronic access all avail-  
17 able cord blood units listed in the Program;

18 “(C) allow transplant physicians and other  
19 appropriate health care professionals to ten-  
20 tatively reserve a cord blood unit for transplan-  
21 tation;

22 “(D) support studies and demonstration  
23 and outreach projects for the purpose of in-  
24 creasing cord blood donation to ensure a geneti-  
25 cally diverse collection of cord blood units; and

1           “(E) coordinate with the Secretary to  
2           carry out information and educational activities  
3           for the purpose of increasing cord blood dona-  
4           tion and promoting the availability of cord  
5           blood units as a transplant option.

6           “(3) SINGLE POINT OF ACCESS.—If the Sec-  
7           retary enters into a contract with more than one en-  
8           tity to perform the functions outlined in this sub-  
9           section, the Secretary shall establish procedures to  
10          ensure that health care professionals and patients  
11          are able to obtain, consistent with the functions de-  
12          scribed in paragraphs (1)(A) and (2)(A), cells from  
13          adult donors and cord blood units through a single  
14          point of access.

15          “(4) DEFINITION.—The term ‘qualified cord  
16          blood stem cell bank’ means a cord blood stem cell  
17          bank that—

18                 “(A) has obtained all applicable Federal  
19                 and State licenses, certifications, registrations  
20                 (including pursuant to the regulations of the  
21                 Food and Drug Administration), and other au-  
22                 thorizations required to operate and maintain a  
23                 cord blood stem cell bank;

24                 “(B) has implemented donor screening,  
25                 cord blood collection practices, and processing

1 methods intended to protect the health and  
2 safety of donors and transplant recipients to  
3 improve transplant outcomes, including with re-  
4 spect to the transmission of potentially harmful  
5 infections and other diseases;

6 “(C) is accredited by an accreditation body  
7 recognized pursuant to a public process by the  
8 Secretary;

9 “(D) has established a system of strict  
10 confidentiality to protect the identity and pri-  
11 vacy of patients and donors in accordance with  
12 existing Federal and State law; and

13 “(E) has established a system for encour-  
14 aging donation by a genetically diverse group of  
15 donors.”;

16 (4) in subsection (c)—

17 (A) in paragraph (1), by striking “The  
18 Registry shall carry out a program for the re-  
19 cruitment” and inserting “With respect to bone  
20 marrow, the Program shall carry out a program  
21 for the recruitment”;

22 (B) in paragraph (2)(A)—

23 (i) in the matter preceding clause (i),  
24 by striking the first sentence and inserting  
25 “In carrying out the program under para-

1 graph (1), the Program shall carry out in-  
2 formational and educational activities, in  
3 coordination with organ donation public  
4 awareness campaigns operated through the  
5 Department of Health and Human Serv-  
6 ices, for purposes of recruiting individuals  
7 to serve as donors of bone marrow and  
8 shall test and enroll with the Program po-  
9 tential donors.”; and

10 (ii) in clause (ii), by striking “, in-  
11 cluding providing updates”; and

12 (C) in paragraph (3), by striking “the  
13 availability, as a potential treatment option, of  
14 receiving a transplant of bone marrow from an  
15 unrelated donor” and inserting “transplants  
16 from unrelated donors as a treatment option  
17 and resources for identifying and evaluating  
18 other therapeutic alternatives”;

19 (5) in subsection (d)—

20 (A) in paragraph (1), by striking “The  
21 Registry shall” and inserting “With respect to  
22 bone marrow, the Program shall”;

23 (B) in paragraph (2)(C), by inserting “and  
24 assist with information regarding third party

1 payor matters” after “ongoing search for a  
2 donor”;

3 (C) in subparagraphs (C), (D), and (E) of  
4 paragraph (2), by striking the term “subsection  
5 (b)(1)” each place such term appears and in-  
6 serting “subsection (b)(1)(A)”;

7 (D) in paragraph (2)(F)—

8 (i) by redesignating clause (v) as  
9 clause (vi); and

10 (ii) by inserting after clause (iv) the  
11 following:

12 “(v) Information concerning issues  
13 that patients may face after a transplant  
14 regarding continuity of care and quality of  
15 life.”; and

16 (E) in paragraph (3)(B), by striking “Of-  
17 fice may” and inserting “Office shall”;

18 (6) in the matter preceding paragraph (1) in  
19 subsection (e), by striking “the Secretary shall” and  
20 inserting “with respect to bone marrow, the Sec-  
21 retary shall”;

22 (7) by amending subsection (f) to read as fol-  
23 lows:

24 “(f) COMMENT PROCEDURES.—The Secretary shall  
25 establish and provide information to the public on proce-

1 dures under which the Secretary shall receive and consider  
2 comments from interested persons relating to the manner  
3 in which the Program is carrying out the duties of the  
4 Program.”;

5 (8) by amending subsection (g) to read as fol-  
6 lows:

7 “(g) CONSULTATION.—In developing policies affect-  
8 ing the Program, the Secretary shall consult with the Ad-  
9 visory Council, the Department of Defense Marrow Donor  
10 Recruitment and Research Program operated by the De-  
11 partment of the Navy, and the board of directors of each  
12 entity awarded a contract under this section.”;

13 (9) in subsection (h)—

14 (A) by striking “APPLICATION.—” and in-  
15 serting “CONTRACTS.—”;

16 (B) by striking “To be eligible” and insert-  
17 ing the following:

18 “(1) APPLICATION.—To be eligible”; and

19 (C) by adding at the end the following:

20 “(2) CONSIDERATIONS.—In awarding contracts  
21 under this section, the Secretary shall give substan-  
22 tial weight to the continued safety of donors and pa-  
23 tients and other factors deemed appropriate by the  
24 Secretary.”; and

25 (10) by striking subsection (l).

1 (b) STEM CELL THERAPEUTIC OUTCOMES DATA-  
2 BASE.—Section 379A of the Public Health Service Act (42  
3 U.S.C. 274l) is amended to read as follows:

4 **“SEC. 379A. STEM CELL THERAPEUTIC OUTCOMES DATA-**  
5 **BASE.**

6 “(a) ESTABLISHMENT.—The Secretary shall by con-  
7 tract establish and maintain a scientific database of infor-  
8 mation relating to patients who have been recipients of  
9 stem cell therapeutics product (including bone marrow,  
10 cord blood, or other such product) from a biologically un-  
11 related donor.

12 “(b) INFORMATION.—The outcomes database shall  
13 include information with respect to patients described in  
14 subsection (a), transplant procedures, and such other in-  
15 formation as the Secretary determines to be appropriate,  
16 to conduct an ongoing evaluation of the scientific and clin-  
17 ical status of transplantation involving recipients of bone  
18 marrow from biologically unrelated donors and recipients  
19 of a stem cell therapeutics product.

20 “(c) ANNUAL REPORT ON PATIENT OUTCOMES.—  
21 The Secretary shall require the entity awarded a contract  
22 under this section to submit to the Secretary an annual  
23 report concerning patient outcomes with respect to each  
24 transplant center, based on data collected and maintained  
25 by the entity pursuant to this section.

1       “(d) PUBLICLY AVAILABLE DATA.—The outcomes  
2 database shall make relevant scientific information not  
3 containing individually identifiable information available  
4 to the public in the form of summaries and data sets to  
5 encourage medical research and to provide information to  
6 transplant programs, physicians, patients, entities award-  
7 ed a contract under section 379 donor registries, and cord  
8 blood stem cell banks.”.

9       (c) DEFINITIONS.—Part I of title III of the Public  
10 Health Service Act (42 U.S.C. 274k et seq.) is amended  
11 by inserting after section 379A the following:

12 **“SEC. 379A–1. DEFINITIONS.**

13       “In this part:

14               “(1) The term ‘Advisory Council’ means the ad-  
15 visory council established by the Secretary under  
16 section 379(a)(1).

17               “(2) The term ‘bone marrow’ means the cells  
18 found in adult bone marrow and peripheral blood.

19               “(3) The term ‘outcomes database’ means the  
20 database established by the Secretary under section  
21 379A.

22               “(4) The term ‘Program’ means the C.W. Bill  
23 Young Cell Transplantation Program established  
24 under section 379.”.

1 (d) AUTHORIZATION OF APPROPRIATIONS.—Section  
2 379B of the Public Health Service Act (42 U.S.C. 274m)  
3 is amended to read as follows:

4 **“SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.**

5 “(a) IN GENERAL.—For the purpose of carrying out  
6 this part, there are authorized to be appropriated  
7 \$28,000,000 for fiscal year 2006 and \$32,000,000 for  
8 each of fiscal years 2007 through 2010.

9 “(b) EMERGENCY CONTINGENCY RESPONSE CAPA-  
10 BILITIES.—In addition to the amounts authorized to be  
11 appropriated under subsection (a), there is authorized to  
12 be appropriated \$2,000,000 for the maintenance and ex-  
13 pansion of emergency contingency response capabilities  
14 under section 379(b)(1)(C).”.

15 (e) CONFORMING AMENDMENTS.—Part I of title III  
16 of the Public Health Service Act (42 U.S.C. 274k et seq.)  
17 is amended—

18 (1) in the title heading, by striking “**NA-**  
19 **TIONAL BONE MARROW DONOR REG-**  
20 **ISTRY**” and inserting “**C.W. BILL YOUNG**  
21 **CELL TRANSPLANTATION PROGRAM**”;

22 and

23 (2) in section 379, as amended by this sec-  
24 tion—

1 (A) in subsection (a), by striking the term  
2 “board” each place such term appears and in-  
3 serting “Advisory Council”;

4 (B) in subsection (c)—

5 (i) in the matter preceding subpara-  
6 graph (A) in paragraph (1), by striking  
7 “Such program” and inserting “Such re-  
8 cruitment program”;

9 (ii) in paragraph (2), by striking  
10 “program under paragraph (1)” and in-  
11 serting “recruitment program under para-  
12 graph (1)”; and

13 (iii) in paragraph (3), by striking  
14 “program under paragraph (1)” and in-  
15 serting “recruitment program under para-  
16 graph (1)”;

17 (C) in subsection (d)(2)(E), by striking  
18 “Registry program” and inserting “Program”;

19 (D) in subsection (e)—

20 (i) in the matter preceding paragraph  
21 (1), by striking “participating in the pro-  
22 gram, including the Registry,” and insert-  
23 ing “participating in the Program, includ-  
24 ing”; and



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