

109TH CONGRESS
1ST SESSION

H. R. 2520

IN THE SENATE OF THE UNITED STATES

MAY 26, 2005

Received

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”.

6 **SEC. 2. CORD BLOOD INVENTORY.**

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

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

16 (1) to acquire, tissue-type, test, cryopreserve,
17 and store donated units of human cord blood ac-
18 quired with the informed consent of the donor in a
19 manner that complies with applicable Federal and
20 State regulations;

21 (2) to make cord blood units that are collected
22 pursuant to this section or otherwise and meet all
23 applicable Federal standards available to transplant
24 centers for stem cell transplantation;

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

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

7 (5) to submit data for inclusion in the stem cell
8 therapeutic outcomes database maintained under
9 section 379A of the Public Health Service Act, as
10 amended by this Act.

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

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

21 (2) in the event of abandonment of this activity
22 prior to the expiration of such period, will transfer
23 the units collected pursuant to this section to an-
24 other qualified cord blood stem cell bank approved

1 by the Secretary to ensure continued availability of
2 cord blood units.

3 (d) DURATION OF CONTRACTS.—

4 (1) IN GENERAL.—The Secretary may not enter
5 into any contract under this section for a period
6 that—

7 (A) exceeds 3 years; or

8 (B) ends after September 30, 2010.

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

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

16 (B) the Secretary does not receive an ap-
17 plication for a contract under this section from
18 any qualified cord blood stem cell bank that has
19 not previously entered into a contract under
20 this section or the Secretary determines that
21 the outstanding inventory need cannot be met
22 by the one or more qualified cord blood stem
23 cell banks that have submitted an application
24 for a contract under this section.

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

3 (f) DEFINITIONS.—In this section:

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

8 (2) The term “cord blood donor” means a
9 mother who has delivered a baby and consents to do-
10 nate the neonatal blood remaining in the placenta
11 and umbilical cord after separation from the new-
12 born baby.

13 (3) The term “human cord blood unit” means
14 the neonatal blood collected from the placenta and
15 umbilical cord.

16 (4) The term “qualified cord blood stem cell
17 bank” has the meaning given to that term in section
18 379(b) of the Public Health Service Act, as amended
19 by this Act.

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

22 (g) AUTHORIZATION OF APPROPRIATIONS.—

23 (1) FISCAL YEAR 2006.—Any amounts appro-
24 priated to the Secretary for fiscal year 2004 or 2005
25 for the purpose of assisting in the collection or

1 maintenance of human cord blood shall remain avail-
2 able to the Secretary until the end of fiscal year
3 2006 for the purpose of carrying out this section.

4 (2) SUBSEQUENT FISCAL YEARS.—There are
5 authorized to be appropriated to the Secretary
6 \$15,000,000 for each of fiscal years 2007, 2008,
7 2009, and 2010 to carry out this section. Amounts
8 appropriated pursuant to this paragraph shall re-
9 main available for obligation through the end of fis-
10 cal year 2010.

11 **SEC. 3. C.W. BILL YOUNG CELL TRANSPLANTATION PRO-**
12 **GRAM.**

13 (a) NATIONAL PROGRAM.—Section 379 of the Public
14 Health Service Act (42 U.S.C. 274k) is amended—

15 (1) in the section heading, by striking “**NA-**
16 **TIONAL REGISTRY**” and inserting “**NATIONAL**
17 **PROGRAM**”;

18 (2) in subsection (a)—

19 (A) in the matter preceding paragraph (1),
20 by striking “The Secretary shall by contract”
21 and all that follows through the end of such
22 matter and inserting “The Secretary, acting
23 through the Administrator of the Health Re-
24 sources and Services Administration, shall by
25 one or more contracts establish and maintain a

1 C.W. Bill Young Cell Transplantation Program
2 that has the purpose of increasing the number
3 of transplants for recipients suitably matched to
4 biologically unrelated donors of bone marrow
5 and cord blood, and that meets the require-
6 ments of this section. The Secretary may award
7 a separate contract to perform each of the
8 major functions of the Program described in
9 paragraphs (1) and (2) of subsection (b) if
10 deemed necessary by the Secretary to operate
11 an effective and efficient system. The Secretary
12 shall conduct a separate competition for the ini-
13 tial establishment of the cord blood functions of
14 the Program. The Program shall be under the
15 general supervision of the Secretary. The Sec-
16 retary shall establish an Advisory Council to ad-
17 vise, assist, consult with, and make rec-
18 ommendations to the Secretary on matters re-
19 lated to the activities carried out by the Pro-
20 gram. The members of the Advisory Council
21 shall be appointed in accordance with the fol-
22 lowing:”;

23 (B) in paragraph (1), by striking “except
24 that” and all that follows and inserting “except
25 that—

1 “(A) such limitations shall not apply to the
2 Chair of the Advisory Council (or the Chair-
3 elect) or to the member of the Advisory Council
4 who most recently served as the Chair; and

5 “(B) 1 additional consecutive 2-year term
6 may be served by any member of the Advisory
7 Council who has no employment, governance, or
8 financial affiliation with any donor center, re-
9 cruitment group, transplant center, or cord
10 blood stem cell bank.”;

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

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

14 “(A) shall include as voting members a
15 balanced number of representatives including
16 representatives of marrow donor centers and
17 marrow transplant centers, representatives of
18 cord blood stem cell banks and participating
19 birthing hospitals, recipients of a bone marrow
20 transplant and cord blood transplants, persons
21 who require such transplants, family members
22 of such a recipient or family members of a pa-
23 tient who has requested the assistance of the
24 Program in searching for an unrelated donor of
25 bone marrow or cord blood, persons with exper-

1 tise in blood stem cell transplantation including
2 cord blood, persons with expertise in typing,
3 matching, and transplant outcome data anal-
4 ysis, persons with expertise in the social
5 sciences, and members of the general public;
6 and

7 “(B) shall include as nonvoting members
8 representatives from the Department of De-
9 fense Marrow Donor Recruitment and Research
10 Program operated by the Department of the
11 Navy, the Division of Transplantation of the
12 Health Resources and Services Administration,
13 the Food and Drug Administration, and the
14 National Institutes of Health.”; and

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

16 “(5) Members of the Advisory Council shall be
17 chosen so as to ensure objectivity and balance and
18 reduce the potential for conflicts of interest. The
19 Secretary shall establish bylaws and procedures—

20 “(A) to prohibit any member of the Advi-
21 sory Council who has an employment, govern-
22 ance, or financial affiliation with a donor cen-
23 ter, recruitment group, transplant center, or
24 cord blood stem cell bank from participating in
25 any decision that materially affects the center,

1 recruitment group, transplant center, or cord
2 blood stem cell bank; and

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

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

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

9 “(B) not later than 6 months after the
10 date of the enactment of the Stem Cell Thera-
11 peutic and Research Act of 2005, a report of
12 recommendations on the scientific factors nec-
13 essary to define a cord blood unit as a high-
14 quality unit.”;

15 (3) by amending subsection (b) to read as fol-
16 lows:

17 “(b) FUNCTIONS.—

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

20 “(A) operate a system for listing, search-
21 ing, and facilitating the distribution of bone
22 marrow that is suitably matched to candidate
23 patients;

24 “(B) carry out a program for the recruit-
25 ment of bone marrow donors in accordance with

1 subsection (c), including with respect to increas-
2 ing the representation of racial and ethnic mi-
3 nority groups (including persons of mixed an-
4 cestry) in the enrollment of the Program;

5 “(C) maintain and expand medical emer-
6 gency contingency response capabilities in con-
7 cert with Federal programs for response to
8 threats of use of terrorist or military weapons
9 that can damage marrow, such as ionizing radi-
10 ation or chemical agents containing mustard, so
11 that the capability of supporting patients with
12 marrow damage from disease can be used to
13 support casualties with marrow damage;

14 “(D) carry out informational and edu-
15 cational activities in accordance with subsection
16 (c);

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

20 “(F) provide for a system of patient adv-
21 ocacy through the office established under sub-
22 section (d);

23 “(G) provide case management services for
24 any potential donor of bone marrow to whom
25 the Program has provided a notice that the po-

1 tential donor may be suitably matched to a par-
2 ticular patient (which services shall be provided
3 through a mechanism other than the system of
4 patient advocacy under subsection (d)), and
5 conduct surveys of donors and potential donors
6 to determine the extent of satisfaction with
7 such services and to identify ways in which the
8 services can be improved;

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

19 “(I) support studies and demonstration
20 and outreach projects for the purpose of in-
21 creasing the number of individuals who are will-
22 ing to be marrow donors to ensure a genetically
23 diverse donor pool;

24 “(J) conduct and support research to im-
25 prove the availability, efficiency, safety, and

1 cost of transplants from unrelated donors and
2 the effectiveness of Program operations; and

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

6 Subsections (c) through (e) apply with respect to
7 each entity awarded a contract under this section
8 with respect to bone marrow.

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

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

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

23 “(C) allow transplant physicians and other
24 appropriate health care professionals to ten-

1 tatively reserve a cord blood unit for transplan-
2 tation;

3 “(D) support studies and demonstration
4 and outreach projects for the purpose of in-
5 creasing cord blood donation to ensure a geneti-
6 cally diverse collection of cord blood units; and

7 “(E) coordinate with the Secretary to
8 carry out information and educational activities
9 for the purpose of increasing cord blood dona-
10 tion and promoting the availability of cord
11 blood units as a transplant option.

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

21 “(4) DEFINITION.—The term ‘qualified cord
22 blood stem cell bank’ means a cord blood stem cell
23 bank that—

24 “(A) has obtained all applicable Federal
25 and State licenses, certifications, registrations

1 (including pursuant to the regulations of the
2 Food and Drug Administration), and other au-
3 thorizations required to operate and maintain a
4 cord blood stem cell bank;

5 “(B) has implemented donor screening,
6 cord blood collection practices, and processing
7 methods intended to protect the health and
8 safety of donors and transplant recipients to
9 improve transplant outcomes, including with re-
10 spect to the transmission of potentially harmful
11 infections and other diseases;

12 “(C) is accredited by an accreditation body
13 recognized pursuant to a public process by the
14 Secretary;

15 “(D) has established a system of strict
16 confidentiality to protect the identity and pri-
17 vacy of patients and donors in accordance with
18 existing Federal and State law; and

19 “(E) has established a system for encour-
20 aging donation by a genetically diverse group of
21 donors.”;

22 (4) in subsection (c)—

23 (A) in paragraph (1), by striking “The
24 Registry shall carry out a program for the re-
25 cruitment” and inserting “With respect to bone

1 marrow, the Program shall carry out a program
2 for the recruitment”;

3 (B) in paragraph (2)(A)—

4 (i) in the matter preceding clause (i),
5 by striking the first sentence and inserting
6 “In carrying out the program under para-
7 graph (1), the Program shall carry out in-
8 formational and educational activities, in
9 coordination with organ donation public
10 awareness campaigns operated through the
11 Department of Health and Human Serv-
12 ices, for purposes of recruiting individuals
13 to serve as donors of bone marrow and
14 shall test and enroll with the Program po-
15 tential donors.”; and

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

18 (C) in paragraph (3), by striking “the
19 availability, as a potential treatment option, of
20 receiving a transplant of bone marrow from an
21 unrelated donor” and inserting “transplants
22 from unrelated donors as a treatment option
23 and resources for identifying and evaluating
24 other therapeutic alternatives”;

25 (5) in subsection (d)—

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

4 (B) in paragraph (2)(C), by inserting “and
5 assist with information regarding third party
6 payor matters” after “ongoing search for a
7 donor”;

8 (C) in subparagraphs (C), (D), and (E) of
9 paragraph (2), by striking the term “subsection
10 (b)(1)” each place such term appears and in-
11 serting “subsection (b)(1)(A)”;

12 (D) in paragraph (2)(F)—

13 (i) by redesignating clause (v) as
14 clause (vi); and

15 (ii) by inserting after clause (iv) the
16 following:

17 “(v) Information concerning issues
18 that patients may face after a transplant
19 regarding continuity of care and quality of
20 life.”; and

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

23 (6) in the matter preceding paragraph (1) in
24 subsection (e), by striking “the Secretary shall” and

1 inserting “with respect to bone marrow, the Sec-
2 retary shall”;

3 (7) by amending subsection (f) to read as fol-
4 lows:

5 “(f) COMMENT PROCEDURES.—The Secretary shall
6 establish and provide information to the public on proce-
7 dures under which the Secretary shall receive and consider
8 comments from interested persons relating to the manner
9 in which the Program is carrying out the duties of the
10 Program.”;

11 (8) by amending subsection (g) to read as fol-
12 lows:

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

19 (9) in subsection (h)—

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

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

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

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

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

6 (10) by striking subsection (l).

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

10 **“SEC. 379A. STEM CELL THERAPEUTIC OUTCOMES DATA-**
11 **BASE.**

12 “(a) ESTABLISHMENT.—The Secretary shall by con-
13 tract establish and maintain a scientific database of infor-
14 mation relating to patients who have been recipients of
15 stem cell therapeutics product (including bone marrow,
16 cord blood, or other such product) from a biologically un-
17 related donor.

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

1 “(c) ANNUAL REPORT ON PATIENT OUTCOMES.—
2 The Secretary shall require the entity awarded a contract
3 under this section to submit to the Secretary an annual
4 report concerning patient outcomes with respect to each
5 transplant center, based on data collected and maintained
6 by the entity pursuant to this section.

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

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

18 **“SEC. 379A-1. DEFINITIONS.**

19 “In this part:

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

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

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

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

7 (d) AUTHORIZATION OF APPROPRIATIONS.—Section
8 379B of the Public Health Service Act (42 U.S.C. 274m)
9 is amended to read as follows:

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

11 “(a) IN GENERAL.—For the purpose of carrying out
12 this part, there are authorized to be appropriated
13 \$28,000,000 for fiscal year 2006 and \$32,000,000 for
14 each of fiscal years 2007 through 2010.

15 “(b) EMERGENCY CONTINGENCY RESPONSE CAPA-
16 BILITIES.—In addition to the amounts authorized to be
17 appropriated under subsection (a), there is authorized to
18 be appropriated \$2,000,000 for the maintenance and ex-
19 pansion of emergency contingency response capabilities
20 under section 379(b)(1)(C).”.

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

24 (1) in the title heading, by striking “**NA-**
25 **TIONAL BONE MARROW DONOR REG-**

1 **ISTRY”** and inserting **“C.W. BILL YOUNG**
2 **CELL TRANSPLANTATION PROGRAM”**;

3 and

4 (2) in section 379, as amended by this sec-
5 tion—

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

9 (B) in subsection (c)—

10 (i) in the matter preceding subpara-
11 graph (A) in paragraph (1), by striking
12 “Such program” and inserting “Such re-
13 cruitment program”;

14 (ii) in paragraph (2), by striking
15 “program under paragraph (1)” and in-
16 serting “recruitment program under para-
17 graph (1)”;

18 (iii) in paragraph (3), by striking
19 “program under paragraph (1)” and in-
20 serting “recruitment program under para-
21 graph (1)”;

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

24 (D) in subsection (e)—

- 1 (i) in the matter preceding paragraph
2 (1), by striking “participating in the pro-
3 gram, including the Registry,” and insert-
4 ing “participating in the Program, includ-
5 ing”; and
- 6 (ii) in paragraph (6), by striking “the
7 program” and inserting “the Program”;
8 and
- 9 (E) by striking the term “Registry” each
10 place such term appears and inserting “Pro-
11 gram”.

Passed the House of Representatives May 24, 2005.

Attest:

JEFF TRANDAHL,

Clerk.