

Calendar No. 156109TH CONGRESS
1ST SESSION**S. 1317**

To provide for the collection and maintenance of cord blood units for the treatment of patients and research, and to amend the Public Health Service Act to authorize the Bone Marrow and Cord Blood Cell Transplantation Program to increase the number of transplants for recipients suitably matched to donors of bone marrow and cord blood.

IN THE SENATE OF THE UNITED STATES

JUNE 27, 2005

Mr. HATCH (for himself, Mr. DODD, Mr. BURR, Mr. REED, Mr. ENSIGN, Mrs. CLINTON, Ms. MIKULSKI, Mr. FRIST, Mrs. MURRAY, Mr. TALENT, Ms. COLLINS, Mr. SCHUMER, Mr. VOINOVICH, Mr. HARKIN, Mr. BROWNBACK, Mr. DEWINE, Mr. ROBERTS, Mrs. DOLE, Mrs. FEINSTEIN, Mr. GRASSLEY, Mr. HAGEL, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 11, 2005

Reported by Mr. ENZI, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To provide for the collection and maintenance of cord blood units for the treatment of patients and research, and to amend the Public Health Service Act to authorize the Bone Marrow and Cord Blood Cell Transplantation Program to increase the number of transplants for reci-

ents suitably matched to donors of bone marrow and cord blood.

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 “Bone Marrow and
 5 Cord Blood Therapy 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 banks to assist in the collection and
 10 maintenance of 150,000 new units of high-quality cord
 11 blood to be made available for transplantation through the
 12 Bone Marrow and Cord Blood 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 cord blood acquired with
 18 the informed consent of the donor in a manner that
 19 complies with applicable Federal and State regula-
 20 tions;

21 (2) to encourage donation from a genetically di-
 22 verse population;

23 (3) to make cord blood units that are collected
 24 pursuant to this section or otherwise and meet all

1 applicable Federal standards available to transplant
2 centers for transplantation;

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

6 (5) to make data available, as required by the
7 Secretary and consistent with section 379(e)(3) of
8 the Public Health Service Act (42 U.S.C.
9 274k(e)(3)), as amended by this Act, in a standard-
10 ized electronic format, as determined by the Sec-
11 retary, for the Bone Marrow and Cord Blood Cell
12 Transplantation Program; and

13 (6) to submit data in a standardized electronic
14 format for inclusion in the stem cell therapeutic out-
15 comes database maintained under section 379A of
16 the Public Health Service Act, as amended by this
17 Act.

18 (c) RELATED CORD BLOOD DONORS.—

19 (1) IN GENERAL.—The Secretary shall establish
20 a 3-year demonstration project under which qualified
21 cord blood banks receiving a contract under this sec-
22 tion may use a portion of the funding under such
23 contract for the collection and storage of cord blood
24 units for a family where a first-degree relative has
25 been diagnosed with a condition that will benefit

1 from transplantation (including selected blood dis-
2 orders, malignancies, metabolic storage disorders,
3 hemoglobinopathies, and congenital
4 immunodeficiencies) at no cost to such family. Quali-
5 fied cord blood banks collecting cord blood units
6 under this paragraph shall comply with the require-
7 ments of paragraphs (1), (2), (3), and (5) of sub-
8 section (b).

9 (2) AVAILABILITY.—Qualified cord blood banks
10 that are operating a program under paragraph (1)
11 shall provide assurances that the cord blood units in
12 such banks will be available for directed transplan-
13 tation until such time that the cord blood unit is re-
14 leased for transplantation or is transferred by the
15 family to the Bone Marrow and Cord Blood Cell
16 Transplantation Program in accordance with guid-
17 ance or regulations promulgated by the Secretary.

18 (3) INVENTORY.—Cord blood units collected
19 through the program under this section shall not be
20 counted toward the 150,000 inventory goal under
21 the Bone Marrow and Cord Blood Cell Transplan-
22 tation Program.

23 (4) REPORT.—Not later than 90 days after the
24 date on which the project under paragraph (1) is
25 terminated by the Secretary, the Secretary shall sub-

1 mit to Congress a report on the outcomes of the
2 project that shall include the recommendations of
3 the Secretary with respect to the continuation of
4 such project.

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

12 (1) will participate in the Bone Marrow and
13 Cord Blood Cell Transplantation Program for a pe-
14 riod of at least 10 years;

15 (2) will make cord blood units collected pursu-
16 ant to this section available through the Bone Mar-
17 row and Cord Blood Cell Transplantation Program
18 in perpetuity; and

19 (3) if the Secretary determines through an as-
20 sessment, or through petition by the applicant, that
21 a cord blood bank is no longer operational or does
22 not meet the requirements of section 379(c)(4) of
23 the Public Health Service Act (as added by this Act)
24 and as a result may not distribute the units, trans-
25 fer the units collected pursuant to this section to an-

1 other qualified cord blood bank approved by the Sec-
2 retary to ensure continued availability of cord blood
3 units.

4 (c) DURATION OF CONTRACTS.—

5 (1) IN GENERAL.—Except as provided in para-
6 graph (2), the term of each contract entered into by
7 the Secretary under this section shall be for 10
8 years. The Secretary shall ensure that Federal funds
9 provided under any such contract terminate on the
10 earlier of—

11 (A) the date that is 3 years after the date
12 on which the contract is entered into; or

13 (B) September 30, 2010.

14 (2) EXTENSIONS.—Subject to paragraph
15 (1)(B), the Secretary may extend the period of fund-
16 ing under a contract under this section to exceed a
17 period of 3 years if—

18 (A) the Secretary finds that 150,000 new
19 units of high-quality cord blood have not yet
20 been collected pursuant to this section; and

21 (B) the Secretary does not receive an ap-
22 plication for a contract under this section from
23 any qualified cord blood bank that has not pre-
24 viously entered into a contract under this sec-
25 tion or the Secretary determines that the out-

1 standing inventory need cannot be met by the
2 one or more qualified cord blood banks that
3 have submitted an application for a contract
4 under this section.

5 (3) PREFERENCE.—In considering contract ex-
6 tensions under paragraph (2), the Secretary shall
7 give preference to qualified cord blood banks that
8 the Secretary determines have demonstrated a supe-
9 rior ability to satisfy the requirements described in
10 subsection (b) and to achieve the overall goals for
11 which the contract was awarded.

12 (f) REGULATIONS.—The Secretary may promulgate
13 regulations to carry out this section.

14 (g) DEFINITIONS.—In this section:

15 (1) The term “Bone Marrow and Cord Blood
16 Cell Transplantation Program” means the Bone
17 Marrow and Cord Blood Cell Transplantation Pro-
18 gram under section 379 of the Public Health Service
19 Act, as amended by this Act.

20 (2) The term “cord blood donor” means a
21 mother who has delivered a baby and consents to do-
22 nate the neonatal blood remaining in the placenta
23 and umbilical cord after separation from the new-
24 born baby.

1 (3) The term “cord blood unit” means the neo-
2 natal blood collected from the placenta and umbilical
3 cord of a single newborn baby.

4 (4) The term “first-degree relative” means a
5 sibling or parent who is one meiosis away from a
6 particular individual in a family.

7 (5) The term “qualified cord blood bank” has
8 the meaning given to that term in section 379(e)(4)
9 of the Public Health Service Act, as amended by this
10 Act.

11 (6) The term “Secretary” means the Secretary
12 of Health and Human Services.

13 (h) AUTHORIZATION OF APPROPRIATIONS.—

14 (1) EXISTING FUNDS.—Any amounts appro-
15 priated to the Secretary for fiscal year 2004 or 2005
16 for the purpose of assisting in the collection or
17 maintenance of cord blood shall remain available to
18 the Secretary until the end of fiscal year 2007.

19 (2) SUBSEQUENT FISCAL YEARS.—There are
20 authorized to be appropriated to the Secretary
21 \$15,000,000 for each of fiscal years 2007, 2008,
22 2009, and 2010 to carry out this section.

23 (3) LIMITATION.—Not to exceed 5 percent of
24 the amount appropriated under this section in each
25 of fiscal years 2007 through 2009 may be used to

1 carry out the demonstration project under sub-
2 section (e).

3 **SEC. 3. BONE MARROW AND CORD BLOOD CELL TRANS-**
4 **PLANTATION PROGRAM.**

5 (a) NATIONAL PROGRAM.—Section 379 of the Public
6 Health Service Act (42 U.S.C. 274k) is amended to read
7 as follows:

8 **“SEC. 379. NATIONAL PROGRAM.**

9 “(a) ESTABLISHMENT.—The Secretary, acting
10 through the Administrator of the Health Resources and
11 Services Administration, shall by one or more contracts
12 establish and maintain a Bone Marrow and Cord Blood
13 Cell Transplantation Program (referred to in this section
14 as the ‘Program’) that has the purpose of increasing the
15 number of transplants for recipients suitably matched to
16 biologically unrelated donors of bone marrow and cord
17 blood, and that meets the requirements of this section.
18 The Secretary may award a separate contract to perform
19 each of the major functions of the Program described in
20 paragraphs (1) and (2) of subsection (e) if deemed nec-
21 essary by the Secretary to operate an effective and effi-
22 cient system that is in the best interest of patients. The
23 Secretary shall conduct a separate competition for the ini-
24 tial establishment of the cord blood functions of the Pro-
25 gram. The Program shall be under the general supervision

1 of the Secretary. The Secretary shall establish an Advisory
2 Council to advise, assist, consult with, and make rec-
3 ommendations to the Secretary on matters related to the
4 activities carried out by the Program. The members of the
5 Advisory Council shall be appointed in accordance with the
6 following:

7 “(1) Each member of the Advisory Council
8 shall serve for a term of 2 years, and each such
9 member may serve as many as 3 consecutive 2-year
10 terms, except that

11 “(A) such limitations shall not apply to the
12 Chair of the Advisory Council (or the Chair-
13 elect) or to the member of the Advisory Council
14 who most recently served as the Chair; and

15 “(B) 1 additional consecutive 2-year term
16 may be served by any member of the Advisory
17 Council who has no employment, governance, or
18 financial affiliation with any donor center, re-
19 cruitment organization, transplant center, or
20 cord blood bank.

21 “(2) A member of the Advisory Council may
22 continue to serve after the expiration of the term of
23 such member until a successor is appointed.

24 “(3) In order to ensure the continuity of the
25 Advisory Council, the Advisory Council shall be ap-

1 pointed so that each year the terms of approximately
2 one-third of the members of the Advisory Council ex-
3 pire.

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

5 “(A) shall include as voting members a
6 balanced number of representatives including
7 representatives of marrow donor centers and
8 marrow transplant centers; representatives of
9 cord blood banks and participating birthing
10 hospitals; recipients of a bone marrow trans-
11 plant; recipients of a cord blood transplant; per-
12 sons who require such transplants; family mem-
13 bers of such a recipient or family members of
14 a patient who has requested the assistance of
15 the Program in searching for an unrelated
16 donor of bone marrow or cord blood; persons
17 with expertise in bone marrow and cord blood
18 transplantation; persons with expertise in typ-
19 ing, matching, and transplant outcome data
20 analysis; persons with expertise in the social
21 sciences; basic scientists with expertise in the
22 biology of adult stem cells; and members of the
23 general public; and

24 “(B) shall include as nonvoting members
25 representatives from the Department of De-

1 fense Marrow Donor Recruitment and Research
2 Program operated by the Department of the
3 Navy; the Division of Transplantation of the
4 Health Resources and Services Administration;
5 the Food and Drug Administration; and the
6 National Institutes of Health.

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

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

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

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

23 “(A) an annual report on the activities ear-
24 ried out under this section; and

1 “(B) not later than 6 months after the
2 date of the enactment of the Bone Marrow and
3 Cord Blood Therapy and Research Act of 2005,
4 a report of recommendations on the scientific
5 factors necessary to define a cord blood unit as
6 a high-quality unit.

7 “(b) ACCREDITATION.—The Secretary shall, through
8 a public process, recognize one or more accreditation enti-
9 ties for the accreditation of cord blood banks.

10 “(c) FUNCTIONS.—

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

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

17 “(B) consistent with paragraph (3), permit
18 transplant physicians, other appropriate health
19 care professionals, and patients to search by
20 means of electronic access all available bone
21 marrow donors listed in the Program;

22 “(C) carry out a program for the recruit-
23 ment of bone marrow donors in accordance with
24 subsection (d), including with respect to in-
25 creasing the representation of racial and ethnic

1 minority groups (including persons of mixed an-
2 cestry) in the enrollment of the Program;

3 “(D) maintain and expand medical contin-
4 gency response capabilities, in coordination with
5 Federal programs, to prepare for and respond
6 effectively to biological, chemical, or radiological
7 attacks, and other public health emergencies
8 that can damage marrow, so that the capability
9 of supporting patients with marrow damage
10 from disease can be used to support casualties
11 with marrow damage;

12 “(E) carry out informational and edu-
13 cational activities in accordance with subsection
14 (d);

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

18 “(G) provide for a system of patient advo-
19 cacy through the office established under sub-
20 section (g);

21 “(H) provide case management services for
22 any potential donor of bone marrow to whom
23 the Program has provided a notice that the po-
24 tential donor may be suitably matched to a par-

1 ticular patient through the office established
2 under subsection (g);

3 “(I) 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 in a standard-
7 ized electronic format on the number and per-
8 centage of patients at each of the various stages
9 of the search process, including data regarding
10 the furthest stage reached, the number and per-
11 centage of patients who are unable to complete
12 the search process, and the reasons underlying
13 such circumstances;

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

19 “(K) facilitate and support research to im-
20 prove the availability, efficiency, safety, and
21 cost of transplants from unrelated donors and
22 the effectiveness of Program operations.

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

1 “(A) operate a system for listing, search-
2 ing, and facilitating the distribution of donated
3 cord blood units that are suitably matched to
4 candidate patients and meet all applicable Fed-
5 eral and State regulations (including informed
6 consent and Food and Drug Administration
7 regulations) from a qualified cord blood bank;

8 “(B) consistent with paragraph (3), allow
9 transplant physicians, other appropriate health
10 care professionals, and patients to search by
11 means of electronic access all available cord
12 blood units made available through the Pro-
13 gram;

14 “(C) allow transplant physicians and other
15 appropriate health care professionals to reserve,
16 as defined by the Secretary, a cord blood unit
17 for transplantation;

18 “(D) support studies and demonstration
19 and outreach projects for the purpose of in-
20 creasing cord blood donation to ensure a geneti-
21 cally diverse collection of cord blood units;

22 “(E) provide for a system of patient advoc-
23 eacy through the office established under sub-
24 section (g);

1 “(F) coordinate with the qualified cord
2 blood banks to carry out informational and edu-
3 cational activities in accordance with subsection
4 (f);

5 “(G) maintain and expand medical contin-
6 geney response capabilities, in coordination with
7 Federal programs, to prepare for and respond
8 effectively to biological, chemical, or radiological
9 attacks, and other public health emergencies
10 that can damage marrow, so that the capability
11 of supporting patients with marrow damage
12 from disease can be used to support casualties
13 with marrow damage; and

14 “(H) with respect to the system under sub-
15 paragraph (A), collect, analyze, and publish
16 data in a standardized electronic format, as re-
17 quired by the Secretary, on the number and
18 percentage of patients at each of the various
19 stages of the search process, including data re-
20 garding the furthest stage reached, the number
21 and percentage of patients who are unable to
22 complete the search process, and the reasons
23 underlying such circumstances.

24 “(3) SINGLE POINT OF ACCESS; SUBMISSION OF
25 DATA.—

1 “(A) SINGLE POINT OF ACCESS.—The Sec-
2 retary shall ensure that health care profes-
3 sionals and patients are able to, at a minimum,
4 locate, consistent with the functions described
5 in paragraphs (1)(A) and (2)(A), cells from
6 bone marrow donors and cord blood units
7 through a single electronic point of access.

8 “(B) STANDARD DATA.—The Secretary
9 shall require all recipients of contracts under
10 this section to make available a standard
11 dataset for purposes of subparagraph (A) in a
12 standardized electronic format that enables
13 transplant physicians to compare among and
14 between bone marrow donors and cord blood
15 units to ensure the best possible match for the
16 patient.

17 “(4) DEFINITION.—The term ‘qualified cord
18 blood bank’ means a cord blood bank that—

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

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

8 “(C) is accredited by an accreditation enti-
9 ty recognized by the Secretary under subsection
10 (b);

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

15 “(E) has established a system for encour-
16 aging donation by a genetically diverse group of
17 donors; and

18 “(F) has established a system to confiden-
19 tially maintain linkage between a cord blood
20 unit and a maternal donor.

21 “(d) BONE MARROW RECRUITMENT; PRIORITIES; IN-
22 FORMATION AND EDUCATION.—

23 “(1) RECRUITMENT; PRIORITIES.—The Pro-
24 gram shall carry out activities for the recruitment of
25 bone marrow donors. Such recruitment program

1 shall identify populations that are underrepresented
2 among potential donors enrolled with the Program.
3 In the case of populations that are identified under
4 the preceding sentence:

5 “(A) The Program shall give priority to
6 carrying out activities under this part to in-
7 crease representation for such populations in
8 order to enable a member of such a population,
9 to the extent practicable, to have a probability
10 of finding a suitable unrelated donor that is
11 comparable to the probability that an individual
12 who is not a member of an underrepresented
13 population would have.

14 “(B) The Program shall consider racial
15 and ethnic minority groups (including persons
16 of mixed ancestry) to be populations that have
17 been identified for purposes of this paragraph,
18 and shall carry out subparagraph (A) with re-
19 spect to such populations.

20 “(2) INFORMATION AND EDUCATION REGARD-
21 ING RECRUITMENT, TESTING AND ENROLLMENT.—

22 “(A) IN GENERAL.—The Program shall
23 carry out informational and educational activi-
24 ties, in coordination with organ donation public
25 awareness campaigns operated through the De-

1 partment of Health and Human Services, for
2 purposes of recruiting individuals to serve as
3 donors of bone marrow, and shall test and en-
4 roll with the Program potential bone marrow
5 donors. Such information and educational ac-
6 tivities shall include the following:

7 “(i) Making information available to
8 the general public, including information
9 describing the needs of patients with re-
10 spect to donors of bone marrow.

11 “(ii) Educating and providing infor-
12 mation to individuals who are willing to
13 serve as potential bone marrow donors.

14 “(iii) Training individuals in request-
15 ing individuals to serve as potential bone
16 marrow donors.

17 “(B) PRIORITIES.—In carrying out infor-
18 mational and educational activities under sub-
19 paragraph (A), the Program shall give priority
20 to recruiting individuals to serve as donors of
21 bone marrow for populations that are identified
22 under paragraph (1).

23 “(3) TRANSPLANTATION AS TREATMENT OP-
24 TION.—In addition to activities regarding recruit-
25 ment, the recruitment program under paragraph (1)

1 shall provide information to physicians, other health
2 care professionals, and the public regarding bone
3 marrow transplants from unrelated donors as a
4 treatment option.

5 “(4) IMPLEMENTATION OF SUBSECTION.—The
6 requirements of this subsection shall be carried out
7 by the entity that has been awarded a contract by
8 the Secretary under subsection (a) to carry out the
9 functions described in subsection (c)(1).

10 “(c) BONE MARROW CRITERIA, STANDARDS, AND
11 PROCEDURES.—The Secretary shall enforce, for partici-
12 pating entities, including the Program, individual marrow
13 donor centers, marrow donor registries, marrow collection
14 centers, and marrow transplant centers—

15 “(1) quality standards and standards for tissue
16 typing; obtaining the informed consent of donors;
17 and providing patient advocacy;

18 “(2) donor selection criteria, based on estab-
19 lished medical criteria, to protect both the donor and
20 the recipient and to prevent the transmission of po-
21 tentially harmful infectious diseases such as the vi-
22 ruses that cause hepatitis and the etiologic agent for
23 Acquired Immune Deficiency Syndrome;

24 “(3) procedures to ensure the proper collection
25 and transportation of the marrow;

1 “(4) standards for the system for patient advo-
2 eacy operated under subsection (g), including stand-
3 ards requiring the provision of appropriate informa-
4 tion (at the start of the search process and through-
5 out the process) to patients and their families and
6 physicians;

7 “(5) standards that—

8 “(A) require the establishment of a system
9 of strict confidentiality of records relating to
10 the identity, address, HLA type, and managing
11 marrow donor center for marrow donors and
12 potential marrow donors; and

13 “(B) prescribe the purposes for which the
14 records described in subparagraph (A) may be
15 disclosed, and the circumstances and extent of
16 the disclosure; and

17 “(6) in the case of a marrow donor center or
18 marrow donor registry participating in the program,
19 procedures to ensure the establishment of a method
20 for integrating donor files, searches, and general
21 procedures of the center or registry with the Pro-
22 gram.

23 “(f) CORD BLOOD RECRUITMENT; PRIORITIES; IN-
24 FORMATION AND EDUCATION.—

1 “(1) RECRUITMENT; PRIORITIES.—The Pro-
2 gram shall support activities, in cooperation with
3 qualified cord blood banks, for the recruitment of
4 cord blood donors. Such recruitment program shall
5 identify populations that are underrepresented
6 among cord blood donors. In the case of populations
7 that are identified under the preceding sentence:

8 “(A) The Program shall give priority to
9 supporting activities under this part to increase
10 representation for such populations in order to
11 enable a member of such a population, to the
12 extent practicable, to have a probability of find-
13 ing a suitable cord blood unit that is com-
14 parable to the probability that an individual
15 who is not a member of an underrepresented
16 population would have:

17 “(B) The Program shall consider racial
18 and ethnic minority groups (including persons
19 of mixed ancestry) to be populations that have
20 been identified for purposes of this paragraph,
21 and shall support activities under subparagraph
22 (A) with respect to such populations.

23 “(2) INFORMATION AND EDUCATION REGARD-
24 ING RECRUITMENT; TESTING AND DONATION.—

1 “(A) IN GENERAL.—In carrying out the
2 recruitment program under paragraph (1), the
3 Program shall support informational and edu-
4 cational activities in coordination with qualified
5 cord blood banks and organ donation public
6 awareness campaigns operated through the De-
7 partment of Health and Human Services, for
8 purposes of recruiting pregnant women to serve
9 as donors of cord blood. Such information and
10 educational activities shall include the following:

11 “(i) Making information available to
12 the general public, including information
13 describing the needs of patients with re-
14 spect to cord blood units.

15 “(ii) Educating and providing infor-
16 mation to pregnant women who are willing
17 to donate cord blood units.

18 “(iii) Training individuals in request-
19 ing pregnant women to serve as cord blood
20 donors.

21 “(B) PRIORITIES.—In carrying out infor-
22 mational and educational activities under sub-
23 paragraph (A), the Program shall give priority
24 to supporting the recruitment of pregnant
25 women to serve as donors of cord blood for pop-

1 ulations that are identified under paragraph
2 (1).

3 ~~“(3) TRANSPLANTATION AS TREATMENT OP-~~
4 ~~TION.—~~In addition to activities regarding recruit-
5 ment, the recruitment program under paragraph (1)
6 shall provide information to physicians, other health
7 care professionals, and the public regarding cord
8 blood transplants from donors as a treatment option.

9 ~~“(4) IMPLEMENTATION OF SUBSECTION.—~~The
10 requirements of this subsection shall be carried out
11 by the entity that has been awarded a contract by
12 the Secretary under subsection (a) to carry out the
13 functions described in subsection (c)(2).

14 ~~“(g) PATIENT ADVOCACY AND CASE MANAGEMENT~~
15 ~~FOR BONE MARROW AND CORD BLOOD.—~~

16 ~~“(1) IN GENERAL.—~~The Secretary shall estab-
17 lish and maintain, through a contract or other
18 means determined appropriate by the Secretary, an
19 office of patient advocacy (in this subsection referred
20 to as the ‘Office’).

21 ~~“(2) GENERAL FUNCTIONS.—~~The Office shall
22 meet the following requirements:

23 ~~“(A) The Office shall be headed by a direc-~~
24 ~~tor.~~

1 “(B) The Office shall be staffed by individ-
2 uals with expertise in bone marrow and cord
3 blood therapy covered under the Program.

4 “(C) The Office shall operate a system for
5 patient advocacy, which shall be separate from
6 mechanisms for donor advocacy, and which
7 shall serve patients for whom the Program is
8 conducting, or has been requested to conduct, a
9 search for a bone marrow donor or cord blood
10 unit.

11 “(D) In the case of such a patient, the Of-
12 fice shall serve as an advocate for the patient
13 by directly providing to the patient (or family
14 members, physicians, or other individuals acting
15 on behalf of the patient) individualized services
16 with respect to efficiently utilizing the system
17 under paragraphs (1) and (2) of subsection (e)
18 to conduct an ongoing search for a bone mar-
19 row donor or cord blood unit and assist with in-
20 formation regarding third party payor matters.

21 “(E) In carrying out subparagraph (D),
22 the Office shall monitor the system under para-
23 graphs (1) and (2) of subsection (e) to deter-
24 mine whether the search needs of the patient

1 involved are being met, including with respect
2 to the following:

3 “(i) Periodically providing to the pa-
4 tient (or an individual acting on behalf of
5 the patient) information regarding bone
6 marrow donors or cord blood units that are
7 suitably matched to the patient, and other
8 information regarding the progress being
9 made in the search.

10 “(ii) Informing the patient (or such
11 other individual) if the search has been in-
12 terrupted or discontinued.

13 “(iii) Identifying and resolving prob-
14 lems in the search, to the extent prac-
15 ticable.

16 “(F) The Office shall ensure that the fol-
17 lowing data are made available to patients:

18 “(i) The resources available through
19 the Program.

20 “(ii) A comparison of transplant cen-
21 ters regarding search and other costs that
22 prior to transplantation are charged to pa-
23 tients by transplant centers.

24 “(iii) The post-transplant outcomes
25 for individual transplant centers.

1 “(iv) Information concerning issues
2 that patients may face after a transplant.

3 “(v) Such other information as the
4 Program determines to be appropriate.

5 “(G) The Office shall conduct surveys of
6 patients (or family members, physicians, or
7 other individuals acting on behalf of patients)
8 to determine the extent of satisfaction with the
9 system for patient advocacy under this sub-
10 section, and to identify ways in which the sys-
11 tem can be improved to best meet the needs of
12 patients.

13 “(3) CASE MANAGEMENT.—

14 “(A) IN GENERAL.—In serving as an advo-
15 cate for a patient under paragraph (2), the Of-
16 fice shall provide individualized case manage-
17 ment services directly to the patient (or family
18 members, physicians, or other individuals acting
19 on behalf of the patient), including—

20 “(i) individualized case assessment;
21 and

22 “(ii) the functions described in para-
23 graph (2)(D) (relating to progress in the
24 search process).

1 “(B) POSTSEARCH FUNCTIONS.—In addi-
2 tion to the case management services described
3 in paragraph (1) for patients, the Office shall,
4 on behalf of patients who have completed the
5 search for a bone marrow donor or cord blood
6 unit, provide information and education on the
7 process of receiving a transplant, including the
8 post-transplant process.

9 “(h) COMMENT PROCEDURES.—The Secretary shall
10 establish and provide information to the public on proce-
11 dures under which the Secretary shall receive and consider
12 comments from interested persons relating to the manner
13 in which the Program is carrying out the duties of the
14 Program.

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

21 “(j) CONTRACTS.—

22 “(1) APPLICATION.—To be eligible to enter into
23 a contract under this section, an entity shall submit
24 to the Secretary and obtain approval of an applica-
25 tion at such time, in such manner, and containing

1 such information as the Secretary shall by regulation
2 prescribe.

3 “(2) CONSIDERATIONS.—In awarding contracts
4 under this section, the Secretary shall give consider-
5 ation to the continued safety of donors and patients
6 and other factors deemed appropriate by the Sec-
7 retary.

8 “(k) ELIGIBILITY.—Entities eligible to receive a con-
9 tract under this section shall include private nonprofit en-
10 tities.

11 “(l) RECORDS.—

12 “(1) RECORDKEEPING.—Each recipient of a
13 contract or subcontract under subsection (a) shall
14 keep such records as the Secretary shall prescribe,
15 including records that fully disclose the amount and
16 disposition by the recipient of the proceeds of the
17 contract, the total cost of the undertaking in connec-
18 tion with which the contract was made, and the
19 amount of the portion of the cost of the undertaking
20 supplied by other sources, and such other records as
21 will facilitate an effective audit.

22 “(2) EXAMINATION OF RECORDS.—The Sec-
23 retary and the Comptroller General of the United
24 States shall have access to any books, documents,
25 papers, and records of the recipient of a contract or

1 subcontract entered into under this section that are
 2 pertinent to the contract, for the purpose of con-
 3 ducting audits and examinations.

4 “(m) PENALTIES FOR DISCLOSURE.—Any person
 5 who discloses the content of any record referred to in sub-
 6 section (e)(4)(D) or (e)(5)(A) without the prior written
 7 consent of the donor or potential donor with respect to
 8 whom the record is maintained, or in violation of the
 9 standards described in subsection (e)(5)(B), shall be im-
 10 prisoned for not more than 2 years or fined in accordance
 11 with title 18, United States Code, or both.”.

12 (b) STEM CELL THERAPEUTIC OUTCOMES DATA-
 13 BASE.—Section 379A of the Public Health Service Act (42
 14 U.S.C. 2741) is amended to read as follows:

15 **“SEC. 379A. STEM CELL THERAPEUTIC OUTCOMES DATA-**
 16 **BASE.**

17 “(a) ESTABLISHMENT.—The Secretary shall by con-
 18 tract establish and maintain a scientific database of infor-
 19 mation relating to patients who have been recipients of
 20 a stem cell therapeutics product (including bone marrow,
 21 cord blood, or other such product) from a donor.

22 “(b) INFORMATION.—The outcomes database shall
 23 include information in a standardized electronic format
 24 with respect to patients described in subsection (a), diag-
 25 nosis, transplant procedures, results, long-term follow-up,

1 and such other information as the Secretary determines
2 to be appropriate, to conduct an ongoing evaluation of the
3 scientific and clinical status of transplantation involving
4 recipients of a stem cell therapeutics product from a
5 donor.

6 “(e) **ANNUAL REPORT ON PATIENT OUTCOMES.**—
7 The Secretary shall require the entity awarded a contract
8 under this section to submit to the Secretary an annual
9 report concerning patient outcomes with respect to each
10 transplant center, based on data collected and maintained
11 by the entity pursuant to this section.

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

20 (e) **DEFINITIONS.**—Part I of title III of the Public
21 Health Service Act (42 U.S.C. 274k et seq.) is amended
22 by inserting after section 379A the following:

23 **“SEC. 379A-1. DEFINITIONS.**

24 “In this part:

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

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

6 “(3) The term ‘outcomes database’ means the
7 database established by the Secretary under section
8 379A.

9 “(4) The term ‘Program’ means the Bone Mar-
10 row and Cord Blood Cell Transplantation Program
11 established under section 379.”.

12 (d) **AUTHORIZATION OF APPROPRIATIONS.**—Section
13 379B of the Public Health Service Act (42 U.S.C. 274m)
14 is amended to read as follows:

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

16 “For the purpose of carrying out this part, there are
17 authorized to be appropriated \$34,000,000 for fiscal year
18 2006 and \$38,000,000 for each of fiscal years 2007
19 through 2010.”.

20 (e) **CONFORMING AMENDMENTS.**—Part I of title III
21 of the Public Health Service Act (42 U.S.C. 274k et seq.)
22 is amended in the part heading, by striking “**NA-**
23 **TIONAL BONE MARROW DONOR REG-**
24 **ISTRY**” and inserting “**BONE MARROW AND**

1 **CORD BLOOD CELL TRANSPLANTATION**
 2 **PROGRAM**”.

3 **SEC. 4. REPORT ON LICENSURE OF CORD BLOOD UNITS.**

4 Not later than 90 days after the date of enactment
 5 of this Act, the Secretary of Health and Human Services,
 6 in consultation with the Commissioner of Food and Drugs,
 7 shall submit to Congress a report concerning the progress
 8 made by the Food and Drug Administration in developing
 9 requirements for the licensing of cord blood units.

10 **SECTION 1. SHORT TITLE.**

11 *This Act may be cited as the “Stem Cell Therapeutic*
 12 *and Research Act of 2005”.*

13 **SEC. 2. CORD BLOOD INVENTORY.**

14 *(a) IN GENERAL.—The Secretary of Health and*
 15 *Human Services shall enter into one-time contracts with*
 16 *qualified cord blood banks to assist in the collection and*
 17 *maintenance of 150,000 new units of high-quality cord*
 18 *blood to be made available for transplantation through the*
 19 *C.W. Bill Young Cell Transplantation Program and to*
 20 *carry out the requirements of subsection (b).*

21 *(b) REQUIREMENTS.—The Secretary shall require each*
 22 *recipient of a contract under this section—*

23 *(1) to acquire, tissue-type, test, cryopreserve, and*
 24 *store donated units of cord blood acquired with the*
 25 *informed consent of the donor, as determined by the*

1 *Secretary pursuant to section 379(c) of the Public*
2 *Health Service Act, in a manner that complies with*
3 *applicable Federal and State regulations;*

4 *(2) to encourage donation from a genetically di-*
5 *verse population;*

6 *(3) to make cord blood units that are collected*
7 *pursuant to this section or otherwise and meet all ap-*
8 *plicable Federal standards available to transplant*
9 *centers for transplantation;*

10 *(4) to make cord blood units that are collected,*
11 *but not appropriate for clinical use, available for*
12 *peer-reviewed research;*

13 *(5) to make data available, as required by the*
14 *Secretary and consistent with section 379(d)(3) of the*
15 *Public Health Service Act (42 U.S.C. 274k(d)(3)), as*
16 *amended by this Act, in a standardized electronic for-*
17 *mat, as determined by the Secretary, for the C.W. Bill*
18 *Young Cell Transplantation Program; and*

19 *(6) to submit data in a standardized electronic*
20 *format for inclusion in the stem cell therapeutic out-*
21 *comes database maintained under section 379A of the*
22 *Public Health Service Act, as amended by this Act.*

23 *(c) RELATED CORD BLOOD DONORS.—*

24 *(1) IN GENERAL.—The Secretary shall establish*
25 *a 3-year demonstration project under which qualified*

1 cord blood banks receiving a contract under this sec-
2 tion may use a portion of the funding under such
3 contract for the collection and storage of cord blood
4 units for a family where a first-degree relative has
5 been diagnosed with a condition that will benefit from
6 transplantation (including selected blood disorders,
7 malignancies, metabolic storage disorders,
8 hemoglobinopathies, and congenital
9 immunodeficiencies) at no cost to such family. Quali-
10 fied cord blood banks collecting cord blood units under
11 this paragraph shall comply with the requirements of
12 paragraphs (1), (2), (3), and (5) of subsection (b).

13 (2) AVAILABILITY.—Qualified cord blood banks
14 that are operating a program under paragraph (1)
15 shall provide assurances that the cord blood units in
16 such banks will be available for directed transplan-
17 tation until such time that the cord blood unit is re-
18 leased for transplantation or is transferred by the
19 family to the C.W. Bill Young Cell Transplantation
20 Program in accordance with guidance or regulations
21 promulgated by the Secretary.

22 (3) INVENTORY.—Cord blood units collected
23 through the program under this section shall not be
24 counted toward the 150,000 inventory goal under the
25 C.W. Bill Young Cell Transplantation Program.

1 (4) *REPORT.*—Not later than 90 days after the
2 date on which the project under paragraph (1) is ter-
3 minated by the Secretary, the Secretary shall submit
4 to Congress a report on the outcomes of the project
5 that shall include the recommendations of the Sec-
6 retary with respect to the continuation of such
7 project.

8 (d) *APPLICATION.*—To seek to enter into a contract
9 under this section, a qualified cord blood bank shall submit
10 an application to the Secretary at such time, in such man-
11 ner, and containing such information as the Secretary may
12 reasonably require. At a minimum, an application for a
13 contract under this section shall include a requirement that
14 the applicant—

15 (1) will participate in the C.W. Bill Young Cell
16 Transplantation Program for a period of at least 10
17 years;

18 (2) will make cord blood units collected pursuant
19 to this section available through the C.W. Bill Young
20 Cell Transplantation Program in perpetuity or for
21 such time as determined viable by the Secretary; and

22 (3) if the Secretary determines through an as-
23 sessment, or through petition by the applicant, that a
24 cord blood bank is no longer operational or does not
25 meet the requirements of section 379(d)(4) of the Pub-

1 *lic Health Service Act (as added by this Act) and as*
2 *a result may not distribute the units, transfer the*
3 *units collected pursuant to this section to another*
4 *qualified cord blood bank approved by the Secretary*
5 *to ensure continued availability of cord blood units.*

6 *(e) DURATION OF CONTRACTS.—*

7 *(1) IN GENERAL.—Except as provided in para-*
8 *graph (2), the term of each contract entered into by*
9 *the Secretary under this section shall be for 10 years.*
10 *The Secretary shall ensure that no Federal funds shall*
11 *be obligated under any such contract after the earlier*
12 *of—*

13 *(A) the date that is 3 years after the date*
14 *on which the contract is entered into; or*

15 *(B) September 30, 2010.*

16 *(2) EXTENSIONS.—Subject to paragraph (1)(B),*
17 *the Secretary may extend the period of funding under*
18 *a contract under this section to exceed a period of 3*
19 *years if—*

20 *(A) the Secretary finds that 150,000 new*
21 *units of high-quality cord blood have not yet*
22 *been collected pursuant to this section; and*

23 *(B) the Secretary does not receive an appli-*
24 *cation for a contract under this section from any*
25 *qualified cord blood bank that has not previously*

1 *entered into a contract under this section or the*
2 *Secretary determines that the outstanding inven-*
3 *tory need cannot be met by the one or more*
4 *qualified cord blood banks that have submitted*
5 *an application for a contract under this section.*

6 (3) *PREFERENCE.*—*In considering contract ex-*
7 *tensions under paragraph (2), the Secretary shall give*
8 *preference to qualified cord blood banks that the Sec-*
9 *retary determines have demonstrated a superior abil-*
10 *ity to satisfy the requirements described in subsection*
11 *(b) and to achieve the overall goals for which the con-*
12 *tract was awarded.*

13 (f) *REGULATIONS.*—*The Secretary may promulgate*
14 *regulations to carry out this section.*

15 (g) *DEFINITIONS.*—*In this section:*

16 (1) *The term “C. W. Bill Young Cell Transplan-*
17 *tation Program” means the C.W. Bill Young Cell*
18 *Transplantation Program under section 379 of the*
19 *Public Health Service Act, as amended by this Act.*

20 (2) *The term “cord blood donor” means a mother*
21 *who has delivered a baby and consents to donate the*
22 *neonatal blood remaining in the placenta and umbil-*
23 *ical cord after separation from the newborn baby.*

1 (3) *The term “cord blood unit” means the neo-*
2 *natal blood collected from the placenta and umbilical*
3 *cord of a single newborn baby.*

4 (4) *The term “first-degree relative” means a sib-*
5 *ling or parent who is one meiosis away from a par-*
6 *ticular individual in a family.*

7 (5) *The term “qualified cord blood bank” has the*
8 *meaning given to that term in section 379(d)(4) of the*
9 *Public Health Service Act, as amended by this Act.*

10 (6) *The term “Secretary” means the Secretary of*
11 *Health and Human Services.*

12 (h) *AUTHORIZATION OF APPROPRIATIONS.—*

13 (1) *EXISTING FUNDS.—Any amounts appro-*
14 *priated to the Secretary for fiscal year 2004 or 2005*
15 *for the purpose of assisting in the collection or main-*
16 *tenance of cord blood shall remain available to the*
17 *Secretary until the end of fiscal year 2007.*

18 (2) *SUBSEQUENT FISCAL YEARS.—There are au-*
19 *thorized to be appropriated to the Secretary*
20 *\$15,000,000 for each of fiscal years 2007, 2008, 2009,*
21 *and 2010 to carry out this section.*

22 (3) *LIMITATION.—Not to exceed 5 percent of the*
23 *amount appropriated under this section in each of*
24 *fiscal years 2007 through 2009 may be used to carry*
25 *out the demonstration project under subsection (c).*

1 **SEC. 3. C.W. BILL YOUNG CELL TRANSPLANTATION PRO-**
2 **GRAM.**

3 (a) *NATIONAL PROGRAM.*—Section 379 of the Public
4 Health Service Act (42 U.S.C. 274k) is amended to read
5 as follows:

6 **“SEC. 379. NATIONAL PROGRAM.**

7 “(a) *ESTABLISHMENT.*—The Secretary, acting through
8 the Administrator of the Health Resources and Services Ad-
9 ministration, shall by one or more contracts establish and
10 maintain a C.W. Bill Young Cell Transplantation Program
11 (referred to in this section as the ‘Program’), successor to
12 the National Bone Marrow Donor Registry, that has the
13 purpose of increasing the number of transplants for recipi-
14 ents suitably matched to biologically unrelated donors of
15 bone marrow and cord blood, and that meets the require-
16 ments of this section. The Secretary may award a separate
17 contract to perform each of the major functions of the Pro-
18 gram described in paragraphs (1) and (2) of subsection (d)
19 if deemed necessary by the Secretary to operate an effective
20 and efficient system that is in the best interest of patients.
21 The Secretary shall conduct a separate competition for the
22 initial establishment of the cord blood functions of the Pro-
23 gram. The Program shall be under the general supervision
24 of the Secretary. The Secretary shall establish an Advisory
25 Council to advise, assist, consult with, and make rec-
26 ommendations to the Secretary on matters related to the

1 *activities carried out by the Program. The members of the*
2 *Advisory Council shall be appointed in accordance with the*
3 *following:*

4 “(1) *Each member of the Advisory Council shall*
5 *serve for a term of 2 years, and each such member*
6 *may serve as many as 3 consecutive 2-year terms, ex-*
7 *cept that*

8 “(A) *such limitations shall not apply to the*
9 *Chair of the Advisory Council (or the Chair-*
10 *elect) or to the member of the Advisory Council*
11 *who most recently served as the Chair; and*

12 “(B) *1 additional consecutive 2-year term*
13 *may be served by any member of the Advisory*
14 *Council who has no employment, governance, or*
15 *financial affiliation with any donor center, re-*
16 *ruitment organization, transplant center, or*
17 *cord blood bank.*

18 “(2) *A member of the Advisory Council may con-*
19 *tinue to serve after the expiration of the term of such*
20 *member until a successor is appointed.*

21 “(3) *In order to ensure the continuity of the Ad-*
22 *visory Council, the Advisory Council shall be ap-*
23 *pointed so that each year the terms of approximately*
24 *one-third of the members of the Advisory Council ex-*
25 *pire.*

1 “(4) *The membership of the Advisory Council—*

2 “(A) *shall include as voting members a bal-*
3 *anced number of representatives including rep-*
4 *resentatives of marrow donor centers and mar-*
5 *row transplant centers, representatives of cord*
6 *blood banks and participating birthing hospitals,*
7 *recipients of a bone marrow transplant, recipi-*
8 *ents of a cord blood transplant, persons who re-*
9 *quire such transplants, family members of such*
10 *a recipient or family members of a patient who*
11 *has requested the assistance of the Program in*
12 *searching for an unrelated donor of bone marrow*
13 *or cord blood, persons with expertise in bone*
14 *marrow and cord blood transplantation, persons*
15 *with expertise in typing, matching, and trans-*
16 *plant outcome data analysis, persons with exper-*
17 *tise in the social sciences, basic scientists with*
18 *expertise in the biology of adult stem cells, and*
19 *members of the general public; and*

20 “(B) *shall include as nonvoting members*
21 *representatives from the Department of Defense*
22 *Marrow Donor Recruitment and Research Pro-*
23 *gram operated by the Department of the Navy,*
24 *the Division of Transplantation of the Health*
25 *Resources and Services Administration, the Food*

1 *and Drug Administration, and the National In-*
2 *stitutes of Health.*

3 “(5) *Members of the Advisory Council shall be*
4 *chosen so as to ensure objectivity and balance and re-*
5 *duce the potential for conflicts of interest. The Sec-*
6 *retary shall establish bylaws and procedures—*

7 “(A) *to prohibit any member of the Advi-*
8 *sory Council who has an employment, govern-*
9 *ance, or financial affiliation with a donor cen-*
10 *ter, recruitment organization, transplant center,*
11 *or cord blood bank from participating in any de-*
12 *cision that materially affects the center, recruit-*
13 *ment organization, transplant center, or cord*
14 *blood bank; and*

15 “(B) *to limit the number of members of the*
16 *Advisory Council with any such affiliation.*

17 “(6) *The Secretary, acting through the Advisory*
18 *Council, shall submit to the Congress—*

19 “(A) *an annual report on the activities car-*
20 *ried out under this section; and*

21 “(B) *not later than 6 months after the date*
22 *of the enactment of the Stem Cell Therapeutic*
23 *and Research Act of 2005, a report of rec-*
24 *ommendations on the scientific factors necessary*

1 to define a cord blood unit as a high-quality
2 unit.

3 “(b) *ACCREDITATION.*—The Secretary shall, through a
4 public process, recognize one or more accreditation entities
5 for the accreditation of cord blood banks.

6 “(c) *INFORMED CONSENT.*—The Secretary shall,
7 through a public process, examine issues of informed con-
8 sent, including—

9 “(1) the appropriate timing of such consent; and

10 “(2) the information provided to the maternal
11 donor regarding all of her medically appropriate cord
12 blood options.

13 Based on such examination, the Secretary shall require that
14 the standards used by the accreditation entities recognized
15 under subsection (b) ensure that a cord blood unit is ac-
16 quired with the informed consent of the maternal donor.

17 “(d) *FUNCTIONS.*—

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

20 “(A) operate a system for identifying,
21 matching, and facilitating the distribution of
22 bone marrow that is suitably matched to can-
23 didate patients;

24 “(B) consistent with paragraph (3), permit
25 transplant physicians, other appropriate health

1 *care professionals, and patients to search by*
2 *means of electronic access all available bone*
3 *marrow donors listed in the Program;*

4 “(C) *carry out a program for the recruit-*
5 *ment of bone marrow donors in accordance with*
6 *subsection (e), including with respect to increas-*
7 *ing the representation of racial and ethnic mi-*
8 *nority groups (including persons of mixed ances-*
9 *try) in the enrollment of the Program;*

10 “(D) *maintain and expand medical contin-*
11 *gency response capabilities, in coordination with*
12 *Federal programs, to prepare for and respond ef-*
13 *fectively to biological, chemical, or radiological*
14 *attacks, and other public health emergencies that*
15 *can damage marrow, so that the capability of*
16 *supporting patients with marrow damage from*
17 *disease can be used to support casualties with*
18 *marrow damage;*

19 “(E) *carry out informational and edu-*
20 *cational activities in accordance with subsection*
21 *(e);*

22 “(F) *at least annually update information*
23 *to account for changes in the status of individ-*
24 *uals as potential donors of bone marrow;*

1 “(G) provide for a system of patient advo-
2 cacy through the office established under sub-
3 section (h);

4 “(H) provide case management services for
5 any potential donor of bone marrow to whom the
6 Program has provided a notice that the potential
7 donor may be suitably matched to a particular
8 patient through the office established under sub-
9 section (h);

10 “(I) with respect to searches for unrelated
11 donors of bone marrow that are conducted
12 through the system under subparagraph (A), col-
13 lect, analyze, and publish data in a standardized
14 electronic format on the number and percentage
15 of patients at each of the various stages of the
16 search process, including data regarding the fur-
17 thest stage reached, the number and percentage of
18 patients who are unable to complete the search
19 process, and the reasons underlying such cir-
20 cumstances;

21 “(J) support studies and demonstration and
22 outreach projects for the purpose of increasing
23 the number of individuals who are willing to be
24 marrow donors to ensure a genetically diverse
25 donor pool; and

1 “(K) facilitate research with the appro-
2 priate Federal agencies to improve the avail-
3 ability, efficiency, safety, and cost of transplants
4 from unrelated donors and the effectiveness of
5 Program operations.

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

8 “(A) operate a system for identifying,
9 matching, and facilitating the distribution of do-
10 nated cord blood units that are suitably matched
11 to candidate patients and meet all applicable
12 Federal and State regulations (including in-
13 formed consent and Food and Drug Administra-
14 tion regulations) from a qualified cord blood
15 bank;

16 “(B) consistent with paragraph (3), allow
17 transplant physicians, other appropriate health
18 care professionals, and patients to search by
19 means of electronic access all available cord
20 blood units made available through the Program;

21 “(C) allow transplant physicians and other
22 appropriate health care professionals to reserve,
23 as defined by the Secretary, a cord blood unit for
24 transplantation;

1 “(D) support studies and demonstration
2 and outreach projects for the purpose of increas-
3 ing cord blood donation to ensure a genetically
4 diverse collection of cord blood units;

5 “(E) provide for a system of patient advo-
6 cacy through the office established under sub-
7 section (h);

8 “(F) coordinate with the qualified cord
9 blood banks to support informational and edu-
10 cational activities in accordance with subsection
11 (g);

12 “(G) maintain and expand medical contin-
13 gency response capabilities, in coordination with
14 Federal programs, to prepare for and respond ef-
15 fectively to biological, chemical, or radiological
16 attacks, and other public health emergencies that
17 can damage marrow, so that the capability of
18 supporting patients with marrow damage from
19 disease can be used to support casualties with
20 marrow damage; and

21 “(H) with respect to the system under sub-
22 paragraph (A), collect, analyze, and publish data
23 in a standardized electronic format, as required
24 by the Secretary, on the number and percentage
25 of patients at each of the various stages of the

1 *search process, including data regarding the fur-*
2 *thest stage reached, the number and percentage of*
3 *patients who are unable to complete the search*
4 *process, and the reasons underlying such cir-*
5 *cumstances.*

6 “(3) *SINGLE POINT OF ACCESS; STANDARD*
7 *DATA.—*

8 “(A) *SINGLE POINT OF ACCESS.—The Sec-*
9 *retary shall ensure that health care professionals*
10 *and patients are able to search electronically for*
11 *and facilitate access to, in the manner and to the*
12 *extent defined by the Secretary and consistent*
13 *with the functions described in paragraphs*
14 *(1)(A) and (2)(A), cells from bone marrow do-*
15 *ners and cord blood units through a single point*
16 *of access.*

17 “(B) *STANDARD DATA.—The Secretary shall*
18 *require all recipients of contracts under this sec-*
19 *tion to make available a standard dataset for*
20 *purposes of subparagraph (A) in a standardized*
21 *electronic format that enables transplant physi-*
22 *cians to compare among and between bone mar-*
23 *row donors and cord blood units to ensure the*
24 *best possible match for the patient.*

1 “(4) *DEFINITION.*—*The term ‘qualified cord*
2 *blood bank’ means a cord blood bank that—*

3 “(A) *has obtained all applicable Federal*
4 *and State licenses, certifications, registrations*
5 *(including pursuant to the regulations of the*
6 *Food and Drug Administration), and other au-*
7 *thorizations required to operate and maintain a*
8 *cord blood bank;*

9 “(B) *has implemented donor screening, cord*
10 *blood collection practices, and processing meth-*
11 *ods intended to protect the health and safety of*
12 *donors and transplant recipients to improve*
13 *transplant outcomes, including with respect to*
14 *the transmission of potentially harmful infec-*
15 *tions and other diseases;*

16 “(C) *is accredited by an accreditation enti-*
17 *ty recognized by the Secretary under subsection*
18 *(b);*

19 “(D) *has established a system of strict con-*
20 *fidentiality to protect the identity and privacy of*
21 *patients and donors in accordance with existing*
22 *Federal and State law;*

23 “(E) *has established a system for encour-*
24 *aging donation by a genetically diverse group of*
25 *donors; and*

1 “(F) has established a system to confiden-
2 tially maintain linkage between a cord blood
3 unit and a maternal donor.

4 “(e) *BONE MARROW RECRUITMENT; PRIORITIES; IN-*
5 *FORMATION AND EDUCATION.—*

6 “(1) *RECRUITMENT; PRIORITIES.—The Program*
7 *shall carry out activities for the recruitment of bone*
8 *marrow donors. Such recruitment program shall*
9 *identify populations that are underrepresented among*
10 *potential donors enrolled with the Program. In the*
11 *case of populations that are identified under the pre-*
12 *ceding sentence:*

13 “(A) *The Program shall give priority to*
14 *carrying out activities under this part to in-*
15 *crease representation for such populations in*
16 *order to enable a member of such a population,*
17 *to the extent practicable, to have a probability of*
18 *finding a suitable unrelated donor that is com-*
19 *parable to the probability that an individual*
20 *who is not a member of an underrepresented*
21 *population would have.*

22 “(B) *The Program shall consider racial and*
23 *ethnic minority groups (including persons of*
24 *mixed ancestry) to be populations that have been*
25 *identified for purposes of this paragraph, and*

1 *shall carry out subparagraph (A) with respect to*
2 *such populations.*

3 “(2) *INFORMATION AND EDUCATION REGARDING*
4 *RECRUITMENT; TESTING AND ENROLLMENT.—*

5 “(A) *IN GENERAL.—The Program shall*
6 *carry out informational and educational activi-*
7 *ties, in coordination with organ donation public*
8 *awareness campaigns operated through the De-*
9 *partment of Health and Human Services, for*
10 *purposes of recruiting individuals to serve as do-*
11 *nors of bone marrow, and shall test and enroll*
12 *with the Program potential bone marrow donors.*
13 *Such information and educational activities*
14 *shall include the following:*

15 “(i) *Making information available to*
16 *the general public, including information*
17 *describing the needs of patients with respect*
18 *to donors of bone marrow.*

19 “(ii) *Educating and providing infor-*
20 *mation to individuals who are willing to*
21 *serve as potential bone marrow donors.*

22 “(iii) *Training individuals in request-*
23 *ing individuals to serve as potential bone*
24 *marrow donors.*

1 “(B) *PRIORITIES.*—*In carrying out infor-*
2 *mational and educational activities under sub-*
3 *paragraph (A), the Program shall give priority*
4 *to recruiting individuals to serve as donors of*
5 *bone marrow for populations that are identified*
6 *under paragraph (1).*

7 “(3) *TRANSPLANTATION AS TREATMENT OP-*
8 *TION.*—*In addition to activities regarding recruit-*
9 *ment, the recruitment program under paragraph (1)*
10 *shall provide information to physicians, other health*
11 *care professionals, and the public regarding bone*
12 *marrow transplants from unrelated donors as a treat-*
13 *ment option.*

14 “(4) *IMPLEMENTATION OF SUBSECTION.*—*The re-*
15 *quirements of this subsection shall be carried out by*
16 *the entity that has been awarded a contract by the*
17 *Secretary under subsection (a) to carry out the func-*
18 *tions described in subsection (d)(1).*

19 “(f) *BONE MARROW CRITERIA, STANDARDS, AND PRO-*
20 *CEDURES.*—*The Secretary shall enforce, for participating*
21 *entities, including the Program, individual marrow donor*
22 *centers, marrow donor registries, marrow collection centers,*
23 *and marrow transplant centers—*

1 “(1) *quality standards and standards for tissue*
2 *typing, obtaining the informed consent of donors, and*
3 *providing patient advocacy;*

4 “(2) *donor selection criteria, based on established*
5 *medical criteria, to protect both the donor and the re-*
6 *cipient and to prevent the transmission of potentially*
7 *harmful infectious diseases such as the viruses that*
8 *cause hepatitis and the etiologic agent for Acquired*
9 *Immune Deficiency Syndrome;*

10 “(3) *procedures to ensure the proper collection*
11 *and transportation of the marrow;*

12 “(4) *standards for the system for patient advo-*
13 *cacy operated under subsection (h), including stand-*
14 *ards requiring the provision of appropriate informa-*
15 *tion (at the start of the search process and throughout*
16 *the process) to patients and their families and physi-*
17 *cians;*

18 “(5) *standards that—*

19 “(A) *require the establishment of a system*
20 *of strict confidentiality of records relating to the*
21 *identity, address, HLA type, and managing*
22 *marrow donor center for marrow donors and po-*
23 *tential marrow donors; and*

24 “(B) *prescribe the purposes for which the*
25 *records described in subparagraph (A) may be*

1 *disclosed, and the circumstances and extent of*
2 *the disclosure; and*

3 “(6) *in the case of a marrow donor center or*
4 *marrow donor registry participating in the program,*
5 *procedures to ensure the establishment of a method for*
6 *integrating donor files, searches, and general proce-*
7 *dures of the center or registry with the Program.*

8 “(g) *CORD BLOOD RECRUITMENT; PRIORITIES; INFOR-*
9 *MATION AND EDUCATION.—*

10 “(1) *RECRUITMENT; PRIORITIES.—The Program*
11 *shall support activities, in cooperation with qualified*
12 *cord blood banks, for the recruitment of cord blood do-*
13 *nors. Such recruitment program shall identify popu-*
14 *lations that are underrepresented among cord blood*
15 *donors. In the case of populations that are identified*
16 *under the preceding sentence:*

17 “(A) *The Program shall give priority to*
18 *supporting activities under this part to increase*
19 *representation for such populations in order to*
20 *enable a member of such a population, to the ex-*
21 *tent practicable, to have a probability of finding*
22 *a suitable cord blood unit that is comparable to*
23 *the probability that an individual who is not a*
24 *member of an underrepresented population*
25 *would have.*

1 “(B) *The Program shall consider racial and*
2 *ethnic minority groups (including persons of*
3 *mixed ancestry) to be populations that have been*
4 *identified for purposes of this paragraph, and*
5 *shall support activities under subparagraph (A)*
6 *with respect to such populations.*

7 “(2) *INFORMATION AND EDUCATION REGARDING*
8 *RECRUITMENT; TESTING AND DONATION.—*

9 “(A) *IN GENERAL.—In carrying out the re-*
10 *ruitment program under paragraph (1), the*
11 *Program shall support informational and edu-*
12 *cational activities in coordination with qualified*
13 *cord blood banks and organ donation public*
14 *awareness campaigns operated through the De-*
15 *partment of Health and Human Services, for*
16 *purposes of recruiting pregnant women to serve*
17 *as donors of cord blood. Such information and*
18 *educational activities shall include the following:*

19 “(i) *Making information available to*
20 *the general public, including information*
21 *describing the needs of patients with respect*
22 *to cord blood units.*

23 “(ii) *Educating and providing infor-*
24 *mation to pregnant women who are willing*
25 *to donate cord blood units.*

1 “(iii) *Training individuals in request-*
2 *ing pregnant women to serve as cord blood*
3 *donors.*

4 “(B) *PRIORITIES.—In carrying out infor-*
5 *mational and educational activities under sub-*
6 *paragraph (A), the Program shall give priority*
7 *to supporting the recruitment of pregnant*
8 *women to serve as donors of cord blood for popu-*
9 *lations that are identified under paragraph (1).*

10 “(3) *TRANSPLANTATION AS TREATMENT OP-*
11 *TION.—In addition to activities regarding recruit-*
12 *ment, the recruitment program under paragraph (1)*
13 *shall provide information to physicians, other health*
14 *care professionals, and the public regarding cord*
15 *blood transplants from donors as a treatment option.*

16 “(4) *IMPLEMENTATION OF SUBSECTION.—The re-*
17 *quirements of this subsection shall be carried out by*
18 *the entity that has been awarded a contract by the*
19 *Secretary under subsection (a) to carry out the func-*
20 *tions described in subsection (d)(2).*

21 “(h) *PATIENT ADVOCACY AND CASE MANAGEMENT FOR*
22 *BONE MARROW AND CORD BLOOD.—*

23 “(1) *IN GENERAL.—The Secretary shall establish*
24 *and maintain, through a contract or other means de-*
25 *termined appropriate by the Secretary, an office of*

1 *patient advocacy (in this subsection referred to as the*
2 *'Office').*

3 “(2) *GENERAL FUNCTIONS.—The Office shall*
4 *meet the following requirements:*

5 “(A) *The Office shall be headed by a direc-*
6 *tor.*

7 “(B) *The Office shall be staffed by individ-*
8 *uals with expertise in bone marrow and cord*
9 *blood therapy covered under the Program.*

10 “(C) *The Office shall operate a system for*
11 *patient advocacy, which shall be separate from*
12 *mechanisms for donor advocacy, and which shall*
13 *serve patients for whom the Program is con-*
14 *ducting, or has been requested to conduct, a*
15 *search for a bone marrow donor or cord blood*
16 *unit.*

17 “(D) *In the case of such a patient, the Of-*
18 *fice shall serve as an advocate for the patient by*
19 *directly providing to the patient (or family*
20 *members, physicians, or other individuals acting*
21 *on behalf of the patient) individualized services*
22 *with respect to efficiently utilizing the system*
23 *under paragraphs (1) and (2) of subsection (d)*
24 *to conduct an ongoing search for a bone marrow*

1 donor or cord blood unit and assist with infor-
2 mation regarding third party payor matters.

3 “(E) In carrying out subparagraph (D), the
4 Office shall monitor the system under para-
5 graphs (1) and (2) of subsection (d) to determine
6 whether the search needs of the patient involved
7 are being met, including with respect to the fol-
8 lowing:

9 “(i) Periodically providing to the pa-
10 tient (or an individual acting on behalf of
11 the patient) information regarding bone
12 marrow donors or cord blood units that are
13 suitably matched to the patient, and other
14 information regarding the progress being
15 made in the search.

16 “(ii) Informing the patient (or such
17 other individual) if the search has been in-
18 terrupted or discontinued.

19 “(iii) Identifying and resolving prob-
20 lems in the search, to the extent practicable.

21 “(F) The Office shall ensure that the fol-
22 lowing data are made available to patients:

23 “(i) The resources available through
24 the Program.

1 “(ii) *A comparison of transplant cen-*
2 *ters regarding search and other costs that*
3 *prior to transplantation are charged to pa-*
4 *tients by transplant centers.*

5 “(iii) *The post-transplant outcomes for*
6 *individual transplant centers.*

7 “(iv) *Information concerning issues*
8 *that patients may face after a transplant.*

9 “(v) *Such other information as the*
10 *Program determines to be appropriate.*

11 “(G) *The Office shall conduct surveys of pa-*
12 *tients (or family members, physicians, or other*
13 *individuals acting on behalf of patients) to deter-*
14 *mine the extent of satisfaction with the system*
15 *for patient advocacy under this subsection, and*
16 *to identify ways in which the system can be im-*
17 *proved to best meet the needs of patients.*

18 “(3) *CASE MANAGEMENT.—*

19 “(A) *IN GENERAL.—In serving as an advo-*
20 *cate for a patient under paragraph (2), the Of-*
21 *fice shall provide individualized case manage-*
22 *ment services directly to the patient (or family*
23 *members, physicians, or other individuals acting*
24 *on behalf of the patient), including—*

1 “(i) *individualized case assessment;*
2 *and*

3 “(ii) *the functions described in para-*
4 *graph (2)(D) (relating to progress in the*
5 *search process).*

6 “(B) *POSTSEARCH FUNCTIONS.—In addi-*
7 *tion to the case management services described in*
8 *paragraph (1) for patients, the Office shall, on*
9 *behalf of patients who have completed the search*
10 *for a bone marrow donor or cord blood unit, pro-*
11 *vide information and education on the process of*
12 *receiving a transplant, including the post-trans-*
13 *plant process.*

14 “(i) *COMMENT PROCEDURES.—The Secretary shall es-*
15 *tablish and provide information to the public on procedures*
16 *under which the Secretary shall receive and consider com-*
17 *ments from interested persons relating to the manner in*
18 *which the Program is carrying out the duties of the Pro-*
19 *gram. The Secretary may promulgate regulations under*
20 *this section.*

21 “(j) *CONSULTATION.—In developing policies affecting*
22 *the Program, the Secretary shall consult with the Advisory*
23 *Council, the Department of Defense Marrow Donor Recruit-*
24 *ment and Research Program operated by the Department*

1 *of the Navy, and the board of directors of each entity award-*
2 *ed a contract under this section.*

3 “(k) *CONTRACTS.*—

4 “(1) *APPLICATION.*—*To be eligible to enter into*
5 *a contract under this section, an entity shall submit*
6 *to the Secretary and obtain approval of an applica-*
7 *tion at such time, in such manner, and containing*
8 *such information as the Secretary shall by regulation*
9 *prescribe.*

10 “(2) *CONSIDERATIONS.*—*In awarding contracts*
11 *under this section, the Secretary shall give consider-*
12 *ation to the continued safety of donors and patients*
13 *and other factors deemed appropriate by the Sec-*
14 *retary.*

15 “(l) *ELIGIBILITY.*—*Entities eligible to receive a con-*
16 *tract under this section shall include private nonprofit enti-*
17 *ties.*

18 “(m) *RECORDS.*—

19 “(1) *RECORDKEEPING.*—*Each recipient of a con-*
20 *tract or subcontract under subsection (a) shall keep*
21 *such records as the Secretary shall prescribe, includ-*
22 *ing records that fully disclose the amount and dis-*
23 *position by the recipient of the proceeds of the con-*
24 *tract, the total cost of the undertaking in connection*
25 *with which the contract was made, and the amount*

1 of the portion of the cost of the undertaking supplied
 2 by other sources, and such other records as will facili-
 3 tate an effective audit.

4 “(2) *EXAMINATION OF RECORDS.*—The Secretary
 5 and the Comptroller General of the United States
 6 shall have access to any books, documents, papers,
 7 and records of the recipient of a contract or sub-
 8 contract entered into under this section that are perti-
 9 nent to the contract, for the purpose of conducting au-
 10 dits and examinations.

11 “(n) *PENALTIES FOR DISCLOSURE.*—Any person who
 12 discloses the content of any record referred to in subsection
 13 (d)(4)(D) or (f)(5)(A) without the prior written consent of
 14 the donor or potential donor with respect to whom the
 15 record is maintained, or in violation of the standards de-
 16 scribed in subsection (f)(5)(B), shall be imprisoned for not
 17 more than 2 years or fined in accordance with title 18,
 18 United States Code, or both.”.

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

22 “**SEC. 379A. STEM CELL THERAPEUTIC OUTCOMES DATA-**
 23 **BASE.**

24 “(a) *ESTABLISHMENT.*—The Secretary shall by con-
 25 tract establish and maintain a scientific database of infor-

1 *mation relating to patients who have been recipients of a*
2 *stem cell therapeutics product (including bone marrow, cord*
3 *blood, or other such product) from a donor.*

4 “(b) *INFORMATION.*—*The outcomes database shall in-*
5 *clude information in a standardized electronic format with*
6 *respect to patients described in subsection (a), diagnosis,*
7 *transplant procedures, results, long-term follow-up, and*
8 *such other information as the Secretary determines to be*
9 *appropriate, to conduct an ongoing evaluation of the sci-*
10 *entific and clinical status of transplantation involving re-*
11 *cipients of a stem cell therapeutics product from a donor.*

12 “(c) *ANNUAL REPORT ON PATIENT OUTCOMES.*—*The*
13 *Secretary shall require the entity awarded a contract under*
14 *this section to submit to the Secretary an annual report*
15 *concerning patient outcomes with respect to each transplant*
16 *center, based on data collected and maintained by the entity*
17 *pursuant to this section.*

18 “(d) *PUBLICLY AVAILABLE DATA.*—*The outcomes*
19 *database shall make relevant scientific information not con-*
20 *taining individually identifiable information available to*
21 *the public in the form of summaries and data sets to encour-*
22 *age medical research and to provide information to trans-*
23 *plant programs, physicians, patients, entities awarded a*
24 *contract under section 379 donor registries, and cord blood*
25 *banks.”.*

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

4 **“SEC. 379A–1. DEFINITIONS.**

5 *“In this part:*

6 *“(1) The term ‘Advisory Council’ means the ad-*
7 *visory council established by the Secretary under sec-*
8 *tion 379(a)(1).*

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

11 *“(3) The term ‘outcomes database’ means the*
12 *database established by the Secretary under section*
13 *379A.*

14 *“(4) The term ‘Program’ means the C.W. Bill*
15 *Young Cell Transplantation Program established*
16 *under section 379.”.*

17 (d) *AUTHORIZATION OF APPROPRIATIONS.*—*Section*
18 *379B of the Public Health Service Act (42 U.S.C. 274m)*
19 *is amended to read as follows:*

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

21 *“For the purpose of carrying out this part, there are*
22 *authorized to be appropriated \$34,000,000 for fiscal year*
23 *2006 and \$38,000,000 for each of fiscal years 2007 through*
24 *2010.”.*

1 (e) *CONFORMING AMENDMENTS.*—Part I of title III of
2 *the Public Health Service Act (42 U.S.C. 274k et seq.) is*
3 *amended in the part heading, by striking “**NATIONAL***
4 ***BONE MARROW DONOR REGISTRY” and in-***
5 *serting “**C. W. BILL YOUNG CELL TRANSPLAN-***
6 ***TATION PROGRAM”.***

7 *SEC. 4. REPORT ON LICENSURE OF CORD BLOOD UNITS.*

8 *Not later than 90 days after the date of enactment of*
9 *this Act, the Secretary of Health and Human Services, in*
10 *consultation with the Commissioner of Food and Drugs,*
11 *shall submit to Congress a report concerning the progress*
12 *made by the Food and Drug Administration in developing*
13 *requirements for the licensing of cord blood units.*

Calendar No. 156

109TH CONGRESS
1ST Session
S. 1317

A BILL

To provide for the collection and maintenance of cord blood units for the treatment of patients and research, and to amend the Public Health Service Act to authorize the Bone Marrow and Cord Blood Cell Transplantation Program to increase the number of transplants for recipients suitably matched to donors of bone marrow and cord blood.

JULY 11, 2005

Reported with an amendment