Calendar No. 156

109TH 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 recipi-

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

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Bone Marrow and Cord Blood Therapy and Research Act of 2005''.

SEC. 2. CORD BLOOD INVENTORY.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into one-time contracts with qualified cord blood banks to assist in the collection and maintenance of 150,000 new units of high-quality cord blood to be made available for transplantation through the Bone Marrow and Cord Blood Cell Transplantation Program and to carry out the requirements of subsection (b).

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

(1) to acquire, tissue-type, test, cryopreserve, and store donated units of cord blood acquired with the informed consent of the donor in a manner that complies with applicable Federal and State regulations;

(2) to encourage donation from a genetically diverse population;

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

applicable Federal standards available to transplant centers for transplantation;

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

(5) to make data available, as required by the Secretary and consistent with section 379(e)(3) of the Public Health Service Act (42 U.S.C. 274k(e)(3)), as amended by this Act, in a standardized electronic format, as determined by the Secretary, for the Bone Marrow and Cord Blood Cell Transplantation Program; and

(6) to submit data in a standardized electronic format for inclusion in the stem cell therapeutic outcomes database maintained under section 379A of the Public Health Service Act, as amended by this Act.

(c) RELATED CORD BLOOD DONORS.—

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

from transplantation (including selected blood disorders, malignancies, metabolic storage disorders, hemoglobinopathies, and congenital immunodeficiencies) at no cost to such family. Qualified cord blood banks collecting cord blood units under this paragraph shall comply with the requirements of paragraphs (1), (2), (3), and (5) of subsection (b).

(2) AVAILABILITY.—Qualified cord blood banks that are operating a program under paragraph (1) shall provide assurances that the cord blood units in such banks will be available for directed transplantation until such time that the cord blood unit is released for transplantation or is transferred by the family to the Bone Marrow and Cord Blood Cell Transplantation Program in accordance with guidance or regulations promulgated by the Secretary.

(3) INVENTORY.—Cord blood units collected through the program under this section shall not be counted toward the 150,000 inventory goal under the Bone Marrow and Cord Blood Cell Transplantation Program.

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

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

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

(1) will participate in the Bone Marrow and Cord Blood Cell Transplantation Program for a period of at least 10 years;

(2) will make cord blood units collected pursuant to this section available through the Bone Marrow and Cord Blood Cell Transplantation Program in perpetuity; and

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

other qualified cord blood bank approved by the Secretary to ensure continued availability of cord blood units.

(c) DURATION OF CONTRACTS.—

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

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

(B) September 30, 2010.

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

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

(B) the Secretary does not receive an application for a contract under this section from any qualified cord blood bank that has not previously entered into a contract under this section or the Secretary determines that the out-

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

~~(3) PREFERENCE.—In considering contract extensions under paragraph (2), the Secretary shall give preference to qualified cord blood banks that the Secretary determines have demonstrated a superior ability to satisfy the requirements described in subsection (b) and to achieve the overall goals for which the contract was awarded.~~

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

~~(g) DEFINITIONS.—In this section:~~

~~(1) The term "Bone Marrow and Cord Blood Cell Transplantation Program" means the Bone Marrow and Cord Blood Cell Transplantation Program under section 379 of the Public Health Service Act, as amended by this Act.~~

~~(2) The term "cord blood donor" means a mother who has delivered a baby and consents to donate the neonatal blood remaining in the placenta and umbilical cord after separation from the newborn baby.~~

(3) The term ''cord blood unit'' means the neonatal blood collected from the placenta and umbilical cord of a single newborn baby.

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

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

(6) The term ''Secretary'' means the Secretary of Health and Human Services.

(h) AUTHORIZATION OF APPROPRIATIONS.—

(1) EXISTING FUNDS.—Any amounts appropriated to the Secretary for fiscal year 2004 or 2005 for the purpose of assisting in the collection or maintenance of cord blood shall remain available to the Secretary until the end of fiscal year 2007.

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

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

carry out the demonstration project under subsection (c).

SEC. 3. BONE MARROW AND CORD BLOOD CELL TRANSPLANTATION PROGRAM.

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

"SEC. 379. NATIONAL PROGRAM.

''(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall by one or more contracts establish and maintain a Bone Marrow and Cord Blood Cell Transplantation Program (referred to in this section as the 'Program') that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood, and that meets the requirements of this section. The Secretary may award a separate contract to perform each of the major functions of the Program described in paragraphs (1) and (2) of subsection (c) if deemed necessary by the Secretary to operate an effective and efficient system that is in the best interest of patients. The Secretary shall conduct a separate competition for the initial establishment of the cord blood functions of the Program. The Program shall be under the general supervision

of the Secretary. The Secretary shall establish an Advisory Council to advise, assist, consult with, and make recommendations to the Secretary on matters related to the activities carried out by the Program. The members of the Advisory Council shall be appointed in accordance with the following.

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

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

"(B) 1 additional consecutive 2-year term may be served by any member of the Advisory Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank.

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

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

pointed so that each year the terms of approximately one-third of the members of the Advisory Council expire.

"(4) The membership of the Advisory Council—

"(A) shall include as voting members a balanced number of representatives including representatives of marrow donor centers and marrow transplant centers, representatives of cord blood banks and participating birthing hospitals, recipients of a bone marrow transplant, recipients of a cord blood transplant, persons who require such transplants, family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood, persons with expertise in bone marrow and cord blood transplantation, persons with expertise in typing, matching, and transplant outcome data analysis, persons with expertise in the social sciences, basic scientists with expertise in the biology of adult stem cells, and members of the general public; and

"(B) shall include as nonvoting members representatives from the Department of De-

fense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, the Division of Transplantation of the Health Resources and Services Administration, the Food and Drug Administration, and the National Institutes of Health.

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

"(A) to prohibit any member of the Advisory Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and

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

"(6) The Secretary, acting through the Advisory Council, shall submit to the Congress—

"(A) an annual report on the activities carried out under this section; and

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

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

"(c) FUNCTIONS.—

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

"(A) operate a system for listing, searching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients;

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

"(C) carry out a program for the recruitment of bone marrow donors in accordance with subsection (d), including with respect to increasing the representation of racial and ethnic

minority groups (including persons of mixed ancestry) in the enrollment of the Program;

''(D) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage;

''(E) carry out informational and educational activities in accordance with subsection (d);

''(F) at least annually update information to account for changes in the status of individuals as potential donors of bone marrow;

''(G) provide for a system of patient advocacy through the office established under subsection (g);

''(H) provide case management services for any potential donor of bone marrow to whom the Program has provided a notice that the potential donor may be suitably matched to a par-

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

"(I) with respect to searches for unrelated donors of bone marrow that are conducted through the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances;

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

"(K) facilitate and support research to improve the availability, efficiency, safety, and cost of transplants from unrelated donors and the effectiveness of Program operations.

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

"(A) operate a system for listing, searching, and facilitating the distribution of donated cord blood units that are suitably matched to candidate patients and meet all applicable Federal and State regulations (including informed consent and Food and Drug Administration regulations) from a qualified cord blood bank;

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

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

"(D) support studies and demonstration and outreach projects for the purpose of increasing cord blood donation to ensure a genetically diverse collection of cord blood units;

"(E) provide for a system of patient advocacy through the office established under subsection (g);

"(F) coordinate with the qualified cord blood banks to carry out informational and educational activities in accordance with subsection (f);

"(G) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage; and

"(H) with respect to the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format, as required by the Secretary, on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances.

"(3) SINGLE POINT OF ACCESS; SUBMISSION OF DATA.—

"(A) SINGLE POINT OF ACCESS.—The Secretary shall ensure that health care professionals and patients are able to, at a minimum, locate, consistent with the functions described in paragraphs (1)(A) and (2)(A), cells from bone marrow donors and cord blood units through a single electronic point of access.

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

"(4) DEFINITION.—The term 'qualified cord blood bank' means a cord blood bank that—

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

"(B) has implemented donor screening, cord blood collection practices, and processing methods intended to protect the health and safety of donors and transplant recipients to improve transplant outcomes, including with respect to the transmission of potentially harmful infections and other diseases;

"(C) is accredited by an accreditation entity recognized by the Secretary under subsection (b);

"(D) has established a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with existing Federal and State law;

"(E) has established a system for encouraging donation by a genetically diverse group of donors; and

"(F) has established a system to confidentially maintain linkage between a cord blood unit and a maternal donor.

"(d) BONE MARROW RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

"(1) RECRUITMENT; PRIORITIES.—The Program shall carry out activities for the recruitment of bone marrow donors. Such recruitment program

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

"(A) The Program shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

"(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

"(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

"(A) IN GENERAL.—The Program shall carry out informational and educational activities, in coordination with organ donation public awareness campaigns operated through the De-

partment of Health and Human Services, for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Program potential bone marrow donors. Such information and educational activities shall include the following:

"(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

"(ii) Educating and providing information to individuals who are willing to serve as potential bone marrow donors.

"(iii) Training individuals in requesting individuals to serve as potential bone marrow donors.

"(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

"(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1)

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

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

''(c) BONE MARROW CRITERIA, STANDARDS, AND PROCEDURES.—The Secretary shall enforce, for participating entities, including the Program, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

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

''(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

''(3) procedures to ensure the proper collection and transportation of the marrow;

‘‘(4) standards for the system for patient advocacy operated under subsection (g), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;

‘‘(5) standards that—

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

‘‘(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

‘‘(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Program.

‘‘(f) CORD BLOOD RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

"(1) RECRUITMENT; PRIORITIES.—The Program shall support activities, in cooperation with qualified cord blood banks, for the recruitment of cord blood donors. Such recruitment program shall identify populations that are underrepresented among cord blood donors. In the case of populations that are identified under the preceding sentence:

"(A) The Program shall give priority to supporting activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable cord blood unit that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

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

"(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND DONATION.—

"(A) IN GENERAL.—In carrying out the recruitment program under paragraph (1), the Program shall support informational and educational activities in coordination with qualified cord blood banks and organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting pregnant women to serve as donors of cord blood. Such information and educational activities shall include the following:

"(i) Making information available to the general public, including information describing the needs of patients with respect to cord blood units.

"(ii) Educating and providing information to pregnant women who are willing to donate cord blood units.

"(iii) Training individuals in requesting pregnant women to serve as cord blood donors.

"(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to supporting the recruitment of pregnant women to serve as donors of cord blood for pop-

ulations that are identified under paragraph (1).

''(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding cord blood transplants from donors as a treatment option.

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

''(g) PATIENT ADVOCACY AND CASE MANAGEMENT FOR BONE MARROW AND CORD BLOOD.—

''(1) IN GENERAL.—The Secretary shall establish and maintain, through a contract or other means determined appropriate by the Secretary, an office of patient advocacy (in this subsection referred to as the 'Office').

''(2) GENERAL FUNCTIONS.—The Office shall meet the following requirements:

''(A) The Office shall be headed by a director.

"(B) The Office shall be staffed by individuals with expertise in bone marrow and cord blood therapy covered under the Program.

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

"(D) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under paragraphs (1) and (2) of subsection (c) to conduct an ongoing search for a bone marrow donor or cord blood unit and assist with information regarding third party payor matters.

"(E) In carrying out subparagraph (D), the Office shall monitor the system under paragraphs (1) and (2) of subsection (c) to determine whether the search needs of the patient

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

"(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding bone marrow donors or cord blood units that are suitably matched to the patient, and other information regarding the progress being made in the search.

"(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

"(iii) Identifying and resolving problems in the search, to the extent practicable.

"(F) The Office shall ensure that the following data are made available to patients:

"(i) The resources available through the Program.

"(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

"(iii) The post-transplant outcomes for individual transplant centers.

''(iv) Information concerning issues that patients may face after a transplant.

''(v) Such other information as the Program determines to be appropriate.

''(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved to best meet the needs of patients.

''(3) CASE MANAGEMENT.—

''(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

''(i) individualized case assessment; and

''(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

''(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office shall, on behalf of patients who have completed the search for a bone marrow donor or cord blood unit, provide information and education on the process of receiving a transplant, including the post-transplant process.

''(h) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Program is carrying out the duties of the Program.

''(i) CONSULTATION.—In developing policies affecting the Program, the Secretary shall consult with the Advisory Council, the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, and the board of directors of each entity awarded a contract under this section.

''(j) CONTRACTS.—

''(1) APPLICATION.—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing

such information as the Secretary shall by regulation prescribe.

''(2) CONSIDERATIONS.—In awarding contracts under this section, the Secretary shall give consideration to the continued safety of donors and patients and other factors deemed appropriate by the Secretary.

''(k) ELIGIBILITY.—Entities eligible to receive a contract under this section shall include private nonprofit entities.

''(l) RECORDS.—

''(1) RECORDKEEPING.—Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

''(2) EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or

subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

''(m) PENALTIES FOR DISCLOSURE.—Any person who discloses the content of any record referred to in subsection (c)(4)(D) or (c)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (c)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, United States Code, or both.''.

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

''SEC. 379A. STEM CELL THERAPEUTIC OUTCOMES DATABASE.

''(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a donor.

''(b) INFORMATION.—The outcomes database shall include information in a standardized electronic format with respect to patients described in subsection (a), diagnosis, transplant procedures, results, long-term follow-up,

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

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

''(d) PUBLICLY AVAILABLE DATA.—The outcomes database shall make relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets to encourage medical research and to provide information to transplant programs, physicians, patients, entities awarded a contract under section 379 donor registries, and cord blood banks.''.

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

''SEC. 379A–1. DEFINITIONS.

''In this part:

''(1) The term 'Advisory Council' means the advisory council established by the Secretary under section 379(a)(1).

''(2) The term 'bone marrow' means the cells found in adult bone marrow and peripheral blood.

''(3) The term 'outcomes database' means the database established by the Secretary under section 379A.

''(4) The term 'Program' means the Bone Marrow and Cord Blood Cell Transplantation Program established under section 379.''.

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

''SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

''For the purpose of carrying out this part, there are authorized to be appropriated $34,000,000 for fiscal year 2006 and $38,000,000 for each of fiscal years 2007 through 2010.''.

(e) CONFORMING AMENDMENTS.—Part I of title III of the Public Health Service Act (42 U.S.C. 274k et seq.) is amended in the part heading, by striking ''**NATIONAL BONE MARROW DONOR REGISTRY**'' and inserting ''**BONE MARROW AND**

~~**CORD BLOOD CELL TRANSPLANTATION PROGRAM**~~''.

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

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stem Cell Therapeutic and Research Act of 2005''.

SEC. 2. CORD BLOOD INVENTORY.

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

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

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

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

(2) to encourage donation from a genetically diverse population;

(3) to make cord blood units that are collected pursuant to this section or otherwise and meet all applicable Federal standards available to transplant centers for transplantation;

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

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

(6) to submit data in a standardized electronic format for inclusion in the stem cell therapeutic outcomes database maintained under section 379A of the Public Health Service Act, as amended by this Act.

(c) RELATED CORD BLOOD DONORS.—

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

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

(2) AVAILABILITY.—Qualified cord blood banks that are operating a program under paragraph (1) shall provide assurances that the cord blood units in such banks will be available for directed transplantation until such time that the cord blood unit is released for transplantation or is transferred by the family to the C.W. Bill Young Cell Transplantation Program in accordance with guidance or regulations promulgated by the Secretary.

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

(4) REPORT.—Not later than 90 days after the date on which the project under paragraph (1) is terminated by the Secretary, the Secretary shall submit to Congress a report on the outcomes of the project that shall include the recommendations of the Secretary with respect to the continuation of such project.

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

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

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

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

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

(e) DURATION OF CONTRACTS.—

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

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

(B) September 30, 2010.

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

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

(B) the Secretary does not receive an application for a contract under this section from any qualified cord blood bank that has not previously

entered into a contract under this section or the Secretary determines that the outstanding inventory need cannot be met by the one or more qualified cord blood banks that have submitted an application for a contract under this section.

(3) PREFERENCE.—In considering contract extensions under paragraph (2), the Secretary shall give preference to qualified cord blood banks that the Secretary determines have demonstrated a superior ability to satisfy the requirements described in subsection (b) and to achieve the overall goals for which the contract was awarded.

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

(g) DEFINITIONS.—In this section:

(1) The term "C. W. Bill Young Cell Transplantation Program" means the C.W. Bill Young Cell Transplantation Program under section 379 of the Public Health Service Act, as amended by this Act.

(2) The term "cord blood donor" means a mother who has delivered a baby and consents to donate the neonatal blood remaining in the placenta and umbilical cord after separation from the newborn baby.

(3) The term "cord blood unit" means the neonatal blood collected from the placenta and umbilical cord of a single newborn baby.

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

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

(6) The term "Secretary" means the Secretary of Health and Human Services.

(h) AUTHORIZATION OF APPROPRIATIONS.—

(1) EXISTING FUNDS.—Any amounts appropriated to the Secretary for fiscal year 2004 or 2005 for the purpose of assisting in the collection or maintenance of cord blood shall remain available to the Secretary until the end of fiscal year 2007.

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

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

SEC. 3. C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM.

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

"SEC. 379. NATIONAL PROGRAM.

"(a) ESTABLISHMENT.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall by one or more contracts establish and maintain a C.W. Bill Young Cell Transplantation Program (referred to in this section as the 'Program'), successor to the National Bone Marrow Donor Registry, that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood, and that meets the requirements of this section. The Secretary may award a separate contract to perform each of the major functions of the Program described in paragraphs (1) and (2) of subsection (d) if deemed necessary by the Secretary to operate an effective and efficient system that is in the best interest of patients. The Secretary shall conduct a separate competition for the initial establishment of the cord blood functions of the Program. The Program shall be under the general supervision of the Secretary. The Secretary shall establish an Advisory Council to advise, assist, consult with, and make recommendations to the Secretary on matters related to the

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

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

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

"(B) 1 additional consecutive 2-year term may be served by any member of the Advisory Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank.

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

"(3) In order to ensure the continuity of the Advisory Council, the Advisory Council shall be appointed so that each year the terms of approximately one-third of the members of the Advisory Council expire.

"(4) The membership of the Advisory Council—

"(A) shall include as voting members a balanced number of representatives including representatives of marrow donor centers and marrow transplant centers, representatives of cord blood banks and participating birthing hospitals, recipients of a bone marrow transplant, recipients of a cord blood transplant, persons who require such transplants, family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood, persons with expertise in bone marrow and cord blood transplantation, persons with expertise in typing, matching, and transplant outcome data analysis, persons with expertise in the social sciences, basic scientists with expertise in the biology of adult stem cells, and members of the general public; and

"(B) shall include as nonvoting members representatives from the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, the Division of Transplantation of the Health Resources and Services Administration, the Food

and Drug Administration, and the National Institutes of Health.

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

"(A) to prohibit any member of the Advisory Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and

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

"(6) The Secretary, acting through the Advisory Council, shall submit to the Congress—

"(A) an annual report on the activities carried out under this section; and

"(B) not later than 6 months after the date of the enactment of the Stem Cell Therapeutic and Research Act of 2005, a report of recommendations on the scientific factors necessary

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

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

"(c) INFORMED CONSENT.—The Secretary shall, through a public process, examine issues of informed consent, including—

"(1) the appropriate timing of such consent; and

"(2) the information provided to the maternal donor regarding all of her medically appropriate cord blood options.

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

"(d) FUNCTIONS.—

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

"(A) operate a system for identifying, matching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients;

"(B) consistent with paragraph (3), permit transplant physicians, other appropriate health

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

"(C) carry out a program for the recruitment of bone marrow donors in accordance with subsection (e), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Program;

"(D) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage;

"(E) carry out informational and educational activities in accordance with subsection (e);

"(F) at least annually update information to account for changes in the status of individuals as potential donors of bone marrow;

"(G) provide for a system of patient advocacy through the office established under subsection (h);

"(H) provide case management services for any potential donor of bone marrow to whom the Program has provided a notice that the potential donor may be suitably matched to a particular patient through the office established under subsection (h);

"(I) with respect to searches for unrelated donors of bone marrow that are conducted through the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances;

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

"(K) facilitate research with the appropriate Federal agencies to improve the availability, efficiency, safety, and cost of transplants from unrelated donors and the effectiveness of Program operations.

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

"(A) operate a system for identifying, matching, and facilitating the distribution of donated cord blood units that are suitably matched to candidate patients and meet all applicable Federal and State regulations (including informed consent and Food and Drug Administration regulations) from a qualified cord blood bank;

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

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

"(D) support studies and demonstration and outreach projects for the purpose of increasing cord blood donation to ensure a genetically diverse collection of cord blood units;

"(E) provide for a system of patient advocacy through the office established under subsection (h);

"(F) coordinate with the qualified cord blood banks to support informational and educational activities in accordance with subsection (g);

"(G) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage; and

"(H) with respect to the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format, as required by the Secretary, on the number and percentage of patients at each of the various stages of the

search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances.

"(3) SINGLE POINT OF ACCESS; STANDARD DATA.—

"(A) SINGLE POINT OF ACCESS.—The Secretary shall ensure that health care professionals and patients are able to search electronically for and facilitate access to, in the manner and to the extent defined by the Secretary and consistent with the functions described in paragraphs (1)(A) and (2)(A), cells from bone marrow donors and cord blood units through a single point of access.

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

"(4) DEFINITION.—The term 'qualified cord blood bank' means a cord blood bank that—

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

"(B) has implemented donor screening, cord blood collection practices, and processing methods intended to protect the health and safety of donors and transplant recipients to improve transplant outcomes, including with respect to the transmission of potentially harmful infections and other diseases;

"(C) is accredited by an accreditation entity recognized by the Secretary under subsection (b);

"(D) has established a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with existing Federal and State law;

"(E) has established a system for encouraging donation by a genetically diverse group of donors; and

"(F) has established a system to confidentially maintain linkage between a cord blood unit and a maternal donor.

"(e) BONE MARROW RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

"(1) RECRUITMENT; PRIORITIES.—The Program shall carry out activities for the recruitment of bone marrow donors. Such recruitment program shall identify populations that are underrepresented among potential donors enrolled with the Program. In the case of populations that are identified under the preceding sentence:

"(A) The Program shall give priority to carrying out activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

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

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

"(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND ENROLLMENT.—

"(A) IN GENERAL.—The Program shall carry out informational and educational activities, in coordination with organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Program potential bone marrow donors. Such information and educational activities shall include the following:

"(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

"(ii) Educating and providing information to individuals who are willing to serve as potential bone marrow donors.

"(iii) Training individuals in requesting individuals to serve as potential bone marrow donors.

"(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

"(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding bone marrow transplants from unrelated donors as a treatment option.

"(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(1).

"(f) BONE MARROW CRITERIA, STANDARDS, AND PROCEDURES.—The Secretary shall enforce, for participating entities, including the Program, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

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

"(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

"(3) procedures to ensure the proper collection and transportation of the marrow;

"(4) standards for the system for patient advocacy operated under subsection (h), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;

"(5) standards that—

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

"(B) prescribe the purposes for which the records described in subparagraph (A) may be

disclosed, and the circumstances and extent of the disclosure; and

"(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Program.

"(g) CORD BLOOD RECRUITMENT; PRIORITIES; INFORMATION AND EDUCATION.—

"(1) RECRUITMENT; PRIORITIES.—The Program shall support activities, in cooperation with qualified cord blood banks, for the recruitment of cord blood donors. Such recruitment program shall identify populations that are underrepresented among cord blood donors. In the case of populations that are identified under the preceding sentence:

"(A) The Program shall give priority to supporting activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable cord blood unit that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

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

"(2) INFORMATION AND EDUCATION REGARDING RECRUITMENT; TESTING AND DONATION.—

"(A) IN GENERAL.—In carrying out the recruitment program under paragraph (1), the Program shall support informational and educational activities in coordination with qualified cord blood banks and organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting pregnant women to serve as donors of cord blood. Such information and educational activities shall include the following:

"(i) Making information available to the general public, including information describing the needs of patients with respect to cord blood units.

"(ii) Educating and providing information to pregnant women who are willing to donate cord blood units.

"(iii) Training individuals in requesting pregnant women to serve as cord blood donors.

"(B) PRIORITIES.—In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to supporting the recruitment of pregnant women to serve as donors of cord blood for populations that are identified under paragraph (1).

"(3) TRANSPLANTATION AS TREATMENT OPTION.—In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding cord blood transplants from donors as a treatment option.

"(4) IMPLEMENTATION OF SUBSECTION.—The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(2).

"(h) PATIENT ADVOCACY AND CASE MANAGEMENT FOR BONE MARROW AND CORD BLOOD.—

"(1) IN GENERAL.—The Secretary shall establish and maintain, through a contract or other means determined appropriate by the Secretary, an office of

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

"(2) GENERAL FUNCTIONS.—The Office shall meet the following requirements:

"(A) The Office shall be headed by a director.

"(B) The Office shall be staffed by individuals with expertise in bone marrow and cord blood therapy covered under the Program.

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

"(D) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under paragraphs (1) and (2) of subsection (d) to conduct an ongoing search for a bone marrow

donor or cord blood unit and assist with information regarding third party payor matters.

"(E) In carrying out subparagraph (D), the Office shall monitor the system under paragraphs (1) and (2) of subsection (d) to determine whether the search needs of the patient involved are being met, including with respect to the following:

"(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding bone marrow donors or cord blood units that are suitably matched to the patient, and other information regarding the progress being made in the search.

"(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

"(iii) Identifying and resolving problems in the search, to the extent practicable.

"(F) The Office shall ensure that the following data are made available to patients:

"(i) The resources available through the Program.

"(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

"(iii) The post-transplant outcomes for individual transplant centers.

"(iv) Information concerning issues that patients may face after a transplant.

"(v) Such other information as the Program determines to be appropriate.

"(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved to best meet the needs of patients.

"(3) CASE MANAGEMENT.—

"(A) IN GENERAL.—In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

"(i) individualized case assessment; and

"(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

"(B) POSTSEARCH FUNCTIONS.—In addition to the case management services described in paragraph (1) for patients, the Office shall, on behalf of patients who have completed the search for a bone marrow donor or cord blood unit, provide information and education on the process of receiving a transplant, including the post-transplant process.

"(i) COMMENT PROCEDURES.—The Secretary shall establish and provide information to the public on procedures under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Program is carrying out the duties of the Program. The Secretary may promulgate regulations under this section.

"(j) CONSULTATION.—In developing policies affecting the Program, the Secretary shall consult with the Advisory Council, the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department

of the Navy, and the board of directors of each entity awarded a contract under this section.

"(k) CONTRACTS.—

"(1) APPLICATION.—To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

"(2) CONSIDERATIONS.—In awarding contracts under this section, the Secretary shall give consideration to the continued safety of donors and patients and other factors deemed appropriate by the Secretary.

"(l) ELIGIBILITY.—Entities eligible to receive a contract under this section shall include private nonprofit entities.

"(m) RECORDS.—

"(1) RECORDKEEPING.—Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount

of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

"(2) EXAMINATION OF RECORDS.—The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

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

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

"SEC. 379A. STEM CELL THERAPEUTIC OUTCOMES DATABASE.

"(a) ESTABLISHMENT.—The Secretary shall by contract establish and maintain a scientific database of infor-

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

"(b) INFORMATION.—The outcomes database shall include information in a standardized electronic format with respect to patients described in subsection (a), diagnosis, transplant procedures, results, long-term follow-up, and such other information as the Secretary determines to be appropriate, to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of a stem cell therapeutics product from a donor.

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

"(d) PUBLICLY AVAILABLE DATA.—The outcomes database shall make relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets to encourage medical research and to provide information to transplant programs, physicians, patients, entities awarded a contract under section 379 donor registries, and cord blood banks.".

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

"SEC. 379A–1. DEFINITIONS.

"In this part:

"(1) The term 'Advisory Council' means the advisory council established by the Secretary under section 379(a)(1).

"(2) The term 'bone marrow' means the cells found in adult bone marrow and peripheral blood.

"(3) The term 'outcomes database' means the database established by the Secretary under section 379A.

"(4) The term 'Program' means the C.W. Bill Young Cell Transplantation Program established under section 379.".

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

"SEC. 379B. AUTHORIZATION OF APPROPRIATIONS.

"For the purpose of carrying out this part, there are authorized to be appropriated $34,000,000 for fiscal year 2006 and $38,000,000 for each of fiscal years 2007 through 2010.".

*(e) CONFORMING AMENDMENTS.—Part I of title III of the Public Health Service Act (42 U.S.C. 274k et seq.) is amended in the part heading, by striking "**NATIONAL BONE MARROW DONOR REGISTRY**" and inserting "**C. W. BILL YOUNG CELL TRANSPLANTATION PROGRAM**".*

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

Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Commissioner of Food and Drugs, shall submit to Congress a report concerning the progress made by the Food and Drug Administration in developing 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