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109TH CONGRESS
1ST SESSION

H. R. 2520

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

IN THE HOUSE OF REPRESENTATIVES

MAY 23, 2005

Mr. SMITH of New Jersey (for himself, Mr. BARTON of Texas, Mr. DAVIS of Alabama, Mr. DELAY, Mr. DEAL of Georgia, Mr. BLUNT, Mr. TOWNS, Mr. DAVIS of Kentucky, Ms. FOXX, Mr. SHIMKUS, Mr. STUPAK, Mr. RENZI, Mr. CANTOR, Mr. PAYNE, Mr. GREEN of Wisconsin, Mr. MCINTYRE, Mr. FERGUSON, Mr. NORWOOD, Ms. MILLENDER-MCDONALD, Mr. EVERETT, Mr. KENNEDY of Minnesota, Mr. CONYERS, Mr. BOUSTANY, Mr. LIPINSKI, Mr. ADERHOLT, Mr. BURGESS, Mr. WELDON of Florida, Mr. PENCE, Mrs. MYRICK, Mr. RYUN of Kansas, Mr. PITTS, Mr. MCCAUL of Texas, Mr. WAMP, Mr. CHABOT, Mr. MURPHY, Mr. INGLIS of South Carolina, Mr. TERRY, Mr. FORTENBERRY, Mr. NEUGEBAUER, Mr. STEARNS, Mr. WALSH, Mr. MCCOTTER, Mr. FOSSELLA, Mrs. JO ANN DAVIS of Virginia, Mr. HASTINGS of Washington, Mrs. DRAKE, Ms. HART, Mr. BURTON of Indiana, Mr. KING of New York, Mr. HAYWORTH, Mr. SULLIVAN, Mr. FITZPATRICK of Pennsylvania, Mr. GUTKNECHT, Mr. SHADEGG, Mr. AKIN, Mr. SOUDER, Mr. HAYES, Mr. BOOZMAN, Mr. DOOLITTLE, Mr. PRICE of Georgia, Mr. MEEK of Florida, Mr. KLINE, Mr. FORD, Mr. HYDE, Mrs. MUSGRAVE, Mr. FORBES, Mr. SAM JOHNSON of Texas, Mr. TANCREDO, Mr. DANIEL E. LUNGREN of California, Mr. MARSHALL, Ms. ESHOO, Mr. SODREL, Mr. PUTNAM, Mr. CANNON, Mr. LINCOLN DIAZ-BALART of Florida, Mr. CLAY, Ms. ROS-LEHTINEN, Mr. MCHENRY, and Mr. FRANKS of Arizona) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To provide for the collection and maintenance of human

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

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 ''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 stem cell banks to assist in the collection and maintenance of 150,000 units of high-quality human 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 human cord blood acquired with the informed consent of the donor in a manner that complies with applicable Federal and State regulations;

(2) 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 stem cell transplantation;

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

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

(5) to submit data 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) APPLICATION.—To seek to enter into a contract under this section, a qualified cord blood stem cell 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 an assurance that the applicant—

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

(2) in the event of abandonment of this activity prior to the expiration of such period, will transfer the units collected pursuant to this section to an-

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

(d) DURATION OF CONTRACTS.—

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

(A) exceeds 3 years; or

(B) ends after September 30, 2010.

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

(A) the Secretary finds that 150,000 units of high-quality human 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 stem cell 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 stem cell banks that have submitted an application for a contract under this section.

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

(f) 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 ''human cord blood unit'' means the neonatal blood collected from the placenta and umbilical cord.

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

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

(g) AUTHORIZATION OF APPROPRIATIONS.—

(1) FISCAL YEAR 2006.—Any amounts appropriated to the Secretary for fiscal year 2004 or 2005 for the purpose of assisting in the collection or

maintenance of human cord blood shall remain available to the Secretary until the end of fiscal year 2006 for the purpose of carrying out this section.

(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. Amounts appropriated pursuant to this paragraph shall remain available for obligation through the end of fiscal year 2010.

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—

(1) in the section heading, by striking ''**NATIONAL REGISTRY**'' and inserting ''**NATIONAL PROGRAM**'';

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''The Secretary shall by contract'' and all that follows through the end of such matter and inserting ''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 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 (b) if deemed necessary by the Secretary to operate an effective and efficient system. 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:'';

(B) in paragraph (1), by striking ''except that'' and all that follows and inserting ''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 group, transplant center, or cord blood stem cell bank.'';

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

''(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 stem cell banks and participating birthing hospitals, recipients of a bone marrow transplant and cord blood transplants, 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 exper-

tise in blood stem cell transplantation including cord blood, persons with expertise in typing, matching, and transplant outcome data analysis, persons with expertise in the social sciences, 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.''; and

(D) by adding at the end the following:

''(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 group, transplant center, or cord blood stem cell bank from participating in any decision that materially affects the center,

recruitment group, transplant center, or cord blood stem cell 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.'';

(3) by amending subsection (b) to read as follows:

''(b) 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) carry out a program for the recruitment of bone marrow donors in accordance with

subsection (c), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Program;

''(C) maintain and expand medical emergency contingency response capabilities in concert with Federal programs for response to threats of use of terrorist or military weapons that can damage marrow, such as ionizing radiation or chemical agents containing mustard, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage;

''(D) carry out informational and educational activities in accordance with subsection (c);

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

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

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

tential donor may be suitably matched to a particular patient (which services shall be provided through a mechanism other than the system of patient advocacy under subsection (d)), and conduct surveys of donors and potential donors to determine the extent of satisfaction with such services and to identify ways in which the services can be improved;

''(H) with respect to searches for unrelated donors of bone marrow that are conducted through the system under subparagraph (A), collect, analyze, and publish data 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;

''(I) 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;

''(J) conduct and support research to improve the availability, efficiency, safety, and

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

''(K) assist qualified cord blood stem cell banks in the Program in accordance with paragraph (3).

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

''(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 stem cell bank;

''(B) allow transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available cord blood units listed in the Program;

''(C) allow transplant physicians and other appropriate health care professionals to ten-

tatively reserve 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; and

"(E) coordinate with the Secretary to carry out information and educational activities for the purpose of increasing cord blood donation and promoting the availability of cord blood units as a transplant option.

"(3) SINGLE POINT OF ACCESS.—If the Secretary enters into a contract with more than one entity to perform the functions outlined in this subsection, the Secretary shall establish procedures to ensure that health care professionals and patients are able to obtain, consistent with the functions described in paragraphs (1)(A) and (2)(A), cells from adult donors and cord blood units through a single point of access.

"(4) DEFINITION.—The term 'qualified cord blood stem cell bank' means a cord blood stem cell 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 stem cell 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 body recognized pursuant to a public process by the Secretary;

''(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; and

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

(4) in subsection (c)—

(A) in paragraph (1), by striking ''The Registry shall carry out a program for the recruitment'' and inserting ''With respect to bone

marrow, the Program shall carry out a program for the recruitment'';

(B) in paragraph (2)(A)—

(i) in the matter preceding clause (i), by striking the first sentence and inserting ''In carrying out the program under paragraph (1), 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 donors.''; and

(ii) in clause (ii), by striking '', including providing updates''; and

(C) in paragraph (3), by striking ''the availability, as a potential treatment option, of receiving a transplant of bone marrow from an unrelated donor'' and inserting ''transplants from unrelated donors as a treatment option and resources for identifying and evaluating other therapeutic alternatives'';

(5) in subsection (d)—

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

(B) in paragraph (2)(C), by inserting ''and assist with information regarding third party payor matters'' after ''ongoing search for a donor'';

(C) in subparagraphs (C), (D), and (E) of paragraph (2), by striking the term ''subsection (b)(1)'' each place such term appears and inserting ''subsection (b)(1)(A)'';

(D) in paragraph (2)(F)—

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

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

''(v) Information concerning issues that patients may face after a transplant regarding continuity of care and quality of life.''; and

(E) in paragraph (3)(B), by striking ''Office may'' and inserting ''Office shall'';

(6) in the matter preceding paragraph (1) in subsection (e), by striking ''the Secretary shall'' and

inserting ''with respect to bone marrow, the Secretary shall'';

(7) by amending subsection (f) to read as follows:

''(f) 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.'';

(8) by amending subsection (g) to read as follows:

''(g) 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.'';

(9) in subsection (h)—

(A) by striking ''APPLICATION.—'' and inserting ''CONTRACTS.—'';

(B) by striking ''To be eligible'' and inserting the following:

''(1) APPLICATION.—To be eligible''; and

(C) by adding at the end the following:

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

(10) by striking subsection (l).

(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 stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a biologically unrelated donor.

''(b) INFORMATION.—The outcomes database shall include information with respect to patients described in subsection (a), transplant procedures, 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 bone marrow from biologically unrelated donors and recipients of a stem cell therapeutics product.

''(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 stem cell 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.

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

''(b) EMERGENCY CONTINGENCY RESPONSE CAPABILITIES.—In addition to the amounts authorized to be appropriated under subsection (a), there is authorized to be appropriated $2,000,000 for the maintenance and expansion of emergency contingency response capabilities under section 379(b)(1)(C).''.

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

(1) in the title heading, by striking ''**NATIONAL BONE MARROW DONOR REG-**

ISTRY'' and inserting ''**C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM**''; and

(2) in section 379, as amended by this section—

(A) in subsection (a), by striking the term ''board'' each place such term appears and inserting ''Advisory Council'';

(B) in subection (c)—

(i) in the matter preceding subparagraph (A) in paragraph (1), by striking ''Such program'' and inserting ''Such recruitment program'';

(ii) in paragraph (2), by striking ''program under paragraph (1)'' and inserting ''recruitment program under paragraph (1)''; and

(iii) in paragraph (3), by striking ''program under paragraph (1)'' and inserting ''recruitment program under paragraph (1)'';

(C) in subsection (d)(2)(E), by striking ''Registry program'' and inserting ''Program'';

(D) in subsection (e)—

(i) in the matter preceding paragraph (1), by striking ''participating in the program, including the Registry,'' and inserting ''participating in the Program, including''; and

(ii) in paragraph (6), by striking ''the program'' and inserting ''the Program''; and

(E) by striking the term ''Registry'' each place such term appears and inserting ''Program''.

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