

So the last 5 years both Secretary Thompson and Secretary Leavitt have not been able to get this whole program up and running. Now we have this same cast of characters telling the country that we have got to implement the Medicare bill right now when plenty of people in this body, led by Ms. SCHAKOWSKY of Illinois and Mr. STARK from California, it said on the Medicare bill that we should push back the deadline for people who want to benefit from the Medicare prescription drug benefit program, who want to benefit but cannot yet make their minds up because of the complexity of it. And they will be actually financially penalized if they do not make that decision more quickly than many seniors feel that they are capable of making.

At the same time, we are also doing nothing to allow the Secretary of CMS to bring down the price of prescription drugs. In fact, this institution, this body, prohibited the government from negotiating lower prices. So while Secretary Thompson and now Secretary Leavitt could not get their act together on this, they seem to want to move forward too quickly on Medicare, forcing seniors to make a choice prematurely in the minds of many seniors or pay an economic financial penalty for every month they delay, and at the same time doing nothing to bring the price of prescription drugs down.

It all fits together in a peculiar way, Mr. Speaker. That does not mean this bill is not important. I join my colleague, Mr. DEAL, in support of it. As always, there is a little bigger picture here.

Mr. Speaker, I yield back the balance of my time.

Mr. DEAL of Georgia. Mr. Speaker, I yield myself such time as I may consume.

While my colleague, Mr. BROWN of Ohio, is my copartner in the issue of health care and he and I share many things in common, this bill being one of them, and I would disagree with his comments with regard to Medicare part D, I for one am pleased that we are finally offering senior citizens of this country the opportunity to have a prescription drug benefit plan.

We can disagree on that, and we will probably have some disagreements in the future; but I do want to thank Mr. BROWN of Ohio and his staff and the others on the minority side for their cooperation in dealing with this issue that is before us today on pathology licensure.

I think that it is a bill that we need to act on quickly, and hopefully our colleagues across the way will do likewise.

Mr. DINGELL. Mr. Speaker, I support H.R. 4568, the "Proficiency Testing Improvement Act of 2005," which requires the Secretary of the Department of Health and Human Services to update the federal program to test the proficiency of individual laboratory professionals who read Pap tests. This bill delays implementation of the program first proposed in 1992 so that revisions, including those rec-

ommended by the Clinical Laboratory Improvement Advisory Committee, can be made. Importantly, these revisions are required to be made within one year, and must be made before proficiency testing can resume.

This is a commonsense measure that will assure that regulations implemented by the Federal Government reflect current science, technology, and medical practice. I urge my colleagues to support it.

Mr. DEAL of Georgia. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. MCHUGH). The question is on the motion offered by the gentleman from Georgia (Mr. DEAL) that the House suspend the rules and pass the bill, H.R. 4568.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

#### STEM CELL THERAPEUTIC AND RESEARCH ACT OF 2005

Mr. DEAL of Georgia. Mr. Speaker, I move to suspend the rules and concur in the Senate amendment to the bill (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.

The Clerk read as follows:

Senate amendment:

Strike out all after the enacting clause and insert:

##### 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 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 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.

“(1) 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. 274i) 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 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.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Georgia (Mr. DEAL) and the gentleman from Colorado (Ms. DEGETTE) each will control 20 minutes.

The Chair recognizes the gentleman from Georgia.

GENERAL LEAVE

Mr. DEAL of Georgia. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on H.R. 2520.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Georgia?

There was no objection.

Mr. DEAL of Georgia. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in strong support of H.R. 2520, the Stem Cell Therapeutic and Research Act of 2005. This legislation will expand the number of stem cell options available to Americans suffering from life-threatening diseases.

Every year, nearly two-thirds of the approximately 200,000 patients in need of a bone marrow transplant will not find a marrow donor that matches within their families. These patients must rely on the help of strangers to donate bone marrow or transplant. To assist these patients, Congress established the National Bone Marrow Registry to quickly facilitate unrelated donor transplants. Through this program, Congress made a significant investment to connect patients with a rich source of stem cells that offer immediate clinical benefits.

With scientific advances, Congress must now make changes to reflect new therapeutic options. Cord blood stem cell units have been shown to be a suitable alternative to adult bone marrow for the treatment of many diseases, including sickle cell anemia. This is an

especially important advancement for those Americans who have desperately searched for a bone marrow donor, but could not find a suitable match, even with the help of the National Bone Marrow Registry. As another rich source of stem cells, cord blood transplant is another chance at life for many patients.

The bill before us today builds on the critical investments we have made over the past two decades with the National Bone Marrow Registry and retools this design into a new, more comprehensive stem cell transplantation program which will include not only bone marrow but cord blood units.

Through a competitive contracting process, this new program will allow transplant doctors and patients to access information about cord blood units and bone marrow donors at the same time through a single point of access. This new program does not create a preference for either cord blood or bone marrow. Instead, it will provide comprehensive information about both sources to stem cells to doctors and patients and allow them to make the clinically most appropriate choice.

I would like to recognize Congressman BILL YOUNG. It is his drive and steadfast support for an idea of a national registry for bone marrow that lead to the program's creation. Mr. YOUNG has continuously supported improving this program and does so today by reformatting the program's design. I am pleased that Congress is recognizing his dedication by naming the new program the C.W. Bill Young Cell Transplantation Program.

Lastly, I would like to note that through the discussions with the Senate, we have improved the original House bill to make the program more effective, including improved patient advocacy and case management services. We have created a new demonstration program to allow families with a sick child who could be helped with a cord blood transplant from a sibling to bank cord blood from newborns should they decide to have another child. We have also expanded the clinical outcomes database to include biologically related donors in addition to unrelated donors.

Finally, we require the Food and Drug Administration to provide a report on its progress in developing licensure requirements for cord blood units.

Mr. Speaker, I reserve the balance of my time.

Ms. DEGETTE. Mr. Speaker, I yield myself such time as I may consume. Mr. Speaker, I want to thank my colleague and friend from Georgia on the Energy and Commerce Committee for his leadership on issues like this.

Mr. Speaker, I rise today in support of this legislation; however, I am concerned that the other body has chosen to send us only the cord blood bill today. This bill is essentially the same bill that the House passed last May by a vote of 431-1. The legislation is important, and it will help advance med-

ical research which is why I support it and why we passed it by such an overwhelming majority last spring. What we need to be clear about, though, is what this bill really will and will not do; and we also need to be clear that this bill is not a substitute for embryonic stem cell research, the Castle-DeGette bill, H.R. 810, which is an important bill to advance scientific research to affect diseases that will potentially kill millions of Americans.

Like adult stem cells, umbilical cord stem cells have proven over the last decade or so to be a reliable source of blood-forming stem cells that are used as a technique to treat blood diseases like leukemia and lymphoma. That established technique has led to about 600 cord blood transplants which were performed in the United States in 2004 to treat blood disorders. But these cord blood cells are not regenerative and they are not reprogramming, which is why they cannot be used to be made into other types of stem cells that can cure other types of diseases besides blood-related diseases.

It is true that cord blood has been reliably used for a number of years, and that is why it is so important that we pass this cord blood registry. But we must not overstate or exaggerate the capabilities of cord stem cells. Significant limitations exist that must be considered.

Unlike human embryonic stem cells, stem cells from umbilical blood cord cannot continually reproduce themselves. Instead of proliferating, they quickly evolve into specialized cells. Umbilical cord stem cells cannot be induced to form diverse nonblood cell types, as I mentioned. Although some initial experiments appear to be promising, few stem cell researchers now believe that umbilical cords will be a reliable source of replacement cells other than blood cells.

Now, I support this very early research that I talked about, as I support any kind of research that could lead to stem cells that could cure diseases. But these studies are few, and they have not shown conclusive results.

Finally, umbilical cord stem cells are in short supply. Only a small number of cells can be obtained from each umbilical cord, making it hard to obtain enough stem cells for treatment.

□ 1600

Because of the limitations, we must also support embryonic stem cell research. I do not need to tell the House that, though, because we already did that with support from both sides of the aisle.

Last May, this House passed both the umbilical cord stem cell legislation along with H.R. 810, the Stem Cell Research Enhancement Act. H.R. 810, co-sponsored by myself and Congressman MIKE CASTLE, expands the number of embryonic stem cell lines that are eligible for federally funded research. The goal of the legislation is to accelerate scientific progress toward life-saving

cures and treatments for a wide range of diseases, not just blood-related diseases.

Unfortunately, the other body has not yet embraced the wisdom of the people's House. Here is what has happened in our country because of our failure to federally fund embryonic stem cell research: As I think we can all agree, the National Institutes of Health is not only one of the foremost institutions, probably the foremost institution for medical research in the world, but it also stands as the gold standard in the world in defining ethical research. Because NIH is not able to fund embryonic stem cell research, it is limited in its ability to define the ethics for that research, certainly in this country but definitely abroad.

Many here have heard about the embryonic stem cell studies that have been done in South Korea, and frankly, Mr. CASTLE and I, the research community and others have warned for a long time that when you take embryonic stem cell research offshore, not only do you lose your ethical ability to oversee that research, but you also lose the ability to make sure that the studies are done in a scientifically sound manner. We saw what we hoped to be some tremendous advancements in South Korea last year, but now what we are seeing is news out of South Korea that the scientific method and also the ethics have been called into question.

If we allowed ethical stem cell research, looked over by the National Institutes of Health, in this country, this would not happen, and we would have advances in science fueled by the engine of the NIH but also overseen by their ethical guidelines.

That is why we need to pass H.R. 810. We need to make sure that we bring the ethics as well as the scientific method back under the umbrella of the NIH so that we can continue to be a leader in this research in the world.

Mr. Speaker, it is time for the other body of Congress to move forward on swift passage of H.R. 810 so that we can retain our leadership position in the world.

Again, I support the bill that is before us today. It is a very important registry for cord blood, and it is also important for expansion of cord blood for blood diseases that affect so many, including in the minority community, but we also need to move forward with H.R. 810 so that we can have scientific progress that is done in an ethical manner and that will cover the waterfront in curing diseases that will affect millions of Americans.

Mr. Speaker, I reserve the balance of my time.

Mr. DEAL of Georgia. Mr. Speaker, I ask unanimous consent that the gentleman from Texas (Mr. BURGESS) be allowed to control the remainder of the time on our side.

The SPEAKER pro tempore (Mr. BOOZMAN). Is there objection to the request of the gentleman from Georgia?

There was no objection.

Mr. BURGESS. Mr. Speaker, I yield 3 minutes to the gentleman from New Jersey (Mr. SMITH).

Mr. SMITH of New Jersey. Mr. Speaker, I thank my friend for yielding me the time.

Mr. Speaker, it occurred to me on the way to work this afternoon that it is especially fitting that during this season of holiness and faith and surpassing religious significance that Congress send to the President a bill designed to effectuate cures of some of the most devastating diseases and cancers on earth.

Not only has God in His wisdom and goodness created a placenta and umbilical cord to nurture and protect the precious life of an unborn child, but now we know that another gift awaits us immediately after birth. Something very special is left behind, cord blood that is teeming with life-saving stem cells. Indeed, it is one of the best kept secrets in America that umbilical cord blood stem cells and adult stem cells are curing people of a myriad of terrible conditions and disease and are now showing the plasticity and pluripotency that my previous colleague just mentioned. So I would hasten to correct the gentlelady from Colorado that cord blood stem cells are not just for blood-related diseases, it also has the capability increasingly, as research shows, to do other miraculous things as well.

Let me just remind Members that we passed this legislation 6 months ago. Many things have happened since those 6 months. Much progress has been made. This bill will establish a national program to collect upwards of 150,000 units, with great diversity, so that most Americans who suffer from anomalies that could be cured by cord blood will be able to get it.

Let me thank so many people, the Speaker, TOM DELAY, ROY BLUNT, JOE BARTON whom we all pray for and wish a very speedy recovery. Let me thank my friend on the other side of the aisle, the gentleman from Alabama (Mr. DAVIS) and the Congressional Black Caucus for the yeoman's work that they expended in getting this legislation first passed in the House, then passed over on the Senate side, because there was a Democratic hold on it regrettably, TOM HARKIN, but then he lifted it.

Let me especially thank Senator FRIST for the good work he did; SAM BROWNBACK; MIKE ENZI; ORRIN HATCH; JON KYL; so many others as well as so many here; the gentleman from Florida (Mr. WELDON); the gentleman from Pennsylvania (Mr. PITTS); the gentleman from California (Mr. DANIEL E. LUNGREN); the gentleman from Indiana (Mr. PENCE) and I could go on and on. I have a list of three pages of people who have been instrumental in getting this legislation to the point where it will be passed and sent down to the President for signature.

Let me especially thank Cassie Bevan in the Majority Leader's Office

who has worked so hard. She is amazing. John Cusey, on September 11, 2001, put together our first drafting meeting on this legislation. He too is amazing. That is how far back it goes. It has been a long time coming, and so many others. Cheryl Jaeger, Chuck Clapton, Kikki Kless in the Speaker's Office, Nicole Gustafson and Autumn Fredericks in the ProLife Caucus, Eric Euling in Senator FRIST's office and Doug Branch with Senator BROWNBACK and some of the others were outstanding. I will put the full statement in regarding all the many, many fine people who worked on this.

I will insert the remainder of my statement and the material I referred to previously at this point in the RECORD.

Cord-blood stem cells are, as we speak, treating and curing patients. Amazingly, we are on the threshold of systematically turning medical waste, umbilical cords and placentas, into medical miracles for huge numbers of very sick and terminally ill patients who suffer from such maladies as leukemia and sickle cell anemia. And because this legislation promotes cord-blood research as well, we can expect new and expanded uses of these very versatile stem cells.

For the first time ever, our bill establishes a nationwide stem cell transplantation system. It also authorizes the national bone marrow transplant system and combines both under a new program, providing an easy, single-access point for information for doctors and patients and for the purpose of collecting and analyzing outcomes data.

The cord blood stem cell portion of this bill will provide federal funding to increase the number of cord blood units available to match and treat patients. The goal is to reach a total inventory of 150,000 units so that matched stem cells will be available to treat more than 90 percent of patients, especially focusing on providing genetic diversity. The legislation would also link all the cord blood banks participating in the inventory program into a search system that would allow transplant physicians to search for cord blood and bone marrow matches through a single access point. The national program would promote stem cell research by requiring any participating cord blood banks to donate units not suitable for transplant because of disease or size to researchers who are working on new applications for cord blood stem cells. The National Bone Marrow Registry authorization expired on September 30, 2003. The bill reauthorizes an updated program through fiscal year 2010 for \$34 million in FY06 and \$38 million for each additional year of the program.

In the more than 6 months since we passed this bill, even more advances have been made in the field. Peer-reviewed studies have been published showing increased plasticity and flexibility. In August, it was released that cord blood stem cells are as flexible as embryonic stem cells. Two young Maryland siblings have been cured of severe combined immune deficiency syndrome by cord blood from unrelated donors. Victims of Krabbe's and Hurler's diseases have found new hope in cord blood treatments—these are severe genetic neurological diseases that kill most of their victims before they reach 2 years old. A Duke University group treated newborns with cord blood—

the lead author, Dr. Maria Escolar, now reports of the oldest survivor that the seven-year-old is "now running, jumping and doing well in school." Earlier this month, Michelle Farrar from Leesburg, Virginia, traveled to South Korea to be treated for her spinal cord injury. True hope exists for countless other medical conditions, ranging from heart attacks to muscular dystrophy to diabetes.

Just over a month ago, Dr. Brian Mason, an OB/GYN at Detroit's St. John Hospital, explained that "People literally are dying on the transplant list who could be cured with this." I am so happy that for those people, delayed action on this bill has ended. No longer will they be denied access to the cures that are out there. Those suffering from the nearly 70 often terminal diseases will now get the cures that the legislation will make available to them. The door to the treatments that have cured people like Keone Penn, Steven Sprague, and Jacklyn Albanese will now be opened for thousands of others.

As I mentioned before, there are so many people who deserve thanks in helping get this bill moved through the legislative process on both sides of the Hill. Among those people are Rich Doerflinger and Mark Gallagher from the U.S. Conference of Catholic Bishops, Dr. David Prentice and David Christensen from the Family Research Council, the staff of the New York Blood Center including Pablo Rubenstein, Cladd Stevens, and Kathleen Reichert, Sue Ramthun who has been so personally invested in this issue, Dr. Edward Guindi at Cordus and NBA Hall of Famer Julius "Dr. J" Erving, Richie Weiblinger with the Senate Budget Committee, and the folks at Concerned Women for American, Focus on the Family, and the Susan B. Anthony List. I am ecstatic that we are passing it through here today and getting it to the President, so that we may set up this network that will absolutely save thousands of lives.

Ms. DEGETTE. Mr. Speaker, I am delighted to yield 2½ minutes to the gentleman from Alabama (Mr. DAVIS).

Mr. DAVIS of Alabama. Mr. Speaker, I thank my friend from Colorado for yielding.

Let me first begin by congratulating my friend from New Jersey (Mr. SMITH) for what he has done in the last several years, and I thank my friend from New Jersey for letting me walk just a short stem of this path with you. You asked me a couple of years ago to join you as the lead Democratic sponsor on this bill, but let the record very clearly reflect that way before that this was a cause of yours. It was something you believed in very strongly, and I thank you for your persistence, and I thank you for your courage on this issue.

Let me just say a couple of things. First of all, I want to thank our colleagues in the Senate. As the gentleman from New Jersey just said, initially, there was a reluctance to move this bill in the Senate, not because of any doubts about the substance of the bill. This bill has been the classic example of uncontroversial legislation, but there were some in the Senate who believed that this bill should not be given a vote unless the stem cell bill was given a vote.

I understood the force of their argument. I voted for the stem cell bill on

this side. I understood the political analysis they were making, but every now and then, this Chamber gets to do something that shines beyond politics. Every now and then, this Chamber gets to find something that we can give the American people that does not admit to a liberal or conservative or Democrat or Republican level, and in the last 24 hours, that happened.

So I thank Senator HARKIN and I thank Senator REID for deciding to take the politics out of this issue, on our side of the aisle, Democratic side. I thank them for letting this bill come to a vote, and this is a good Christmas present to give to many families around this country who have the tragedy of sickle cell anemia, who have the tragedy of diabetes in their family and who count on some look to science to improve it.

The final point that I will make, I will pick up on what my friend, the gentlewoman from Colorado (Ms. DEGETTE), said. I happen to think that God gave us the power of genius for a reason. God gave us the power of genius to somehow close the gap between this imperfect world and what we could be. This is an example of that power of genius being used to save lives.

I agree with her that stem cell research is an example of the power of genius. So I simply say in conclusion, this is what happens when we find a paradigm, a way of talking about issues that cuts us out of the crisscross of politics.

This is good legislation. I thank the gentleman from New Jersey for working with me on it and urge the Members of this House to pass it.

Mr. BURGESS. Mr. Speaker, it is now my pleasure to yield 2 minutes to the gentlewoman from Ohio (Mrs. SCHMIDT).

(Mrs. SCHMIDT asked and was given permission to revise and extend her remarks.)

Mrs. SCHMIDT. Mr. Speaker, I thank the gentleman from Texas for yielding me this time.

Mr. Speaker, I rise in strong support of H.R. 2520, the Stem Cell Therapeutic Research Act. Cord blood is already making a groundbreaking difference in the treatment of patients who are suffering from over 67 diseases, including leukemia and sickle cell disease. Cord blood is tremendously versatile. Its transplants do not require exact matches. It is frozen, and it is ready to go. It works for adults. Cord blood benefits minority patients who have difficulty finding exact matches and others with rare tissue types.

The possibilities for cord blood in research are almost limitless since cord blood can potentially become any cell type in the body, and it is plentiful, since it is derived from umbilical cords that hospitals routinely discard.

H.R. 2520 will provide Federal funding to increase the number of cord blood units available for patient genetic matching and treatment, link all cord blood banks in a searchable inventory

and promote research in cord blood stem cell research.

This is a bill we can truly support. I urge my colleagues to vote for this legislation that will help create new hope and new opportunities for doctors and patients who are urgently seeking cures.

God always gives us a spare part. Umbilical cords are that spare part.

Ms. DEGETTE. Mr. Speaker, I am happy to yield 2 minutes to the gentleman from Illinois (Mr. LIPINSKI).

Mr. LIPINSKI. Mr. Speaker, I would like to thank my friend from Colorado for yielding me time.

Mr. Speaker, this is a great day for the countless number of Americans who may receive the gift of health and prolonged life because of what will be provided in this bill.

Cord blood and bone marrow stem cell treatments have been proven effective in combating over 65 different debilitating diseases, including leukemia, sickle cell anemia and osteoporosis.

Cord blood transplants have proven to be a viable alternative for those with difficulty finding an exact bone marrow match. Since the match does not have to be exact, this research benefits both children and adults alike and is especially helpful for people of various races and ethnicities. This bill will offer a much greater opportunity for a cure for thousands of Americans around this country who often struggle with blood matches.

But cord blood also holds the great potential of producing pleural potential cells that could cure many other diseases such as juvenile diabetes, a disease that I live with every day.

Mr. Speaker, I am proud that we are acting to advance the possibility that this type of treatment will provide. A national cord blood bank will facilitate the expanded use of proven treatment to improve the health of so many Americans inflicted with these horrible diseases. This is a great Christmas gift of health to the American people.

Mr. BURGESS. Mr. Speaker, it is now my pleasure to yield 2 minutes to the gentleman from Florida (Mr. WELDON), someone who has really been a leader in this issue.

Mr. WELDON of Florida. Mr. Speaker, I thank the gentleman from Texas for yielding me the time, and I rise in strong support of this piece of legislation. I am extremely pleased that we were able to see the Senate finally move it forward and that it is going to move from here on to the President's desk.

The reason I am very pleased is this is not theoretical, as some treatment modalities that we often talk about in this body. This is real and now. There have been 67 different diseases in humans reported in the medical literature successfully treated with cord blood. So we are not even talking about research anymore. We are talking about clinical applications.

Indeed, one of those diseases I am most excited about, and that is sickle

cell anemia. I had the opportunity to treat sickle cell anemia in my clinical practice, and I can tell my colleagues here that is one of the most unfortunate conditions to see a young child writhing in pain on a gurney in an emergency room in a sickle cell crisis. And to be told that cord blood stem cells have cured children with sickle cell anemia, I never thought in my life that I would actually see the day when sickle cell anemia could be cured.

This bill authorizes funds for the expansion of the existing bone marrow bank, which is a bank that essentially I am registered with. It has my name, and if somebody needs a transplant, they can try to find me and get my blood, but in this case, we are taking the placental blood and the cord blood from 3 million live births a year and creating a bank so that everybody would have a match and the potential for regenerative medicine would be here and now.

□ 1615

So I am very, very pleased that we are bringing this to the floor. I am very glad it is finally going to move on to the President's desk, because people will be helped by this now. I am also very delighted to have been part of it, and Mr. SMITH deserves a tremendous amount of credit for his unflagging efforts on this.

Ms. DEGETTE. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Delaware (Mr. CASTLE), my compadre and cosponsor of H.R. 810.

Mr. CASTLE. Mr. Speaker, I thank the gentlewoman from Colorado for yielding me this time, and I am also pleased to rise in support of this legislation, as we did before when it was on the floor of the House of Representatives. I think it does make a difference.

But we do need to understand some of the differences amongst the various things that we are talking about, because this is essentially dealing with a blood type of stem cell. It is great for use in a lot of blood diseases, as has been pointed out, particularly leukemia, lymphoma, and perhaps others at a later time.

But even with those benefits, we need to stress some of the limitations. And one of them is just the difficulty of getting these and the lack of them. I have actually visited a storage location for these and have seen that as a real problem.

Embryonic stem cells, which are in H.R. 810, which Senator FRIST promises will be brought up sometime in the course of the next year, do not have those limitations. It allows these embryonic stem cells to be used in a way that they could be formed into any stem cell in your body, and that is just not true of the cells that are before us here today. They have the potential to treat a wide range of diseases and injuries because they can reproduce themselves almost indefinitely. The best scientific evidence in this country indicates that umbilical stem cells can do neither at this time.

My point is this: we need, as far as I am concerned, to advance all of this type of research. That is really what it is all about. We need to give people an opportunity. We need to understand that one out of three people in the United States of America, and I assume across the world, and perhaps a greater percentage across the world, suffer from some type of disease that could be helped by stem cell research.

For that reason, in my judgment, we need to do everything in our power here in the Congress of the United States to pass any of this legislation that would help advance the medical research that could save or help the lives of so many people across the United States and across the world. For that reason, I absolutely support this legislation.

But I would beseech everybody to really understand the science and the medicine behind all of the stem cell legislation, including embryonic stem cell legislation, so that we can come to agreement as to complete stem cell research to aid everybody. And the sooner we do that, the better. Every day that is lost is a day that somebody is going to be ill longer. And we need to get about it as soon as we possibly can.

Mr. BURGESS. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Pennsylvania (Ms. HART).

Ms. HART. Mr. Speaker, I thank the gentleman for yielding me this time and for the opportunity to speak in support of this bill.

I was here when we passed the bill on the House side earlier in the year; and I am very pleased, especially pleased today, that the Senate chose to agree with us that this is an exceptionally valuable treatment now. And it is one that we must address and make more easily available to all Americans now.

People talk about all different kinds of stem cell research, but cord blood stem cells are being used today. Cord blood has cured people today. Cord blood, if made available, can cure a whole lot of people tomorrow. It is rich in the type of stem cell that is similar to those found in bone marrow, and bone marrow transplants have been done for years. However, cord blood is better. Physicians tell us that it is a better treatment and a treatment that is more likely to be successful.

It makes sense for us in Congress to work hard to try to fund the NIH to help cure diseases. It makes most sense for us to help make available cures that are already known to work. This bill will allow more collection of cord blood stem cells. It will allow the collection and storage of those from diverse populations that currently may not be able to access this kind of treatment. It will help many, many more people who can be cured with cord blood to be cured.

That is what we are about here, Mr. Speaker. The story of Keone Penn, who actually had a connection to my hometown of Pittsburgh, his doctor, now at

the university, helped cure him of a very severe form of sickle cell anemia with treatment from cord blood. Anthony Dones, who had a cord blood transplant, was cured of a very rare form of osteoporosis using cord blood. Katherine Marguerite Sutter, at only 5 months was diagnosed with AML. She too was cured by use of cord blood, and the story I like the most, because on the Web site for the New York Cord Blood Center, it shows a picture of her in her wedding gown. She suffered through transfusions for 20 years before she too was cured with cord blood.

Mr. Speaker, I am very pleased to be here today and also very pleased to have bipartisan support for this bill, because it will help many, many more people tomorrow.

Ms. DEGETTE. Mr. Speaker, I am happy to yield 2 minutes to the gentleman from California (Ms. MILLENDER-MCDONALD).

Ms. MILLENDER-MCDONALD. Mr. Speaker, I want to thank Representative CHRIS SMITH for his tireless efforts in bringing this very important life-saving legislation forward and getting me to work with him to get the Senate to do the right thing and put this forward.

I would also like to say I supported the stem cell research bill also because I feel it has a broader significance to lifesaving measures. In this 21st century, we cannot afford to not look at both of these as provisions for helping to save the lives of American people. This is why I stand before you today in support of H.R. 2520.

Too many members of the minority population live with life-threatening diseases. We must provide them with the benefits of cord blood stem cells. Cord blood stem cells can be used for bone marrow reconstitution by transplantation to recipients with certain abnormalities such as leukemia and lymphoma, genetic disorders such as sickle cell anemia, and acquired diseases.

The promise of using stem cells for medical treatment has been the focus of research projects that are showing encouraging results. Cord blood stem cells have been triggered to differentiate into neural cells, which could lead to treatments for diseases such as Alzheimer's and Parkinson's. They have also proven their ability to turn into blood vessel cells, which could someday benefit treatment for heart disease, allowing patients to essentially grow their own bypass.

We need the hope that cord blood stem cells can bring. Sickle cell anemia is the most common inherited blood disorder in the United States, affecting 70,000 to 80,000 Americans. The disease occurs in approximately one in 500 African American newborns. People with sickle cell disease have a diminished quality of life and greatly enhanced fatality rate.

The suffering has gone on far too long. We must use every resource at our disposal to cure this and other

blood-related diseases. In my district, I have a lot of young children who have sickle cell disease. These cord blood cells would certainly help in furthering their lives.

I ask all my colleagues to please support H.R. 2520. I believe it should pass today.

Mr. BURGESS. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from Nebraska (Mr. FORTENBERRY).

Mr. FORTENBERRY. Mr. Speaker, this is a bright day for many individuals suffering from previously untreatable diseases, and I commend our colleagues in the Senate for passing the Stem Cell Therapeutic Research Act of 2005. It was the right thing to do. It will save many lives and avoid the ethically divisive issue of the destruction of human embryos for stem cell research.

As we have heard today, cord blood stem cells have helped effectively treat over 67 diseases in human beings, including leukemia, sickle cell, lupus, multiple sclerosis, type I diabetes, Parkinson's, and even blindness. Cord blood cells show great promise for helping spinal cord patients, many of whom have experienced improved sensation and movement from cord blood stem cell treatments.

Cord blood stem cells also possess the regenerative flexibility to form virtually every type of human tissue. And research has shown these cells are far less susceptible to transplant rejection than bone marrow.

I want to commend my colleague, Mr. SMITH, for his tireless effort in this regard, and for the leadership of Mr. DAVIS on this important issue. Their efforts transcend political differences. Mr. Speaker, this bill truly represents good science.

Ms. DEGETTE. Mr. Speaker, I yield 1½ minutes to the gentleman from Texas (Ms. JACKSON-LEE).

Ms. JACKSON-LEE of Texas. Mr. Speaker, I want to thank the distinguished gentleman from Colorado for yielding me this time and for the leadership she has given, along with the Congressman from Delaware on this stem cell legislation, and we hope that we will see that move.

I want to thank Mr. SMITH, Mr. DAVIS, Ms. MILLENDER-MCDONALD, and the many others who have been so supportive on this legislation, the collection and maintenance of human cord blood stems. Just a few minutes from now we will be discussing the NASA reauthorization bill, and I raise that point because I believe it is the mission of the United States to be at the forefront of science and research to save lives.

The world looks to our leadership, our labs, our scientists, our inventors, our medical professionals as they do to the Texas Medical Center to be able to add enhancement to the quality of lives. In my community alone, I realize that the organizations that fight against leukemia, multiple sclerosis,

lupus, and sickle cell anemia are looking forward to the passage of this legislation and a new day of research.

Those newborn African American babies who are born with sickle cell also will benefit from this kind of research. But this does not highlight a particular minority group. This research, this maintenance of the human cord blood stem cells will in actuality provide the underpinnings of the research for all kinds of medical science.

So I ask my colleagues to support this legislation. And the important aspect of it singularly is for America to take her rightful and prominent place in medical research to save lives around the world.

Mr. BURGESS. Mr. Speaker, I am pleased to yield 2 minutes to the gentleman from California (Mr. DANIEL E. LUNGREN).

Mr. DANIEL E. LUNGREN of California. Mr. Speaker, I rise in strong support of H.R. 2520. The fact of the matter is, I believe all of us would like to support the application of science and technical research to the problems of the day. There are times when we have moral dilemmas, and reference has been made to another bill involving embryonic stem cells which does divide many people in this country because of the ethical dilemma that is presented.

That is why it is so wonderful we have come today in support, those who may find themselves on the other side of the dilemma in the other respect, and come in common support for the cord blood stem cell bill. This is both a therapeutic and research bill. It is therapeutic in that it affords the banking of units that will be allowed to help people now, diseases that can be affected by the use of these units now.

So much of what we do here is theoretical. We hope that things might be accomplished by what we do. But we know that this will accomplish success right away. Secondly, it allows for research to see how far we can go in this area. It gives the opportunity for this which would otherwise be thrown away, placenta blood and the blood from the cord that is thrown away now on every single day, to be utilized for both research and for life-giving purposes.

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Mr. Speaker, if I had the ability to, I would change the name of this bill to the Giving Life Twice bill, once with the production of new life and secondly with the use of that blood that otherwise would be thrown away to help someone else sustain their life; or we could call this the Lifeline bill. We are extending a lifeline of hope to those who otherwise would have no hope.

This is a joyous day here in this body. People may disagree on other matters, coming together in strong support for a bill that will save lives and save lives now.

Ms. DEGETTE. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, today we are fortunate to take the first step of what I see as a

two-step process, and that is passage of this cord blood bill which, as I said, we passed last May in this House by an overwhelming vote.

The second step, of course, will be when the other body passes H.R. 810, which also passed last May, and when that bill is finally signed into law.

The two bills working together will greatly expand availability of research and of cures for Americans who suffer not just from blood-related diseases but from diseases like Alzheimer's, Parkinson's, nerve damage, and so many other diseases that cannot be reached simply by cord blood. That is the day that a true dawning of a new scientific era will occur in this country.

This is a good bill today, and I urge all of my colleagues to support it, and I want to thank my colleagues on both sides of the aisle for their co-sponsorship. But let us be clear exactly what this bill does. It authorizes a new granted program to provide subsidies to cord blood stem cell banks to expand the inventory of high quality cord blood units. It sets up a registry for cord blood, which will in some cases take the place of bone marrow transplants which it is beginning to supersede. This will be enormously important, particularly for sickle cell patients who will be helped. The bill also authorizes research on the clinical outcomes of patients who are recipients of a stem cell therapeutics product from biologically related and unrelated donors. That is what this bill does. This bill does not set up any cures for any diseases, nor does it do anything to put ethical controls onto stem cell research and other types of research that are scientifically being explored now and need the oversight of the National Institutes of Health.

So this is a good start. I commend all my colleagues. It is going to make us all feel good to go home for the holidays knowing that certain classes of patients will be helped. But I would say to my friends on both sides of the aisle, let us not stop there. In the second session of this Congress, let us take the bold scientific step necessary to provide cures for diseases that affect tens of millions of Americans and citizens around the world.

Mr. Speaker, I yield back the balance of my time.

Mr. BURGESS. Mr. Speaker, I yield myself the remaining time.

Mr. Speaker, I believe this is a bold scientific step to pass this legislation today, and I am pleased that the Senate released their hold on it and passed this bill. It is good legislation.

We heard during the arguments on the previous bill that was debated here on the floor, science certainly moves a lot more swiftly than the legislative process, and that is certainly true in this case today. By allowing this bill, we are going to allow hundreds, perhaps thousands of Americans the opportunity for a cure that we were withholding by delaying passage of this bill.

I have heard diseases like Alzheimer's and Parkinson's referenced. Alzheimer's and Parkinson's, unfortunately, are unlikely to be cured by umbilical cord stem cells, but they are also unlikely to be cured by embryonic stem cell research. The promise for cure for these diseases lies in protein science and our understanding of the human genome, not in stem cell research.

This bill is a good bill because it authorizes a significant amount of money for the collection, the documentation and the maintenance of 150,000 new stem cell lines. These are pluripotential cells.

What has changed since we had our debate on the stem cell lines here last spring? Well, we have read a lot of stuff in the newspapers just the past 2 weeks about some of the changes, some of the research that has now been withdrawn. Think about this, Mr. Speaker: We do not even know what research is just out there over the horizon. What if we unlock some of the proteinemic keys that allow us to understand what signals one cell to another? What if we could make the umbilical cord stem cell behave more like the embryonic stem cell? Think of that, Mr. Speaker. Then we have got 150,000 lines banked and ready to go when that research which is being done in my home State of Texas at the University of Texas Southwestern Medical School, if that research shows the promise that it one day may, we will have 150,000 cell lines banked and ready to go.

Mr. Speaker, this procedure, this technique, this ability to bank umbilical cord cells allows for there to be greater diversity within the marrow donor pool than was previously known. It has been difficult to get minority populations to become marrow donors. Now we will be able to collect that cell material at the time of birth painlessly, at no risk to anyone, material that was otherwise going to be discarded, and it will be put into these stem cell lines. And the database will be there for people to reference and find these life-saving cures that will be now available by umbilical cord stem cells.

We are expanding America's inventory of cord blood cells today, and that is a good thing for all Americans. Whether they are sick or not, one day they may need this technology. We have the ability and the capacity within our hands to expand this program and save American lives, and I say that is a good thing.

Ms. EDDIE BERNICE JOHNSON of Texas. Mr. Speaker, I rise today in support of H.R. 2520, the Stem Cell Therapeutic and Research Act of 2005.

Long before my days as the Ranking Member on the Research Subcommittee, I have been a strong advocate of all types of research.

Stem cell research holds the potential to help paralyzed people walk, help blind people see, and re-generate organ tissue without immune rejection.

As our colleagues on the other side of the Capitol concur, H.R. 2520 is a good start. This bill would allow the Secretary of Health and Human Services to work with cord blood banks to collect and maintain cord blood for the purpose of stem cell research.

The cord blood would be collected with informed consent, in a manner that complies with Federal and State regulations, and from a genetically diverse population.

It is my hope that this legislation will give us a taste of the marvelous potential of stem cell research, and I urge my colleagues to support this legislation.

Mr. HOLT. Mr. Speaker, I rise to congratulate the State of New Jersey on its national leadership in efforts to treat deadly and debilitating illnesses. Yesterday, New Jersey became the first State in the Nation to award public funds to conduct human embryonic stem cell research.

Under the leadership of Acting Governor Richard Codey and NJCST Executive Director Sherrie Preische, the New Jersey Commission on Science and Technology (NJCST) will award 17 grants totaling \$5 million to scientists at corporate, non-profit, and university laboratories to research the potential of stem cells as a means to diagnose, treat, cure, and prevent disease. Each scientist will receive around \$300,000 to conduct their research. Three of these grants will go to scientists researching embryonic stem cells.

Since the formation of the New Jersey Stem Cell Institute, New Jersey has established itself as a leader in furthering potentially life-saving research on adult stem cells. And by awarding these research grants, New Jersey is actively working to support groundbreaking research on embryonic stem cells, which hold great promise in improving health care as we know it.

Embryonic stem cells—undifferentiated cells produced early in embryonic development—offer possible treatments for a variety of diseases from cancer to Parkinson's disease to diabetes. Ultimately, scientists may be able to develop reparative tissue, treat a host of debilitating diseases, and even generate organs specifically tailored to a person's unique genetic blueprint. This research offers mankind the prospect of overcoming devastating diseases, affording us the opportunity to live longer, healthier lives. For these advances to take place, we must invest public funding in critical research to support scientists, rather than restrict them.

I am proud that the people of New Jersey have committed public funds for this important research, and I am glad that New Jersey has moved quickly to distribute grants to researchers so that their work can begin. I am particularly pleased that these grants were awarded after exhaustive ethical review led by former Princeton University President Harold Shapiro, and that research ethics will play an important role as the awardees move forward with their research.

I am confident that States who have established programs with similar goals will move quickly to support this research as well. But despite the forward thinking and progressive research that New Jersey and other states are exploring, it is unfortunate that the Federal Government has delayed and restricted research using federal dollars. I am hopeful that the leadership of New Jersey to fund embryonic stem cell research will have tremendous

dividends, not just for New Jersey, but for society. New Jersey understands that it is ethical and wise to invest in research that will benefit so many. The Federal Government must recognize this fact as well.

Again, I congratulate New Jersey for supporting ground-breaking research on embryonic stem cells. I ask unanimous consent to include a list of the researchers who have received these important stem cell research grants in the RECORD.

Mr. BURGESS. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. BOOZMAN). The question is on the motion offered by the gentleman from Georgia (Mr. DEAL) that the House suspend the rules and concur in the Senate amendment to the bill, H.R. 2520.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mr. BURGESS. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this question will be postponed.

#### STATE HIGH RISK POOL FUNDING EXTENSION ACT OF 2005

Mr. BURGESS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4519) to amend the Public Health Service Act to extend funding for the operation of State high risk health insurance pools.

The Clerk read as follows:

H.R. 4519

*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 "State High Risk Pool Funding Extension Act of 2005".

##### SEC. 2. EXTENSION OF FUNDING FOR OPERATION OF STATE HIGH RISK HEALTH INSURANCE POOLS.

Section 2745 of the Public Health Service Act (42 U.S.C. 300gg-45) is amended to read as follows:

##### "SEC. 2745. RELIEF FOR HIGH RISK POOLS.

"(a) SEED GRANTS TO STATES.—The Secretary shall provide from the funds appropriated under subsection (d)(1)(A) a grant of up to \$1,000,000 to each State that has not created a qualified high risk pool as of the date of enactment of the State High Risk Pool Funding Extension Act of 2005 for the State's costs of creation and initial operation of such a pool.

"(b) GRANTS FOR OPERATIONAL LOSSES.—

"(1) IN GENERAL.—In the case of a State that has established a qualified high risk pool that—

"(A) restricts premiums charged under the pool to no more than 200 percent of the premium for applicable standard risk rates;

"(B) offers a choice of two or more coverage options through the pool; and

"(C) has in effect a mechanism reasonably designed to ensure continued funding of losses incurred by the State in connection with operation of the pool after the end of the last fiscal year for which a grant is provided under this paragraph;

the Secretary shall provide, from the funds appropriated under paragraphs (1)(B)(i) and (2)(A) of subsection (d) and allotted to the State under paragraph (2), a grant for the losses incurred by the State in connection with the operation of the pool.

"(2) ALLOTMENT.—Subject to paragraph (4), the amounts appropriated under paragraphs (1)(B)(i) and (2)(A) of subsection (d) for a fiscal year shall be allotted and made available to the States (or the entities that operate the high risk pool under applicable State law) that qualify for a grant under paragraph (1) as follows:

"(A) An amount equal to 40 percent of such appropriated amount for the fiscal year shall be allotted in equal amounts to each qualifying State that is one of the 50 States or the District of Columbia and that applies for a grant under this subsection.

"(B) An amount equal to 30 percent of such appropriated amount for the fiscal year shall be allotted among qualifying States that apply for such a grant so that the amount allotted to such a State bears the same ratio to such appropriated amount as the number of uninsured individuals in the State bears to the total number of uninsured individuals (as determined by the Secretary) in all qualifying States that so apply.

"(C) An amount equal to 30 percent of such appropriated amount for the fiscal year shall be allotted among qualifying States that apply for such a grant so that the amount allotted to a State bears the same ratio to such appropriated amount as the number of individuals enrolled in health care coverage through the qualified high risk pool of the State bears to the total number of individuals so enrolled through qualified high risk pools (as determined by the Secretary) in all qualifying States that so apply.

"(3) SPECIAL RULE FOR POOLS CHARGING HIGHER PREMIUMS.—In the case of a qualified high risk pool of a State which charges premiums that exceed 150 percent of the premium for applicable standard risks, the State shall use at least 50 percent of the amount of the grant provided to the State to carry out this subsection to reduce premiums for enrollees.

"(4) LIMITATION FOR TERRITORIES.—In no case shall the aggregate amount allotted and made available under paragraph (2) for a fiscal year to States that are not the 50 States or the District of Columbia exceed \$1,000,000.

##### "(c) BONUS GRANTS FOR SUPPLEMENTAL CONSUMER BENEFITS.—

"(1) IN GENERAL.—In the case of a State that is one of the 50 States or the District of Columbia, that has established a qualified high risk pool, and that is receiving a grant under subsection (b)(1), the Secretary shall provide, from the funds appropriated under paragraphs (1)(B)(i) and (2)(B) of subsection (d) and allotted to the State under paragraph (3), a grant to be used to provide supplemental consumer benefits to enrollees or potential enrollees (or defined subsets of such enrollees or potential enrollees) in qualified high risk pools.

"(2) BENEFITS.—A State shall use amounts received under a grant under this subsection to provide one or more of the following benefits:

"(A) Low-income premium subsidies.

"(B) A reduction in premium trends, actual premiums, or other cost-sharing requirements.

"(C) An expansion or broadening of the pool of individuals eligible for coverage, such as through eliminating waiting lists, increasing enrollment caps, or providing flexibility in enrollment rules.

"(D) Less stringent rules, or additional waiver authority, with respect to coverage of pre-existing conditions.

"(E) Increased benefits.