

## HR 2520

Stem Cell Therapeutic and Research Act of 2005

**Congress:** 109 (2005–2007, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** May 23, 2005

**Current Status:** Became Public Law No: 109-129.

**Latest Action:** Became Public Law No: 109-129. (Dec 20, 2005)

**Law:** 109-129 (Enacted Dec 20, 2005)

**Official Text:** <https://www.congress.gov/bill/109th-congress/house-bill/2520>

### Sponsor

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**Name:** Rep. Smith, Christopher H. [R-NJ-4]

**Party:** Republican • **State:** NJ • **Chamber:** House

**Cosponsors** (78 total)

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| Rep. Hastings, Doc [R-WA-4]             | R · WA               |             | May 23, 2005       |
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| Rep. Shimkus, John [R-IL-19]               | R · IL        |      | May 23, 2005 |
| Rep. Sodrel, Michael E. [R-IN-9]           | R · IN        |      | May 23, 2005 |
| Rep. Souder, Mark E. [R-IN-3]              | R · IN        |      | May 23, 2005 |
| Rep. Stearns, Cliff [R-FL-6]               | R · FL        |      | May 23, 2005 |
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| Rep. Sullivan, John [R-OK-1]               | R · OK        |      | May 23, 2005 |
| Rep. Tancredo, Thomas G. [R-CO-6]          | R · CO        |      | May 23, 2005 |
| Rep. Terry, Lee [R-NE-2]                   | R · NE        |      | May 23, 2005 |
| Rep. Towns, Edolphus [D-NY-10]             | D · NY        |      | May 23, 2005 |
| Rep. Walsh, James T. [R-NY-25]             | R · NY        |      | May 23, 2005 |
| Rep. Wamp, Zach [R-TN-3]                   | R · TN        |      | May 23, 2005 |
| Rep. Weldon, Dave [R-FL-15]                | R · FL        |      | May 23, 2005 |

## Committee Activity

| Committee                     | Chamber | Activity    | Date         |
|-------------------------------|---------|-------------|--------------|
| Energy and Commerce Committee | House   | Referred to | May 24, 2005 |

## Subjects & Policy Tags

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### Policy Area:

Health

### Related Bills

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| Bill          | Relationship      | Last Action  |
|---------------|-------------------|--|
| 109 S<br>1317 | Companion<br>bill | <b>Aug 31, 2005:</b> By Senator Enzi from Committee on Health, Education, Labor, and Pensions filed written report under authority of the order of the Senate of 07/29/2005. Report No. 109-129. |

**(This measure has not been amended since it was passed by the Senate on December 16, 2005. The summary of that version is repeated here.)**

Stem Cell Therapeutic and Research Act of 2005 - (Sec. 2) Requires the Secretary of Health and Human Services to contract with qualified cord blood stem cell 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. Requires the Secretary to require that contract recipients: (1) acquire, tissue-type, test, cryopreserve, and store donated units of human cord blood acquired with the informed consent of the donor in a manner that complies with federal and state regulations; (2) encourage donation from a genetically diverse population; (3) make collected cord blood units available for stem cell transplantation or, if not appropriate for clinical use, available for peer-reviewed research; (4) make data available in a standardized electronic format for the Program; and (5) submit data in a standardized format for inclusion in the stem cell therapeutics outcome database.

Requires the Secretary to establish a three-year demonstration project under which qualified cord blood banks may use a portion of the funding received under a contract for the collection and storage of cord blood units for a family where a relative has been diagnosed with a condition that will benefit from transplantation at no cost to such family. Excludes cord blood collected under such project from the 150,000 units to be collected for the Program. Sets forth reporting requirements.

Establishes ten years as the term of such Program contracts. Requires the Secretary to give preference to qualified cord blood banks that have demonstrated a superior ability to satisfy the requirements and achieve the contract goals. Authorizes appropriations.

(Sec. 3) Amends the Public Health Service Act to rewrite provisions requiring the Secretary to establish and maintain a National Bone Marrow Donor Registry to require the Secretary, acting through the Administrator of the Health Resources and Services Administration (HRSA), to establish and maintain the C.W. Bill Young Cell Transplantation Program to increase the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood. Requires the Secretary to establish a related advisory council on Program activities.

Requires the Secretary to: (1) recognize one or more accreditation entities for the accreditation of cord blood banks; and (2) examine issues of informed consent, including the timing of such consent and the information provided to the maternal donor regarding all of her medically appropriate cord blood options.

Adds as Program requirements with respect to bone marrow: (1) permitting transplant physicians, other health care professionals, and patients to search by means of electronic access all available bone marrow donors listed in the Program; (2) maintaining and expanding medical contingency response capabilities 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 (3) facilitating research with federal agencies to improve the availability, efficiency, safety, and cost of transplants from unrelated donors and the effectiveness of Program operations.

Sets forth Program requirements with respect to cord blood, including: (1) operating a system for identifying, matching, and facilitating the distribution from a qualified cord blood bank of donated cord blood units that are suitably matched to candidate patients and meet all applicable federal and state regulations; (2) allowing transplant physicians, other health

care professionals, and patients to search by means of electronic access all available cord blood units made available through the Program; (3) allowing transplant physician and other health care professionals to reserve a cord blood unit for transplantation; (4) supporting studies and demonstration and outreach projects for the purpose of increasing cord blood donation to ensure a genetically diverse collection of cord blood units; (5) providing for a system of patient advocacy; (6) coordinating with the qualified cord blood banks to support informational and educational activities; (7) maintaining and expanding medical contingency response capabilities to prepare for and respond to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow; and (8) collecting, analyzing, and publishing data in a standardized electronic format on the number and percentage of patients at each of the various stages of the search process.

Requires the Secretary to: (1) ensure that health care professionals and patients are able to search electronically for and facilitate access to cells from bone marrow donors and cord blood units through a single point of access; and (2) require all contract recipients under this Act to make data available in a standardized electronic format that enables transplant physicians to compare among bone marrow donors and cord blood units to ensure the best possible match for the patient.

Requires the Program to carry out activities for the recruitment of bone marrow donors and cord blood donors, including by (1) identifying populations that are underrepresented among potential donors enrolled with the Program; (2) giving priority to increasing representation for such populations; and (3) considering racial and ethnic minority groups to be such populations.

Requires the Program to carry out informational and educational activities to recruit individuals to serve as donors of bone marrow and pregnant women to serve as donors of cord blood, including by: (1) making information available to the general public; (2) educating and providing information to potential donors; (3) training individuals in requesting donors; (4) giving priority to recruiting donors for underrepresented populations; and (5) providing information to physicians, other health care professionals, and the public regarding bone marrow transplants from unrelated donors and cord blood transplants for donors as treatment options.

Requires the Secretary to enforce for participating entities: (1) quality standards and standards for tissue-typing, obtaining the informed consent of donors, and providing patient advocacy; (2) donor selection criteria to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases; (3) procedures to ensure the proper collection and transportation of the marrow; (4) standards for patient advocacy; and (5) confidentiality standards.

Requires the Secretary to establish and maintain an office of patient advocacy to: (1) operate a system for patient advocacy to serve patients for whom the Program is searching for a bone marrow donor or cord blood unit; (2) serve as an advocate for the patient by directly providing individualized services on the efficient utilization of the system to conduct an ongoing search and assist with information regarding third party payors; (3) monitor the searching system to determine whether the needs of the patient involved are being met; (4) conduct surveys of patients, family members, physicians, or other individuals acting on behalf of a patient to determine the extent of satisfaction with the system for patient advocacy; (5) provide individualized case management services; and (6) provide information and education on the process of receiving a transplant after a completed search.

Requires the Secretary to give consideration to the continued safety of donors and patients and other factors in awarding contracts under this Act. Requires contract recipients to keep records. Prescribes criminal penalties for violations of confidentiality provisions.

Requires the Secretary to establish and maintain a scientific database of information relating to recipients of a stem cell therapeutics product, including bone marrow and cord blood, from a donor. Requires the database to make relevant scientific information not containing individually identifiable information available to the public to encourage medical research and to provide information to interested parties.

Authorizes appropriations.

(Sec. 4) Requires the Secretary to submit to Congress a report on the progress made by the Food and Drug Administration (FDA) in developing requirements for the licensing of cord blood units.

## Actions Timeline

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- **Dec 20, 2005:** Signed by President.
- **Dec 20, 2005:** Became Public Law No: 109-129.
- **Dec 19, 2005:** Presented to President.
- **Dec 17, 2005:** Mr. Deal (GA) moved that the House suspend the rules and agree to the Senate amendment. (consideration: CR H12063-12072, H12142-12143)
- **Dec 17, 2005:** DEBATE - The House proceeded with forty minutes of debate on the motion to suspend the rules and agree to the Senate amendment to H.R. 2520.
- **Dec 17, 2005:** At the conclusion of debate, the Yeas and Nays were demanded and ordered. Pursuant to the provisions of clause 5, rule I, the chair announced that further proceedings on the motion would be postponed.
- **Dec 17, 2005:** Resolving differences -- House actions: On motion that the House suspend the rules and agree to the Senate amendment Agreed to by the Yeas and Nays: (2/3 required): 413 - 0 (Roll no. 664).(text as House agree to Senate amendment: CR H12063-12066)
- **Dec 17, 2005:** On motion that the House suspend the rules and agree to the Senate amendment Agreed to by the Yeas and Nays: (2/3 required): 413 - 0 (Roll no. 664). (text as House agree to Senate amendment: CR H12063-12066)
- **Dec 17, 2005:** Motion to reconsider laid on the table Agreed to without objection.
- **Dec 17, 2005:** Cleared for White House.
- **Dec 16, 2005:** Measure laid before Senate by unanimous consent. (consideration: CR S13930-13931)
- **Dec 16, 2005:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.
- **Dec 16, 2005:** Passed Senate with an amendment by Unanimous Consent.
- **Dec 16, 2005:** Message on Senate action sent to the House.
- **Oct 24, 2005:** Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 256.
- **May 26, 2005:** Received in the Senate.
- **May 24, 2005:** Mr. Barton (TX) moved to suspend the rules and pass the bill.
- **May 24, 2005:** Considered under suspension of the rules. (consideration: CR H3795-3809)
- **May 24, 2005:** DEBATE - The House proceeded with forty minutes of debate on H.R. 2520.
- **May 24, 2005:** At the conclusion of debate, the Yeas and Nays were demanded and ordered. Pursuant to the provisions of clause 8, rule XX, the Chair announced that further proceedings on the motion would be postponed.
- **May 24, 2005:** Referred to the Subcommittee on Health.
- **May 24, 2005:** Considered as unfinished business. (consideration: CR H3852)
- **May 24, 2005:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 431 - 1 (Roll no. 205).(text: CR H3795-3797)
- **May 24, 2005:** On motion to suspend the rules and pass the bill Agreed to by the Yeas and Nays: (2/3 required): 431 - 1 (Roll no. 205). (text: CR H3795-3797)
- **May 24, 2005:** Motion to reconsider laid on the table Agreed to without objection.
- **May 23, 2005:** Introduced in House
- **May 23, 2005:** Referred to the House Committee on Energy and Commerce.

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