

## S 1317

Stem Cell Therapeutic and Research Act of 2005

**Congress:** 109 (2005–2007, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Jun 27, 2005

**Current Status:** By Senator Enzi from Committee on Health, Education, Labor, and Pensions filed written report under

**Latest Action:** 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. (Aug 31, 2005)

**Official Text:** <https://www.congress.gov/bill/109th-congress/senate-bill/1317>

### Sponsor

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**Name:** Sen. Hatch, Orrin G. [R-UT]

**Party:** Republican • **State:** UT • **Chamber:** Senate

**Cosponsors** (34 total)

<b>Cosponsor</b>	<b>Party / State</b>	<b>Role</b>	<b>Date Joined</b>
Sen. Burr, Richard [R-NC]	R · NC		Jun 27, 2005
Sen. Dodd, Christopher J. [D-CT]	D · CT		Jun 27, 2005
Sen. Ensign, John [R-NV]	R · NV		Jun 27, 2005
Sen. Reed, Jack [D-RI]	D · RI		Jun 27, 2005
Sen. Brownback, Sam [R-KS]	R · KS		Jun 28, 2005
Sen. Clinton, Hillary Rodham [D-NY]	D · NY		Jun 28, 2005
Sen. Collins, Susan M. [R-ME]	R · ME		Jun 28, 2005
Sen. Frist, William H. [R-TN]	R · TN		Jun 28, 2005
Sen. Harkin, Tom [D-IA]	D · IA		Jun 28, 2005
Sen. Mikulski, Barbara A. [D-MD]	D · MD		Jun 28, 2005
Sen. Murray, Patty [D-WA]	D · WA		Jun 28, 2005
Sen. Schumer, Charles E. [D-NY]	D · NY		Jun 28, 2005
Sen. Talent, Jim [R-MO]	R · MO		Jun 28, 2005
Sen. Voinovich, George V. [R-OH]	R · OH		Jun 28, 2005
Sen. DeWine, Mike [R-OH]	R · OH		Jun 29, 2005
Sen. Dole, Elizabeth [R-NC]	R · NC		Jun 29, 2005
Sen. Feinstein, Dianne [D-CA]	D · CA		Jun 29, 2005
Sen. Roberts, Pat [R-KS]	R · KS		Jun 29, 2005
Sen. Grassley, Chuck [R-IA]	R · IA		Jun 30, 2005
Sen. Hagel, Chuck [R-NE]	R · NE		Jul 1, 2005
Sen. Durbin, Richard J. [D-IL]	D · IL		Jul 11, 2005
Sen. Kyl, Jon [R-AZ]	R · AZ		Jul 13, 2005
Sen. Pryor, Mark L. [D-AR]	D · AR		Jul 14, 2005
Sen. Thune, John [R-SD]	R · SD		Jul 14, 2005
Sen. Specter, Arlen [R-PA]	R · PA		Jul 15, 2005
Sen. Jeffords, James M. [I-VT]	I · VT		Jul 20, 2005
Sen. Enzi, Michael B. [R-WY]	R · WY		Jul 21, 2005
Sen. Lugar, Richard G. [R-IN]	R · IN		Jul 22, 2005
Sen. Chambliss, Saxby [R-GA]	R · GA		Jul 29, 2005
Sen. Isakson, Johnny [R-GA]	R · GA		Sep 6, 2005
Sen. Bayh, Evan [D-IN]	D · IN		Oct 6, 2005
Sen. Coleman, Norm [R-MN]	R · MN		Oct 17, 2005
Sen. Murkowski, Lisa [R-AK]	R · AK		Dec 12, 2005
Sen. Santorum, Rick [R-PA]	R · PA		Dec 14, 2005

**Committee Activity**

<b>Committee</b>	<b>Chamber</b>	<b>Activity</b>	<b>Date</b>
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Jul 11, 2005

## Subjects & Policy Tags

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### Policy Area:

Health

### Related Bills

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Bill	Relationship	Last Action
109 HR 2520	Companion bill	<b>Dec 20, 2005:</b> Became Public Law No: 109-129.

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.

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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- **Aug 31, 2005:** 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.
- **Jul 11, 2005:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Enzi with an amendment in the nature of a substitute. Without written report.
- **Jul 11, 2005:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 156.
- **Jun 29, 2005:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jun 27, 2005:** Introduced in Senate
- **Jun 27, 2005:** Sponsor introductory remarks on measure. (CR S7433)
- **Jun 27, 2005:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S7434-7437)

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