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# Stem Cell Research

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## Summary

On August 9, 2001, President Bush announced that for the first time federal funds will be used to support research on human embryonic stem cells, but funding will be limited to "existing stem cell lines." According to the President's speech, more than 60 stem cell lines currently exist. However, a June 2001 National Institutes of Health (NIH) report on stem cell research states that about 30 cell lines have been derived from embryos or fetal tissue, another source of cells with very similar properties. The NIH report also states that research studies "indicate that it is now possible to grow these cells for up to two years" in the laboratory, implying that their life span or utility may be limited.

Embryonic stem cells have the ability to develop into virtually any cell in the body, and may have the potential to treat medical conditions such as diabetes and Parkinson's disease. In January 1999 the Department of Health and Human Services determined that the current ban on federal funding of human embryo research does not prohibit funding human embryonic stem cell research. NIH published guidelines for support of such research in August 2000. These actions rekindled debate over the difficult ethical and social issues surrounding embryo and fetal tissue research. Some Members of Congress strongly disagreed with the HHS decision and believe such research is banned by a rider that affected NIH funding for FY1996 and has been attached to the Labor, HHS and Education appropriations acts for FY1997-FY2001.

In the past, President Bush had stated he did not support federal funding of research on stem cells derived from either human embryos or fetal tissue obtained via abortion but would support research using cells derived from fetal tissue obtained via miscarriages. However, many scientists contend that such tissue is for the most part unsuitable for research due to the presence of genetic defects. Others point to the potential of adult stem cells obtained from tissues such as bone marrow. They argue that adult stem cells should be pursued instead of embryonic stem cells because they believe the derivation of stem cells from either embryos or aborted fetuses is ethically unacceptable. Other scientists believe adult stem cells should not be the sole target of research because of important scientific and technical limitations.

The 107th Congress has begun consideration of several bills on the topic of stem cell research and the related area of human cloning. On July 31, 2001, the House rejected **H.R. 2172** (Greenwood) and passed **H.R. 2505** (Weldon). **H.R. 2172** would ban human cloning only when it is used in human reproduction. In contrast, **H.R. 2505** (**S. 790**, Brownback) would ban the process of human cloning when it is used for reproductive purposes as well as research and therapeutic uses of human cloning which would involve stem cells. **S. 723** (Specter) and **H.R. 2059** (McDermott) would give NIH authority to fund the derivation of stem cells from embryos, an activity forbidden under the NIH guidelines and prohibited by the appropriation bill rider. These bills would prohibit support of embryo research unrelated to stem cells and would therefore create a more permanent legislative prohibition than the appropriations rider, which must be renewed each year. This report, which will be updated as needed, discusses the status of research and key issues associated with human embryonic stem cells.

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## Background: Basic Research and Potential Applications

**Basic Research.** Although most cells within an animal or human being are committed to fulfilling a single function in an organ like the skin or heart, a unique and important set of cells exists that is not so specialized. These *stem cells* – cells that retain the ability to become many or all of the different cell types in the body – play a critical role in repairing organs and body tissues throughout life. Although the term "stem cells" refers to these repair cells within an adult organism, a more fundamental variety of stem cells is found in the early stage embryo. These embryonic stem cells may have a greater ability to become different types of body cells than adult stem cells.

The earliest embryonic stem cells are referred to as *totipotent*, indicating that they can develop into an entire organism because they can produce both the embryo and the tissues required to support it in the uterus. Later in development, embryonic stem cells lose the ability to form these supporting tissues, but are still able to develop into almost any cell type found in the body. These *pluripotent* embryonic stem cells are the current focus of intense research interest.

**Possible Sources of Stem Cells**

– 1-week-old embryos created via IVF for the treatment of infertility

– 5- to 9-week-old embryos or fetuses obtained through elective abortion

– embryos created via IVF for research purposes

– embryos created via SCNT (somatic cell nuclear transfer, or cloning)

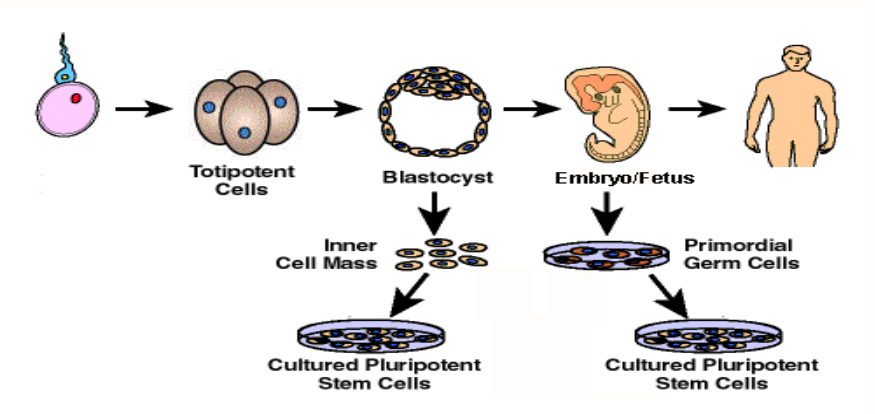
– adult tissues (bone marrow, umbilical cord blood)

Embryonic stem cells were first isolated from mice in 1981, and until recently, scientists have used only animal embryonic stem cells in research. In November 1998, two groups published the results of their work on human stem cells from embryos or fetuses.[1] In both cases, the embryos and fetuses were donated for research purposes following a process of informed consent. University of Wisconsin researchers derived stem cells from 1-week-old embryos, also called blastocysts, produced via *in vitro*

[1] For human development, the term embryo is used for the first 8 weeks after fertilization, and fetus for the 9th week through birth. In contrast, HHS regulations define fetus as "the product of conception from the time of implantation." (45 CFR 46.203)

fertilization (IVF) for the treatment of infertility.[2] Because the stem cells are located within the embryo, the process of removing the cells destroys the embryo. Johns Hopkins University investigators derived cells with very similar properties from 5- to 9-week-old embryos or fetuses obtained through elective abortions.

**Figure 1: Stem Cells via IVF Embryo or Fetal Tissue**




**Source**: Figure 1 is based on a figure contained in a May 2000 report by the National Institutes of Health entitled *Stem Cells: A Primer*, which can be found at: [http://www.nih.gov/news/stemcell/primer.htm].

The Jones Institute for Reproductive Medicine, located in Norfolk, Virginia, announced in July 2001 that it had created human embryos via IVF for the purpose of deriving human embryonic stem cells.[3] Although the Jones Institute work, which was begun in 1997, does not represent a research advance, according to experts in academia and industry, it "might be the first time in the United States that a human embryo had been created solely for research" rather than for the treatment of infertile couples.[4] A representative of the Jones Institute, Dr. William E. Gibbons, states that several ethics panels approved the work, and contends that such "fresh" embryos may have advantages over the frozen embryos remaining after infertility treatment. Unlike couples utilizing fertility clinics, the egg donors were younger, "possibly yielding more robust embryos." The egg and sperm donors underwent psychological and medical evaluation and were informed of the research goals.

Another potential source of embryonic stem cells is somatic[5] cell nuclear transfer (SCNT), the cloning procedure used to produce Dolly, the sheep. Geron Corporation, a Menlo Park, California biotechnology company, and Advanced Cell

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[2] IVF embryos that are produced in excess of need are usually frozen in liquid nitrogen for future use by the couple. If the couple decides that their family is complete, they may elect to discard the embryos, donate the embryos for research, or allow another couple to adopt the embryo.

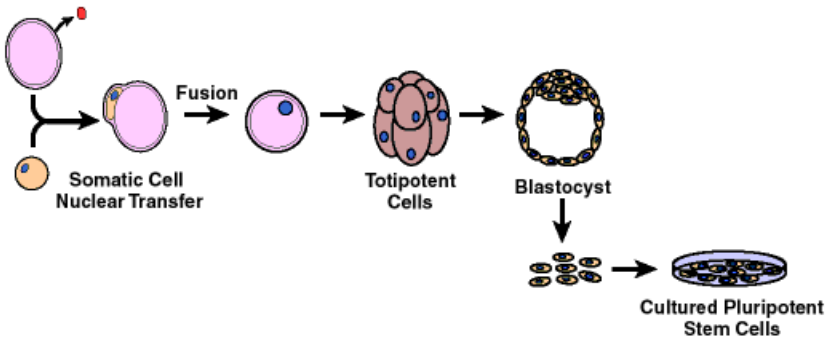
[3] Stolberg, Sheryl Gay. Scientists Create Scores of Embryos to Harvest Cells. *The New York Times*, July 11, 2001, pp. A1, A15.

[4] Ibid., p. A15.

[5] A somatic cell is a body cell, as opposed to a germ cell, which is an egg or sperm cell.

Technology Co. of Worcester, Massachusetts, are currently funding work on stem cells created via this process.[6] In SCNT, the nucleus of an egg is removed and replaced by the nucleus from a mature body cell, such as a skin cell. The cell created via SCNT would be allowed to reach the 1-week (blastocyst) stage and the stem cells would then be removed, as in the University of Wisconsin work. An alternate SCNT approach is the fusion of adult human cells with egg cells of other animals. In 1996, researchers at the University of Massachusetts fused a human cheek cell with a cow egg cell. The resulting hybrid cell had "embryo-like" characteristics and was generated for the purpose of making stem cells. This method was at one time being pursued by Advanced Cell Technology Co.[7]

**Figure 2: Stem Cells Via Somatic Cell Nuclear Transfer**




**Source**: Figure 2 is from a May 2000 report by the National Institutes of Health entitled *Stem Cells: A Primer*, which can be found at: [http://www.nih.gov/news/stemcell/primer.htm].

Stem cells obtained from adult organisms are also the focus of research. There have been a number of recent publications on adult stem cells from a variety of different sources, such as bone marrow and the umbilical cord following birth. Some advocate that this path should be pursued instead of embryonic stem cells because they believe the derivation of stem cells from either IVF embryos or aborted fetuses is ethically unacceptable. However, other scientists believe adult stem cells should not be the sole target of research because of important scientific and technical limitations. Adult stem cells may not be as versatile in developing into various types of tissue as embryonic stem cells, and the location of the cells in the body might rule out safe and easy access. For these reasons, they argue that both adult and embryonic stem cells should be the subject of research.

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[6] Weiss, Rick. Embryo Work Raises Spector of Human Harvesting. *The Washington Post*, June 14, 1999. p. A01; and, Stolberg, Sheryl Gay. Company Using Cloning to Yield Stem Cells. *The New York Times*, July 13, 2001, p. A13.

[7] Hall, Stephen S. The Recycled Generation. *The New York Times Magazine*, January 30, 2000. p. 30-35, 46, 74, 78-79.

**Potential Applications.** Stem cell research was chosen by *Science* magazine in 1999 as its "breakthrough of the year." Stem cells provide the opportunity to study the growth and differentiation of individual cells. Understanding these processes could provide insights into the causes of birth defects, genetic abnormalities, and other disease states. If normal development were better understood, it might be possible to prevent or correct some of these conditions.

Stem cells could be used to produce large amounts of one cell type to test new drugs for effectiveness and chemicals for toxicity. Stem cells might be transplanted into the body to treat disease or injury (e.g., spinal cord). The damaging side effects of medical treatments might be repaired with stem cell treatment. For example, cancer chemotherapy destroys immune cells in patients making it difficult to fight off a broad range of diseases; correcting this adverse effect would be a major advance.

Before stem cells can be applied to human medical problems, substantial advances in basic cell biology and clinical technique are required. The potential benefits mentioned previously are likely only after many more years of research. Technical hurdles include developing the ability to control the differentiation of stem cells into a desired cell type (like a heart or nerve cell), and, if stem cells are to be used for transplantation, the problem of immune rejection must also be overcome. However, if the SCNT technique (cloning) was employed using a cell nucleus from the patient, stem cells created via this method would be genetically identical to the patient and would presumably be recognized by the patient's immune system, thus avoiding any tissue rejection problems.

## Federal Funding of Research

On August 9, 2001, President Bush announced that federal funds will be used to support research on human embryonic stem cells, but funding will be limited to "existing stem cell lines." According to the President's speech, more than 60 stem cell lines currently exist. However, a scientific review, prepared by NIH, of the status of the research and its applications states that about 30 cell lines have been derived from embryos or fetal tissue. The scientific review was released on July 18, 2001, at a hearing on stem cell research held by the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education.[8] The NIH report also states that research studies "indicate that it is now possible to grow these cells for up to two years" in the laboratory, implying that their life span or utility may be limited and that additional cell lines beyond those existing to date may be needed if this line of research is to be pursued. The NIH report does not make any recommendations, but argues that both embryonic and adult stem cell research should be pursued. (See also Congressional Actions section of this report.)

In the past, President Bush has indicated that he does not support the federal funding of research on stem cells derived from either human embryos or fetal tissue

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[8] National Institutes of Health, Department of Health and Human Services. *Stem cells: scientific progress and future research directions*, June 2001. The NIH scientific report can be found at: [http://www.nih.gov/news/stemcell/scireport.htm].

obtained from abortions.[9] He has indicated his support for stem cell research using cells derived from fetal tissue obtained from spontaneous abortions (miscarriages). However, scientists contend that such tissue is for the most part unsuitable for research due to the presence of genetic defects or other anomalies. At one time, Secretary of HHS Tommy G. Thompson stated that he is very much in favor of stem cell research.[10] Secretary Thompson is the former Governor of Wisconsin, and as noted above, University of Wisconsin researchers published in November 1998 the results of their work in deriving stem cells from 1-week-old embryos produced via IVF for the treatment of infertility.

To date, no federal funds have been used to support research on stem cells derived from either source.[11] The work at the University of Wisconsin and Johns Hopkins University was supported by private funding from Geron Corporation. Private funding for experiments involving embryos was required because Congress attached a rider to legislation that affected FY1996 NIH funding. This rider, originally introduced by Representative Jay Dickey, prohibited HHS from using appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed. This same rider has been attached to the Labor, HHS and Education appropriations acts for FY1997 through FY2001.[12] The current rider, Section 510 of the FY2001 Labor, HHS and Education Appropriations Act, included in the Consolidated Appropriations Act, 2001 (P.L. 106-554), prohibits HHS from using FY2001 appropriated funds for:

> (1) the creation of a human embryo or embryos for research purposes; or
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 [the Human Subject Protection regulations] ... that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes [sperm or egg] or human diploid cells [cells that have two sets of chromosomes, such as somatic cells].

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[9] Kondracke, M. M. Bush wisely orders study of fetal, stem cell issues. *Roll Call*, February 1, 2001; and, Kornblut, A. E. Bush says he opposes using fetal tissue from abortions. *The Boston Globe*, January 27, 2001.

[10] Healy, P. HHS chief decries nomination lag. *The Boston Globe*, May 22, 2001.

[11] However, federal funds have been provided for research on adult stem cells. In FY2000, the total amount spent by NIH on stem cell research was $256 million. The total can be broken down as follows: human adult stem cell research, $147 million; animal adult stem cell research, $79 million; animal embryonic stem cell research, $30 million.

[12] The rider language has not changed significantly from year to year. The original rider can be found in Section 128 of P.L. 104-99; it affected NIH funding for FY1996 contained in P.L. 104-91. For subsequent fiscal years, the rider is found in Title V, General Provisions, of the Labor, HHS and Education appropriations acts in the following public laws: FY1997, P.L. 104-208; FY1998, P.L. 105-78; FY1999, P.L. 105-277; FY2000, P.L. 106-113; and FY2001, P.L. 106-554.

There is no similar federal prohibition on fetal tissue research; however, other restrictions do apply (see below).

**HHS Legal Opinion.** Following the November 1998 announcement on the derivation of human embryonic stem cells, NIH requested a legal opinion from HHS on whether federal funds could be used to support research on human stem cells derived from embryos or fetal tissue. The January 15, 1999, response from HHS General Counsel Harriet Rabb found that current law prohibiting the use of HHS appropriations for human embryo research (the above-mentioned rider) would not apply to research using human stem cells "because such cells are not a human embryo within the statutory definition." The finding was based, in part, on HHS's determination that the statutory ban on human embryo research defines an embryo as an *organism* that when implanted in the uterus is capable of becoming a human being. Human pluripotent stem cells are not and cannot develop into an organism; they lack the capacity to become organisms even if they are transferred to a uterus. As a result, HHS maintained that NIH could support research that uses stem cells derived through private funds, but could not support research that itself, with federal funds, derives stem cells from embryos because of the federal ban in the rider.

Regarding research using stem cells derived from fetal tissue, HHS found that to the extent human stem cells are legally considered fetal tissue, they would be subject to certain other restrictions that safeguard against the inappropriate use of fetuses. For example, a statutory ban on sale for valuable consideration prohibits researchers with federal support from paying for the tissue, except reasonable payments associated with transportation, implantation, processing, preservation, quality control or storage of the tissue or cells. Other restrictions include the criminal prohibition on the directed donation of fetal tissue and restrictions on fetal tissue transplantation research conducted or funded by HHS.[13]

In addition, such research may be conducted only in accordance with applicable state or local law.[14] According to a report published by the National Bioethics Advisory Commission, nine states – FL, LA, ME, MA, MI, MN, ND, PA and RI, – ban IVF embryo research entirely.[15] Six states – AZ, IN, ND, OH, OK, and SD – ban research on aborted fetuses or embryos.[16] However, in December 2000, the AZ law

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[13] The NIH Revitalization Act of 1993 (P.L. 103-43) allows federal support of human fetal tissue transplantation research using tissue from induced abortions under certain conditions only if the transplantation is for *therapeutic purposes*. The Act contains several provisions intended to decouple the decision to have the abortion from the choice to donate the tissue for transplantation and to insulate the decision from financial considerations.

[14] See 45 CFR 46.210.

[15] Andrews, Lori B. *State Regulation of Embryo Stem Cell Research*. In National Bioethics Advisory Commission, Ethical Issues in Human Stem Cell Research, v. II, Commissioned Papers, January 2000.

[16] Ibid.

was overturned by a federal court.[17] A number of states ban payment for either IVF embryos or aborted fetuses or embryos.

**NIH Guidelines.** Shortly after the opinion by the HHS General Counsel, NIH disclosed that the agency planned to fund research on pluripotent stem cells derived from human embryos and fetal tissue once appropriate guidelines were developed and an oversight committee established. NIH Director Harold Varmus appointed a working group which began drafting guidelines in April 1999. Draft guidelines were published in the *Federal Register* on December 2, 1999. About 50,000 comments were received during the public comment period which ended February 22, 2000.

On August 23, 2000, NIH released final guidelines on the support of human embryonic and fetal stem cell research; *Federal Register* publication occurred on August 25, 2000.[18] The guidelines state that "studies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment." The NIH will not fund research directly involving the derivation of human stem cells from embryos; this is currently prohibited by the previously mentioned appropriation rider. In this respect, the NIH is more restrictive than other groups such as the National Bioethics Advisory Commission (NBAC)[19] and an expert British panel,[20] which both recommended support for the derivation of stem cells from such embryos. The NIH guidelines allow funding of research to derive stem cells from fetal tissue, as well as research utilizing such stem cells; this is in agreement with NBAC recommendations and current law.

Other areas of research ineligible for NIH funding under the guidelines include: (1) research in which human stem cells are utilized to create or contribute to a human embryo; (2) research in which human stem cells are combined with an animal embryo;

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[17] Stolberg, Sheryl Gay. Washington Not Alone in Cell Debate. *The New York Times*, July 23, 2001, p. A12.

[18] The NIH guidelines can be found at:
[http://www.nih.gov/news/stemcell/stemcellguidelines.htm].

[19] The September 1999 NBAC report, Ethical Issues in Human Stem Cell Research, can be found at [http://www.bioethics.gov]. NBAC was established by Executive Order 12975 on October 3, 1995; a September 16, 1999 executive order extended the NBAC charter until October 2001. NBAC makes recommendations to the National Science and Technology Council on bioethical issues arising from research on human biology and behavior. The commission has already completed reports on human cloning, the use of human biological materials, and treating persons with mental disorders. On November 14, 1998, President Clinton requested NBAC to conduct a review of the issues associated with stem cell research.

[20] The British report *Stem Cell Research: Medical Progress With Responsibility*, was released along with nine recommendations on August 16, 2000. Full text of the report can be found at: [http://www.doh.gov.uk/cegc/stemcellreport.htm]. On December 19, 2000, the House of Commons voted (366-174) to allow stem cell research using embryos up to 14 days old. (*Washington FAX*, December 21, 2000.) On January 22, 2001, the House of Lords also voted (212-92) in favor of allowing research on human embryonic stem cells. (*Washington FAX*, January 24, 2001.)

(3) research in which human stem cells are used for reproductive cloning of a human; (4) research in which human stem cells are *derived* using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; (5) research *utilizing* human stem cells that were derived using somatic cell nuclear transfer; and (6) research utilizing stem cells that were derived from human embryos created for research purposes, rather than for infertility treatment. The NBAC report is silent on areas 1-3 and in agreement with the guidelines on areas 4-6.

NIH began accepting grant applications for research projects utilizing human stem cells immediately following publication of the guidelines; the deadline for submitting a grant application was March 15, 2001. All such applications are to be reviewed by the new NIH Human Pluripotent Stem Cell Review Group (HPSCRG), which was established to ensure compliance with the guidelines. James Kushner, director of the University of Utah General Clinical Research Center, will serve as chair of the HPSCRG. Applications will also undergo the normal NIH peer-review process.

In mid-April 2001, HHS announced that it was postponing the first meeting of the HPSCRG until the review of policy decisions on stem cell research made during the Clinton Administration is completed.[21] The group's first meeting had been scheduled for April 25, 2001. According to media sources, only three grant applications were submitted to NIH, and one was subsequently withdrawn.[22] Presumably, scientists are reluctant to invest the time and effort into preparing the necessary paperwork for the NIH grant application process when the prospects of receiving federal funding are so uncertain. In a related development, one of the leading U.S. researchers on stem cells, Roger Pederson of the University of California, San Francisco, is reportedly moving his laboratory to the United Kingdom for "the possibility of carrying out my research with human embryonic stem cells with public support."[23] Human embryonic stem cell research was approved overwhelmingly by the House of Commons in December 2000 and the House of Lords in January 2001.[24]

## Congressional Actions

The January 15, 1999 opinion by HHS General Counsel Harriet Rabb and the decision by NIH to fund human embryonic stem cell research in the near future was strongly opposed by many Members of Congress. In a February 11, 1999 letter from 70 Members to HHS Secretary Donna Shalala, they stated that "any NIH action to initiate funding of such research would violate both the letter and the spirit of the federal law banning federal support for research in which human embryos are harmed or destroyed." The authors of the letter also objected to HHS General Counsel Rabb's definition of human embryo: "an entity is an embryo only if one can show that

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[21] Boahene, A. K. Stem cell research group cancels inaugural meeting pending HHS review of NIH research guidelines. *Washington FAX*, April 19, 2001.

[22] Recer, P. Stem Cell Studies said Hurt by Doubt. *AP Online*, May 2, 2001.

[23] Zitner, Aaron. Uncertainty is thwarting stem cell researchers. *Los Angeles Times*, July 16, 2001, pp. A1, A8.

[24] See footnote 20.

it is capable, if implanted in the womb, of becoming a born human being." The letter stated that "this narrow definition has no support whatsoever in federal law."

In a February 23, 1999 letter, Secretary of HHS Donna Shalala responded that the definition of embryo used in the HHS opinion "relies on the definition provided in the statute itself." Secretary Shalala's letter stated that the federal ban only applies to research in which human embryos are discarded or destroyed but "not to research preceding or following on such projects [in which human embryos are discarded or destroyed]. Moreover, ... there is nothing in the legislative history to suggest that the provision was intended to prohibit funding for research in which embryos – organisms – are not involved."

The stem cell research issue threatened to hold up passage of the FY2000 Labor, Health and Human Services and Education appropriations bill. In the House, Representative Jay Dickey proposed an amendment to restrict federally funded stem cell research to work on cells derived from fetal tissue. Representative Dickey, the author of the congressional funding ban on embryo research, withdrew his amendment at the request of House leadership who were concerned that controversial amendments might slow down passage of the appropriation bill. In the Senate, the issue held up passage of the FY2000 LHHS appropriation bill until Senate leadership agreed to drop language endorsing the research and take it up as a separate bill in the second session.

On February 4, 2000, a group of 20 Republican Senators sent a letter to DHHS in opposition to the proposed NIH guidelines for support of human embryonic stem cell research asserting that such support is contrary to the requirements of the agency's appropriations language. The authors of the letter asked that NIH withdraw the proposed guidelines, and indicated that should the NIH adopt the draft guidelines, further steps might be taken to oppose them, including a possible lawsuit to enforce the federal ban.[25]

On July 17, 2001, a hearing on stem cell research was held by the House Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources. Testifying at the hearing were two couples who gave birth to children following the adoption of surplus frozen embryos created at fertility clinics. The Subcommittee also heard testimony from Gerald Fischbach, former director of the National Institute of Neurological Diseases and Stroke, and currently in the health and biomedical sciences department at Columbia University. Dr. Fischbach stated at the hearing that "it is irresponsible to claim that adult stem cells are superior to embryonic cells in their ability to proliferate or in the diversity of their descendants."[26] He also warned against a compromise proposal that would limit federal funding of stem cell research to a small number of stem cell lines. "Unfortunately, this would cripple research ... Stem cell lines derived from different fertilized eggs are not identical, and the same line may not be optimal for all disorders."

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[25] Brainard, Jeffrey. Twenty GOP Senators Urge NIH Not to Finance Stem-Cell Research. *The Chronicle of Higher Education*, February 25, 2000. p. A40.

[26] Davis, Matthew. Divisive House Hearing Brings Out Emotional Views on Embryonic Stem Cell Research. *Washington Fax*, July 18, 2001.

On July 18, 2001, a hearing on stem cell research was held by the Senate Appropriations Subcommittee on Labor, Health and Human Services and Education. As mentioned previously, at the hearing the NIH released the scientific review of stem cell research that was prepared for the Bush administration. The report does not make any recommendations. The NIH report indicates that at the time the report was written, there were 30 cell lines of human stem cells that had been derived from either human embryos or fetal tissue, and that the cell lines are capable of growing under laboratory conditions for up to 2 years. The report states that adult stem cells are rare and often difficult to identify, isolate and purify. When grown under laboratory conditions, most adult stem cells are unable to proliferate in an unspecialized state for long periods of time. When researchers have been able to grow adult stem cells for long periods of time under laboratory conditions, they have not been able to direct the adult stem cells to become specialized as functionally useful cells. Such a setback would need to be overcome in order to provide cells useful for transplantation into patients to treat medical conditions such as diabetes or spinal cord injury.

Also at the July 18 Senate hearing, Senator Bill Frist announced his position in favor of federal funding for stem cell research and outlined a 10-point plan for allowing such research to proceed. Senator Frist is said to be advising President Bush on the issue. The 10 points delineated in Senator Frist's statement before the Subcommittee are as follows:[27]

1. The creation of human embryos solely for research purposes should be strictly prohibited.

2. Strengthen and codify the current ban on federal funding for the derivation of embryonic stem cells.

3. Prohibit all human cloning to prevent the creation and exploitation of life for research purposes.

4. Increase federal funding for research on adult stem cells to ensure the pursuit of all promising areas of stem cell research.

5. Allow federal funding for research using only those embryonic stem cells derived from blastocysts that are left over after IVF and would otherwise be discarded.

6. To ensure that blastocysts used for stem cell research are only those that would otherwise be discarded, require a comprehensive informed consent process establishing a clear separation between potential donors' primary decision to donate blastocysts for adoption or to discard blastocysts and their subsequent option to donate blastocysts for research purposes. Such a process, modeled in part on well-established and broadly accepted organ

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[27] Senator Frist's principles on human stem cell research can be found at: [http://www.senate.gov/~frist/Press_Center/News_Releases/01-144/Stem_Cell_Research_Standards/stem_cell_research_standards.html].

and tissue donation practices, will ensure that donors are fully informed of all their options.

7. Restrict federally-funded research using embryonic stem cells derived from blastocysts to a limited number of cell lines. In addition, authorize federal funding for embryonic stem cell research for 5 years to ensure ongoing congressional oversight.

8. Establish appropriate public oversight mechanisms, including a national research registry, to ensure the transparent, in-depth monitoring of federally-funded and federally-regulated stem cell research and to promote ethical, high quality research standards.

9. Establish an ongoing scientific review of stem cell research by the Institute of Medicine (IOM) and create an independent Presidential advisory panel to monitor evolving bioethical issues in the area of stem cell research. In addition, require the Secretary of HHS to report to Congress annually on the status of federal grants for stem cell research, the number of stem cell lines created, the results of stem cell research, the number of grant applications received and awarded, and the amount of federal funding provided.

10. Because stem cell research would be subject to new, stringent federal requirements, ensure that informed consent and oversight regulations applicable to federally-funded fetal tissue research are consistent with these new rules.

**Stem Cell Legislation.** **S. 723** (Specter), introduced on April 5, 2001, would give NIH authority to fund the derivation of stem cells from surplus IVF embryos, an activity forbidden under the NIH guidelines and prohibited by the appropriation bill rider. In contrast, the bill broadly prohibits support of embryo research unrelated to stem cells. By amending the Public Health Service Act, this provision represents a more permanent legislative prohibition than the appropriations rider (which must be renewed each year) banning support of research involving the destruction of human embryos. A companion bill, **H.R. 2059** (McDermott) was introduced in the House on June 5, 2001. On January 30, 2001, **H.Res. 17** (Maloney) was introduced "expressing the sense of the Congress supporting federal funding of pluripotent stem cell research."

**H.R. 2096** (Smith), introduced on June 7, 2001, authorizes the Secretary of HHS to establish a National Stem Cell Donor Bank in order to make "qualifying human stem cells" available for research and therapeutic purposes. Qualifying human stem cells are defined in the bill as "human stem cells obtained from human placentas, umbilical cord blood, organs or tissues of a living or deceased human being who has been born, or organs or tissues of unborn human offspring who died of natural causes (such as spontaneous abortion)."

**Cloning Legislation.** On July 19, 2001, the House Judiciary Subcommittee on Crime approved **H.R. 2505** (Weldon) by voice vote. **H.R. 2505** would ban the process of human cloning, called somatic cell nuclear transfer (SCNT), when it is used

for reproductive purposes as well as for research and therapeutic uses, which would involve stem cells. The bill's language specifically bans the importation of any product derived from an embryo created via SCNT, and therefore would presumably prevent U.S. citizens from receiving treatments for diabetes, cancer, or Parkinson's disease that were created overseas. The bill includes a criminal penalty of imprisonment of not more than 10 years and a civil penalty of not less than $1 million and not more than 2 times the gross gain of the violator. A companion bill, **S. 790** (Brownback), has been introduced in the Senate.

On July 24, 2001, the House Judiciary Committee approved **H.R. 2505** by a vote of 18 to 11 and defeated a substitute that was identical to **H.R. 2172** (Greenwood) by a vote of 11 to19. **H.R. 2172** would ban only human reproductive cloning but contains the same criminal and civil penalties as **H.R. 2505** when SCNT is used "with the intent to initiate a pregnancy." The ban contained in **H.R. 2172** would sunset after 10 years. The Bush Administration announced its approval of **H.R. 2505** on July 24, 2001.

On July 31, 2001, the House passed **H.R. 2505** by a vote of 265-162. Prior to the vote on **H.R. 2505**, the House defeated a substitute amendment, **H.R. 2172**, by a vote of 178 to 249. During debate, supporters of **H.R. 2505** argued that a partial ban on human cloning, such as **H.R. 2172**, would be impossible to enforce. Critics of **H.R. 2505** argued that SCNT creates a "clump of cells" rather than an embryo, and that the measure would curtail medical research and prevent Americans from receiving life-saving treatments created overseas.

Some legal scholars believe a congressional ban on human cloning may be unconstitutional because it would infringe upon the right to make reproductive decisions which is "protected under the constitutional right to privacy and the constitutional right to liberty."[28] More importantly for the issue of stem cell research, a ban on human cloning for research purposes raises other constitutional issues: scientists' right to personal liberty and right to free speech.[29] In the opinion of some legal scholars, any limits the government might place on the use of cloning in scientific inquiry or human reproduction would have to be "narrowly tailored to further a compelling state interest."[30]

As stated previously (under NIH Guidelines section of this report), in their current form, the NIH Guidelines on Stem Cell Research would not fund research in which: human stem cells are used for reproductive cloning of a human; human stem cells are *derived* using cloning (SCNT – somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg); or, human stem cells that were derived using cloning (SCNT) are *utilized* in a research project.

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[28] Andrews, L. B. Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning. *Harvard Journal of Law and Technology*, summer 1998. p. 643-680.

[29] Ibid., p. 661.

[30] Ibid., p. 667.

## Ethical Issues

The central controversy surrounding human stem cell research is the source of the cells. The debate primarily arises from differences in deeply held religious and philosophic views. For most who believe that the embryo is a human being from the moment of fertilization, the derivation of stem cells from either very early or pre-implantation embryos created by IVF or from the tissues of aborted fetuses is ethically unacceptable. From this viewpoint, even though the proposed guidelines do not support activities which *directly* destroy embryos, support of research on components of the embryo would tacitly endorse such destruction.

Supporters of this view argue therefore that the guidelines would violate federal bans on human embryo research. From this perspective, the possible benefits of stem cell research cannot and should not justify the actions necessary to obtain the cells. Opponents of stem cell research propose that research on *adult* stem cells, which they claim could provide similar therapeutic benefits without the need for fetal cells, be supported instead. Not all scientists agree, however, that adult stem cells hold as much potential as embryonic stem cells.

Those who support embryonic stem cell research believe that pre-implantation embryos do not have the same moral and legal status as persons. They acknowledge that embryos are genetically human, but hold that they do not have the same moral relevance because they lack specific capacities, including consciousness, reasoning and sentience.[31] The NBAC received testimony from witnesses of many religious traditions that were open to the use of early embryos (remaining from infertility treatments) for stem cell research as well as many who were opposed. "Jewish and Islamic ethicists supported stem cell research while Protestant and Catholics were mixed. ... [W]hile the early human embryo is worthy of respect, it ought not to be given personal moral status until there has been sufficient development of the embryo."[32]

Supporters argue that the potential human health and scientific benefits the research holds should be an ethical argument for its support. Patient groups have also asserted that, because of the potential of human stem cells for the treatment of disease, it is immoral to discourage such research because it could save many lives. In addition, supporters believe that the oversight which would come with federal grant support would result in better and more ethically controlled research in the field than if funding was from private sources alone. Supporters also argue that the efforts of both federally supported and privately supported researchers are necessary to keep the United States at the forefront of what they believe is a very important, cutting edge area of science.

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[31] Presentation by Steinbock, B., Department of Philosophy, SUNY, Albany, New York. NIH Human Embryo Research Panel Meeting. February 3, 1994.

[32] Wildes, Kevin W. The Stem Cell Report. *America*, October 16, 1999. p. 12-14.