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Background and Legal Issues Related to Stem Cell Research

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Summary

In August 2001, President Bush announced that federal funds, with certain restrictions, may be used to conduct research on human embryonic stem cells. Federal research is limited to "the more than 60" existing stem cell lines that were derived (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducements to the donors. No federal funds may be used for the derivation or use of stem cell lines derived from newly destroyed embryos; the creation of any human embryos for research purposes; or cloning of human embryos for any purposes. Legislation that responds to the limitations imposed by the President's 2001 announcement has been introduced in the last two Congresses. During the 110th Congress, at least 10 bills, including the Stem Cell Research Enhancement Act of 2007 (H.R. 3/S. 5/S. 997), have been introduced.

Human Embryonic Stem Cells. Human embryonic stem cells are "master cells," able to develop into almost any cell in the human body. Building on earlier stem cell research, in 1998, researchers at the University of Wisconsin isolated cells from the inner cell mass of the early human embryo, called the blastocyst, and developed the first human embryonic stem cell lines.[1] Research has focused on the potential that these cells can offer to treat or mitigate diseases and conditions and to generate replacement tissues for disfunctioning cells or organs.[2] Research efforts have focused on spinal cord injury, multiple sclerosis, Parkinson's disease, Alzheimer's disease, diabetes, and other diseases or conditions. Scientists hope to use specialized cells to replace dysfunctional cells in the

[1] Nat'l Inst. of Health, U.S. Dep't of Health & Hum. Services, *Stem Cells: Scientific Progress and Future Research Directions* 4 (2001), *available at* [http://stemcells.nih.gov/info/scireport/2001report.htm].

[2] For additional information on stem cell research, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin D. Williams.

brain, spinal cord, pancreas, and other organs.[3] The sources for stem cells include one week old embryos (blastocysts) created via in vitro fertilization (IVF) to treat infertility; five to nine week old embryos or fetuses obtained through elective abortion; embryos created through IVF for research purposes; embryos created through cloning or somatic cell nuclear transfer; and adult tissues (umbilical cord blood, bone marrow). Controversy surrounds the derivation of stem cells from human embryos and fetuses. In order to derive or extract the stem cells found within the embryo, the embryo is destroyed in the removal process. The earliest embryonic stem cells are called totipotent cells, which means they can develop into an entire organism, producing both the embryo and tissues required to support it in the uterus. At a later stage of development, pluripotent embryonic stem cells exist and can develop into almost any type of cell in the body. These stem cells cannot form the supporting tissues, as seen with totipotent cells.[4] Human embryonic stem cells found in the early stage embryo are believed to have a greater ability to become different types of body cells and have more uses than adult stem cells.

Background and Recent Presidential and Congressional Action

Executive Action. When President Bush took office in January 2001, he announced that he would conduct a review of the stem cell research issue and ordered the Department of Health and Human Services (HHS) to review the National Institutes of Health's (NIH) guidelines issued by the former administration. During the review period, NIH suspended its review of applications from researchers seeking federal funds to perform human embryonic stem cell research. On August 9, 2001, President Bush announced that federal funds would be available to support limited human embryonic stem cell research. The new policy provides that federal funds may be used for research on "the more than 60" existing stem cell lines that have already been derived or were already in existence as of the date of the announcement.[5] In identifying the stem cell lines as being eligible for federal funding, the President said these embryos, from which the existing stem cell lines were created, had been destroyed previously and could not develop as human beings.

Under the new policy, federal agencies, primarily NIH, will consider applications for funding if certain standards or eligibility criteria are met. The White House fact sheet setting forth the President's policy states: federal funds will only be used for research on existing stem cell lines that were derived (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any

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[3] *Id*. at 4-6.

[4] Generally, for human development, the term embryo is used for the first eight weeks after fertilization and the term fetus for the 9th week through birth. HHS regulations define fetus as "the product of conception from the time of implantation." 45 C.F.R. § 46.203.

[5] President's Address to the Nation on Stem Cell Research From Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (August 9, 2001). The number of available embryonic stem cell lines is now understood to be much lower than 60. Although 78 cell lines are listed on the Human Embryonic Stem Cell Registry as eligible for use in federal research, only 22 lines are identified as being available. For additional information on the Human Embryonic Stem Cell Registry, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin D. Williams.

financial inducements to the donors.[6] The President directed NIH to examine the derivation of all existing stem cell lines and create a registry of those lines. Pursuant to this new policy, no federal funds will be used for: (1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) cloning of human embryos for any purposes. The new policy replaces previously issued stem cell guidelines and policies. The policy also requires the creation of the President's Council on Bioethics to study stem cells and embryo research as well as other issues. NIH has listed entities that have developed stem cells lines that meet the President's criteria and are eligible for federal funding (the Human Embryonic Stem Cell Registry). The President also stated that in FY2001, the government will spend $250 million on research involving stem cells from other sources (e.g., umbilical cord, placenta, adult, and animal tissues).

Background and Congressional Activity. Prior to President Bush's stem cell announcement, and over the past years, federal law has prohibited HHS from funding human *embryo* research. No federal funds have been used to support research on stem cells derived from human embryos. Research in this area has been done through private funding. Subsequent to several phases of action, in December 1994, President Clinton, through an executive directive, prohibited federal funding on research to support the creation of human embryos for research purposes and directed NIH not to allocate resources for such research.[7] The order banning funding for such research was followed in 1996 by a legislative ban that was enacted in NIH's funding measure.[8] Congress has passed a similar ban annually since that time. The original congressional ban stated that federally appropriated funds could not be used for the creation of a human embryo or embryos for research purposes or for 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 C.F.R. § 46.208(a)(2) and 42 U.S.C. § 289g(b). The ban defined "human embryo or embryos" to include any organism, not protected as a human subject under 45 C.F.R. § 46 (Human Subject Protection regulations) that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes (sperm or egg.) The rider language has not changed significantly over the years. In the subsequent fiscal years after FY1996, the rider was enacted in Title V (General Provisions) of the Labor, HHS and Education appropriations acts. The prohibition does not ban fetal tissue research, although other restrictions apply.

Advances in medical science proceeded and in 1998 critical developments were recognized by scientists at the University of Wisconsin. These researchers were able to isolate human embryonic stem cells and coax them to grow into specialized cells. In light of the presidential and legislative bans, NIH requested a legal opinion from the General Counsel of HHS on whether federal funds could be used to support research on human stem cells derived from embryos or fetal tissue. HHS' General Counsel, Harriet Rabb, concluded that then-current law prohibiting the use of HHS appropriated funds for human embryo research would not apply to research using stem cells "because such cells are not

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[6] *Id*.

[7] Statement on Federal Funding of Research on Human Embryos, 30 Weekly Comp. Pres. Doc. 2459 (December 2, 1994).

[8] Balanced Budget Downpayment Act, 1996, P.L. 104-99, § 128, 110 Stat. 26, 34 (1996).

a human embryo within the statutory definition."[9] General Counsel Rabb determined that the statutory ban on human embryo research defines embryo as an "organism" that when implanted in the uterus is capable of becoming a human being. The opinion stated that pluripotent stem cells are not and cannot develop into an organism, as defined in the statute. HHS concluded that NIH could fund research that uses stem cells derived from the embryo by private funds. But, because of the language in the rider, NIH could not fund research that, with federal funds, derived the stem cells from embryos.

Some members of Congress strongly opposed HHS' view and believed that the legislative ban, that would continue through FY2001, covered and prohibited such research. Others supported both the administration's position and the funding of such research. In response to those opposed to the HHS opinion, and the subsequently published NIH guidelines, Secretary Shalala stated in a letter that the definition of embryo used in the HHS legal opinion relied on the definition of embryo in the statute and that the ban applied only to research in which human embryos are discarded or destroyed but not to research preceding or following "on such projects."[10] The letter stated: "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."

After the HHS legal opinion, and despite expressions of congressional opposition, NIH indicated that it would fund research on pluripotent stem cells derived from human embryos and fetal tissue once guidelines were issued and an oversight committee was established. Draft guidelines were published in the *Federal Register* in December 1999 and final guidelines were issued in August 2000.[11] The guidelines provided 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. Based upon HHS's interpretation, funds could not be used to extract or derive the stem cells from the embryo, thereby destroying the embryo. NIH initiated the applications process but ultimately funding was not granted to the applications. The prior administration's process was then overtaken by events and the new policy was set.

Congressional interest in stem cell research has continued steadily since the President's announcement in 2001. During the 109th Congress, at least seven bills involving stem cell research were introduced. Two of the measures were enacted. On December 20, 2005, the President signed H.R. 2520, the Stem Cell Therapeutic and Research Act of 2005, a measure that provides for the collection and maintenance of human cord blood stem cells for the treatment of patients and for research (P.L. 109-129).

S. 3504, the Fetus Farming Prohibition Act of 2006, was signed by the President on July 19, 2006 (P.L. 109-242). The act amends the Public Health Service Act (PHSA) to make it unlawful for any person or entity involved or engaged in interstate commerce to

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[9] Letter from HHS Gen. Counsel Harriet Rabb to Harold Varmus, Director, NIH, January 15, 1999.

[10] Letter from Secretary Shalala to the Honorable Jay Dickey, February 23, 1999.

[11] 64 Fed. Reg.67576 (1999); 65 Fed. Reg. 51,976 (2000), respectively.

either solicit or knowingly acquire, receive, or accept a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue, or knowingly acquire, receive, or accept tissue or cells obtained from a human embryo or fetus that was gestated in the uterus of a nonhuman animal.

A third measure, H.R. 810, the Stem Cell Research Enhancement Act of 2005, was passed by Congress, but vetoed by the President on July 19, 2006.[12] H.R. 810 would have amended the PHSA to direct the Secretary of HHS to conduct and support research that utilizes human embryonic stem cells without regard to the date on which the stem cells were derived from a human embryo. To be eligible for use in research conducted or supported by the Secretary, the stem cells would have been required to meet certain conditions. For example, only stem cells derived from human embryos that were donated from in vitro fertilization clinics, were created for the purposes of fertility treatment, and were in excess of the clinical need of the individuals seeking such treatment would have been eligible for use.

In his veto message, the President expressed a need to balance scientific progress with the country's ethical responsibilities:

> H.R. 810 would overturn my Administration's balanced policy on embryonic stem cell research. If this bill were to become law, American taxpayers for the first time in our history would be compelled to fund the deliberate destruction of human embryos. Crossing this line would be a grave mistake and would needlessly encourage a conflict between science and ethics that can only do damage to both and harm our Nation as a whole.[13]

A vote to override the veto was unsuccessful.[14]

Finally, S. 2754, the Alternative Pluripotent Stem Cell Therapies Enhancement Act, would have amended the PHSA to direct the Secretary of HHS to conduct and support basic and applied research to develop techniques for the isolation, derivation, production, or testing of stem cells that are not derived from a human embryo. S. 2754 indicated that the research contemplated by the measure would not have affected any policy, guideline, or regulation regarding embryonic stem cell research or human cloning by somatic cell nuclear transfer. S. 2754 was passed by the Senate on July 18, 2006 by a vote 100-0. The House did not vote on the measure.

In the 110th Congress, at least 10 bills involving stem cell research have been introduced.[15] H.R. 3, the Stem Cell Research Enhancement Act of 2007, a measure that is identical in language to the Stem Cell Research Enhancement Act of 2005, was passed by the House on January 11, 2007, by a vote of 253-174. A companion measure, S. 5, was passed by the Senate on April 11, 2007, by a vote of 63-34. S. 5 includes the

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[12] A companion bill, S. 471, was introduced by Sen. Arlen Specter on February 28, 2005.

[13] 152 Cong. Rec. H5435 (daily ed. July 19, 2006) (Stem Cell Research Enhancement Act of 2005 — Veto Message From the President of the United States (H. Doc. No. 109-127)).

[14] *See* 152 Cong. Rec. H5450 (daily ed. July 19, 2006) (the vote was 235-193).

[15] For additional discussion of stem cell research legislation in the 110th Congress, see CRS Report RL33540, *supra* note 2.

language of H.R. 3, as well as the language of the Alternative Pluripotent Stem Cell Therapies Enhancement Act from the 109th Congress.