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Background and Legal Issues Related to Stem Cell Research

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Summary

With certain restrictions, the President has announced that federal funds 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 will 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.

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 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

[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/PDFs/fullrptstem.pdf.

[2] For additional information on stem cell research, see CRS Report RL31015, *Stem Cell Research*.

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

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 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

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[4] Generally, for human development, the term embryo is used for the first 8 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] Fact Sheet, Office of the Press Secretary, White House, President's Embryonic Stem Cell Research Policy (August 9, 2001), *available at* http://www.whitehouse.gov/news/releases/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 RL31015, *Stem Cell Research*.

[6] *Id.*

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 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

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

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

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

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 since the President's announcement in 2001. During the 108th Congress, four bills involving stem cell research have been introduced. H.R. 3960, the Stem Cell Replenishment Act of 2004, was introduced by Rep. Juanita Millender-McDonald on March 11, 2004. H.R. 3960 would allow federal funds to be used for research on human embryonic stem cells regardless of the date on which the derivation process for such stem cells was initiated or completed.

H.R. 2852, the Cord Blood Stem Cell Act of 2003, was introduced on July 24, 2003 by Rep. Christopher H. Smith. A similar bill, S. 1717, was introduced on October 3, 2003 by Sen. Orrin G. Hatch. Both bills would authorize the Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, to enter into contracts with qualified cord blood stem cell banks to assist in the establishment, provision, and maintenance of a National Network of Cord Blood Stem Cell Banks that would contain at least 150,000 units of human cord blood stem cells.

S. 303, the Human Cloning Ban and Stem Cell Research Protection Act of 2003, was introduced on February 5, 2003 by Sen. Orrin G. Hatch. S. 303 would prohibit any person or other legal entity from conducting or attempting to conduct human cloning. The term

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

[11] 64 Fed. Reg.67576 (1999); 65 Fed. Reg. 51976 (2000), respectively.

"human cloning" is defined by the bill to mean "implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus."[12] Research otherwise involving nuclear transplantation would not be prohibited. However, such research would be subject to human subject protection regulations.

In addition to the four bills, other measures that would prohibit cloning have been introduced. Because cloning is one method of obtaining embryos for stem cell production, these bills are worth noting. H.R. 534, the Human Cloning Prohibition Act of 2003, was introduced on February 5, 2003 by Rep. Dave Weldon. The House passed H.R. 534 on February 27, 2003 by a vote of 241-155. H.R. 534 would prohibit any person or entity from knowingly performing or attempting to perform human cloning. The term "human cloning" is defined by the bill to mean "human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) that is genetically virtually identical to an existing or previously existing human organism."[13] Cloning for reproductive purposes, as well as therapeutic purposes, would appear to be prohibited by the bill. The Human Cloning Prohibition Act of 2003 was introduced as S. 245 in the Senate by Sen. Sam Brownback on January 29, 2003.

H.R. 801, the Cloning Prohibition Act of 2003, was introduced on February 13, 2003 by Rep. James C. Greenwood. H.R. 801 would prohibit reproductive cloning, but seem to allow therapeutic cloning. H.R. 801 would require cloning research to be conducted in accordance with regulations for the protection of human subjects.

Note: This report was authored originally by Diane T. Duffy.

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[12] S. 303, 108th Cong. § 101 (2003).

[13] H.R. 534, 108th Cong. § 2 (2003) (as passed by the House of Representatives).