

CRS Report for Congress

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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 64¹ 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. Several lawsuits have been filed relating to stem cell research, and questions have been raised concerning access to existing stem cell lines by federal researchers.

Human Embryonic Stem Cells. Human embryonic stem cells are “master cells” and are 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.² 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.³ 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.⁴ 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 (SCNT); and adult tissues (umbilical cord blood, bone marrow). Controversy surrounds the

¹ The number was originally noted as 60 stem cell lines.

² “Stem cells: Scientific Progress and Future Research Directions,” NIH, HHS, available at [<http://www.nih.gov/news/stemcell/scireport.htm>], Summary, p. 4.

³ For more information on stem cell research, see CRS Report RL31015, *Stem Cell Research*.

⁴ Id. at pp. 4-6.

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.⁵ 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 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 64 existing stem cell lines that have already been derived or were already in existence as of the date of the announcement. In identifying the 64 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 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

⁵ 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.

⁶ President's embryonic stem cell research policy, Fact Sheet, White House, Office of the Press Secretary, August 9, 2001, [<http://www.whitehouse.gov/news/releases/2001>].

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 by a legislative ban in 1996 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.⁹ The prohibition does not ban fetal tissue research, although other restrictions apply.¹⁰

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."¹¹ 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

⁷ Statement, 30 Weekly Comp. Pres. Doc. 2459, Dec. 2, 1994.

⁸ Balanced Budget Downpayment Act, 1996, Pub. L. No. 104-99, Sec. 128, 110 Stat. 26, 34 (1996).

⁹ For the most recent rider, see, Pub. L. No. 106-554, § 510 (FY2001). For a list of all the annual riders, see CRS Report 31015, *infra*, footnote 12, p. 5. The current text adds at the end of the original language, "...or human diploid cells [cells that have two sets of chromosomes, such as somatic cells.] Federal funds have been provided for adult stem cell research.

¹⁰ With respect to stem cells derived from fetal tissue, these cells and associated research would be subject to certain other restrictions that safeguard against the inappropriate use of fetuses.

¹¹ Letter from HHS Gen. Counsel Harriet Rabb to Harold Varmus, Director, NIH, January 15, 1999.

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.”¹² 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 2000.¹³ 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.

In addition to President Bush’s actions, congressional interest has continued into the 107th Congress. In July 2001, Senator Frist outlined a ten-point plan that favored stem cell research and included, in part, these points: (1) prohibit the creation of human embryos solely for research purposes; (2) strengthen and codify the ban on federal funding for the derivation of embryonic stem cells; (3) prohibit cloning to prevent the creation and exploitation of life for research purposes; (4) increase federal funding for adult 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; and other points.

Various bills or initiatives have been introduced in the 107th Congress on stem cell research or cloning, which in some cases would have an effect on stem cell research. The following highlights major legislation or other initiatives that are likely to receive additional legislative attention this session. On April 5, 2001, Senator Specter introduced S. 723, the Stem Cell Research Act of 2001, which would amend current law and authorize NIH to fund the derivation of stem cells from surplus IVF embryos. This type of research activity is prohibited under the current Labor/HHS appropriation bill rider. The bill was referred to the Senate Committee on Health, Education, Labor, and Pensions. A companion bill to S. 723, H.R. 2059, was introduced by Rep. McDermott. On May 1, 2002, Senators Specter, Feinstein, Hatch and Kennedy, as well as other Senators, introduced S. 2439, the Human Cloning Prohibition Act of 2002. This bill would prohibit human reproductive cloning but would allow cloning for medical research purposes, including stem cell research. The bill was referred the Senate Committee on the Judiciary and is expected to receive heightened legislative attention. H.Res.17 was introduced by Rep. Maloney on January 30, 2001, expressing the sense of the Congress supporting federal funding of pluripotent stem cell research. Other bills have been introduced on stem cell research, but have not received extensive legislative attention: the Responsible Stem Cell Research Act of 2001 (H.R. 2096; companion bill, S. 1349); the Stem Cell Research for Patient Benefit Act (H.R. 2747); the

¹² Letter from Secretary Shalala to the Honorable Jay Dickey, Feb. 23, 1999.

¹³ 64 Fed. Reg.67576 (1999); 65 Fed. Reg. 51976 (2000), respectively.

New Century Health Advantage Act (H.R. 2838); and the Science of Stem Cell Research Act (H.R. 4011), which was introduced in April 2002.

In addition to S. 2439, other cloning bills have been introduced that implicate stem cell research. For instance, H.R. 2505, the Human Cloning Prohibition Act of 2001 (Weldon) was introduced in July 2001 and would amend Title 18, U.S. Code, to prohibit human cloning. The bill was approved by voice vote by the House Judiciary Subcommittee on Crime on July 19, 2001 and approved by the full committee on July 24, 2001.¹⁴ The House passed H.R. 2505 on July 31, 2001. The bill was received in the Senate, and the last action was August 8, 2001.¹⁵ H.R. 2505 has received support from the Administration. While this bill is referred to as a cloning bill and would ban the process of human cloning called somatic cell nuclear transfer when used for reproductive purposes as well as for research and therapeutic uses, it would restrict stem cell research. In addition, Sen. Brownback's bill, S. 1899, the Human Cloning Prohibition Act of 2001, the companion bill to H.R. 2505, was introduced January 28, 2002 and is expected to receive legislative attention this session. As with H.R. 2505, the Administration has expressed support for S. 1899. The Senate also considered, but did not pass, Senator Lott's amendment to H.R. 10, the Railroad Retirement and Survivors' Improvement Act of 2001, which would have imposed a 6-month moratorium on all human cloning research and would have affected stem cell research.

Legal Activity. Several lawsuits have been filed relating to stem cell research issues. In March 2001, a lawsuit was filed in federal court to stop federal funding of human embryonic stem cell research and to overturn the NIH guidelines. In *Nightlight Christian Adoptions, et al. v. Thompson*,¹⁶ the plaintiffs sought declaratory and injunctive relief and challenged the NIH guidelines for the public funding for research involving stem cells derived from human embryos. The plaintiffs, a non-profit adoption agency and others, claim that the NIH guidelines authorizing such research violate the legislative ban found in the appropriations rider which prohibits federal funding of research in which a human embryo is destroyed, discarded, or knowingly subjected to risk of injury or death greater than allowed for research on fetuses in utero under 45 C.F.R 46.208(a)(2) and 42 U.S.C. § 289g(b).¹⁷ The plaintiffs challenge NIH's interpretation that the ban on funding of research using human embryos does not cover embryonic stem cell research, as long as the embryos are not destroyed using federal funds. The complaint states the NIH guidelines are arbitrary and capricious within the meaning of the Administrative Procedure Act, 5 U.S.C. § 706(2), not the product of reasoned decisionmaking, and inconsistent with scientific evidence. A stipulated motion to stay the case was issued in May, 2001, which essentially suspended the lawsuit while the President conducted his review of the NIH guidelines. Although events may have overtaken this lawsuit and rendered the claims moot, the case is still pending before the court.

¹⁴ The full committee defeated a substitute measure that was identical to H.R. 2608 (Greenwood).

¹⁵ For additional and specific legislative details, including amendment and vote information, see CRS Report RL31015, *Stem Cell Research*, by Judith A. Johnson.

¹⁶ Civ. No. 1:01CV00502 (D.D.C. March 8, 2001).

¹⁷ Omnibus Consolidated Appropriations Act of 2001, Pub.L. No. 106-554, § 510, 114 Stat. 2763.

In May 2001, a federal lawsuit was filed claiming the Bush administration illegally withheld federal funding for stem cell research. In *Thomson v. Thompson*¹⁸, actor Christopher Reeve and seven scientists filed suit in the U.S. District Court for the District of Columbia claiming the administration was doing irreparable harm by delaying the development of therapies that could, the plaintiffs argued, save lives. The case challenges new administration's decision to halt funding and the directive to Secretary Thompson to review the NIH guidelines. The plaintiffs claim that administrative procedures were not followed in halting the research that, they argue, is permissible under federal statute.

Another legal action involves licensing, patent, and intellectual property right issues relative to stem cell research. In 1999, Geron Corp. obtained an exclusive license from the Wisconsin Alumni Research Foundation (WARF) for human embryonic stem cell technology developed by Dr. Thomson of the University of Wisconsin. The license grants Geron exclusive commercial rights to develop six types of human cells, *e.g.*, nerve cells, heart and liver cells, derived from stem cells. Later, Geron attempted to exercise its option on commercial rights to additional (12) cell types but WARF countered that the option had expired. On August 13, 2001, the foundation filed a lawsuit¹⁹ in U.S. District Court in Madison, Wisconsin asking the court to declare Geron's exercise of the option invalid. WARF later amended its complaint to ask the court to declare that Geron's license does not cover rights to research products that might be developed from the stem cells. Geron has asked the court to decide the dispute by discerning the meaning of the agreement without a trial.²⁰

In September 2001, NIH began discussions with WARF concerning access by federally-funded researchers to human embryonic stem cells. WARF is said to hold patents affecting 64 stem cell lines, including absolute rights to five lines.²¹ Secretary Thompson announced that an agreement has been reached with WARF that allows federal researchers access. Notwithstanding these developments, the *Geron* case raises legal questions concerning intellectual property rights, patents, licensing, and contract rights. The case also raises questions concerning the degree to which licensees or patent holders will make cells available or impose conditions on their use. Current guidelines on research do not reach the specifics of licensing agreements between grant applicants and patent holders. Those parties may negotiate agreements to license, share, and use the subject matter of the agreement.

¹⁸ Civ. No. 1:01CV00973 (D.D.C., May 8, 2001).

¹⁹ *WARF v. Geron*, Civ. No. 01-C-459-C (D. Wis. Aug. 2001).

²⁰ Geron has received two patents for human embryonic germ cells. See, www.geron.com.

²¹ *Marketletter*, Sept. 3, 2001. Other patent holders are Geron Corp., BresaGen of Australia and ES Cell International of Singapore as well as WARF's nonprofit subsidiary WiCell.