



Legal Issues Related to Human Embryonic Stem Cell Research

Edward C. Liu
Legislative Attorney

July 7, 2009

Congressional Research Service

7-5700

www.crs.gov

RS21044

Summary

Human embryonic stem cells are often described as “master cells” that have the potential to develop into any other type of cell in the human body. Research on embryonic stem cells has given rise to ethical debates, as the removal of an embryonic stem cell from an embryo typically involves the destruction of that embryo. In 2007, researchers in Japan and the United States published reports that they had successfully induced adult human somatic cells to exhibit characteristics similar to embryonic stem cells. Some have argued that these new induced pluripotent stem cells render embryonic stem cell research unnecessary, while others contend that continued embryonic stem cell research is still important.

Under the Bush administration, executive branch policy limited federal funds to stem cell lines that were already in existence on August 9, 2001, and 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.

This executive policy has been replaced by guidelines issued by the National Institutes of Health under the Obama administration. Pursuant to these guidelines, embryonic stem cell lines created after August 9, 2001, are now eligible for funding. However, federal funding for research using human embryonic stem cells is still limited to embryos that were derived from embryos created using in vitro fertilization for reproductive purposes, but which are no longer needed for this purpose. Donors are also still required to provide informed consent, and are prohibited from receiving any financial inducement, either cash or in kind, for the donated embryos. The guidelines also set forth additional documentation and informed consent requirements.

The federal funding of most methods of human embryonic stem cell procurement is still prohibited by federal legislation. No federal funds may be used for the derivation of stem cell lines from newly destroyed embryos; the creation of any human embryos for research purposes; or cloning of human embryos for any purposes. Recipients of federal funds may also be prohibited from discriminating against individuals who are opposed to stem cell research.

Several bills have been introduced in the 111th Congress that would direct the Secretary of Health and Human Services to conduct and support stem cell research. Some of these bills would appear to endorse continued federal funding of human embryonic stem cell research, while others would support only research using stem cells that were not derived from human embryos.

Contents

| | |
|---|---|
| Background Information on Human Embryonic Stem Cells | 1 |
| Federal Funding of Embryonic Stem Cell Research | 2 |
| Restrictions on Federal Funding of Research Using Embryos | 2 |
| The Dickey Amendment and Embryonic Stem Cell Research | 3 |
| Recent Executive Branch Policies | 4 |
| Legislative Activity in the 111th Congress | 6 |
| Conscience Protections | 6 |

Contacts

| | |
|----------------------------------|---|
| Author Contact Information | 7 |
|----------------------------------|---|

Background Information on Human Embryonic Stem Cells

Human embryonic stem cells are often described as “master cells,” able to develop into any other type of cell in the human body.¹ Potential sources for human embryonic stem cells include embryos created via *in vitro* fertilization for either research or reproduction; five to nine week old embryos or fetuses obtained through elective abortion; and embryos created through cloning or somatic cell nuclear transfer. Stem cells which are derived from adult tissues, such as umbilical cord blood or bone marrow, are distinct from embryonic stem cells and do not naturally exhibit the same developmental characteristics or behaviors.

In 1998, researchers at the University of Wisconsin isolated cells from a human embryo early in the developmental cycle and developed the first human embryonic stem cell lines.² Controversy surrounds the removal of stem cells from human embryos and fetuses because most techniques require the destruction of the embryo during the removal process. However, human embryonic stem cells are regarded as possibly having more therapeutic or research potential than stem cells derived from adult tissue. Whereas embryonic stem cells are often classified as either totipotent³ or pluripotent,⁴ stem cells found in adult sources may only have the capacity to differentiate into a few types of cells.⁵

Recent discoveries may lessen the demand for embryonic stem cells. In 2007, researchers in Japan and the United States published reports that they had successfully induced human somatic cells to exhibit pluripotent characteristics.⁶ This advancement notwithstanding, many stem cell researchers continue to argue that embryonic stem cell procurement is necessary in order to provide, among other things, the “gold standard” against which other means of pluripotent stem cell procurement are measured.⁷

Research utilizing human embryonic stem cell lines has focused on the potential that these cells can offer to advance the treatment or mitigation of diseases and conditions and to generate

¹ In contrast, differentiated somatic cells, which perform the “day to day” functions of the body, are not thought to give rise to other types of cells absent human intervention. See, e.g., *infra* footnote 6 and accompanying text.

² 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>.

³ The earliest embryonic stem cells are called totipotent cells as they can develop into an entire organism, producing both the embryo and tissues required to support it in the uterus. PRESIDENT'S COUNCIL ON BIOETHICS, *Alternative Sources of Human Pluripotent Stem Cells*, at 5 n.* (2005), available at <http://www.bioethics.gov>.

⁴ Pluripotent stem cells can develop into almost any type of cell in the body, but these stem cells cannot form the supporting tissues necessary for gestation, as seen with totipotent cells. *Id.*

⁵ For example, hematopoietic stem cells found in adult bone marrow and umbilical cord blood only appear to naturally give rise to various types of blood cells. PRESIDENT'S COUNCIL ON BIOETHICS, *Monitoring Stem Cell Research*, at 3 (2004), available at <http://www.bioethics.gov>.

⁶ James A. Thomson et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells*, 318 SCIENCE 1917 (2007); Shinya Yamanaka et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131(5) CELL 861 (2007).

⁷ Robert Lee Holtz, *Stem-Cell Researchers Claim Embryo Labs Are Still a Necessity*, THE WALL ST. J., Jan. 4, 2008, at B1.

replacement tissues for disfunctioning cells or organs.⁸ Examples of research efforts include spinal cord injury, multiple sclerosis, Parkinson's disease, Alzheimer's disease, and diabetes. Researchers also hope to use specialized cells to replace dysfunctional cells in the brain, spinal cord, pancreas, and other organs.⁹ In January of 2009, the Food and Drug Administration approved a clinical trial to evaluate a therapy for spinal cord injuries that was developed using embryonic stem cell lines.¹⁰

Federal Funding of Embryonic Stem Cell Research

Historically, there have been two sequential phases of research involving human embryonic stem cells: (1) research in which stem cells are produced from human embryonic tissue; and (2) research in which embryonic stem cells are used to study human development or illness. As the state of scientific knowledge and expertise has advanced, the federal government has taken various positions regarding the propriety of federally funding research at each stage. Currently, the use of federal funds for embryonic stem cell procurement is prohibited. In contrast, the guidelines governing the use of federal funds to support research using embryonic stem cell lines already in existence are currently being drafted by the National Institutes of Health (NIH).

Restrictions on Federal Funding of Research Using Embryos

While federal law has regulated federal funding of fetal research since 1974,¹¹ federal funding of embryonic research has only been restricted since 1994, when President Clinton, through an executive directive, prohibited federal funding of such research.¹² Subsequently, in 1996, Congress enacted a legislative ban in the funding measure of the NIH and has continued to pass a similar ban annually since that time.¹³

The congressional ban, often referred to as the Dickey Amendment,¹⁴ prohibits federally appropriated funds from being used for either the creation of human 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.¹⁵ 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.¹⁶ As the collection of embryonic stem cells often entails

⁸ 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.

⁹ *Id.* at 4-6.

¹⁰ Andrew Pollack, *Milestone in Research in Stem Cells*, NEW YORK TIMES, Jan. 23, 2009, at 1.

¹¹ National Research Service Award Act of 1974, P.L. 93-348, § 213, 88 Stat. 342 (1974).

¹² Statement on Federal Funding of Research on Human Embryos, 30 Weekly Comp. Pres. Doc. 2459 (December 2, 1994).

¹³ Balanced Budget Downpayment Act, 1996, P.L. 104-99, § 128, 110 Stat. 26, 34 (1996).

¹⁴ The amendment is so named for its principal sponsor, Rep. Jay Dickey.

¹⁵ This term was defined as risk 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).

¹⁶ The rider language has not changed significantly over the years and is currently found in Title V of the Labor, HHS, and Education appropriations act. P.L. 111-8, div. F, § 509 (2009).

the destruction of or harm to an embryo, the Dickey Amendment effectively forecloses federal funding of embryonic stem cell procurement.¹⁷

Despite the absence of federal funding, embryonic research has continued with other sources of funding. In 1998, after the inclusion of the Dickey Amendment, landmark developments were recognized by scientists at the University of Wisconsin when researchers were able to isolate stem cells from human embryos and coax them to grow into specialized cells.¹⁸ This development led some to question whether federal funds could be used in subsequent research involving these cell lines.

The Dickey Amendment and Embryonic Stem Cell Research

In January of 1999, the General Counsel of Health and Human Services (HHS) concluded that the Dickey Amendment's prohibitions against 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."¹⁹ HHS concluded that NIH could fund research that uses stem cells derived from the embryo by private funds. However, because of the language in the Dickey Amendment, NIH could not fund research that actually derived the stem cells from embryos.²⁰

Some Members of Congress strongly opposed HHS's interpretation and believed that the legislative ban covered and prohibited funding such research. In response to this opposition, HHS 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."²¹ Secretary Shalala also noted that "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."²²

NIH published draft guidelines for funding of stem cell research in the Federal Register in December of 1999 and final guidelines were issued in August of 2000.²³ Based upon HHS's interpretation, the guidelines stated that funds could not be used to extract or derive stem cells from an embryo, thereby destroying it. However, studies utilizing pluripotent stem cell lines derived from human embryos could be conducted using NIH funds provided that the cells were derived (1) without federal funds, (2) from human embryos that were created for the purposes of fertility treatment, and (3) were in excess of the clinical need of the individuals seeking such

¹⁷ *But see* CRS Report RL33554, *Stem Cell Research: Ethical Issues*, by Erin D. Williams and Judith A. Johnson, at 13-15 (discussing potential methods of creating embryonic stem cell lines without destroying human embryos).

¹⁸ James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 *SCIENCE* 1145 (1998).

¹⁹ Letter from HHS Gen. Counsel Harriet Rabb to Harold Varmus, Director, NIH, January 15, 1999. General Counsel Rabb determined that the statutory ban on human embryonic research defined an 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.

²⁰ The guidelines published by NIH on July 7, 2009, reiterate the agency's position that embryonic stem cell lines are not embryos for purposes of the Dickey Amendment. 74 Fed. Reg. 32174.

²¹ Letter from Secretary Shalala to Rep. Jay Dickey, February 23, 1999.

²² *Id.*

²³ 64 Fed. Reg. 67,576 (Dec. 2, 1999); 65 Fed. Reg. 51,976 (Aug. 25, 2000).

treatment. NIH initiated the applications process, but that process was overtaken by events and a new administration's policy was set forth.

Recent Executive Branch Policies

When President George W. Bush took office in January of 2001, he announced his intent to conduct a review of the stem cell research issue and ordered HHS to review the NIH guidelines issued by the previous administration. During this transition period, NIH suspended its review of applications from researchers seeking federal funds to perform embryonic stem cell research. Subsequently, on August 9, 2001, President Bush announced that federal funds would be available to human embryonic stem cell research on a restricted basis. The new policy would provide federal funds to be used for research only on existing stem cell lines that were already in existence as of the date of the announcement.²⁴ In identifying the stem cell lines as being eligible for federal funding, President Bush 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 policy announced on August 9, 2001, federal agencies, primarily NIH, would be permitted to fund embryonic stem cell research if certain eligibility criteria were met. Federal funds could 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.²⁵

On March 9, 2009, President Obama issued an executive order revoking the restrictions on human embryonic stem cell funding established under the Bush administration.²⁶ Pursuant to this executive order, NIH published final guidelines for federally funded human embryonic stem cell research on July 7, 2009.²⁷

Pursuant to these guidelines, embryonic stem cell lines created after August 9, 2001, are now eligible for federal funding. However, some of the restrictions that existed under the Bush administration remain. Specifically, federal funding for research using human embryonic stem cells is still limited to embryos that were derived from embryos created using in vitro fertilization for reproductive purposes, but which are no longer needed for this purpose.²⁸ Additionally, donors are still required to provide informed consent, and are prohibited from receiving any payment, either cash or in kind, for the donated embryos.²⁹

²⁴ President's Address to the Nation on Stem Cell Research From Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (August 9, 2001).

²⁵ *Id.* The policy also required the creation of the President's Council on Bioethics to study stem cells and embryonic research as well as other issues.

²⁶ Exec. Order No. 13505 (Mar. 9, 2009), available at http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-Cells/.

²⁷ 74 Fed. Reg. 32170 (July 7, 2009).

²⁸ *Id.* at 32174. In response to comments received regarding alternative methods of creating embryonic stem cells, NIH noted the lack of a consensus regarding the "complex ethical and scientific issues" presented with somatic cell nuclear transfer (SCNT) or parthenogenesis. *Id.* at 32171. For more information on SCNT, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin D. Williams, at 4-5.

²⁹ *Id.*

The guidelines also impose certain specific documentation requirements applicable to newly derived stem cell lines. Donors must be presented with documentation that

- describes alternatives to donation for research purposes;
- explains that no payments, cash or in kind, were offered for the donated embryos;
- explains that neither consenting nor refusing to donate embryos for research would affect the quality of care provided; and
- clearly separates the decision to create human embryos for reproductive purposes from the decision to donate human embryos for research purposes.³⁰

The guidelines also require the donor to be informed of the following information at the time consent is sought:

- that the embryos will be used to derive human embryonic stem cell lines for research;
- what will happen to the embryos in the derivation process;
- that cell lines derived from the embryos might be kept for many years;
- that the donation is made without any restriction or direction regarding the individuals who may receive medical benefit from the donation;
- that the research is not intended to provide direct medical benefit to the donor;
- that the results of research using derived stem cells may have commercial potential, and that the donor will not receive financial or any other benefits from any such commercial development; and
- whether information that could identify the donor will be available to researchers.³¹

NIH received many comments regarding the application of these informed consent requirements to existing human embryonic stem cell lines. As NIH noted,

in the more than a decade between the discovery of [human embryonic stem cells] and today, many lines were derived consistent with ethical standards and/or guidelines developed by various states, countries, and other entities such as the International Society for Stem Cell Research ... and the National Academy of Sciences These various policies have many common features, rely on a consistent ethical base, and require an informed consent process, but they differ in details of implementation.³²

In order to accommodate these existing lines, applicants for federal funds may seek review of their informed consent forms, written policies, and other documents by a Working Group of the Advisory Committee to the Director (ACD). The ACD will then make a recommendation to the Director of NIH, with whom the ultimate decision lies.³³ Donations that occur in the United States on or after the effective date of the guidelines must comply with the standards set forth by NIH.

³⁰ *Id.*

³¹ *Id.* at 32174-5.

³² *Id.* at 32172.

³³ *Id.* at 32175.

However, research using lines derived from donations that occur in foreign countries on or after the effective date of the guidelines may comply with its standards or, alternatively, pursue federal funds through the ACD review and recommendation process described above.³⁴

Legislative Activity in the 111th Congress

Congressional interest in stem cell research continued steadily since President Bush's policy announcement in 2001. Despite the introduction of various bills to both promote and limit federal funding of stem cell research, there exists no legislative enactment defining what types of post-procurement embryonic stem cell research are eligible to receive federal funding.

In the 111th Congress, H.R. 872, the Stem Cell Research Improvement Act of 2009, contains language that is largely similar to the earlier Stem Cell Research Enhancement Acts of 2005³⁵ and 2007,³⁶ and would amend the PHSA to direct the Secretary of HHS to conduct and support research involving embryonic stem cell lines that met the same criteria enumerated in the prior bills. This bill would additionally require guidelines governing such research to be issued by the Director of NIH within 90 days of enactment, and periodically reviewed every three years. H.R. 873, the Stem Cell Research Enhancement Act of 2009, would also amend the PHSA to direct the Secretary of HHS to conduct and support the same type of embryonic stem cell research. This bill would also require guidelines to be issued within 60 days of enactment, but would not require further periodic review of those guidelines. S. 487, also entitled the Stem Cell Research Enhancement Act of 2009, is identical to S. 5 in the 110th Congress.

Other bills introduced during the 111th Congress are aimed at supporting some types of stem cell research, but appear to exclude most embryonic stem cell research. H.R. 877, the Patients First Act of 2009 would direct the Secretary of HHS to conduct and support research on pluripotent stem cells, but appears to exclude research upon stem cell lines that were derived from embryonic sources. S. 99, the Ethical Stem Cell Research Tax Credit Act of 2009, would provide businesses a credit equal to 30% of "qualified stem cell research expenses."³⁷ Qualified stem cell research expenses do not appear to include embryonic stem cell procurement activities, insofar as those activities would subject a human embryo to destruction, discarding, or risk of injury. Research activities using embryonic stem cell lines that were derived in a manner which subject a human embryo to destruction, discarding, or risk of injury would not appear to be eligible for the tax credit proposed by this bill.

Conscience Protections

Federal law protects individuals from being required to perform or assist in the performance of federally funded research that is morally or religiously objectionable to them.³⁸ This protection, which would likely encompass objections to research on embryonic stem cell lines, is only

³⁴ *Id.*

³⁵ H.R. 810.

³⁶ S. 5. On June 7, 2007, the House passed S. 5 by a vote of 247-176, but it was ultimately vetoed by President Bush.

³⁷ This bill is similar to S. 2863 in the 110th Congress.

³⁸ 42 U.S.C. § 300a-7(d). For a more in-depth discussion of this provision and other conscience clauses, see CRS Report RL34703, *The History and Effect of Abortion Conscience Clause Laws*, by Jon O. Shimabukuro.

triggered in instances where the objectionable research is federally funded.³⁹ Therefore it is unlikely to arise in the context of embryonic stem cell procurement, as federal funds may not be used for those purposes.

Facilities that receive biomedical or behavioral research grants are additionally prohibited from discriminating among any employment or staff privileges based upon an individual's opinions of, or prior refusals to participate in, health services or research activities that are contrary to his religious beliefs or moral convictions.⁴⁰ This would appear to prevent recipients of NIH grants from discriminating against individuals that are opposed to stem cell research.

In December of 2008, the Bush administration issued final regulations reiterating these protections and additionally requiring recipients of federal funds to certify, in writing, that they will refrain from these prohibited actions.⁴¹ The Obama administration has indicated that it intends to rescind these regulations.⁴²

Author Contact Information

Edward C. Liu
Legislative Attorney
eliu@crs.loc.gov, 7-9166

³⁹ 42 U.S.C. § 300a-7(d).

⁴⁰ 42 U.S.C. § 300a-7(c)(2).

⁴¹ 45 C.F.R. §§ 88.4(d), 88.5. *See* 73 Fed. Reg. 78,071-101.

⁴² 74 Fed. Reg. 10207 (Mar. 10, 2009). *See also* Rob Stein, *Health Workers' Conscience Rule Set to Be Voided*, WASHINGTON POST, Feb. 28, 2009, at A1.