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*Background and Legal Issues Related to Human
Embryonic Stem Cell Research*

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January 25, 2008

Abstract. Federal funding of human embryonic stem cell procurement is prohibited by actions of both Congress and the current administration. Similarly, executive branch policy currently regulates the availability of federal funds for research using independently created embryonic stem cell lines. Pursuant to President Bush's August 2001 announcement, federal funds may be used to conduct research on certain human embryonic stem cells. Federal funding 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. During the 110th Congress, at least 10 bills responding to the limitations imposed by the President's 2001 announcement, including the Stem Cell Research Enhancement Act of 2007 (H.R. 3/S. 5/S. 997), have been introduced but none have yet become law.

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Background and Legal Issues Related to Human Embryonic Stem Cell Research

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Summary

Federal funding of human embryonic stem cell procurement is prohibited by actions of both Congress and the current administration. Similarly, executive branch policy currently regulates the availability of federal funds for research using independently created embryonic stem cell lines. Pursuant to President Bush's August 2001 announcement, federal funds may be used to conduct research on certain human embryonic stem cells. Federal funding 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. During the 110th Congress, at least 10 bills responding to the limitations imposed by the President's 2001 announcement, including the Stem Cell Research Enhancement Act of 2007 (H.R. 3/S. 5/S. 997), have been introduced but none have yet become law.

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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 potential than stem cells derived from adult tissue. Whereas embryonic stem cells are 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 treat or mitigate diseases and conditions and to generate replacement tissues for disfunctioning cells or organs.⁸ Examples of research efforts include spinal cord injury, multiple

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.

⁸ For additional information on stem cell research, see CRS Report RL33540, *Stem Cell Research: Federal Research* (continued...)

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

Executive and Legislative Actions

Historically, there have been two sequential phases of research implicating human embryonic stem cells: (1) research on human embryonic tissue that produces stem cells; and (2) research using those stem cells 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 in both phases is subject to certain restrictions. The scope of these restrictions will be discussed below.

Federal Funding of Embryonic Research and The Dickey Amendment

While federal law has regulated federal funding of fetal research since 1974,¹⁰ federal funding of embryonic research has only been restricted since 1994, when President Clinton, through an executive directive, prohibited federal funding of such research.¹¹ Subsequently, in 1996, Congress enacted a legislative ban in the funding measure of the National Institutes of Health and has continued to pass a similar ban annually since that time.¹²

Known as the Dickey Amendment,¹³ the congressional ban 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.¹⁴ 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.¹⁵ 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

(...continued)

Funding and Oversight, by Judith A. Johnson and Erin D. Williams.

⁹ *Id.* at 4-6.

¹⁰ National Research Service Award Act of 1974, P.L. 93-348, § 213, 88 Stat. 342 (1974).

¹¹ Statement on Federal Funding of Research on Human Embryos, 30 Weekly Comp. Pres. Doc. 2459 (December 2, 1994).

¹² Balanced Budget Downpayment Act, 1996, P.L. 104-99, § 128, 110 Stat. 26, 34 (1996).

¹³ The amendment is so named for its principal sponsor, Rep. Jay Dickey.

¹⁴ 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).

¹⁵ The rider language has not changed significantly over the years and is currently found in Title V of the Labor, HHS, and Education appropriations acts. P.L. 110-161, § 509 (2007).

were able to isolate stem cells from human embryos and coax them to grow into specialized cells.¹⁶

The Dickey Amendment and Stem Cell Research

After the development of privately funded human embryonic stem cell lines, questions arose as to whether federal funds could be used in subsequent research involving these cell lines. In January of 1999, HHS's General Counsel concluded that the 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."¹⁷ 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 derived the stem cells from embryos.

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."¹⁸ 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 2000.¹⁹ 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 treatment. NIH initiated the applications process, but that process was overtaken by events and a new administration's policy was set forth.

Presidential Policy and Human Embryonic Stem Cell Research

When President Bush took office in January of 2001, he announced the conduct of 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

¹⁶ James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 *SCIENCE* 1145 (1998).

¹⁷ 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.

¹⁸ Letter from Secretary Shalala to Rep. Jay Dickey, February 23, 1999. The letter also 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."

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

of the announcement.²⁰ 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 that 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.²¹

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.²² NIH maintains a list of entities that have developed stem cells lines that meet the President's criteria and are eligible for federal funding.²³

Recent Congressional Activity

Congressional interest in stem cell research has continued steadily since President Bush's policy announcement in 2001. During the 109th Congress, at least seven bills involving stem cell research were introduced, two of which were enacted.²⁴ 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, 2006.²⁵ H.R. 810 would have amended the Public Health Service Act (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.²⁶ A vote to override the veto was unsuccessful.²⁷

²⁰ President's Address to the Nation on Stem Cell Research From Crawford, Texas, 37 Weekly Comp. Pres. Doc. 1149 (August 9, 2001).

²¹ *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.

²² *Id.* Some of these prohibitions appear to incorporate legislative prohibitions from the Dickey Amendment. *See, supra* note 15 and accompanying text.

²³ 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, *supra* footnote 8 at 14-15.

²⁴ H.R. 2520, 110th Cong., Stem Cell Therapeutic and Research Act of 2005 (providing for the collection and maintenance of human cord blood stem cells) (enacted as P.L. 109-129). S. 3504, 110th Cong., Fetus Farming Prohibition Act of 2006 (making it unlawful to 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 obtained from a human embryo or fetus that was gestated in the uterus of a nonhuman animal) (enacted as P.L. 109-242).

²⁵ A companion bill, S. 471, was introduced by Sen. Arlen Specter on February 28, 2005.

²⁶ The President argued that the bill would compel taxpayers "to fund the deliberate destruction of human embryos," (continued...)

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.²⁸ 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 language of H.R. 3, as well as the language of the Alternative Pluripotent Stem Cell Therapies Enhancement Act from the 109th Congress. On June 7, 2007, the House passed S. 5 by a vote of 247-176. On June 20, 2007, the President vetoed S. 5.²⁹

Despite the various bills introduced to address stem cell research, there is currently no congressional enactment defining what types of post-procurement embryonic stem cell research are eligible to receive federal funding. Because the current administration is term-limited, a change in administrations is imminent. It is possible that the current administration's stem cell policies will be discontinued or enhanced. Absent any congressional enactment, potential policies of the new administration could range from total funding of all embryonic stem cell research to the complete denial of federal funds for such research.

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and that "crossing this line would ... needlessly encourage a conflict between science and ethics that can only do damage to both and harm our Nation as a whole." 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)).

²⁷ See 152 Cong. Rec. H5450 (daily ed. July 19, 2006) (the vote was 235-193).

²⁸ For additional discussion of stem cell research legislation in the 110th Congress, see CRS Report RL33540, *Stem Cell Research: Federal Research Funding and Oversight*, by Judith A. Johnson and Erin D. Williams, *supra* footnote 8 at 25-29.

²⁹ Message to the Senate of the United States (June 20, 2007), *available at* <http://www.whitehouse.gov/news/releases/2007/06/print/20070620-5.html>. The President observed, "S. 5, like the bill I vetoed last year, would overturn today's carefully balanced policy on stem cell research. Compelling American taxpayers to support the deliberate destruction of human embryos would be a grave mistake."