New Federal Initiatives Project

Embryonic Stem Cell Research

By
O. Carter Snead*

May 19, 2010

The Federalist Society
for Law and Public Policy Studies

Embryonic Stem Cell Research

Pluripotent cells ("stem cells") are unique and valuable because they are undifferentiated (meaning that they have the capacity to become any kind of tissue in the body) and, in principle, self-renewing (that is, they can reproduce themselves indefinitely without losing their pluripotency). They can be derived from the inner-cell mass of the early human embryo (embryonic stem cells), the gonadal ridge of the early human fetus (embryonic germ cells), and perhaps from a variety of other sources, including amniotic fluid, bone marrow, adipose cells, etc.[1] Recent developments suggest that adult cells can be reprogrammed to pluripotency through the introduction of certain genetic factors.

The primary normative question raised by the practice of embryonic stem cell research is whether (and under what circumstances) it is morally defensible to disaggregate (and thus destroy) living human embryos in order to derive stem cells for purposes of basic research that may someday yield regenerative therapies. The public question at issue for the past twelve years has been whether and to what extent to fund such research with taxpayer dollars. This issue raises additional contested normative questions about moral complicity, respect for conscience in a pluralistic society, the moral and political significance of government endorsement (e.g., through federal funding), and the obligations of citizenship.

On Monday, March 9, 2009, President Obama issued Executive Order 13505, titled "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells."[2] This order authorizes the Secretary of Health and Human Services and the National Institutes of Health (NIH) to "support and conduct responsible, scientifically worthy human stem cell research, including embryonic stem cell research, to the extent permitted by law."[3] The order lifted limitations placed by President Bush on federally funded human embryonic stem cell research. Finally, it directed the Secretary and the Director of NIH to issue new guidelines for such research consistent with E.O. 13505. This guidance has now issued. The upshot is that the United States government, for the first time, will fund research that depends on and incentivizes the use and destruction of living human embryos.

To understand the scope and substance of President Obama's policy, it is necessary first to understand the legal and political background against which it was developed. The more than thirty-year history of the embryo-based research funding debate is one of stalemate. In the 1970s, acting on the advice of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the U.S. Department of Health, Education, and Welfare issued regulations requiring any funding for research involving the use and destruction of in vitro human embryos to be approved by the federal Ethics Advisory Board (EAB).[4] In 1979, the EAB issued a report that concluded, in principle, that funding of embryo research was ethical.[5] However, its charter expired shortly thereafter, before it had the opportunity to pass on such proposals for funding.[6] It was never reconstituted, though its approval remained on the books as a legal prerequisite for funding such research. The result was a de facto moratorium on federal funding of embryo research until 1993, when Congress, at the request of President Clinton,[7] nullified the rule requiring EAB approval.[8]

President Clinton convened a panel to advise the NIH Director to recommend guidelines for funding embryo research. The NIH Human Embryo Research Panel issued a report in 1994 recommending funding for embryo research, including proposals in which embryos were created solely for use in such research.[9] President Clinton accepted the general recommendation to fund embryo research, but explicitly rejected the advice to fund proposals requiring the intentional creation of embryos for such use.[10] Before he could act on the recommendations, however, the newly-elected Congress passed an appropriations rider (the Dickey Amendment) which forbade the funding of

> 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 the relevant human subjects protection regulations].[11]

The Dickey Amendment (which has been reauthorized every year since its passage in 1996)[12] seemed to settle the matter until 1998 when researchers derived stem cells from human embryos for the first time.[13] This development provoked renewed enthusiasm in some quarters for federally funded embryo research. It also prompted a closer look at the Dickey Amendment to discern its precise scope. Specifically, did Dickey permit the federal funding of research involving stem cell *lines* that had been derived in the course of privately funded embryo-destructive research? The HHS General Counsel opined that Dickey did not prohibit such funding.[14] This construction of Dickey opened the door for broad federal funding of stem cell research.

Before any funds were made available for such research, however, President George W. Bush was elected. After reviewing the matter, President Bush promulgated his own guidelines for embryonic stem cell research.[15] Under these guidelines, federal funds were not to be "used to create incentives to destroy, or harm, or create living embryos for purposes of research."[16] Concretely, this entailed support for all nonembryonic sources of stem cells, including stem cells derived from adult cells, discarded umbilical cords, and placentas. It also entailed support for research on *embryonic* stem cell lines that had been derived before the announcement of the policy on August 9, 2001, as the embryos had already been destroyed and could thus no longer be saved. The combined approach would allow exploration of many kinds of stem cell research without using taxpayer funds to incentivize the further destruction of embryos.

Over the course of his two terms in office, President Bush explained the ethical foundation underlying his new policy on many occasions. It was driven by two propositions, one empirical and one normative. First, President Bush acknowledged that the human embryo destroyed in embryonic stem cell research is a living organism of the human species (a proposition confirmed by modern embryology) that will, if all goes well, direct itself along a seamless trajectory across all the various biological stages of development. Second, President Bush invoked the American foundational principle of equality, and concluded that it is unjust for some members of the human species to be intentionally used and destroyed for the benefits of others in scientific research (even in those cases where a prior decision has been made that such early-stage human beings are no longer wanted and should be destroyed in any event). The clearest iteration of

President Bush's thinking on this question came in his July 2006 remarks upon vetoing Congressional efforts to liberalize his funding policy:

> Yet we must also remember that embryonic stem cells come from human embryos that are destroyed for their cells. Each of these human embryos is a unique human life with inherent dignity and matchless value. We see that value in the children who are with us today. Each of these children began his or her life as a frozen embryo that was created for in vitro fertilization, but remained unused after the fertility treatments were complete. Each of these children was adopted while still an embryo, and has been blessed with the chance to grow up in a loving family… These boys and girls are not spare parts. (Applause.) They remind us of what is lost when embryos are destroyed in the name of research. They remind us that we all begin our lives as a small collection of cells. And they remind us that in our zeal for new treatments and cures, America must never abandon our fundamental morals…. America was founded on the principle that we are all created equal, and endowed by our Creator with the right to life. We can advance the cause of science while upholding this founding promise. We can harness the promise of technology without becoming slaves to technology. And we can ensure that science serves the cause of humanity instead of the other way around.[17]

In a 2007 Executive Order (discussed immediately below), President Bush likewise confirmed that two key ethical principles driving his approach to federal funding in this context were that "the destruction of nascent life for research violates the principle that no life should be used as a mere means for achieving the medical benefit of another;" and "human embryos and fetuses, as living members of the human species, are not raw materials to be exploited or commodities to be bought and sold."[18] President Bush made it clear, however, that he was committed to pursuing stem cell research to the maximal extent possible, consistent with these principles.

Opponents of President Bush's policy argued that the funding restrictions were unduly narrow, particularly given the perceived breakthrough possibilities of embryonic stem cell research, coupled with the view (held by most advocates of embryonic stem cell research) that human embryos are not entitled to the same moral respect owed to post-natal human beings. Some opponents made the narrower argument that funding should at least be authorized for research on stem cell lines derived from living embryos that were destined to be destroyed in any event.

Later, in response to a host of revolutionary developments regarding the derivation of pluripotent (i.e., stem) cells[19] from non-embryonic sources (including a technique for reprogramming adult cells to be functionally equivalent to embryonic stem cells (induced pluripotent state cells or iPS cells)), President Bush issued an executive order directing the NIH to redouble its efforts to promote such research.[20] As of July 2007, the federal government had made over $3 billion available for all eligible forms of research, including more than $130 million for embryonic stem cell research using cells derived from the pre-August 9, 2001 lines.[21]

The private sector and the States also allocated more than $4.2 billion to support stem cell research, including embryonic stem cell research that fell outside President Bush's guidelines for federally funded research. (California alone passed a law in 2004 allocating $3 billion for embryo research).[22]

President Obama's executive order authorizes funding for all forms of embryonic stem cell research that are "responsible, scientifically worthy, [and] … permitted by law."[23] The order cites as its underpinning the promise of the research and "the broad agreement in the scientific community that the research should be supported by Federal funds."[24] The executive order does not define "responsible" stem cell research or lay out an ethical framework within which this term may be understood and on its face would permit federal funding of research on embryonic stem cell lines derived by whatever means, including from embryos created solely for the sake of research (by, for example, in vitro fertilization or human cloning). The order does however direct the NIH Director to review existing NIH Guidance and other widely recognized guidelines on human stem cell research, including establishing appropriate safeguards, and issue new guidance consistent with the order. The order concludes by revoking President Bush's executive order that had directed NIH to pursue all promising avenues of stem cell research derived without creating human embryos for research purposes or destroying, discarding or harming human embryos, including adult stem cell research and induced pluripotent state cell research.

In his remarks announcing the policy, President Obama added that "a majority of Americans" have now reached a "consensus that we should pursue this research."[25] He did not give his own view of the moral status of the embryo, although he did identify one practice that he deemed unethical in this context – the use of cloning to produce a live born child. He did not, however, explain his ethical objections to this practice. He called upon Congress to act to further promote embryonic stem cell research.

In July 2009, NIH issued its final guidelines implementing President Obama's policy.[26] The guidelines cited two animating normative principles that grounded the regulations: 1) "Responsible research with hESCs has the potential to improve our understanding of human health and/or treat illness; and 2) individuals donating embryos for research purposed should do so freely, with voluntary and informed consent." Neither the guidelines nor the response to comments speak to the question of the moral status of human embryos.

The NIH guidelines authorize funding for a narrower species of research than would be possible under the President's executive order standing on its own. Most importantly, funding is restricted to research on embryonic stem cell lines derived from embryos that were "created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose." The NIH regulations also forbid funding for research in which human embryonic stem cell lines are "introduced into non-human primate blastocysts," or research involving "the breeding of animals where the introduction of hESCs or human induced pluripotent stem cells may contribute to the germ line." The guidelines explicitly forbid funding for research involving embryonic stem cells derived from embryos conceived by human cloning (somatic cell nuclear transfer), parthenogenesis, "and/or IVF embryos created for research purposes." Finally, the guidelines explicitly mention that the Dickey Amendment forbids federal funding for the derivation of embryonic stem cells (i.e., the use and destruction of embryos for stem cell research).

The NIH guidelines also include informed consent provisions requiring applicants to provide documentation that "all options *available in the health facility where treatment was sought*" were explained; no payments were offered for the embryos; and that donors were informed "what would happen to the embryos in the derivation of hESCs for research." For those applicants seeking funding for research involving lines derived before the new policy was announced, an Advisory Committee to the Director of NIH may recommend funding even if the above criteria are not completely met, if it is persuaded that the embryos in question were created by IVF for reproductive purposes, and donated by individuals who gave voluntary written consent. Indeed, the NIH has recently approved several lines derived before 2009 (lines approved for funding by President Bush) following this procedure.

A few concluding observations about the Obama funding policy are in order. First, and most obvious, it is a major departure from longstanding federal neutrality on the question of embryo destructive research. For the first time, the federal government is providing direct financial incentives for research that depends on and therefore potentially incentivizes the use and destruction of living human embryos. Second, even though the NIH guidelines are narrower than the executive order, they do not forbid any research practice that is currently possible or widely practiced.[27] Human embryonic stem cells have not yet been derived from cloned human embryos, and very few researchers create embryos by IVF solely for the sake of research (and very few, if any, donors are willing to conceive embryos for this purpose).[28] Third, the NIH guidelines could be expanded with little difficulty. The scope of permissible research would expand automatically if the Dickey Amendment were ever revoked, and many commentators have interpreted President Obama's invitation to Congress to act in this arena and the NIH regulations' specific citation to Dickey) as forerunners of such legislative action.[29] Fourth, it is notable that the NIH informed consent guidelines do not require the researcher to advise the donor of alternatives to donation outside of the treating facility. Thus, in most cases there will be no requirement to advise donors of the possibility of embryo adoption. The NIH guidelines also do not require the researcher to inform the donor that the embryos will be destroyed in the process of cell derivation. Nor do the NIH guidelines require that the person soliciting donation of embryos be someone other than the donor's treating physician. Fifth, and last, the Obama policy is notable in that it does not offer any normative account of the moral status of the embryo. Nor does it respond to the normative arguments of opponents of embryo-destructive research.

In short, the moral and political debate over embryonic stem cell research continues to roil American society. President Obama's policy puts the prestige and resources of the executive branch squarely behind those who argue strongly in favor of such research.

**Prof. O. Carter Snead is an Associate Professor of Law at the University of Notre Dame Law School.*

---

[1] *See* PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH (2004).
[2] Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 11, 2009), *available at* http://edocket.access.gpo.gov/2009/pdf/E9-5441.pdf.
[3] *Id.* at 10,667.

[4] *See* 46 C.F.R. 46.204(e) (1975), nullified by section 121(c) of the NIH Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 133 (1993), and rescinded by 59 FR 28276 (June 1, 1994).
[5] *See* NATIONAL BIOETHICS ADVISORY COMMISSION, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH 34 (1999) (hereinafter NBAC REPORT), *available at* http://bioethics.georgetown.edu/nbac/stemcell.pdf..
[6] *Id.*
[7] *Id.* at 31.
[8] *See* National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122.
[9] *See* NBAC REPORT, *supra* note 5, at 34.
[10] *See id.*
[11] Pub. L. No. 104-99, Title I, § 128, 110 Stat. 26, 34 (1996)..
[12] *See* Sheryl Gay Stolberg, *Obama Is Leaving Some Stem Cell Issues to Congress*, N.Y. TIMES, Mar. 9, 2009, at A1, *available at* http://www.nytimes.com/2009/03/09/us/politics/09stem.html?_r=1&scp=1&sq=dickey%20amendment&st=cse.
[13] James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145 (1998).
[14] Memorandum from Harriset S. Rabb, General Counsel, Department of Health and Human Services to Harold Varmus, M.D., Director, National Institutes of Healt on Federal Funding for Research Involving Human Pluripotent Stem Cells (Jan. 15, 1999), available online in Guenin, *Mechanics for Implementing New Federal Policy on embryonic Stem Cell Research* (December 30, 2008 (rev), Appendix II, link at http://guenin.med.harvard.edu/Presentations.html .
[15] Press Release, White House, Office of the Press Sec'y, Fact Sheet: Embryonic Stem Cell Research (August 9, 2001), *available at* http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-1.html.
[16] *Id.*
[17] Press Release, White House, Office of the Press Sec'y, President Discusses Stem Cell Research Policy (July 19, 2006), *available at* http://georgewbush-whitehouse.archives.gov/news/releases/2006/07/20060719-3.html. This ethical framework was present from the inception of the Bush policy. *See generally* George W. Bush, *Stem Cell Science and the Preservation of Life*, N.Y. TIMES, August 12, 2001 ("There is at least one bright line: We do not end some lives for the medical benefit of others. For me, this is a matter of conviction: a belief that life, including early life, is biologically human, genetically distinct and valuable."), *available at* http://www.nytimes.com/2001/08/12/opinion/stem-cell-science-and-the-preservation-of-life.html?pagewanted=1.
[18] Expanding Stem Cell Research in Ethically Responsible Ways, Exec. Order No. 13,435, 72 Fed. Reg. 34,589 (June 20, 2007), *available at* http://georgewbush-whitehouse.archives.gov/news/releases/2007/06/20070620-6.html.
[19] Pluripotent cells are cells that have the potential to develop into almost any kind of cell but are not capable of creating an entire organism. Science in Society, Key Terms: Stem Cells, http://scienceinsociety.northwestern.edu/content/key-terms-stem-cells (last visited Apr. 19, 2010).
[20] Exec. Order No. 13,435, 72 Fed. Reg. 34,589 (June 20, 2007).
[21] CONG. RESEARCH SERV., STEM CELL RESEARCH: FEDERAL RESEARCH FUNDING AND OVERSIGHT (2007), *available at* http://www.fas.org/sgp/crs/misc/RL33540.pdf; *see* Exec. Order

No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007); President's Message to the Senate Returning Without Approval the Stem Cell Research Enhancement Act of 2007, 43 Weekly Comp. Pres. Doc. 833 (June 20, 2007).

[22] CONG. RESEARCH SERV., STEM CELL RESEARCH: STATE INITIATIVES (2006), *available at* http://stemcells.nih.gov/staticresources/research/GW-State-Funding.pdf; Sonya Geis, *Rich Donors Help Calif. Fund Stem Cell Research*, WASH. POST, Dec. 19, 2006, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2006/12/18/AR2006121801080.html.

[23] Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-cells/.

[24] *Id.* at Section 1.

[25] Press Release, White House, Office of the Press Sec'y, Remarks of President Barack Obama – As Prepared for Delivery Signing Stem Cell Executive Order and Scientific Integrity Presidential Memorandum (March 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/remarks-of-the-president-as-prepared-for-delivery-signing-of-stem-cell-executive-order-and-scientific-integrity-presidential-memorandum/.

[26] Nat'l Insts. of Health, National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009), *available at* http://edocket.access.gpo.gov/2009/E9-15954.htm.

[27] *Id.*

[28] *See, e.g.*, Nicholas Wade, *Some Scientists See Shift in Stem Cell Hopes*, N.Y. TIMES, Aug. 14, 2006 (discussing future hopes for embryonic stem cell research), *available at* http://www.nytimes.com/2006/08/14/washington/14stem.html?_r=1; Nat'l Insts. of Health, Stem Cell Basics: What Are Embryonic Stem Cells?, http://stemcells.nih.gov/info/basics/basics3.asp (last visited Apr. 19, 2010) ("Most embryonic stem cells are derived from embryos that develop from eggs that have been fertilized *in vitro*—in an *in vitro* fertilization clinic—and then donated for research purposes with informed consent of the donors.").

[29] *See, e.g.*, Sheryl Gay Stolberg, *Obama Is Leaving Some Stem Cell Issues to Congress*, N.Y. TIMES, Mar. 9, 2009, at A1 ("[P]eople on both sides of the stem cell debate say Mr. Obama's announcement [of his lifting of the Bush Administration's stem cell restrictions] could lead to a reconsideration of the [Dickey amendment] on Capitol Hill.").

Related Links

Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 11, 2009)
http://edocket.access.gpo.gov/2009/pdf/E9-5441.pdf

"Obama Lifts Bush's Strict Limits on Stem Cell Research," by Sheryl Gay Stolberg, *The New York Times*, March 9, 2009
http://www.nytimes.com/2009/03/10/us/politics/10stem.html

"The President Politicizes Stem-Cell Research," by Robert P. George and Eric Cohen, *The Wall Street Journal*, March 10, 2009
http://online.wsj.com/article/SB123664280083277765.html

"Falling Behind on Stem-Cell Research," by Christopher Thomas Scott and Jennifer McCormick, *The Boston Globe*, April 18, 2006
http://www.boston.com/news/science/articles/2006/04/18/falling_behind_on_stem_cell_research