Fate of Federal Funding for Comprehensive Embryonic Stem Cell Research Remains in Hands of Congress

By Cynthia S. Marietta, J.D., LL.M. Candidate (Health Law)  
csmarie@central.uh.edu

Introduction

On March 9, 2009, President Obama issued an Executive Order\(^1\) that purportedly removed all barriers to federal funding for human embryonic stem cell (hESC) research.\(^2\) Recognizing that hESC research has the potential to lead to the treatment of many disabling diseases and conditions, President Obama made the following promise when he signed the Executive Order:

\[
[\text{a}t \text{t} \text{his} \text{ moment, the full promise of stem cell research remains unknown. But scientists believe these tiny cells may have the potential to help us understand, and possibly cure, some of our most devastating diseases and conditions. . . . Ultimately, I cannot guarantee that we will find the treatments and cures we seek. . . . But I can promise that we will seek [treatments and cures] – actively, responsibly, and with the urgency required to make up for lost ground. Not just by opening up the new frontier of research today, but by supporting promising research of all kinds. . . .}^{3}
\]

The purpose of President Obama’s Executive Order was three-fold: (1) to remove all limitations placed on embryonic stem cell research by past presidential actions, (2) to expand the National Institutes of Health (NIH) support for the exploration of human stem cell research, and (3) to enhance America’s contribution to important new discoveries and new therapies for the benefit of mankind.\(^4\)

On its face, President Obama’s Order gave great hope for unfettered federal financial support for hESC research. But much to the disappointment of the scientific community, the Order did not resolve the thorny obstacle that has plagued hESC research for years. That obstacle is a 14 year-old Congressional ban on governmental use of public funds for

\(^{1}\) See Executive Order 13505, 74 Fed. Reg. 10667 (Mar. 11, 2009); see also Barack Obama, Executive Order: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Mar. 9, 2009, available through http://www.whitehouse.gov/the_press_office. Embryonic stem cells are unique cells found in the human embryo that are capable of producing any cell type in the developing body. For more explanation of stem cells, see The President’s Council on Bioethics, Monitoring Stem Cell Research: Recent Developments in Stem Cell Research and Therapy: Stem Cells and Their Derivatives, (Jan. 2004), available through http://www.bioethics.gov/reports/stemcell/index.html.


\(^{3}\) Id. (emphasis added).

\(^{4}\) Executive Order 13505, supra note 1.
research in which embryos are created or destroyed. This Congressional ban, otherwise known as the Dickey-Wicker Amendment ("Dickey Amendment"), was originally attached as a rider to the 1996 appropriations bill for the Department of Health and Human Services (HHS) and the NIH, and has been renewed every year since 1996.5 For all practical purposes, the Dickey Amendment prohibits research on embryos and the ability to create stem cell lines because embryos are destroyed when stem cells are extracted from them.6 President Obama does not have the authority to overturn this Congressional ban, only Congress can.

With the science of human embryonic stem cells still in its stage of infancy, researchers believe the Dickey Amendment stifles the progress of stem cell-based therapies for treatment of various medical conditions,7 including diabetes, cardiac disease, Parkinson’s Disease, spinal cord injuries, and amyotrophic lateral sclerosis.8 Proponents of hESC research contend that, unless or until Congress repeals the Dickey Amendment, the full medical potential for human embryonic stem cells will never be completely realized in the United States.9

Background on U.S Policy on Federal Funding of hESC


9 See, e.g., Daley, supra note 7.
The federal government’s decision to fund a research project means more than just an offer of financial resources. It means the government has declared official national support and endorsement of the research project. Moreover, it means the nation as a whole, through the federal government, deems the project to be good and worthy. “When [a research project] is done with public funding, it is done, so to speak, in the name of the country, with its blessing and encouragement.”

Controversies surrounding the morality of certain research projects typically give rise to disputes over the policy on federal funding. The issue of whether taxpayer funds should be used to support embryo research is no exception. Embryo research that involves the destruction of embryos goes directly to the heart of the ongoing debate about the moral status of embryos and the proper treatment for nascent human life. And couched in the middle of this debate is the ethical dilemma: does the end justify the means? With hESC research, the “end” scientists hope to achieve is the relief of human suffering. The “means” entails the destruction of donated embryos.

From a historical perspective, the long-standing debate over whether federal funds should be made available for embryo research originated in 1973, following the landmark United States Supreme Court case of Roe v. Wade, which legalized abortion in the United States. In the wake of Roe v. Wade, Congress was concerned about the potential uses and abuses of aborted fetuses in research. In response to this concern, the Department of Health, Education and Welfare (DHEW), the predecessor of HHS, issued a moratorium on any funding for research using human fetuses or living embryos. Although the moratorium was eventually lifted in 1975, no funds were made available for research.

In 1993, the NIH convened the Human Embryo Research Panel (“Panel”) to consider the issues surrounding embryo research and to prepare guidelines for potential funding applications. The Panel recommended, among other things, that embryos created through the in vitro fertilization process for reproductive purposes should be deemed

---

11 Id.
12 Id.
13 Id.
14 Monitoring Stem Cell Research: Current Federal Law & Policy, supra note 5.
15 Id.
17 Id.
18 Roe v. Wade, 410 U.S. 113 (1973). The U.S. Supreme Court decided this case in 1973, overturning a Texas interpretation of abortion law and making the procedure legal based on the right to privacy.
19 Monitoring Stem Cell Research: Current Federal Law & Policy, supra note 5.
20 Id.
21 Id.
22 Id.
eligible for federal funding within a framework of recognized ethical safeguards. Former President Clinton accepted the Panel’s recommendation and permitted NIH to consider applications for funding research using embryos left-over from IVF procedures. Congress, however, did not endorse the panel’s recommendation, and instead, attached the Dickey Amendment as a rider to the 1996 appropriations bill for the funding of HHS and NIH.

It is significant to note that, while the Dickey Amendment effectively prohibits the use of federal funds to support any research that destroys human embryos, it does not prohibit such research or the use of private funds to support such research. It simply states there will be no federal funding for the creation or destruction of embryos for research.

In 1998, two years after the Dickey Amendment was enacted, privately-funded researchers discovered the ability to isolate human embryonic stem cells, which caused great excitement in the scientific community because of the promising potential for treatment with these cells. Although the language in the Dickey Amendment does not specifically mention stem cells, it appears to close the door on federal funding for any hESC research since the process to derive stem cells requires destruction of embryos. However, in 1999, the General Counsel for HHS interpreted the Dickey Amendment in a more narrow way. She concluded the Dickey Amendment meant that funding could be made available for research on stem cells that were derived from embryos destroyed without federal funds. In other words, she reasoned that, if stem cells were derived from embryos destroyed by private-sector researchers without federal funds, then subsequent research on those derived stem cells may be eligible for federal funding.

Critics of DHHS’ legal interpretation of the Dickey Amendment claim that, although it appears to follow the letter of the law, it violates the spirit of the law and the principles underlying it. Nevertheless, in 2000, the Clinton administration adopted the HHS legal interpretation and drafted specific guidelines to enact it, but the guidelines were never put into practice nor was funding authorized before President Clinton left office.

When President George W. Bush took office, his administration pursued a compromise – a way to fund stem cell research while upholding the spirit and the letter of the Dickey Amendment.

---

23 Id.
24 Id.
25 Monitoring Stem Cell Research: Current Federal Law & Policy, supra note 5; see also Dickey Amendment, supra note 5.
26 Id.
27 Id.
28 Id.
29 Harriet Rabb was DHHS General Counsel in 1999.
30 Monitoring Stem Cell Research: Current Federal Law & Policy, supra note 5.
31 Id.
32 Id.
33 Id.
Amendment.34 On August 9, 2001, President Bush announced his policy on hESC research, using that same date as the timeline for determining which stem cells would be eligible for funding.35 Stem cells derived from embryos before that date would be eligible for funding and those derived after that date would not.36 Moreover, his policy flatly denied funding for the creation of human embryos for research and for cloning.37

Obama Administration’s Current hESC Research Policy

On March 9, 2009, shortly after taking office, President Obama signed an Executive Order announcing his administration’s policy on hESC research and expressly revoking the Bush administration’s policy. The Executive Order stated, in part:

[t]he Secretary of Health and Human Services. . . through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research including human embryonic stem cell research, to the extent permitted by law.38

Although President Obama did not mention the Dickey Amendment in his Executive Order, he subtly alluded to its constraints by stating the NIH may support hESC research to the extent permitted by law. Two days after he signed his Executive Order, President Obama signed the 2009 appropriations bill that renewed the Dickey Amendment, creating what initially appeared to be a contradictory position on hESC research.39 But White House officials subsequently clarified that Obama’s Order complies with the Dickey Amendment.40 Obama’s administration adopted the 1999 HHS legal interpretation of the Dickey Amendment, taking the position that federally-funded researchers can conduct research on stem cell lines derived from embryos that were destroyed in research funded by non-federal sources.

Not only did President Obama promise federal funds to support human stem cell research, but he also ordered the NIH to draft guidelines, including provisions which establish appropriate safeguards for such human stem cell research.41 The NIH published its final guidelines for human stem cell research, effective on July 7, 2009.42

34 Id.
35 Monitoring Stem Cell Research: Current Federal Law & Policy, supra note 5.
36 Id.
37 Id.
38 Executive Order 13505, supra note 1 (emphasis added).
41 Executive Order 13505, supra note 1.
According to the NIH guidelines, federal funding will be allowed for research using hESCs derived from embryos created using IVF for reproductive purposes and no longer needed for those purposes, assuming the research has scientific merit and the embryos were donated after proper informed consent was obtained from the donors.43

In conjunction with these guidelines, the NIH established a Human Embryonic Stem Cell Registry for researchers to determine whether particular hESC lines created in the private sector are deemed eligible for federal funding.44 Currently, there are 44 cell lines deemed eligible for funding, with 114 cell lines currently pending eligibility review.45 Moreover, various institutions have reported their intent to submit 233 additional cell lines for eligibility review.46 As compared to the 21 stem cell lines available during the Bush administration,47 the Obama administration has opened the door, giving researchers potential access to hundreds of other eligible stem cell lines.

Now, despite having greater access to stem cell lines, federally-backed researchers argue the Dickey Amendment is self-limiting and will ultimately lead to missed research opportunities by preventing efficient and effective research.48 For instance, these researchers cannot create and investigate their stem cell lines to model human disease.49 They claim such investigations could provide new insights into disease pathology potentially leading to treatment.50 Instead, they will now have to wait and rely on their private-sector counterparts to derive cell lines, knowing that projects could potentially be halted because funding from private foundations or philanthropic sources seldom provides predictable, long-term support.51

Opponents of hESC research, including pro-life groups, contend the Obama administration’s interpretation of the Dickey Amendment is too narrow.52 A National Right to Life Committee director claims the Dickey Amendment should be interpreted to mean the federal government cannot fund any research if it involves previous harm to human embryos.53 Another group, the Christian Medical Association, filed a lawsuit along with other plaintiffs, against the HHS, NIH, and others, alleging that federal grants

(draft guidelines for public comment) and 75 Fed. Reg. 8085 (Feb. 23, 2010) (revision to definition of hESC).

43 Id.
46 Id.
48 See Daley, supra note 7.
49 Id.
50 Id.
51 Id.
52 See Ertelt, supra note 40.
53 Id. (citing Douglas Johnson, legislative director of National Right to Life Committee).
for hESC violate the Dickey Amendment.\textsuperscript{54} That lawsuit was dismissed on procedural grounds, leaving the question wide open as to what the Dickey Amendment really means.\textsuperscript{55}

President Obama’s Executive Order has set the stage for Congress to take some action – either to repeal the Dickey Amendment or continue to renew it. As it currently stands, under the Consolidated Appropriations Act of 2010, the Dickey Amendment will remain in effect for the fiscal year ending 2010.\textsuperscript{56} United States Representatives, Diana DeGette (D-CO) and Michael Castle (R-DE), recently introduced bipartisan stem cell research legislation on March 9, 2010. Ironically, it was the one year anniversary of President Obama’s Executive Order. That piece of legislation, called “The Stem Cell Research Advancement Act” is meant to codify President Obama’s Executive Order,\textsuperscript{57} but it does not address the merits of the Dickey Amendment or whether taxpayers will be required to fund research involving the destruction of embryos in the future.

Conclusion

Arguably, until Congress repeals the Dickey Amendment, federally-backed researchers will continue to be impeded in their research. The ball is in Congress’ court. Only time will tell if Congress will be willing to step onto the very slippery slope topic of nascent human life and attempt to answer the hESC research question: does the end justify the means?

Health Law Perspectives (March 2010)
Health Law & Policy Institute
University of Houston Law Center
http://www.law.uh.edu/healthlaw/perspectives/homepage.asp

The opinions, beliefs and viewpoints expressed by the various Health Law Perspectives authors on this web site do not necessarily reflect the opinions, beliefs, viewpoints, or official policies of the Health Law & Policy Institute. The Health Law & Policy Institute is part of the University of Houston Law Center. It is guided by an advisory board consisting of leading academicians, health law practitioners, representatives of area institutions, and public officials. A primary mission of the Institute is to provide policy analysis for members of the Texas Legislature and health and human service agencies in state government.

\textsuperscript{55} Devine, supra note 54.