

Seton Hall University
eRepository @ Seton Hall

Law School Student Scholarship

Seton Hall Law

2013

Human Embryonic Stem Cell Research and the Constitutionality of the Dickey-Wicker Amendment

William McConnell

Follow this and additional works at: https://scholarship.shu.edu/student_scholarship

Recommended Citation

McConnell, William, "Human Embryonic Stem Cell Research and the Constitutionality of the Dickey-Wicker Amendment" (2013).
Law School Student Scholarship. 389.
https://scholarship.shu.edu/student_scholarship/389

Human Embryonic Stem Cell Research and the Constitutionality of the Dickey-Wicker Amendment

William B. McConnell^{1a}

I. INTRODUCTION

Diseases like juvenile-onset diabetes mellitus, Alzheimer's disease, and Parkinson's disease "result from the death or dysfunction of just one or a few cell types."¹ The advent of human embryonic stem cell (hESC) line technology offers great promise to treat such diseases by providing a source of replacement cells.² The brief history of hESC research, however, has been wrought with controversy due to the methods by which the cells are derived, such that legislative, executive, and legal efforts have substantially stymied hESC research progress.³

This note discusses the efforts to hinder hESC research, but focuses specifically on the Dickey-Wicker Amendment which forbids the use of federal funds for any research that creates human embryos, destroys human embryos, or subjects human embryos to risk of injury or death.⁴ This note begins by looking at the science behind hESC research and compares it to alternative forms of stem cell research. This note then examines the controversy surrounding hESC research and some of the arguments against conducting such research. The focus then shifts to executive, legislative, and judicial efforts to hinder hESC research. This note then reviews the Establishment Clause under the First Amendment and the relevant tests that courts have utilized to analyze whether Government statutes and policies violate the Establishment Clause.

^{1a} B.A., Biology, University of Virginia, 2004; M.S., Biology-Genetics, University of Virginia, 2008; J.D., Seton Hall University School of Law, expected 2013. The author is a former developmental genetics researcher who was supported primarily by NIH grants from 2005-2008.

¹ James A. Thomson et al., *Embryonic Stem Cell Lines Derived From Human Blastocysts*, 282 SCI. 1145, 1147 (1998).

² *Id.*

³ See Shannon McGuire, *Embryonic Stem Cells: Marrow of the Dickey Matter*, 11 J. HIGH TECH. L. 160, 181 (2010).

⁴ OMNIBUS APPROPRIATIONS ACT, 2009, Pub.L. No. 111-8, § 509(a)(2), 123 Stat. 524, 803; see also *Sherley v. Sebelius*, 644 F.3d 388, 390 (D.C. Cir. 2011).

Thereafter, this note specifically examines whether the Dickey-Wicker Amendment violates the Establishment Clause using the Supreme Court's endorsement test. Endorsement test analysis suggests the Amendment unconstitutionally advances the Roman Catholic and Protestant belief that personhood or life begins at conception.⁵ Because the Dickey-Wicker Amendment may violate the fundamental freedom that Government "shall make no law respecting an establishment of religion," this note reviews the Amendment subject to strict scrutiny analysis.⁶ As a result of the above analyses, this note supports the conclusion that the Dickey-Wicker Amendment violates the Establishment Clause and fails judicial review subject to strict scrutiny analysis.

II. SCIENCE AND CONTROVERSY

A. Human Embryonic Stem Cell Research

Human embryonic stem cells are distinguished by three characteristics: (1) derivation from a blastocyst-stage human embryo, (2) the ability to replicate indefinitely while remaining undifferentiated, and (3) pluripotency, the potential to develop into any cell type in the body.⁷ The blastocyst-stage of a human embryo is typically reached between five and six days after fertilization of the egg when the embryo is spherical and consists of little more than a single germ layer surrounding an inner cavity.⁸ The most widely used method for harvesting hESCs

⁵ See James F. Childress, *An Ethical Defense of Federal Funding for Human Embryonic Stem Cell Research*, 2 YALE J. HEALTH POL'Y L. & ETHICS 157, 161-62 (2001).

⁶ U.S. CONST. amend. I.

⁷ THOMSON, *supra* note 1, at 1145.

⁸ See *Blastocyst embryo grading pictures and photos from IVF, In Vitro Fertilization*. Advanced Fertility Center of Chicago (last visited Oct. 30, 2011), <http://www.advancedfertility.com/blastocystimages.htm>.

from the blastocyst necessarily results in the destruction of the embryo, a process that has stirred the ethical controversy behind hESC research.⁹

Advanced Cell Technology, Inc. (“ACT”) received a patent in February 2011 for a proprietary new technique the company claims allows for the derivation of hESC lines without destroying the embryos.¹⁰ The method, referred to as the “single-blastomere” technique, was first published in 2006.¹¹ While the technique appears promising, it has come under criticism and is little used because of ACT’s method patent.¹²

Because of the controversy surrounding hESC research, there has been a push to explore other avenues of stem cell research. Some alternative stem cell platforms include adult stem cells, perinatal stem cells, and stem cells bioengineered through somatic cell nuclear transfer (SCNT), and induced pluripotent stem (iPS) cells.¹³ These alternatives, however, are deficient in ways that hESCs are not. Notably, hESCs are truly pluripotent such that they can develop into any cell type in the body, whereas adult stem cells are multipotent, or limited in cell type differentiation, which limits research and therapeutic applications using adult stem cells. are.¹⁴ Adult stem cells are also difficult to isolate from tissue and culture, whereas hESCs are relatively

⁹ See David G. Zacharias, et al., *The Science and Ethics of Induced Pluripotency: What Will Become of Embryonic Stem Cells?*, MAYO CLIN. PROC. 634, 637 (2011).

¹⁰ ADVANCED CELL TECHNOLOGY, PRESS RELEASES, 2/23/11: *ACT Secures Patent to Generate Embryonic Stem Cells Without Embryo Destruction*, available at <http://www.advancedcell.com/news-and-media/press-releases/act-secures-patent-to-generate-embryonic-stem-cells-without-embryo-destruction/index.asp>.

¹¹ See Irina Klimanskaya, Young Chung, Sandy Becker, Shi-Jiang Lu & Robert Lanza, *Human Embryonic Stem Cell Lines Derived from Single Blastomeres*, 444 NATURE 481, 481 (2006); see also Chung et al., *Human Embryonic Stem Cell Lines Generated without Embryo Destruction*, 2 CELL STEM CELL. CORRESPONDENCE 1, 1 (2008).

¹² See e.g. *id.* (demonstrating low efficiency rates compared to the standard method for deriving hESC lines and failing to demonstrate that biopsied blastocysts survive beyond the blastocyst stage of embryonic development).

¹³ ZACHARIAS, *supra* note 9, at 635-36.

¹⁴ See Patricia A. Zuk, et al., *Human Adipose Tissue is a Source of Multipotent Stem Cells*, 13 MOL. BIOL. CELL. 4279, 4292-93 (2002).

easy to isolate from blastocysts and culture.¹⁵ The drawback of utilizing perinatal stem cells collected from umbilical cord blood and amniotic fluid is that they are only multipotent, not pluripotent like hESCs.¹⁶ Stem cells bioengineered through SCNT are “better suited for disease development research than therapeutic application because reprogramming a cell's genome is correlated with health problems in cloned animals.”¹⁷ Induced pluripotent stem cells show great promise in that they demonstrate true pluripotency, but “not all iPS cells generated to date have demonstrated longitudinal functional equivalence to hESCs because of the lack of long-term follow-up studies.”¹⁸ Moreover, the retroviral vectors used to reprogram the iPS cells may cause cancer, depending on where the vectors randomly insert themselves in the genome, with the result that iPS cells currently cannot be used clinically.¹⁹

Although these alternative forms of stem cells exist with similar qualities and similar potentials for medical advances, hESCs are widely regarded as the “gold standard” within the research field because the other sources of stem cells are not necessarily viable options for clinical research and therapeutic applications.²⁰ Renowned iPS cell researcher Juan Carlos Izpisua Belmonte is quoted as saying: “[Embryonic stem] cells are needed to understand the basic mechanism of pluripotency and self-renewal. As such, it is out of the question to even suggest phasing them out. We will be lost without them.”²¹

Human embryonic stem cell research shows great promise to elucidate “developmental events that cannot be studied directly in the intact human embryo but that have important

¹⁵ *Id.*

¹⁶ ZACHARIAS, *supra* note 9, at 635.

¹⁷ MCGUIRE, *supra* note 3, at 184.

¹⁸ ZACHARIAS, *supra* note 9, at 637.

¹⁹ *See id.*

²⁰ *Id.* at 635.

²¹ Belmonte JC, et al., *Induced pluripotent stem cells and reprogramming: seeing the science through the hype*. 10 NAT REV GENET. 878, 878 (2009).

consequences in clinical areas, including birth defects, infertility, and pregnancy loss.”²² Knowledge of normal human development during the early post-implantation period is particularly limited because it is confined to knowledge gained from the study of a limited number of sectioned human embryos and “analogies drawn from the experimental embryology of other species,” like the mouse.²³ Research using hESCs may be particularly valuable for the study of development and tissue function as it differs between mice and humans.²⁴ Research using hESCs may also be utilized to identify new genes using screens based on the in vitro differentiation of hESCs to certain cell fates.²⁵ Such genes might be used for tissue regeneration therapies, as targets for new drugs, or as targets for teratogenic compounds.²⁶ Finally, once the mechanisms of differentiation are deciphered, “large, purified populations of euploid human cells such as cardiomyocytes and neurons will provide a potentially limitless source of cells for drug discovery and transplantation therapies.”²⁷

B. Controversy

When a human sperm and ova unite, their chromosomes combine to form a unique human being capable of developing from a zygote to a blastocyst to an embryo, then fetus, neonate, infant, child, adolescent, and adult.²⁸ “Some argue that the zygote or blastocyst does not constitute a [person] because each lacks the differentiated cells and tissues characteristic of human beings.”²⁹ Some argue that the early blastocyst, embryo, and fetus forms of a human

²² THOMSON, *supra* note 1, at 1146.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ THOMSON, *supra* note 1, at 1146-47.

²⁸ Robert D. Orr, M.D., C.M. and C. Christopher Hook, M.D., *Stem Cell Research: Magical Promise v. Moral Peril*. 2 YALE J. HEALTH POL’Y L. & ETHICS 189, 191.

²⁹ *Id.*

being do not constitute a person, but rather constitute a “potential person.”³⁰ Others, however, argue that life (or personhood) begins immediately upon the union of sperm and egg.³¹

Opponents of hESC research typically subscribe to the latter two arguments and object to the research because harvesting hESCs inevitably results in destruction of the human blastocysts from which hESCs are derived.³² Under the “potential person” argument, destruction of blastocyst-stage embryos equates to the destruction of potential people who would develop into adults if the embryos were implanted in would-be mothers. Under the “personhood at conception” argument, destruction of blastocyst-stage embryos constitutes murder of a person. Correspondingly, opponents of hESC research feel that it is morally and ethically reprehensible to destroy human blastocysts for the purpose of harvesting hESCs to advance science and medical treatment.³³

Different religious perspectives on the morality of hESC derivation flow from the differing premises about the moral status of the early embryo existing outside a woman’s womb.³⁴ Roman Catholicism officially opposes hESC research because the church holds that life begins at conception such that the destruction of an extracorporeal embryo amounts to murder.³⁵ Similarly, Protestant theologians generally hold that moral life begins at conception such that they oppose the destruction of human blastocysts for the collection of hESCs.³⁶ Jewish theologians, however, hold that life begins at birth and an embryo outside the body lacks standing in Jewish law such that hESC research is permissible.³⁷ Similarly, most Muslim,

³⁰ *Id.*

³¹ *See id.*

³² ZACHARIAS, *supra* note 9, at 637.

³³ MCGUIRE, *supra* note 3, at 181.

³⁴ CHILDRESS, *supra* note 5, at 160.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

Hindu, or Buddhist communities do not hold that moral life begins at conception.³⁸

Representatives from the Church of Jesus Christ of the Latter Day Saints (Mormons), on the other hand, hold a neutral view of hESC research.³⁹ Mormon politicians have traditionally supported federal funding for hESC research while remaining “pro-life” and rejecting a woman’s fundamental right to an abortion.⁴⁰

Some of the staunchest opponents of hESC research grant moral status to human embryos and seek to protect human embryos under the law. One of the most recent efforts to protect human embryos occurred in Mississippi, where Initiative 26 was voted upon on November 8, 2011.⁴¹ The initiative sought to amend the state’s constitution to declare that legally protectable life begins at conception.⁴² The initiative was supported by the state’s largest Christian denomination, the Mississippi Baptist Convention.⁴³ Initiative 26 was also supported by Personhood USA, a Colorado-based group that has pushed similar initiatives in Florida, Montana, Ohio, and Oregon.⁴⁴ Critics of Initiative 26 noted that its passage would legally prohibit birth control methods like intrauterine devices (IUDs) and the morning after pill.⁴⁵ Ultimately, the initiative was rejected by more than fifty five percent of voters.⁴⁶

Opponents of hESC research support that hESC research should be abandoned in favor of alternative stem cell research platforms because the alternatives do not present the same moral

³⁸ Ronald M. Green, Political Interventions in U.S. Human Embryo Research: An Ethical Assessment, 38 J.L. MED. & ETHICS 220, 226 (2010).

³⁹ CHILDRESS, *supra* note 5, at 160.

⁴⁰ *Id.* at 160-61.

⁴¹ *Mississippi Defeats Life at Conception Ballot Initiative*, FOX NEWS (Nov. 8, 2011), <http://www.foxnews.com/politics/2011/11/08/mississippi-defeats-life-at-conception-ballot-initiative/>

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

and ethical dilemma as hESC derivation.⁴⁷ Opponents note that tissue compatibility poses a significant technical obstacle to the clinical application of hESCs.⁴⁸ In this regard, opponents suggest that adult stem cells may be more clinically useful than hESCs.⁴⁹ Further, opponents emphasize that adult stem cells have yielded success in treatments for a variety of diseases where hESCs have yet to demonstrate therapeutic use in humans.⁵⁰

III. CURRENT REGULATION

A. The Executive Orders

President George W. Bush issued Executive Order number 13,435 on August 9, 2001 limiting federal funding on stem cell research to sixty existing hESC lines, reasoning that “the life and death decision [had] already been made” for the embryos destroyed to make the lines, so no moral line would be crossed.⁵¹ Outside of those existing hESC lines, the Bush Executive Order forbade the Department of Health and Human Services and consequently the National Institutes of Health (NIH) from conducting research on any new hESC lines that would require the destruction of human embryos.⁵²

On March 9, 2009, President Obama issued Executive Order No. 13,505, revoking President Bush’s August 9, 2001 directive and permitting federal funding of “scientifically worthy” stem cell research, including hESC research to “the extent permitted by law.”⁵³ In his Order, President Obama recognizes the potential of hESC research, stating:

⁴⁷ Richard M. Doerflinger, *The Ethics of Funding Embryonic Stem Cell Research: A Catholic Viewpoint*, 9 KENNEDY INSTITUTE OF ETHICS J. 137, 143 (1999) (discussing the advantages of alternative methods of deriving stem cells).

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ ZACHARIAS, *supra* note 9, at 635.

⁵¹ See Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007); George W. Bush, President of the United States, President Discusses Stem Cell Research (Aug. 9, 2001).

⁵² See *id.*

⁵³ See Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (March 9, 2009).

Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds. For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.⁵⁴

The Order also directed the Secretary of Health and Human Services (HHS) to issue new guidelines to allow hESC research promulgated by the NIH "to the extent permitted by law."⁵⁵ The result of President Obama's Executive Order is that there are currently no hindrances upon hESC research stemming from the Executive Branch of government.

B. The Dickey-Wicker Amendment

1. Description

While there is currently no resistance against hESC research from the Executive Branch of government, there is active resistance from the Legislative Branch. Two days after mandating the March 9, 2009 Order, President Obama signed the Omnibus Appropriations Act of 2009 into law, including what is commonly referred to as the Dickey-Wicker Amendment.⁵⁶

The Dickey-Wicker prohibits the NIH from funding:

(1) the creation of a human embryo or embryos for research purposes; or (2) 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. 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).⁵⁷

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ See § 509(a)(2), *supra* note 4, at 3280–81

⁵⁷ *Id.*

The Dickey-Wicker Amendment has been included in annual appropriations bills since 1996 during the Clinton Administration.⁵⁸ The plain language of the Amendment codifies the condition that no federal funds may be made available for hESC research that either creates human embryos, destroys human embryos, or subjects human embryos to risk of injury or death.⁵⁹ The Amendment defines “human embryo or embryos” to “include any organism, not protected as a human subject under 45 C.F.R. § 46 as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.”⁶⁰

The Dickey-Wicker Amendment was included in the budget bill in 1996, two years before the advent of hESC lines by James A. Thomson in 1998.⁶¹ At that time, the policy rationale of the Dickey-Wicker Amendment concerned stem cell research as it pertained to cloning, *in vitro* fertilization (IVF), and SCNT.⁶² Despite changes in the science of stem cell research, the language of the Dickey-Wicker Amendment has remained virtually unchanged since it was approved in 1996, and it has been attached to every appropriations bill for funding of the Department of HHS since then.⁶³ As a rider to an appropriations bill, the original Amendment had only a single year of effectiveness, but its inclusion in the federal appropriations

⁵⁸ See I. Glenn Cohen, J.D. & Eli Y. Adashi, M.D., *Human Embryonic Stem-Cell Research under Siege – Battle Won but Not the War*, 364 NEW ENG. J. MED. 1, 2 (2011).

⁵⁹ § 509(a)(2), *supra* note 4, at 3280–81; see also *Sherley v. Sebelius*, 644 F.3d 388, 390 (D.C. Cir. 2011).

⁶⁰ § 509(a)(2), *supra* note 4, at 3281.

⁶¹ See Balanced Budget Downpayment Act 1, Pub. L. No. 104-99, § 128, 110 Stat. 26 (1996); Thomson, et al., *supra* note 1, at 1145-47.

⁶² See Owen C.B. Hughes, Alan L. Jakimo & Michael J. Malinowski, *United States Regulation of Stem Cell Research: Recasting Government’s Role and Questions to be Resolved*, 37 HOFSTRA L. REV. 383, 400-01 (2008).

⁶³ Anne Clark Pierson, *Sherley v. Sebelius: Circuit Court Allows Federal Funding of Embryonic Stem Cell Research to Continue for Now*, 38 J.L. MED. & ETHICS 875, 873 (2010).

laws every year since it was adopted has virtually converted the Dickey-Wicker Amendment into “a de facto law without termination.”⁶⁴

The Amendment’s current language absolutely bans the destruction of human embryos for research purposes, effectively forbidding researchers from using federal money to create new hESC lines.⁶⁵ It is unrealistic for American researchers to develop innovative hESC-based therapies without greater access to viable stem cell lines, particularly when only 136 lines are currently available for use by researchers with NIH funding.⁶⁶ Private investments and certain state funds may be used to create embryonic stem cell lines, but even when private funding is used to create a new stem cell line, those hESCs may not be utilized in projects that receive federal funding.⁶⁷

2. Litigation

After President Obama’s revocation of Bush Executive Order 13,435 and subsequent revision of hESC protocols by the Secretary of HHS, the NIH requested public comment on draft guidelines.⁶⁸ The proposed guidelines allowed federal funding of research using hESCs derived from blastocyst-stage embryos created for reproductive purposes but no longer needed for that purpose.⁶⁹ The NIH received nearly 50,000 comments in response to their request for public comment.⁷⁰

⁶⁴ HUGHES, *supra* note 62, at 407.

⁶⁵ § 509(a)(2), *supra* note 4, at 3280–81; *see also* Sherley, *supra* note 59, at 390.

⁶⁶ NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, NIH HUMAN EMBRYONIC STEM CELL REGISTRY, http://http://grants.nih.gov/stem_cells/registry/current.htm (last visited Nov. 30, 2011).

⁶⁷ Claudia Kalb, *A New Stem Cell Era*, NEWSWEEK (Mar. 9, 2009), *archived at* <http://www.webcitation.org/5tGDwwtyA>.

⁶⁸ *Sherley v. Sebelius*, 776 F.Supp.2d 1, 8 (D.D.C. 2011).

⁶⁹ *Id.* at 8.

⁷⁰ *Id.* at 8.

Responding to the comments seeking clarification, the NIH presented its interpretation of the Dickey-Wicker Amendment as not prohibiting federal funding for hESC research.⁷¹ Specifically, the NIH stated that hESCs are not “embryos” under the Dickey-Wicker Amendment such that the Amendment does not forbid hESC research.⁷² Moreover, the NIH distinguished between hESC research and the derivation of hESCs from embryos. The NIH’s stance is that derivation of hESCs results in destruction of embryos and is forbidden by the Dickey-Wicker Amendment.⁷³ However, hESC research in and of itself does not result in the destruction of human embryos, so the Dickey-Wicker Amendment does not forbid hESC research.⁷⁴

A legal challenge to the Guidelines was filed immediately in the District Court for the District of Columbia.⁷⁵ Christian Adoption Agency, Christian Medical Association, embryos, adoptive parents, and two adult stem cell researchers filed suit “to enjoin the Secretary of [HHS] from implementing and applying guidelines” for hESC research promulgated by the NIH.⁷⁶ The action and preliminary injunction on hESC research were dismissed by Judge Lamberth of the District Court on the basis of insufficient injury for standing and mootness.⁷⁷ In a decision composed by Judge Ginsburg, the Court of Appeals reversed the order of the district court and reinstated the motion for a preliminary injunction.⁷⁸ The Court concluded that Drs. Sherley and Deisher, the two adult stem cell researchers, possessed standing because they suffered an actual injury due to increased competition for a fixed amount of available federal funding for general

⁷¹ *Id.* at 8.

⁷² *Id.* at 8.

⁷³ *Sherley*, *supra* note 68, at 8.

⁷⁴ *See id.*

⁷⁵ *See Sherley v. Sebelius*, 686 F. Supp. 2d 1, 8 (D.D.C. 2011) (describing the events that led up to the initial legal challenge brought by plaintiffs).

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

stem cell research.⁷⁹ Given that plaintiffs’ Motion for a Preliminary Injunction was ripe following the Court of Appeals reversal, the District Court found that “the likelihood of success on the merits, irreparable harm to plaintiffs, the balance of the hardships, and public interest each weigh[ed] in favor of a preliminary injunction.”⁸⁰ On appeal by defendants, the Court of Appeals lifted the preliminary injunction, holding that “plaintiffs [were] unlikely to prevail because Dickey Wicker is ambiguous and the NIH seems reasonably to have concluded that, although Dickey Wicker bars funding for the destructive act of deriving [hESCs] from [embryos], it does not prohibit funding a research project in which [hESCs] will be used.”⁸¹ On remand, the District Court, on July 27, 2011, held that the NIH’s determination that funding hESC research comports with the Dickey-Wicker Amendment because embryonic stem cells are not “human embryos” was a permissible interpretation of the statute.⁸² The Court determined that the NIH was entitled to *Chevron* deference, which requires judicial deference to an agency interpretation of an ambiguous statute as long as the interpretation reflects a “permissible construction of the statute.”⁸³

IV. CONSTITUTIONALITY OF THE DICKEY-WICKER AMENDMENT UNDER THE FIRST AMENDMENT ESTABLISHMENT CLAUSE

The Establishment Clause of the First Amendment prohibits the enactment of any law “respecting an establishment of religion.”⁸⁴ Traditionally, the Court has utilized the three-part *Lemon* test to analyze whether legislation comports with the mandate of the Establishment

⁷⁹ *Id.*

⁸⁰ *Sherley v. Sebelius*, 704 F.Supp.2d 63, 70 (D.D.C. 2010).

⁸¹ *Sherley*, *supra* note 59, at 389-90.

⁸² *See Sherley*, *supra* note 68, at 6.

⁸³ *Id.* at 10 (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984)).

⁸⁴ U.S. CONST. amend. I.

Clause.⁸⁵ The statute in question must (1) have been adopted with a secular purpose, (2) with a primary effect “that neither advances nor inhibits religion,” and (3) the statute “must not result in an excessive entanglement of government with religion.”⁸⁶ Violation of any one of the three prongs of the *Lemon* test indicates that the statute in question violates the Establishment Clause.⁸⁷

The Court has more recently implemented use of the endorsement test.⁸⁸ The endorsement test questions whether a “reasonable hypothetical observer” would think that the government is either endorsing or disapproving of religion by enacting the statute in question.⁸⁹ “The endorsement test recognizes that when government transgresses the limits of neutrality and acts in ways that show religious favoritism or sponsorship, it violates the Establishment Clause.”⁹⁰ The endorsement test is developed from the “prohibition against government endorsement of religion” and it “preclude[s] government from conveying or attempting to convey a message that religion or a particular religious belief is *avored* or *preferred*.”⁹¹ In one of the more recent federal cases involving the Establishment Clause, *Kitzmiller v. Dover Area School Dist.*, the court opted to utilize both tests, first applying the endorsement test and then applying the *Lemon* test.⁹² This note, however, will focus solely on application of the endorsement test because the two tests largely overlap.

⁸⁵ *Edwards v. Aguillard*, 482 U.S. 578, 582-83 (1987).

⁸⁶ *Id.* at 583 (citing *Lemon v. Kurtzman*, 403 U.S. 602, 612-13 (1971)).

⁸⁷ *Id.*

⁸⁸ See *Lynch v. Donnelly*, 465 U.S. 668, 691 (1984) (O’Connor, J., concurring); *Cnty. of Allegheny v. ACLU*, 492 U.S. 573 (1989) (demonstrating the first time the majority of the Supreme Court implemented the endorsement test).

⁸⁹ See *Santa Fe Indep. Sch. Dist. v. Doe*, 530 U.S. 290, 308 (2000).

⁹⁰ See *Kitzmiller v. Dover Area Sch. Dist.*, 400 F.Supp.2d 707, 714 (2005).

⁹¹ *Allegheny*, *supra* note 88 (quoting *Wallace v. Jaffree*, 472 U.S. 38, 70 (1985) (O’Connor, J., concurring)).

⁹² See *Kitzmiller*, *supra* note 90, at 714.

Here, the central issue is whether the government has endorsed Christianity by banning federal funding for research that results in the destruction of human embryos. In addressing this issue, one must examine what the government intended to communicate and what the government actually communicated.⁹³ One must determine what message the Dickey-Wicker Amendment conveys to a reasonable, objective observer who knows the policy's language, origins, and legislative history, as well as the history of the community and the broader social and historical context in which the policy arose.⁹⁴ The Third Circuit elaborated further in *Modrovich v. Allegheny County, Pa.* that “the reasonable observer is an informed citizen who is more knowledgeable than the average passerby.”⁹⁵ The reasonable observer is also deemed able to “glean other relevant facts” about the Government action and its history from the face of the action in light of its context.⁹⁶

“Knowing the challenged policy's legislative history, the community's history, and the broader social and historical context in which the policy arose, the objective observer [should consider] the publicly available evidence relevant to the purpose inquiry, but notably [should] not do so to ascertain, strictly speaking, what the governmental purpose actually was.”⁹⁷ Rather, the observer should examine the evidence to determine whether the policy “conveys a message of endorsement or disapproval” of religion, irrespective of the government's intent.⁹⁸

A. Application of the Endorsement Test

⁹³ *Id.* at 714 (citing *Lynch*, *supra* note 88, at 690).

⁹⁴ *Id.* (citing *McCreary Cnty., Ky. v. ACLU*, 545 U.S. 844 (2005) (holding that an objective observer is “presumed to be familiar with the history of the government's actions and competent to learn what history has to show); *Santa Fe*, *supra* note 89, at 308 (holding that an objective observer is familiar with “implementation of” the governmental action at issue); *Selman v. Cobb*, 390 F.Supp.2d 1306 (holding that an objective observer is “familiar with the origins and context of the government-sponsored message at issue and the history of the community where the message is displayed”)).

⁹⁵ *Modrovich v. Allegheny Cnty., Pa.*, 385 F.3d 397, 407 (2004).

⁹⁶ *Id.*

⁹⁷ *Kitzmiller*, *supra* note 90 at 715 (citing *Selman*, *supra* note 94, at 1306-07).

⁹⁸ *Lynch*, 465 U.S. at 690 (O'Connor, J., concurring).

1. Legislative history of the Dickey-Wicker Amendment and the broader social and historical context in which the Amendment arose

This history of the Dickey-Wicker Amendment traces back to when President Clinton first took office as President of the United States. Shortly after assuming his post in 1993, President Clinton selected Nobel Laureate Harold Varmus as the new NIH director.⁹⁹ Director Varmus was determined to revitalize the NIH's study of human fetal tissue and stem cell biology because he recognized the vast potential for medical advances in those particular fields.¹⁰⁰ Dr. Varmus ensured that the National Institutes of Health Revitalization Act of 1993 ("NIHRA") included provisions to promote fetal tissue and stem cell research. The NIHRA was also amended to abolish the requirement that the Ethics Advisory Board, which was no longer in existence, review IVF research proposals.¹⁰¹ Dr. Varmus substituted the old review process for a new one that required the Secretary of HHS to "apply the same risk standard in assessing research proposals for fetuses."¹⁰² The purpose of applying this risk standard was to protect unsuspecting women and their fetuses from unethical manipulation.¹⁰³

The NIH's Human Embryo Research Panel reported its conclusions in September 1994 that federal funds should be provided for research that utilizes excess preimplantation embryos.¹⁰⁴ Further, because studies requiring fertilization of eggs were necessary to address fundamental questions in reproductive medicine, the Panel found it would be unwise to proscribe altogether research on the fertilization and development of oocytes (immature eggs).¹⁰⁵ The Advisory Committee to the Director of NIH unanimously accepted the conclusions of the

⁹⁹ HUGHES, *supra* note 62, at 405.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ HUGHES, *supra* note 62, at 405.

¹⁰⁵ *Id.* at 405.

Panel.¹⁰⁶ President Clinton, however, disregarded the conclusions and on December 2, 1994, specifically rejected federal funding for creating embryos for research.¹⁰⁷

Several Congressional representatives were concerned that President Bush's December 2, 1994 presidential directive only opposed the use of federal funds to create human embryos for research purposes.¹⁰⁸ These representatives sought also to prohibit the use of federal funds for using excess preimplantation human embryos to create pluripotent cell lines.¹⁰⁹ Protestant, conservative, Republican, "pro-life" Representatives Jay Dickey and Roger Wicker were among those concerned Congressmen, and they authored a rider Amendment to the Omnibus Appropriations Act in response.¹¹⁰ Their lobbying efforts ultimately led to the adoption of what became known as the Dickey-Wicker Amendment.¹¹¹

The "normative debate storm clouds over stem cell research" were gathering long before President Bush's Executive Order 13,435.¹¹² The clouds had been present at least as early as President Clinton's reaction to the announcement that the first cloned mammal (Dolly, the sheep) had been produced through SCNT.¹¹³ Dolly had been cloned using SCNT by a team led by Ian Wilmut at the Roslin Institute in Scotland in 1997.¹¹⁴

¹⁰⁶ *Id.* at 406.

¹⁰⁷ *Id.* at 406.

¹⁰⁸ *Id.* at 406.

¹⁰⁹ HUGHES, *supra* note 62, at 406.

¹¹⁰ See *Biography*, ROGER WICKER, U.S. SENATOR, <http://wicker.senate.gov/public/index.cfm?FuseAction=AboutRoger.Biography> (last visited Oct. 31, 2011); See also *About Roger Wicker*, ROGER WICKER, U.S. SENATOR, <http://wickerforsenate.com/about> (last visited Nov. 26, 2011); See *Rep. Jay Dickey, Summary*, LEGISTORM, http://www.legistorm.com/person/bio/66815/Jay_W_Dickey_Jr_.html (last visited Nov. 26, 2011); See also, ON THE ISSUES (Nov. 7, 2000), *Jay Dickey on Principles and Values*, http://www.ontheissues.org/House/Jay_Dickey_Principles+_Values.htm

¹¹¹ *Id.*

¹¹² *Id.* at 411.

¹¹³ *Id.* at 411-12.

¹¹⁴ Ian Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810, 812 (1997).

Public and political reactions to Dolly's birth announcement “illustrated the innate entanglement between SCNT cloning used for research purposes and SCNT used for reproductive purposes.”¹¹⁵ This entanglement is reflected in the following excerpt from the March 28, 2001 White House press briefing on the topic of cloning:

Secretary Ari Fleischer:

MR. FLEISCHER: Well, you know the President's position on stem cells.

Q: No, I know his position on embryonic stem cells. I don't know his position on cloning.

MR. FLEISCHER: But that's not a cloning issue. You just heard the President's position on cloning of humans. That's the President's position.

Q: What about cloning human cells?

MR. FLEISCHER: I'm not aware of the distinction between the issue of cloning human beings and cloning human cells.¹¹⁶

Dolly's tremendous press coverage also contributed heavily to a public hysteria that scientists would begin to “play God” and interfere with the natural order of life, robbing “future individuals of the right to a unique identity” by cloning human beings using SCNT.¹¹⁷ The press coverage afforded Dolly also bolstered the widespread public perception that cloning solely meant the use of scientific techniques to produce exact copies of an entire biological creature, not just cells.¹¹⁸ Scientists, on the other hand, also use the term cloning restrictively to mean using blastocysts in order to derive pluripotent stem cell lines.¹¹⁹

2. What the Government intended to communicate and what the Government actually communicated

¹¹⁵ HUGHES, *supra* note 62, at 413-14.

¹¹⁶ Ari Fleischer, White House Press Sec'y, Press Briefing by Ari Fleischer (Mar. 28, 2001).

¹¹⁷ Kathi E. Hanna, *Cloning/Embryonic Stem Cells*, NATIONAL INSTITUTES OF HEALTH, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (Apr. 2006), <http://www.genome.gov/10004765>.

¹¹⁸ HUGHES, *supra* note 62, at 415.

¹¹⁹ *Id.*

The plain language of the Dickey-Wicker Amendment forbids the use of federal funds for any research that creates human embryos, destroys human embryos, or subjects human embryos to risk of injury or death.¹²⁰ Looking at the language of the Dickey-Wicker Amendment with reference to 45 C.F.R. § 46.204(b) and 42 U.S.C. § 289(g)(b), one may draw two conclusions: (1) Congress accorded the same degree of protection to human embryos under Dickey-Wicker as accorded to human fetuses *in utero* “intended to be carried to term” under 45 C.F.R. § 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)); and (2) Congress sought to restrict both present and future stem cell research beyond the scientific technology in existence in 1996 through the language “or any other means from one or more human gametes or human diploid cells” under Division F, Section 509 (b) of the 2009 Omnibus Appropriations Act.¹²¹ This language captures the use of blastocyst-stage embryos for the derivation of hESCs because the process results in the destruction of the embryos.

In April 2011, the D.C. Circuit in *Sherley* found the language of the Dickey-Wicker Amendment to be ambiguous with regard to the word “research” and whether hESC research resulted in the destruction of human embryos. The D.C. Circuit stated that the term “research” is “flexible enough to describe either a discrete project or an extended process,” a fact that reinforced the Court’s “conclusion that the text is ambiguous.”¹²² Despite the Court’s finding of ambiguity in what the government actually communicated, it appears that the Government intended the language of the Amendment to be read broadly. The Amendment’s expansive language “or any other means” used to restrict future research beyond the technology in 1996 supports an expansive reading of the statute. A broad interpretation of “research” under the

¹²⁰ § 509(a)(2), *supra* note 4, at 803.

¹²¹ HUGHES, *supra* note 62, at 407; OMNIBUS APPROPRIATIONS ACT, *supra* note 56.

¹²² *Sherley*, *supra* note 68, at 14.

statute suggests that destruction of human embryos in federally-funded research violates the mandates of the Dickey-Wicker Amendment, whether the destruction occurs as an upstream or downstream event to the actual, individual experiment being conducted.

3. Whether an objective observer would believe the Dickey-Wicker Amendment promotes religion

Under the endorsement test, a “hypothetical reasonable observer” is presumed to be aware of the history of and the context of the Dickey-Wicker Amendment.¹²³ A “hypothetical reasonable observer” would also recognize that the Dickey-Wicker Amendment bans federal funding for research that results in the destruction of human embryos.¹²⁴ Such an observer is presumed to know the two competing moral ideologies that stem from research involving destruction of human embryos.¹²⁵

The first concerns the principle that moral life begins at conception, a belief widely held and advanced by Protestants and Roman Catholics.¹²⁶ Such an observer would know destruction of an embryo or abortion of a non-viable fetus constitutes murder subject to this Christian principle.¹²⁷ The “hypothetical reasonable observer” would also know that proscribing federally funded researchers from destroying human embryos necessitates that researchers adhere to that Christian principle or risk losing their federal funding.¹²⁸

The second ideology concerns public policy and recognizes the legal status of an embryo is not equal to that of a person such that it is morally wrong to hinder hESC research because of the enormous wealth in medical advances that may result from the research.¹²⁹ A “hypothetical

¹²³ See e.g. *Modrovich*, *supra* note 95, at 407.

¹²⁴ § 509(a)(2), *supra* note 4, at 803.

¹²⁵ MCGUIRE, *supra* note 3, at 181.

¹²⁶ CHILDRESS, *supra* note 5, at 161-62.

¹²⁷ GREEN, *supra* note 38, at 225.

¹²⁸ See *id.*

¹²⁹ MCGUIRE, *supra* note 3, at 181.

reasonable observer” would know that this ideology has an equal respect for human life as the first ideology. However, the focus of this respect is on undeniable people who are actually born and have real medical issues, not on embryos that may or may not develop into adults.

Under the endorsement test, “hypothetical reasonable observer” would know the political underpinnings of the Dickey-Wicker Amendment. Such an observer would recognize that the Dickey-Wicker Amendment was authored by Protestant, Republican Representatives and supported primarily by the Republic political party.¹³⁰ This “hypothetical reasonable observer” would also know that the Republican party has traditionally adopted a “pro-life” stance and a pro-Intelligent Design platform, largely because of the Christian values that the party has historically promoted.¹³¹

A “hypothetical reasonable observer” would recognize the public and cultural context at the time the Dickey-Wicker Amendment originated. This observer would recognize that the public response to the cloning of Dolly combined with the failure to distinguish between two very different meanings of “cloning” contributed to a political environment where legitimate scientific research was often conflated with “playing God.” The observer would also know the Dickey-Wicker Amendment was originally intended to be a rider provision effective for one year but that the Amendment has been attached to federal spending bills every year since 1996, essentially becoming a law without termination.¹³²

Last, a “hypothetical reasonable observer” would know that the plaintiffs in *Sherley* consisted of several Christian organizations and doctors. This observer would know that those

¹³⁰ See ROGER WICKER, *supra* note 110; REP. JAY DICKEY, *supra* note 110.

¹³¹ See ON THE ISSUES, “Republican Party on Abortion,” (last visited on Oct. 30, 2011) http://ontheissues.org/Celeb/Republican_Party_Abortion.htm; Huffington Post, “Where GOP Presidential Candidates Stand on Evolution,” (last visited on Oct. 30, 2011) http://www.huffingtonpost.com/2011/08/24/2012-election-gop-candidates-evolution-_n_934045.html#s333316&title=Rick_Perry

¹³² COHEN, *supra* note 58, at 2.

plaintiffs sought to enjoin hESC research that resulted in the destruction of human embryos, largely because the plaintiffs felt the destruction of those embryos was immoral pursuant to their religious convictions.¹³³

4. Weighing the endorsement test factors

All three factors of the endorsement test appear to weigh strongly against the constitutionality of the Dickey-Wicker Amendment. The Amendment's legislative history and historical context suggest that the Amendment was motivated by religion when enacted in response to scientific advances that some felt amounted to "playing God." The language of the Dickey-Wicker Amendment requires federally funded researchers to adhere to the Christian principle that it is morally wrong to destroy human embryos for the sake of advancing science or risk losing their funding.¹³⁴ A "hypothetical reasonable observer" would recognize that religious beliefs motivated the history of the Amendment and that the Amendment advances a Christian belief. While Protestants and Roman Catholics generally hold that life begins at conception, those in the Jewish, Muslim, Hindu, and Buddhist faiths generally do not share this principle.¹³⁵ In this regard, the Dickey-Wicker Amendment fails subject to constitutional analysis under the Establishment clause because it conveys a message of endorsement of Christianity, regardless of what the government's intent may have been behind the Amendment.

No hypothetical reasonable observer can doubt that the purpose behind the Dickey-Wicker Amendment is to protect embryos as "morally protectable human beings with the same legal claims upon us approaching those of others who are undisputed citizens (children and adults)."¹³⁶ This purpose advances a Protestant and Roman Catholic principle that life begins at

¹³³ GREEN, *supra* note 38, at 225.

¹³⁴ MCGUIRE, *supra* note 3, at 181.

¹³⁵ GREEN, *supra* note 38, at 226.

¹³⁶ *Id.*

conception and appears to express Government favoritism for Christianity over other faiths in violation of the Establishment Clause.

B. Strict scrutiny analysis

The Supreme Court has expressly required strict scrutiny analysis of violations of the Establishment Clause under the First Amendment.¹³⁷ Subject to strict scrutiny analysis, the statute or policy at issue must be narrowly tailored to achieve a compelling government purpose using the least restrictive means.¹³⁸ If the statute or policy is either too broad or serves no compelling government purpose, then the statute is void.¹³⁹

Looking first to the purpose of the Dickey-Wicker Amendment, application of the endorsement test lent considerable insight into the purpose of the Amendment. The “hypothetical reasonable person” analysis supports the argument that the purpose behind the Dickey-Wicker Amendment is to afford embryos with legal and moral protections approaching those of legally recognized people. This purpose advances the Christian belief that life begins at conception. Accepting this, the Government may argue that protecting human life (whether it consists of one cell or a billion) constitutes a secular and compelling government purpose and supports a belief held by many people of various faiths that destroying human embryos is immoral. Thus, prohibiting federal funding to research that destroys human embryos preserves the dignity of human life in support of this compelling purpose.

Proponents of hESC research, however, argue that the putative medical advances from hESC research would promote the very same purpose of protecting human life by providing cures for many of society’s greatest ailments. The difference is that the protected human life is that of a legally recognized person. By contrast, embryos are not legally recognized as people

¹³⁷ See *County of Allegheny v. ACLU*, *supra* note 88, at 608-09; *Lynch*, *supra* note 88, at 687.

¹³⁸ See *Korematsu v. United States*, 323, 323 U.S. 214 (1944).

¹³⁹ See *id.*

subject to the Supreme Court's holding in *Roe v. Wade* and thus have no legally protected interests.¹⁴⁰ One arguing against the Government's position would claim that it is hardly a compelling government interest to protect the interests of excess preimplantation embryos above the interests of the hundreds of thousands of people with diseases who may benefit from the expansion of stem cell lines for hESC research.

Looking next to the construction of the Dickey-Wicker Amendment, the Amendment prohibits federally funding any research that results in the creation, destruction, or endangerment of human embryos. Currently, there are no widely accepted and utilized methods for derivation of hESCs that do not result in the destruction of human embryos.¹⁴¹ There are alternative platforms, however, for obtaining stem cells without destroying human embryos.¹⁴² The Government may argue that the Dickey-Wicker Amendment is narrowly-tailored because it does not prohibit hESC research; rather, the Amendment specifically prevents derivation of hESC lines because their derivation destroys embryos.

The argument against the Government is that the Dickey-Wicker Amendment broadly hinders several forms of biological research because the Amendment is not specific to hESC research. It prohibits various forms of birth control research, IVF research, and birth defects research.¹⁴³ The Dickey-Wicker Amendment hinders hESC research, the "gold standard" of stem cell research platforms, by restricting the number of viable hESC lines available for American scientists. In this regard, proponents of hESC research may argue that the Amendment could be more narrowly tailored to prohibit the destruction of human embryos for a specific type of research.

¹⁴⁰ See *Roe v. Wade*, 410 U.S. 113 (1973) (holding that a mother has a right to an abortion up until viability of the child, at which point the child becomes a legally protected person).

¹⁴¹ See ZACHARIAS, *supra* note 9, at 635.

¹⁴² *Id.* at 635-38.

¹⁴³ See THOMSON, *supra* note 1, at 1146.

The Amendment also broadly applies to all human embryos. Proponents of hESC research may argue that the Amendment could be more narrowly tailored to allow for excess preimplantation embryos from IVF treatments that would ultimately be discarded anyway. The current NIH guidelines are strict in this regard, but the Dickey-Wicker Amendment is not. Congress might further refine the Amendment to allow only for the use of low quality embryos that are non-viable even if implanted in a healthy mother. Once an embryo is labeled as “poor quality” at an IVF clinic, the embryo will be discarded.¹⁴⁴ In this regard, hESC research proponents might argue that once an embryo’s destruction is determined for failing clinical standards, its destruction is no longer related to research and is, hence, less ethically worrisome.¹⁴⁵

V. CONCLUSION

Application of the endorsement test supports the argument that the Dickey-Wicker Amendment is unconstitutional as a violation of the Establishment Clause under the First Amendment of the United States Constitution.¹⁴⁶ Should the Dickey-Wicker Amendment be legally challenged, the court would analyze the Amendment subject to strict scrutiny because it may violate the fundamental, constitutional right that Government “shall make no law respecting an establishment of religion.”¹⁴⁷ Strict scrutiny analysis in this note suggests that the Dickey-Wicker Amendment would fail both the “purpose” prong and “narrow construction” prong and be declared void as unconstitutional. The Government’s hypothetical purpose arguments are not

¹⁴⁴ MCGUIRE, *supra* note 3, at 181 (citing Paul H. Lerou, et al., *Human Embryonic Stem Cell Derivation From Poor-Quality Embryos*, 26 NATURE BIOTECH. 212, 212 (2008) (defining “poor-quality” embryos as those designated “clinically useless based on poor morphology and a low likelihood of generating viable pregnancies” such that they are typically discarded as medical waste).

¹⁴⁵ *Id.* at 167 (citing *Embryos discarded During IVF Create Stem Cell Lines*, US NEWS, Jan. 28, 2008 (describing how “poor quality” embryos may be valuable for hESC research purposes).

¹⁴⁶ U.S. CONST. amend. I.

¹⁴⁷ *Id.*

baseless, but they are weak in that the result would effectively grant human embryos legally protectable status contrary to the Supreme Court's ruling in *Roe v. Wade* that a legally recognized person is viable outside of the mother. Hence, human embryos outside of the mother are non-viable. The Government's argument that the Dickey-Wicker Amendment is narrowly tailored by the least restrictive means appears to fail, as well. The language of the Amendment could be more narrowly composed to restrict the destruction of embryos in the context of specific types of research rather than all research. Moreover, the language of the Amendment could be more narrowly composed to prohibit the destruction of only good quality embryos only. Under a more narrow construction, poor quality embryos that would be discarded by IVF clinics and not develop even if implanted in a mother could be permitted for use in research that may cause their destruction.

The effect of this analysis suggests that a religious principle disputing the moral protection of embryos and fetuses as human beings has "driven 30 years of research obstruction, with serious negative impact on the lives and health of those who are undeniably citizens."¹⁴⁸ As of November 2011, there are over 225,000 undeniable United States citizens waiting for organ transplants, but only a small portion of those people will actually receive the organ they require.¹⁴⁹ Immune responses in organ recipients triggered by foreign cells and tissue often result in the body's rejection of the transplanted tissue or organ, resulting in a fairly low recovery rate of approximately 50%.¹⁵⁰ Human embryonic stem cell-based techniques have the potential to "provide doctors with a renewable source of healthy cells and tissues to repair failing

¹⁴⁸ *Id.*

¹⁴⁹ *Data*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (Nov. 30, 2011, 9:30 PM) <http://optn.transplant.hrsa.gov/data>.

¹⁵⁰ *See* MCGUIRE, *supra* note 3, at 161.

organs.”¹⁵¹ Recently, preliminary results from a phase 1 trial suggest that infusion of cardiac stem cells into heart attack victims improves heart function and reduces infarct size in patients with heart failure.¹⁵² Unfortunately, it appears that hESC research has been unconstitutionally stymied since the inception of the technology in 1998 because of the restrictions imposed by the Dickey-Wicker amendment. Proponents of hESC research contend that this obstruction has subjected countless women “to infertility drug treatments whose safety has been inadequately studied by means of appropriate multi-center clinical trials” and that “children born from these procedures have been exposed to inadequately researched risks.”¹⁵³

Ultimately, it appears that the religious convictions of a few have driven public policy in this arena, leaving us to speculate about how many countless lives might have been saved by medical advances that would have resulted had hESC research and other reproductive research received the full support of government legislation and unrestricted federal funding. The analysis presented here suggests that Congress should either restrict the language of the Dickey-Wicker Amendment or remove the Amendment entirely. In its current form, one could certainly legally challenge the Amendment as unconstitutional and would likely succeed in doing so.

¹⁵¹ *Id.*

¹⁵² Roberto Bolli, M.D., et al., *Cardiac stem cells in patients with ischaemic cardiomyopathy (SCPIO): initial results of a randomized phase 1 trial*, 378 *THE LANCET* 1847 (2011) (discussing a summary of the study findings).

¹⁵³ GREEN, *supra* note 38, at 226.

SECTION 141.1 LAW SCHOOL

2011 DEC -6 P 3:48

OFFICE OF THE REGISTER