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Embryonic Stem Cell Research: With Suitable Regulation and Federal Funding, Life Without Serious Disease Becomes an Attainable Goal

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The author dedicates this note to her father, John W. Gagnon, who so valiantly defied juvenile diabetes until January 18, 2007, and to her grandmother, Eleanor Gilbert, who is ailed by Parkinson's disease, yet continues to amaze us with her seemingly endless supply of energy and smiles. The author thanks them dearly for their abounding passion, sheer courage, and eternal love and support.

INTRODUCTION

Thomas Jefferson wrote that "liberty . . . is the great parent of science and of virtue; and that a nation will be great in both, always in proportion as it is free."² Generations of Americans pride themselves on being citizens of the country granting the most freedoms in the world. Liberty is a cornerstone of our distinguished nation. However, the federal government has gravely impaired that celebrated liberty in the area of scientific research. Federal funding of embryonic stem cell research was prohibited, thereby inhibiting the opportunity for scientific greatness that Jefferson so eloquently described.

Of course, scientific advancement generally does not come without a price tag, especially when the advancement is truly groundbreaking. Sometimes the cost involves endangering our wildlife; other times it involves destroying the environment. In the case of embryonic stem cell research, the price tag for innovation may mean the destruction of embryos. Many Americans

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² Letter from Thomas Jefferson to Joseph Willard (Mar. 24, 1789) (*in* THE THOMAS JEFFERSON PAPERS SER. 1, GEN. CORRESPONDENCE, 1621-1827, at 77 *available at* <http://memory.loc.gov/master/mss/mtj/mtj1/011/0000/0077.jpg>; <http://www.let.rug.nl/~usa/P/tj3/writings/brf/jefl77.htm>) (last visited Nov. 1, 2007).

struggle with this tradeoff: is it worth ending the potential lives of these embryos in order to conduct research that may treat and even cure diseases crippling over 128 million Americans?³

The issue is not whether embryonic stem cell research is legal in the United States. Rather, it is whether the United States government can use taxpayer money to fund embryonic stem cell research. Federal funding from the National Institutes of Health (“NIH”) is not the only source of money for this type of research. Private, not-for-profit organizations may also provide financial support; however, these establishments are less inclined to invest in embryonic stem cell research because it could take years to generate results that shareholders would approve. Furthermore, NIH is the leading financial sponsor of biomedical research in the United States.⁴ If given the authority, NIH could direct much of this funding to embryonic stem cell research. These funds would inevitably shorten the wait for a major scientific breakthrough.

This note discusses the scientific background of stem cell research, ethical considerations surrounding the issue, and past and current governmental regulations that limit federal funding of the research. Additionally, pending legislation and the latest breakthroughs regarding this controversial topic are addressed. Finally, this note concludes with recommendations for a change in the status quo.

I. HUMAN STEM CELLS: BACKGROUND INFORMATION

Scientists have singled out stem cells, as opposed to other kinds of cells in the body, for developing research aimed at treating, and even curing, a wide range of diseases. Three

³ Daniel Perry, *Patients' Voices: The Powerful Sound in the Stem Cell Debate*, Feb. 25, 2000, available at <http://www.jstor.org/view/00368075/sp030008/03x0250p/0?currentResult=00368075%2bsp030008%2b03x0250p%2b0%2c03&searchUrl=http%3A%2F%2Fwww.jstor.org%2Fsearch%2FBasicResults%3Fhp%3D25%26si%3D1%26Query%3Dethics%2Band%2Bstem%2Bcell>.

⁴ Arti K. Rai & Rebecca S. Eisenberg, *The Public and the Private in Biopharmaceutical Research*, Duke Conference on the Public Domain Focus Paper Discussion Drafts 167 (Nov. 9-11, 2001), available at <http://www.law.duke.edu/pd/papers/raiseisen.pdf>.

properties make stem cells distinctive: they are “capable of dividing and renewing themselves for long periods; they are unspecialized; and they can give rise to specialized cell types.”⁵ The unspecialized nature of stem cells means that they do not have “tissue-specific structures” requiring them to function in a certain manner.⁶ However, stem cells can become specialized cell types, such as muscle cells or nerve cells.⁷ This unique combination attracted scientists to stem cells: scientists would be able to transform these unspecialized cells through a process called “differentiation” into certain specialized cells based on the type of tissue needing repair.⁸ In fact, the ability of a stem cell to divide and renew itself is believed to be the reason stem cells earned their name—because scientists observed the many distinctive cells that can *stem* from them.⁹

Two types of stem cells can be derived from humans: embryonic stem cells and adult stem cells.¹⁰ An adult stem cell is an “undifferentiated cell found among differentiated cells in a tissue or organ, [which] can renew itself, and can differentiate to yield the major specialized cell types of the tissue or organ.”¹¹ On the other hand, embryonic stem cells are “derived from embryos that develop from eggs that have been fertilized *in vitro* [outside the living body] . . . and then donated for research purposes with informed consent of the donors. [These] are *not*

⁵ National Institutes of Health, What are the unique properties of stem cells?, <http://stemcells.nih.gov/info/basics/basics2.asp> (last visited Nov. 1, 2007).

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ ANN B. PARSON, THE PROTEUS EFFECT: STEM CELLS AND THEIR PROMISE FOR MEDICINE 2 (2004).

¹⁰ National Institutes of Health, Stem Cell Basics: Introduction, <http://stemcells.nih.gov/info/basics/basics1.asp> (last visited Nov. 2, 2007).

¹¹ National Institutes of Health, What are adult stem cells?, <http://stemcells.nih.gov/info/basics/basics4.asp> (last visited Nov. 2, 2007).

derived from eggs fertilized in a woman's body."¹² Embryonic stem cells are pluripotent, meaning they have the ability to become any type of cell in the body.¹³

There are two primary methods of deriving embryonic stem cells.¹⁴ First, blastocysts¹⁵ that are not used during infertility treatments and are donated to science can be used to derive embryonic stem cells.¹⁶ The second method involves scientists' creation of blastocysts in the laboratory using donated oocytes [developing eggs] and sperm.¹⁷

Adult stem cells are not as adaptable as embryonic stem cells and typically are limited to differentiating into only the cell types in their tissue of origin.¹⁸ While scientists have found that undifferentiated adult stem cells exist in more tissues than had been previously expected, which was a very hopeful discovery, embryonic stem cells continue to be more sought after in stem cell research.¹⁹ "Large numbers of embryonic stem cells can be . . . easily grown in culture, while adult stem cells are rare in mature tissues This is an important distinction, as large numbers of cells are needed for stem cell replacement therapies."²⁰ "[M]ost experts consider 'adult stem

¹² National Institutes of Health, What are embryonic stem cells?, <http://stemcells.nih.gov/info/basics/basics3.asp> (last visited Nov. 2, 2007).

¹³ *Id.*

¹⁴ NATIONAL RESEARCH COUNCIL, GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH 17 (2005) [hereinafter NRC].

¹⁵ *Id.* at 115. Blastocysts are preimplantation embryos that contain between 50-250 cells.

¹⁶ *Id.* at 17.

¹⁷ *Id.*

¹⁸ National Institutes of Health, What are the similarities and differences between embryonic and adult stem cells?, <http://stemcells.nih.gov/info/basics/basics5.asp> (last visited Oct. 31, 2007).

¹⁹ *Id.*

²⁰ *Id.*

cell research' not to be an alternative to [human embryonic stem] . . . cell research, but rather a complementary and important line of investigation.”²¹

There are a few specific uses for human embryonic stem cells that scientists concentrate on; however, without continued rigorous and thorough testing, these cannot come to fruition.²² Human embryonic stem cells may help shine some light on the complexity of human development.²³ “Some of the most serious medical conditions, such as cancer and birth defects, are due to abnormal cell division and differentiation.”²⁴ Scientists are especially concerned with learning and understanding how undifferentiated cells transform into differentiated cells.²⁵ What they do know is that “turning genes [functional units of heredity found in the nucleus of a cell] on and off is central to this process”; however, they do not yet completely understand “the signals that turn specific genes on and off to influence the differentiation of the stem cell.”²⁶

Once this is mastered, scientists expect to substitute dysfunctional cells in the brain, spinal cord, and other affected organs with healthy, specialized cells to treat diseases and conditions, such as Parkinson’s disease, diabetes, multiple sclerosis, stroke, and rheumatoid arthritis.²⁷ These specialized cells would be generated to replace deteriorating or destroyed

²¹ NRC, *supra* note 14, at 17.

²² National Institutes of Health, Stem Cell Basics: Introduction, <http://stemcells.nih.gov/info/basics/basics1.asp> (last visited Oct. 31, 2007).

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ Diane T. Duffy, *Background and Legal Issues Related to Stem Cell Research*, CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS, June 12, 2002, at CRS-1.

tissue.²⁸ For example, in a type 1 diabetic, the insulin-producing pancreas is the affected organ because its cells are destroyed by the diabetic's own immune system.²⁹ However, with further embryonic stem cell research, scientists believe it will be possible to "direct the differentiation of human embryonic stem cells . . . to form insulin-producing cells that eventually could be used in transplantation therapy for diabetics."³⁰ Currently, only the organs or tissues from cadavers or live donors are used to replace deteriorated organs or tissues.³¹ However, the need for donations greatly outweighs the reserve available, thus an alternative is gravely needed, and once the proper research has been done, stem cells can serve as a solution.³²

Another use of human stem cells is to test new drugs, allowing for safer and more effective medicines.³³ The pluripotent quality of stem cells permits a broader range of cell types to be tested.³⁴ However, in order to have effective and accurate drug testing, "the conditions must be identical when comparing different drugs."³⁵ As mentioned previously, scientists do not yet fully understand the signals that turn genes on and off, and therefore are unable to "precisely control the differentiation of stem cells into the specific cell type on which drugs will be

²⁸ National Institutes of Health, What are the potential uses of human stem cells and the obstacles that must be overcome before these potential uses will be realized?, <http://stemcells.nih.gov/info/basics/basics6.asp> (last visited Nov. 1, 2007).

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ National Institutes of Health, What are the potential uses of human stem cells and the obstacles that must be overcome before these potential uses will be realized?, <http://stemcells.nih.gov/info/basics/basics6.asp> (last visited Nov. 5, 2007).

³⁴ *Id.*

³⁵ *Id.*

tested.”³⁶ Upon scientists’ understanding of this crucial process, identical conditions can be created repeatedly for researchers to test the effectiveness and safety of drugs.

The University of Wisconsin-Madison, a pioneering institution in the realm of stem cell research, openly admits that stem cell research is only in its infancy, and “[i]t will likely be several years at best before technologies emerging from embryonic stem cells find clinical application.”³⁷ Despite this, great strides have been made, many of which were made at University of Wisconsin-Madison. For example in 1998, James Thomson and his scientific team successfully isolated and cultured embryonic stem cells from a human blastocyst for the first time.³⁸ Prior to this event, stem cells had only been derived from mouse blastocysts, a discovery made in 1981.³⁹

Nevertheless, there are several major ethical concerns regarding embryonic stem cell research, which have led to governmental action limiting the federal funding of such research.⁴⁰ The next section addresses these concerns.

II. ETHICAL CONSIDERATIONS REGARDING HUMAN EMBRYONIC STEM CELL RESEARCH

The first ethical consideration clouding stem cell research is that the “derivation of [human embryonic stem] cells involves the destruction of the blastocyst, which is regarded by

³⁶ *Id.*

³⁷ The Board of Regents of the University of Wisconsin System, *Embryonic Stem Cells*, <http://www.news.wisc.edu/packages/stemcells/patients.html> (last visited Nov. 5, 2007).

³⁸ NRC, *supra* note 14, at 1.

³⁹ *Id.*

⁴⁰ *See id.* at 47.

some people as a human being.”⁴¹ This consideration calls into question the rights of a human embryo and the level of dignity an embryo should be shown.⁴² Some people, many of whom are situated on the pro-life side of the abortion controversy, believe that embryos should be treated with the same respect and dignity shown already-born humans. They believe that “the identity of a future born person is present in the embryo” and that once an embryo has been created, the potential for a human being to be born is likely.⁴³

A second ethical concern involves the creation of a blastocyst in a laboratory for the sole purpose of destroying it in order to derive a stem cell.⁴⁴ Until an August 2006 discovery by Advanced Cell Technology, Incorporated (“ACT”) proved otherwise (as discussed in section IV)⁴⁵, the removal of undifferentiated cells from the blastocyst destroys the possibility of any life function of that embryo.⁴⁶

People with these concerns often believe that embryonic stem cell research violates the sanctity of life and constitutes murder.⁴⁷ However, proponents of embryonic stem cell research are quick to point out that, while many people hold the view that destroying an embryo is murder, this belief has not carried over into daily life in the United States.⁴⁸ “For example, the

⁴¹ *Id.* at 47-48.

⁴² *Id.* at 48.

⁴³ NRC, *supra* note 14, at 48.

⁴⁴ *Id.*

⁴⁵ *See infra* p. 16.

⁴⁶ Nicholas Wade, *New Stem Cell Method Avoids Destroying Embryos*, N.Y. TIMES, Aug. 23, 2006, available at <http://www.nytimes.com/2006/08/23/science/23cnd-stem.html?ex=1313985600&en=8cfa63885318ecbf&ei=5088&partner=rssnyt&emc=rss> (last visited Nov. 5, 2007); *Stem cells that won't destroy embryo?*, MSNBC, Aug. 24, 2006, <http://www.msnbc.msn.com/id/14481692/> (last visited Nov. 5, 2007).

⁴⁷ NRC, *supra* note 14, at 48.

⁴⁸ *Id.*

natural loss of an embryo in normal human reproduction is not recognized as a death that requires a funeral, and the disposal of human embryos after completion of infertility treatments is not treated as murder by the legal system.”⁴⁹

Proponents of stem cell research weigh the aforementioned ethical considerations against the pain, suffering, and eventual death of people living with diseases and conditions that currently have no cure. More than 128.4 million people in the United States alone suffer from cardiovascular diseases, autoimmune diseases, diabetes, osteoporosis, cancer, Alzheimer’s disease, Parkinson’s disease, severe burns, spinal cord injuries, and birth defects - diseases and conditions which scientists are optimistic could be treated or even cured with embryonic stem cell research.⁵⁰

III. THE FEDERAL GOVERNMENT’S REACTION TO HUMAN EMBRYONIC STEM CELL RESEARCH

A. Regulation of Human Embryonic Stem Cell Research Prior to the Current Administration

The 1970s proved to be a tumultuous decade, marked with advancements in law and science that many question to be advancements at all.⁵¹ In 1973, the United States Supreme Court made a landmark decision in *Roe v. Wade*, legalizing the abortion of a fetus prior to its reaching “viability.”⁵² This decision marked the beginning of a bitter pro-life versus pro-choice

⁴⁹ *Id.*

⁵⁰ Perry, *supra* note 3.

⁵¹ Parson, *supra* note 9, at 134.

⁵² *Id.* (citing *Roe v. Wade*, 410 U.S. 113 (1973)). The Court used the term “viability” to refer to the “point at which the fetus can survive outside of the uterus”

debate, one that continues today.⁵³ In 1978, tensions strained even more when British scientists Robert Edwards and Patrick Steptoe announced that they had created the world's first "test-tube" baby.⁵⁴ The monumental birth of Louise Brown, who was born using *in vitro* fertilization ("IVF"), was shrouded in controversy, as people accused the two scientists of "playing God."⁵⁵

These developments triggered the federal government to create regulations regarding the use of federal funds for research involving human embryos. "In 1975, the Secretary of the Department of Health, Education, and Welfare ("DHEW") announced that the department would fund no proposal for research on human embryos or on IVF unless it was reviewed and approved by a federal ethics advisory board."⁵⁶ While an ethics advisory board was established, it was quickly dissolved in 1980 after researching only one proposal.⁵⁷ In 1988, President Ronald Reagan banned federal funds from being used to support "fetal tissue transplantation research," which used aborted fetuses.⁵⁸ President William Clinton lifted this ban in 1993.⁵⁹ Federal funding for IVF embryo research, which was halted due to a "de-facto moratorium" from 1980 to 1993, regained popularity in 1994, when "the National Institutes of Health's Human Embryo Research Panel concluded that research utilizing excess IVF embryos appeared to constitute acceptable public policy, as long as such research was conducted on embryos before . . . day

⁵³ *Id.* at 136. Pro-life advocates' worst fears were not unfounded: close to 1.5 million fetuses were aborted in the United States every year in the early 1990s. They worried that fetuses were being created and subsequently aborted purely for scientific gain, without consideration of the destruction of potential life.

⁵⁴ *Id.* at 125.

⁵⁵ *Id.*

⁵⁶ NRC, *supra* note 14, at 22.

⁵⁷ *Id.* at 22-23.

⁵⁸ Parson, *supra* note 9, at 135.

⁵⁹ *Id.*

14.”⁶⁰ Between 1993 and early 1995, however, no federal regulations were fashioned to guide scientists using human embryos in their research, even though the opportunity to do so was present.⁶¹

In December 1994, NIH’s Human Embryo Research Panel recommended that federal funding be permitted for research on embryos that were leftover from IVF, as well as for research on embryos generated for the sole purpose of experimentation.⁶² Through Executive Order 12,975, President Clinton refused to allow funding for the latter request, but did permit federal funding for research on unused embryos from IVF.⁶³ Republican Congressional representatives Jay Dickey and Roger Wicker, in an attempt to reverse Clinton’s decision, introduced an amendment that banned federal funding for “research in which a human embryo . . . [is] destroyed, discarded, or knowingly subjected to risk of injury or death.”⁶⁴ In 1996, the Dickey-Wicker Amendment, which was inserted as part of the NIH appropriations bill, became effective when Clinton signed the final bill into law.⁶⁵

In 1999, after James Thomson’s privately funded research led to the first successful isolation and culture of embryonic stem cells from a human blastocyst, Clinton re-examined federal funding of embryonic stem cell research.⁶⁶ On December 2, 1999, NIH, in its *Draft Guidelines for Research Involving Human Pluripotent Stem Cells*, recommended that federal

⁶⁰ *Id.* at 149-50.

⁶¹ *Id.* at 150.

⁶² NRC, *supra* note 14, at 23.

⁶³ *Id.* at 23-24; Exec. Order No. 12,975, 60 Fed. Reg. 52,063 (Oct. 3, 1995) (creating the National Bioethics Advisory Commission (NBAC)).

⁶⁴ Parson, *supra* note 9, at 150.

⁶⁵ *Id.*

⁶⁶ NRC, *supra* note 14, at 24.

funds be used for the creation of stem cells from existing human embryos remaining after IVF, in addition to the already recognized lines of embryonic stem cells.⁶⁷ These guidelines were finalized and issued in 2000.⁶⁸ Also in 2000,

[A] legal finding by the General Counsel of the Department of Health and Human Services (under President Clinton) argued that the wording of the [Dickey-Wicker Amendment] might allow for a loophole by which human embryonic stem cell research could be funded. If embryos were first destroyed with private funding, then subsequent research employing the derived embryonic stem cells . . . might be considered eligible for federal funding. Because such research would require no new embryo destruction, the Department’s lawyers suggested, the legal requirement not to fund research “in which” embryos were destroyed would still technically be obeyed.⁶⁹

Under Clinton’s orders, regulations were drafted to take advantage of this loophole.⁷⁰

However, enactment of these guidelines was halted by the incoming George W. Bush administration.⁷¹

B. Regulation of Human Embryonic Stem Cell Research Under the Current Administration

In January 2001, President George W. Bush “ordered the Department of Health and Human Services (HHS) to review the [NIH]’s guidelines issued by the former administration” regarding stem cell research.⁷² While this review took place, President Bush directed NIH to suspend all applications for the federal funding of research involving embryonic stem cells.⁷³ On

⁶⁷ *Id.*; 64 Fed. Reg. 67,576 (Dec. 2, 1999).

⁶⁸ National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000).

⁶⁹ THE PRESIDENT’S COUNCIL ON BIOETHICS, THE ADMINISTRATION’S HUMAN EMBRYONIC STEM CELL RESEARCH FUNDING POLICY: MORAL AND POLITICAL FOUNDATIONS 2-3 (2003).

⁷⁰ *Id.* at 3.

⁷¹ *Id.*

⁷² Duffy, *supra* note 27, at CRS-2.

⁷³ *Id.*

August 9, 2001, Bush announced to the nation that federal funds would be made available only for embryonic stem cell research on the sixty-four currently existing stem cell lines that had already been derived as of the date of the announcement; therefore, federal funding for research on embryonic stem cell lines not in existence by August 9, 2001 would be prohibited.⁷⁴

Bush's new policy allowed NIH to consider applications for federal funding only if specific criteria had been satisfied regarding how the stem cells had been derived.⁷⁵ “[F]ederal funds will only be used for research on existing stem cell lines that were derived (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducements to the donors.”⁷⁶ Bush further clarified that “no federal funds will be used for: (1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose.”⁷⁷ This new policy, at least temporarily, struck a balance between encouraging scientific breakthrough and “the moral imperative that the government should not be funding the destruction of human life.”⁷⁸

This was the first time in American history that federal funding was to be used for embryonic stem cell research.⁷⁹ President Bush also vowed to spend \$250 million in 2001 on

⁷⁴ *Id.*; See Richard Lacayo, *How Bush Got There*, TIME, Aug. 12, 2001, available at <http://www.time.com/time/magazine/article/0,9171,1101010820-170839,00.html>.

⁷⁵ Duffy, *supra* note 27, at CRS-2.

⁷⁶ *Id.*; Press Release, The White House, Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>.

⁷⁷ Press Release, The White House, Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>.

⁷⁸ Lacayo, *supra* note 74.

⁷⁹ President's Message to the House of Representatives (July 19, 2006), available at <http://www.whitehouse.gov/news/releases/2006/07/20060719-5.html> [hereinafter President's Message to House].

less controversial stem cell research, such as research using umbilical cord, placenta and adult tissues.⁸⁰ It should be emphasized that the President did not ban *research* using human embryos, but instead banned the *federal (taxpayer) funding* of such research, unless certain criteria were met.⁸¹ Embryonic stem cell research could legally continue with the use of private funds.

President Bush made his announcement in hopes that Congress would be satisfied with the compromise.⁸² After all, prior to Bush’s announcement, there was a stirring in the legislature to override his decision, which was expected to be an outright ban on the federal funding of all forms of embryonic stem cell research based on Bush’s religious and political viewpoints.⁸³ At the time, majorities in both the House of Representatives and the Senate supported federal funding of the research.⁸⁴ Even Senator Bill Frist, a Republican physician who advised Bush on a wide variety of healthcare issues, supported embryonic stem cell research, going as far as proposing a plan in July 2001 that would “allow stem cells to be extracted from surplus embryos currently in stock and due for destruction in clinics and labs around the country”⁸⁵ This plan did not receive legislative attention and was never drafted as a bill.⁸⁶ There were, however, seven bills and two companion bills regarding embryonic stem cell research introduced by the

⁸⁰ Duffy, *supra* note 27, at CRS-2.

⁸¹ THE PRESIDENT’S COUNCIL ON BIOETHICS, *supra* note 69, at 5.

⁸² Lacayo, *supra* note 74.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Duffy, *supra* note 27, at CRS-4.

107th Congress, each authorizing the federal funding of embryonic stem cell research, but some also prohibiting human reproductive cloning.⁸⁷ Congress did not pass any of these bills.⁸⁸

In 2004, more than 200 Democratic and Republican House members and fifty-eight bipartisan senators signed memoranda persuading Bush to loosen the restrictions he placed in 2001 on stem cell research; however, these memos were ineffective.⁸⁹ On July 29, 2005, Senate Majority Leader Bill Frist, who in 2001, as mentioned previously, had unsuccessfully tried to capture Congress' attention by developing his own plan regarding the funding of embryonic stem cell research, announced that he "support[ed] legislation to lift President Bush's restrictions on federally financed embryonic stem cell research"⁹⁰ The legislation Frist referred to was H.R. 810, the "Stem Cell Research Enhancement Act of 2005," which was introduced by the 109th Congress.⁹¹ This bill, among several others, was introduced after the determination that nearly 400,000 frozen human embryos were stored in United States fertility clinics.⁹² A study by the University of Pennsylvania and Rutgers University revealed that 84% of clinics regularly discard "extra" embryos by incineration, a destruction method typically used for the disposal of medical waste.⁹³ Another survey concluded that parents of nearly 11,000 frozen embryos across the country had given "explicit permission" for the embryos to be used for scientific research.⁹⁴

⁸⁷ *Id.* at CRS-4-CRS-5.

⁸⁸ *Id.*

⁸⁹ Vicki Kemper, *Reagan's Death May Stir Debate on Stem-Cell Research*, L.A. TIMES, June 8, 2004, at A10.

⁹⁰ Ceci Connolly, *Frist Breaks with Bush on Stem Cell Research*, WASH. POST, July 30, 2005, at A01.

⁹¹ President's Message to House, *supra* note 79.

⁹² Rick Weiss, *400,000 Human Embryos Frozen in U.S.*, WASH. POST, May 8, 2003, at A10.

⁹³ Maria Gallagher, *Human Embryos Routinely Discarded at U.S. Fertility Clinics*, LIFENEWS.COM, Sept. 1, 2004, <http://www.lifenews.com/bio449.html>.

⁹⁴ Weiss, *supra* note 92, at A10.

Despite this consent, the policy Bush set forth in 2001 prohibits federal funding for research on these excess embryos.⁹⁵

H.R. 810, which would have effectively reversed the Dickey-Wicker Amendment's ban on federal funding of research resulting in any undue harm to a human embryo, was passed by the House on May 24, 2005 and the Senate on July 18, 2006, but subsequently vetoed by President Bush on July 19, 2006.⁹⁶ The bill did not receive the two-thirds vote needed in the House to override the presidential veto.⁹⁷ This veto marked the first of Bush's presidency.⁹⁸

IV. ADVANCED CELL TECHNOLOGY'S AUGUST 2006 DISCOVERY

In August 2006, ACT of Worcester, MA announced that it had developed a technique for deriving stem cells without destroying embryos.⁹⁹ This procedure was performed on a two-day-old embryo consisting of eight cells, called a "blastomere."¹⁰⁰ Prior to this discovery, stem cells could only be derived from embryos consisting of 150 cells, a procedure that destroyed the embryos.¹⁰¹

⁹⁵ Duffy, *supra* note 27, at CRS-2.

⁹⁶ GovTrack, *H.R. 810 [109th]: Stem Cell Research Enhancement Act of 2005*, <http://www.govtrack.us/congress/bill.xpd?bill=h109-810> (last visited Nov. 2, 2007); see Dana Bash & Deirdre Walsh, *Bush Vetoes Embryonic Stem-Cell Bill*, CNN.COM, Sept. 25, 2006, <http://www.cnn.com/2006/POLITICS/07/19/stemcells.veto/> (last visited Nov. 2, 2007); President's Message to House, *supra* note 79.

⁹⁷ Bash & Walsh, *supra* note 96.

⁹⁸ *Id.*

⁹⁹ Advanced Cell Technology, *Advanced Cell Technology Announces Technique to Generate Human Embryonic Stem Cells that Maintains Developmental Potential of Embryo*, <http://www.advancedcell.com/press-release/advanced-cell-technology-announces-technique-to-generate-human-embryonic-stem-cells-that-maintains-developmental-potential-of-embryo> (last visited Nov. 2, 2007) [hereinafter ACT]; Wade, *supra* note 46.

¹⁰⁰ Wade, *supra* note 46.

¹⁰¹ *Id.*

In fertility clinics, where the embryo is available outside the mother in the normal course of [IVF], one of these blastomeres can be removed for diagnostic tests [called pre-implantation genetic diagnosis or P.G.D.], such as for Down's syndrome, and the embryo, now with seven cells, can be implanted in the mother if no defect is found. Many such embryos have grown into apparently healthy babies over the ten years . . . the diagnostic tests have been used.¹⁰²

As of July 2007, more than 2,500 healthy children were born following the use of P.G.D. when they were embryos.¹⁰³

Dr. Robert Lanza, Vice President of Research and Scientific Development at ACT, and his team removed a single cell from each of the two-day-old blastomeres, and from these grew two stable embryonic stem cell lines without compromising the embryos' viability.¹⁰⁴ The scientific team reported that "[t]hese cell lines were genetically normal and retained their potential to form all of the cells in the human body, including nerve, liver, blood, vascular, and retinal cells that could potentially be used to treat a range of human diseases."¹⁰⁵

Ronald Green, an ethicist and adviser to ACT, believed that this new method did not violate the Dickey-Wicker Amendment because the embryos were not destroyed or subjected to undue harm, therefore making ACT eligible to receive federal funding for continued research.¹⁰⁶ However, Dr. James Battey, leader of the stem cell task force at NIH, ambiguously stated that it was not yet apparent whether the new method actually did not harm the embryos used, as it still

¹⁰² *Id.*

¹⁰³ Advanced Cell Technology, *Advanced Cell Technology Applauds Inclusion of Stem Cell Provision in \$152 Billion Federal Funding Measure*, <http://www.advancedcell.com/press-release/advanced-cell-technology-applauds-inclusion-of-stem-cell-provision-in-152-billion-federal-funding-measure> (last visited Nov. 2, 2007).

¹⁰⁴ ACT, *supra* note 99.

¹⁰⁵ *Id.*

¹⁰⁶ Wade, *supra* note 46.

subjected the embryos to “some risk.”¹⁰⁷ Also positioned on the opposite end of the spectrum from Green is Dr. Leon Kass, the former chairperson of the President’s Council on Bioethics, who stated, “I do not think that this is the sought-for, morally unproblematic and practically useful approach we need.”¹⁰⁸ Regardless of the ethics of this new approach, it is still in its infancy; the controversial method of stem cell derivation, which results in the destruction of embryos, continues to be the leading technique. The next section addresses action that Congress has taken regarding this contentious method.

V. CONGRESSIONAL ACTION SINCE THE 110TH CONGRESS GAINED POWER

As a result of the midterm elections in November 2006, the Democratic Party became the majority party in both the House of Representatives and the Senate.¹⁰⁹ On January 5, 2007, just one day after the new Congress was sworn in, H.R. 3 was introduced.¹¹⁰ This bill, called the Stem Cell Research Enhancement Act of 2007, would require the Secretary of HHS

[T]o conduct and support research that utilizes human embryonic stem cells, regardless of the date on which the stem cells were derived from a human embryo, provided such embryos: (1) have been donated from [IVF] clinics; (2) were created for the purposes of fertility treatment; (3) were in excess of the needs of the individuals seeking such treatment and would never be implanted in a woman and would otherwise be discarded (as determined in consultation with the individuals seeking fertility

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ United States Senate, Party Division in the Senate, *available at* http://www.senate.gov/pagelayout/history/one_item_and_teasers/partydiv.htm (last visited Oct. 30, 2007); United States House of Representatives, Party Division in the House of Representatives, *available at* http://clerk.house.gov/art_history/house_history/partyDiv.html (last visited Oct. 30, 2007).

¹¹⁰ GovTrack.us, H.R. 3: Stem Cell Research Enhancement Act of 2007, <http://www.govtrack.us/congress/bill.xpd?tab=main&bill=h110-3> (last visited Oct. 30, 2007).

treatment); and (4) were donated by such individuals with written informed consent and without any financial or other inducements.¹¹¹

On January 11, 2007, H.R. 3 was passed in the House by a vote of 253-174, thirty-seven votes short of the two-thirds majority needed to override the presidential veto.¹¹² Of the 253 consistency votes to pass the bill, thirty-seven were Republican and 216 were Democratic.¹¹³ Democratic Representative Diana DeGette, sponsor of H.R. 3, commented that the overwhelming win in the House demonstrated the “tremendous momentum” of Congress on the issue of federal funding for embryonic stem cell research.¹¹⁴ She was hopeful that, with Democratic majorities in the House and the Senate, President Bush would consider “negotiating with Congress over compromising language.”¹¹⁵ However, immediately following the House vote on January 11, Bush issued a “Statement of Administration Policy,” declaring that he “strongly oppose[d]” the passage of H.R. 3 by the House.¹¹⁶ Further emphasizing the President’s point, the Statement expressly states that “[i]f H.R. 3 were presented to the President, he would veto the bill.”¹¹⁷

¹¹¹ GovTrack.us, H.R. 3: Stem Cell Research Enhancement Act of 2007 Summary, <http://www.govtrack.us/congress/bill.xpd?tab=summary&bill=h110-3> (last visited Oct. 23, 2007).

¹¹² Rick Weiss, *House Passes Bill Relaxing Limits on Stem Cell Research*, WASH. POST, Jan. 12, 2007, at A04.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, STATEMENT OF ADMINISTRATION POLICY (Jan. 11, 2007), <http://www.whitehouse.gov/omb/legislative/sap/110-1/hr3sap-h.pdf>.

¹¹⁷ *Id.*

The Senate introduced a bill similar to H.R. 3, called S. 5, on January 4, 2007.¹¹⁸ The Senate's bill differs from H.R. 3 because S. 5 includes language "that would require NIH to research and fund methods of creating embryonic stem cell lines without destroying embryos."¹¹⁹ As expected, S. 5 passed the Senate on April 11, 2007 by a vote of 63-34 and passed the House on June 7, 2007 by a vote of 247-176.¹²⁰ However, as promised, President Bush vetoed the bill on June 20, 2007, and neither the Senate nor the House has voted to override Bush's veto.¹²¹

VI. THE LATEST BREAKTHROUGHS IN STEM CELL RESEARCH

While the discovery made at the beginning of 2007 eludes the stem cell controversy, this note would be remiss without a discussion of it. On January 7, 2007, scientists at Wake Forest University and Harvard University announced that after seven years of research, they discovered that the stem cells extracted from amniotic fluid are just as adaptable as the stem cells derived from human embryos.¹²² Therefore, the stem cells derived from amniotic fluid are capable of being turned into a variety of cell types.¹²³ The researchers further explained that the amniotic fluid used in their research was donated by pregnant women, and the procedure did not harm the

¹¹⁸ GovTrack.us, S. 5: Stem Cell Research Enhancement Act of 2007, <http://www.govtrack.us/congress/bill.xpd?tab=main&bill=s110-5> (last visited Oct. 30, 2007).

¹¹⁹ *House Approves Stem Cell Research Enhancement Act; Bush Threatens Veto*, MEDICAL NEWS TODAY, Jun. 12, 2007, <http://www.medicalnewstoday.com/articles/73631.php>.

¹²⁰ GovTrack.us, S. 5: Stem Cell Research Enhancement Act of 2007, <http://www.govtrack.us/congress/bill.xpd?tab=main&bill=s110-5> (last visited Oct. 30, 2007).

¹²¹ *Id.*

¹²² Associated Press, *Researchers Report Alternative Stem-Cell Source in Amniotic Fluid*, FOXNEWS.COM, Jan. 7, 2007, <http://www.foxnews.com/story/0,2933,242267,00.html>.

¹²³ *Id.*

mother or her fetus.¹²⁴ The downside to this discovery is that “[researchers] still [do not] know exactly how many different cell types can be made from the stem cells found in amniotic fluid . . . [and] that even preliminary tests in patients are years away.”¹²⁵

The latest breakthrough also manages to sidestep the embryonic stem cell controversy. On June 6, 2007, three teams of scientists at Harvard Stem Cell Institute, Whitehead Institute in Cambridge, and Kyoto University in Japan announced that they have “independently turned skin or other tissue from [adult] mice into cells that can create every other part of the body—the defining feature of embryonic stem cells.”¹²⁶ This groundbreaking discovery may mean a significant reduction in the need for embryonic stem cells because identical cells could be derived from adult tissue. “[T]he introduction of just four genes can make old cells act like embryonic cells—essentially making them young again.”¹²⁷ The technique has not yet been applied to humans, and scientists were quick to point out that it was too early to know whether human tissues would react in the same manner as the mouse tissues.¹²⁸ The researchers also agreed that, despite this discovery, human embryonic stem cell research should continue to expand now more than ever.¹²⁹ In the next section, this note proposes a change in the current state of affairs of embryonic stem cell research.

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ William Hathaway, *Cell Technique Could Bypass Embryonic Issue*, COURANT.COM, June 7, 2007, <http://pqasb.pqarchiver.com/courant/access/1284099041.html?dids=1284099041:1284099041&FMT=ABS&FMITS=ABS:FT&type=current&date=Jun+7%2C+2007&author=WILLIAM+HATHAWAY&pub=Hartford+Courant&edition=&startpage=A.1&desc=CELL+TECHNIQUE+COULD+BYPASS+EMBRYO+ISSUE>.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

VII. RECOMMENDATIONS FOR A CHANGE IN STATUS QUO

Some people may sit back and wait for a change in the presidency in November 2008 to see if President Bush's policy, which drastically limits the federal funding of embryonic stem cell research, is modified. Others continue to take action for a change to occur sooner.

One attempt to bring about change prior to the President's 2001 announcement involved *Nightlight Christian Adoptions v. Thompson*, a lawsuit against the NIH Guidelines. Although the plaintiffs' complaint challenged federal funding of embryonic stem cell research, it was, nevertheless, a noble attempt to alter the status quo. In *Nightlight Christian Adoptions v. Thompson*,¹³⁰ adoptive couples of frozen embryos that were destroyed in the process of stem cell derivation filed suit in federal court in March 2001 against the NIH Guidelines finalized in 2000.¹³¹ "[T]he plaintiffs sought declaratory and injunctive relief and challenged the NIH [G]uidelines for the public funding for research involving stem cells derived from human embryos."¹³² The plaintiffs requested that the government cease funding embryonic stem cell research and reverse the NIH Guidelines.¹³³ A "stipulated motion to stay the case was issued" in May 2001, suspending the case while President Bush reviewed the NIH Guidelines.¹³⁴ Since the changes made by the Bush administration during 2001 accomplished the goals of their litigation, on January 14, 2002, the plaintiffs dismissed their lawsuit without prejudice.¹³⁵

¹³⁰ *Nightlight Christian Adoptions v. Thompson*, No. 1L01CV00502 (D.D.C. filed Mar. 8, 2001).

¹³¹ *Stem Cell Research: Hearings Before the Subcomm. on Labor, Health and Human Servs., and Education of the S. Approps. Comm.*, 107th Cong. (2001) (testimony of Richard M. Doerflinger), available at <http://www.nccbuscc.org/prolife/issues/bioethic/stemcelltest71801.htm>.

¹³² Duffy, *supra* note 27, at CRS-5.

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ Christian Legal Society, *Nightlight Christian Adoptions*, available at http://www.clsnet.org/clrfPages/litigation/litigation_Nightlight.php.

Another group that has taken action, albeit on the opposite end of the spectrum, is the Patients' Coalition for Urgent Research (CURE).¹³⁶ In 1999, thirty-six national not-for-profit patient organizations joined to seek federal funding of embryonic stem cell research based on the NIH Guidelines.¹³⁷ The Coalition alleged that:

As taxpayers, patients and their family members are entitled to expect their government to make the most of a substantial public investment in biomedical research through the NIH [A]s the bearers of the ultimate burden when medicine cannot relieve their suffering, patients are the most compelling witnesses to the value of research that quite literally can save their lives.¹³⁸

Daniel Perry, chairperson of CURE, used numbers and figures to explain the rationale behind federal funding of embryonic stem cell research.¹³⁹ “The additional costs in medical and long-term care that are incurred annually in the United States because its Medicare recipients lose their functional independence are calculated at \$26 billion.”¹⁴⁰ For example, diabetes, a disease classified by the Centers for Disease Control and Prevention as an epidemic, is growing at a rate of 8% per year.¹⁴¹ According to a fourteen-month study by the American Diabetes Association and the Georgetown University Health Policy Institute, 6.3% of Americans currently have diabetes, but by 2050 one in three people will have the disease.¹⁴² “In 2002, one in ten

¹³⁶ Perry, *supra* note 3.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ Press Release, American Diabetes Association, Gaps found in all components of private health insurance coverage for people with diabetes (Feb. 8, 2005), <http://diabetes.org/for-media/2005-press-releases/insurance-coverage.jsp>.

¹⁴² *Id.*

healthcare dollars and one in four Medicare dollars went towards diabetes care. The cost of diabetes in America in 2002 was at least \$132 billion.”¹⁴³ Clearly, decreasing the number of Americans who suffer from diabetes will directly correlate to a substantial reduction in Medicare costs for diabetes-related care including blood glucose testing supplies and other diabetic equipment, prescriptions, and medical services.¹⁴⁴ It is in the government’s best interest, at least economically, to invest in stem cell research to allow for a greater percentage of people to live longer, healthier lives, thereby relieving the already significant financial burden on taxpayers.¹⁴⁵

CURE did not have tunnel vision on the issue of stem cell research—the Coalition was well aware of the concerns posed by federal funding.¹⁴⁶ CURE implicitly proposed oversight of the federal funding of embryonic stem cell research, suggesting that donors of embryos should not be paid for their donations and advising that informed consent and the freedom to choose to donate should continue to exist.¹⁴⁷ However, despite making these propositions in 1999-2000, CURE has not remained on the forefront of the stem cell controversy.

President Bush’s policy set forth in 2001 was reasonable and justifiable under the circumstances of that time, a time when stem cell research was truly in its infancy and the vast potential for stem cells was only slightly uncovered. However, seven years and several breakthroughs later, the policy on federal funding of embryonic stem cell research must be updated. While lawsuits and coalitions may create a stirring among scientists, religious organizations, or the general public, the likelihood of either seizing the attention of the federal

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ Perry, *supra* note 3.

¹⁴⁷ *Id.*

government is grim. On the other hand, permitting the federal funding of embryonic stem cell research, while uniformly regulating the activity via an oversight board, is a fair and rational compromise to the dilemma faced by the United States.

Dr. Stan Pelofsky, president of the American Association of Neurological Surgeons, met with President Bush on July 11, 2001 and advised him that federally funded embryonic stem cell research, coupled with oversight, is the best way to appease both sides of this heated and personal debate.¹⁴⁸ He told the President, “[y]ou would perhaps get spectacular benefits down the road . . . and you would also have governmental oversight.”¹⁴⁹

However, the picture is not all rosy, as two concerns surface when considering oversight of embryonic stem cell research: (1) the creation of ethical guidelines that will cover all scientists working with embryonic stem cells and (2) the evaluation and approval of every research procedure.¹⁵⁰ In 2005, the National Research Council and Institute of Medicine of the National Academies (“NRC”) published *Guidelines for Human Embryonic Stem Cell Research*.¹⁵¹ These recommendations truly attempt to “ensure that research with [human embryonic stem] cells is conducted in a responsible and ethically sensitive manner and in compliance with all regulatory requirements”¹⁵² The aspects of procurement, derivation, banking, and use of human embryonic stem cell lines are all given attention to ensure that every step of embryonic stem cell

¹⁴⁸ Lacayo, *supra* note 74.

¹⁴⁹ *Id.*

¹⁵⁰ Gladys B. White, *Foresight, Insight, Oversight*, HASTING CENTER REP. (Mar.-Apr. 1999), at 41, *available at* <http://www.jstor.org/view/00930334/ap060169/06a00170/0?currentResult=00930334%2bap060169%2b06a00170%2b0%2c06&searchUrl=http%3A%2F%2Fwww.jstor.org%2Fsearch%2FBasicResults%3Fhp%3D25%26si%3D1%26Query%3Dethics%2Band%2Bstem%2Bcell>.

¹⁵¹ NRC, *supra* note 14, at 97.

¹⁵² *Id.*

research is done in a highly ethical and transparent manner.¹⁵³ One of the main goals of this oversight is to prevent an underground black market for embryos.¹⁵⁴

NRC also advised that uniform regulations are imperative to maintaining accountability and compliance with standards.¹⁵⁵ After all, if one part of the scientific community is not obligated to abide by these regulations, then there is no real incentive to abide, especially if a cost for compliance is involved.

NRC's recommended guidelines include "all derivation of [human embryonic stem] cell lines and all research that uses [human embryonic stem] cells derived from (1) [b]lastocysts made for reproductive purposes and later obtained for research from [IVF] clinics; [and] (2) [b]lastocysts made specifically for research using IVF"¹⁵⁶ Next, NRC creates categories for different levels of permissible or prohibited stem cell research.¹⁵⁷ At one end of the spectrum is the category prohibiting certain research from being conducted at that time due to aspects of the research that are highly controversial or ethically questionable.¹⁵⁸ NRC recognized one type of research (in addition to two others not relevant to this note topic) that should not be conducted for the time being to be "[r]esearch involving *in vitro* culture of any intact human embryo, regardless of derivation method, for longer than 14 days"¹⁵⁹

¹⁵³ *Id.*

¹⁵⁴ Perry, *supra* note 3.

¹⁵⁵ NRC, *supra* note 14, at 97.

¹⁵⁶ *Id.* at 98.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 99.

At the other end of the spectrum is the category permitting research to be approved after “currently mandated reviews and proper notification of the relevant research institution” are completed.¹⁶⁰ NRC indicated that “[p]urely *in vitro* [human embryonic stem] cell research” that utilizes embryonic stem cell lines which have already been derived falls within this category so long as proper documentation regarding the cell lines exists.¹⁶¹

Finally, the middle category involves research that will be approved after further review by an “Embryonic Stem Cell Research Oversight (ESCRO) committee”¹⁶² NRC recognized one type of research (in addition to two others not relevant to this note topic) represented by this category: creation of new embryonic stem cell lines, no matter how they were created.¹⁶³

Ideally, there should be one ESCRO committee at each institution conducting embryonic stem cell research.¹⁶⁴ These committees should provide oversight for every stage of embryonic stem cell research.¹⁶⁵ Each facility’s committee should review the level of compliance of the research with respect to all applicable regulations, maintain registries of embryonic stem cell research conducted at the facility and any stem cell lines derived or imported, provide education for researchers at the institution, and be the final evaluator of the research procedures and protocols.¹⁶⁶

¹⁶⁰ NRC, *supra* note 14, at 98.

¹⁶¹ *Id.* at 99.

¹⁶² *Id.* at 98.

¹⁶³ *Id.* at 99.

¹⁶⁴ *Id.* at 100.

¹⁶⁵ NRC, *supra* note 14, at 100.

¹⁶⁶ *Id.*

The committee should fairly allocate membership to those of “scientific, medical, and ethical expertise,” but should also include members of the public as well as experts in “developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical and legal issues in [human embryonic stem] cell research.”¹⁶⁷ Researchers and their respective institutions will be held responsible for “conduct[ing] themselves in accordance with professional standards and with integrity.”¹⁶⁸

Regulation must first exist in the procurement of cells to be used in the creation of new embryonic stem cell lines, including procurement of excess IVF blastocysts and those blastocysts created for the sole purpose of stem cell research.¹⁶⁹ First and foremost, written informed consent should be received from each donor every time he/she donates.¹⁷⁰ In addition to notifying the donor that his donated blastocysts will be used in stem cell derivation for research on potential human transplantation, the donor should also be informed that he has the “right to withdraw consent until the blastocysts are actually used in cell line derivation.”¹⁷¹ Additionally, if the donor’s identity will be retained and thus be discoverable to scientists during the cell line research, this should be explained.¹⁷² If the identity is retained, a statement as to whether the donor desires to be contacted regarding any information learned during the research should also be obtained.¹⁷³

¹⁶⁷ *Id.*

¹⁶⁸ *Id.* at 99.

¹⁶⁹ *Id.* at 100.

¹⁷⁰ NRC, *supra* note 14, at 101.

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Id.*

The donor should understand that the research involving his blastocysts will not directly advantage the donor medically.¹⁷⁴ Furthermore, it should be explained that the embryos created will be destroyed during the stem cells' harvesting, given that ACT's new discovery is still in its preliminary stages.¹⁷⁵ Finally, the risks to the donor should be articulated to the donor.¹⁷⁶

Donors shall not receive any form of payment for donating blastocysts to research.¹⁷⁷ When blastocysts are created for the sole purpose of stem cell research, women donating the necessary oocytes should only be compensated for "direct expenses incurred as a result of the procedure" ¹⁷⁸ Likewise, men should not be paid for the donation of sperm for research.¹⁷⁹ Donors should also be advised that the research involving their donations might potentially lead to commercialization of the result; however, the donor will not receive any financial consideration if this is the case.¹⁸⁰

Next, the guidelines for derivation of embryonic stem cell lines are outlined by NRC. Applications for authorization to derive new embryonic stem cell lines from donated embryos or blastocysts must include proof of committee approval of the procurement process.¹⁸¹ "The scientific rationale for the need to generate new . . . cell lines, by whatever means, must be clearly presented, and the basis for the numbers of embryos and blastocysts needed should be

¹⁷⁴ *Id.* at 102.

¹⁷⁵ NRC, *supra* note 14, at 102.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* at 101.

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ NRC, *supra* note 14, at 102.

¹⁸¹ *Id.*

justified.”¹⁸² The guidelines impose these measures to keep a watchful eye over how many new cell lines are created so that a wasteful supply of embryos or blastocysts will not exist.

NRC then lists the guidelines for the banking of embryonic stem cell lines. Institutions that intend to bank embryonic stem cell lines should ensure that donors receive informed consent regarding their donation.¹⁸³ While each facility has the autonomy to create its own specific standards of ethical banking, the guidelines should be standardized and audited for compliance.¹⁸⁴ NRC recommends that uniform tracking systems also be established, in addition to a registry of all stem cell lines banked at the institution.¹⁸⁵

Finally, suggested regulations regarding the research of embryonic stem cell lines are outlined. Of particular note is the recommendation that “research use of existing [human embryonic stem] cells does not require [committee] review unless the research involves introduction of the . . . cells or their derivatives into patients”¹⁸⁶ However, ESCRO committees should closely monitor the use of stem cell lines that were derived specifically for research, requiring documentation of approval for each stage, including procurement and derivation.¹⁸⁷

Overall, NRC’s recommended guidelines allow for the biomedical industry to maintain some of its autonomy. However, the guidelines also hold the researchers and institutions to high ethical standards, allowing for transparency and scientific integrity.

¹⁸² *Id.* at 103.

¹⁸³ *Id.* at 103-4.

¹⁸⁴ *Id.*

¹⁸⁵ NRC, *supra* note 14, at 103-4.

¹⁸⁶ *Id.* at 106.

¹⁸⁷ *Id.* at 105.

CONCLUSION

These guidelines are outlined proposals and have not yet been applied to regulate the federal funding of embryonic stem cell research. However, they are a step in the right direction toward “offer[ing] reassurance to the public and to Congress that the scientific community is attentive to ethical concerns and is capable of self-regulation while moving forward with this important research.”¹⁸⁸ This controversial issue should not be subjected to a zero-sum game where the winner takes all. Federal funding of embryonic stem cell research, coupled with consistent and structured oversight, is the best solution to allow this important research to continue without compromising the ethical values of our country.

There are few people, if any, who do not have at least one family member or friend suffering from one of the many diseases or conditions that stem cell research can help maintain, improve, or even cure. It is unfair to simply say that those who oppose the federal funding of embryonic stem cell research callously disregard their loved ones’ pain and suffering in order to protect excess embryos already scheduled for destruction in clinic incinerators, for this sentiment is untrue. Rather, they seek a rational and reliable compromise that will appease both sides of this equation—one that involves conducting valuable research while also preventing the waste of precious resources. Many successful compromises have been made in our country’s past; with vigilant and thorough consideration of the guidelines accompanying the federal funding of embryonic stem cell research, another successful compromise can certainly be achieved.

¹⁸⁸ *Id.* at 106.