EMBRYONIC STEM CELLS: MARROW OF THE DICKEY MATTER

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I. Introduction

In the United States there are currently over 100,000 people waiting for organ transplants, with only a fraction of those individuals actually receiving them.[1] Recent data shows there were only 14,140 transplants performed between January and June of 2010 and of those transplants only 7,136 recovered.[2] The low recovery rate is caused by immune responses in the recipient triggered by foreign cells and tissue which can lead to a rejection of the transplant tissue or organ.[3] One promising solution for

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1. *See Organ Procurement and Transplantation Network*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *archived at* http://www.webcitation.org/5sv5ik8xG. OPTN developed an online database to efficiently share information regarding organ donors and transplant patients in the United States. *Id*. Institutions rely on this database to help match those waiting for a transplant with donated organs. *Id.*

2. *Id.*

3. *See* Prashant Malhotra, MBBS, et al., *Immunology of Transplant Rejection,* EMEDICINE, *archived at* http://www.webcitation.org/5sv5MCoV1. Damaged tissue triggers an immune response that involves many biochemical cascade pathways. *Id.* The strongest immune response is from allogeneic major histocompatibility complex (MHC) antigens. *Id.* The human type of the MHC is the human leukocyte antigen (HLA), and after a transplantation procedure, donor HLA molecules are processed by the recipient's antigen presenting cells (APCs) and presented to T cells. *Id.* The presence of nonself HLA molecules activate the recipient's T cells, causing an adaptive immune response that results in elimination of donor tissue and graft rejection. *Id.* Compatibility at 3 HLA loci (ie, HLA-A, HLA-B, HLA-DR) can reduce the allogeneic MHC antigens from triggering an immune reaction, increasing the likelihood of a successful transplant. *See* Robert Jean M. Goycoolea, MA et al., *Immunologic Aspects of Organ Transplantation: Histocompatability,* EMEDICINE, *archived at* http://www.webcitation.org/5suwFUmCS.

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meeting the demand of transplants is stem cell-based therapies, which could provide doctors with a renewable source of healthy cells and tissues to repair failing organs.[4] Not only could stem cell-based transplants meet the high demand of organ transplants, but the rate of transplant rejection could be decreased as well by reducing the recipient's immune response.[5]

The therapeutic potential of human embryonic stem cells (hESCs) is one of the many reasons why researchers are so motivated to work with various stem cell lines.[6] Unfortunately, with the controversy surrounding the destruction of the fetus for stem cells and the current restrictions on research involving embryos, there are limited stem cell lines available for testing.[7] The budget bill that funds the National Institute of Health (NIH) contains the restrictive language of the Dickey Amendment, prohibiting the use of federal funds for any research that subjects a human embryo to risk of injury or death.[8] The need to revise U.S. law, specifically the Dickey Amendment, is supported by existing data concerning stem cells, the therapeutic potential of cell-based therapies, and the success of Great Britain's administrative program, the Human Fertilisation and Embryology Authority (HFEA).[9]

This Note discusses the issues surrounding the United States' current research policy involving human embryos and the

4. *See* James A. Thomson et al., *Embryonic Stem Cell Lines Derived From Human Blastocysts,* 282 SCI. 1145, 1147 (1998) (discussing the potential for stem cells to prevent immune rejection of transplanted cells).

5. *See id.* "Strategies to prevent immune rejection of the transplanted cells need to be developed but could include banking ES cells with defined major histocompatibility complex backgrounds or genetically manipulating ES cells to reduce or actively combat immune rejection." *Id.*

6. *See id* at 1146 (discussing the variety of therapeutic applications that are derived from stem cell usage).

7. *See* MICHAEL BELLOMO, STEM CELL DIVIDE 66, 94 (2006) (noting that President Bush's stem cell research policy limited federal funding to only about sixty cell lines).

8. *Id*. at 90-91.

9. *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) (discussing potential policy changes for federal funding of stem cell research). The United Kingdom set up the HFEA to monitor all research involving human embryos. *Id.*

ensuing negative impact on stem cell research. The main thesis explores the differences between the United States and foreign legal policies concerning research on human embryos, analyzing how the variations affect the economic and scientific potential of stem cell therapies. It presents alternative legal guidelines that permit the use of embryos under specific circumstances, while accounting for the delicate ethical and moral issues involved with human embryonic stem cell research. Following these proposals is a discussion about the advantages of an administrative program similar to the HFEA, and the benefits of having this type of framework.

II. History

Embryonic stem cell research is one of many controversial issues currently dividing the United States.[10] One contention is that this type of science threatens the sanctity of human life by seeking to destroy the precious foundation of that life.[11] Another argument holds this area of research has seemingly limitless therapeutic potential and the ability to provide many people who are suffering with a better quality of life.[12] Because of the important ethical and traditional moral issues at stake, this topic has sparked a major political debate resulting in legal constraints that will have unfortunate economic and scientific consequences if not carefully analyzed. [13]

A. Stem Cell Research

In 1998, Dr. James Thomson from the University of Wisconsin first described the successful isolation of pluripotent stem cells from human embryos, launching the idea of stem cell

10. *See id.* at 159 (noting the disagreement over the use of embryonic stem cells for research purposes).

11. *See id.* at 160-61 (discussing differing religious views on stem cell research).

12. *See id.* at 164 (exploring the potential for major medical breakthroughs through stem cell research).

13. *See* BELLOMO, *supra* note 7, at 66, 90-91 (illustrating majority Republican Congress' inclusion of the Dickey Amendment in the 1995 budget bill for the NIH).

research into the forefront of the scientific community.[14] Pluripotent stem cells are undifferentiated body cells, meaning they are without a characteristic structure or function and can differentiate into any type of cell.[15] This characteristic makes stem cells a valuable research tool; the therapeutic value lies in the cells' "degree of developmental plasticity," which varies depending on the type of stem cell.[16] Pluripotent embryonic stem cells have the ability to differentiate into all cell types.[17] In contrast, there are multipotent adult stem cells which are limited to the types of cells they can differentiate into.[18] Adult stem cells may be removed by a simple biopsy, so while their use is not legally or ethically controversial, research potential is limited and exhaustive.[19]

Despite the vast medical possibilities, there are substantial moral, political, and legal obstacles that threaten to impede the

14. *See* Thomson, *supra* note 4, at 1145 (discussing Thomson's method of isolation for in vitro embryonic stem cells).

15. *See* NATIONAL GEOGRAPHIC, THE SCIENCE BOOK 257 (2008) (characterizing pluripotent stem cells); *see also* Michael J. Shamblott et al., *Derivation of Pluripotent Stem Cells From Cultured Human Primordial Germ Cells*, 95 PROC. NAT'L. ACAD. SCI. USA 13726, 13726 (1998) (discussing that with the appropriate combination of growth and differentiation factors, mouse embryonic stem cells can produce hematopoietic and cardiomyocyte cells, neurons, skeletal muscle, and endothelial cells). Pluripotent stem cells "demonstrated ability to differentiate *in vitro* into derivatives of the three embryonic germ layers." Shamblott, *supra* note 15, at 13726.

16. BELLOMO, *supra* note 7, at 31 (characterizing "Plasticity" as the cell's ability to divide indefinitely and develop into various cell types); *see also* NATIONAL GEOGRAPHIC, *supra* note 15, at 257 (noting that "[t]he possibility of producing embryonic stem cells, which can be multiplied in vitro almost infinitely, opens new doors for developmental research, especially in medicine.").

17. *See* NATIONAL GEOGRAPHIC, *supra* note 15, at 257 (discussing the cellular characteristics of embryonic stem cells); Shamblott et al., *supra* note 15, at 13726 (discussing the different cell types that can be derived from pluripotent embryonic stem cells).

18. *See* Patricia A. Zuk et al., *Human Adipose Tissue Is a Source of Multipotent Stem Cells*, 13 MOL. BIOL. CELL. 4279, 4279-80 (2002) (using mesenchymal adult stem cells from bone marrow stroma as an alternative source to embryonic stem cells for mesodermal defect repair). "[U]nlike embryonic stem cells (i.e., MSCs) research on adult-derived stem cells has suggested a more restricted potential." *Id*. at 4292.

19. *See* NATIONAL GEOGRAPHIC, *supra* note 15, at 257 (discussing support for noncontroversial generation of stem cells); *see also* Zuk et al., *supra* note 18, at 4292 (discussing the limited research potential of adult derived stem cells).

advancement of this research.[20] The therapeutic potential of embryonic stem cells is extensive, including cures for heart failure, Alzheimer's disease, and spinal-cord injuries.[21] Moreover, pluripotent embryonic stem cells are economically valuable, offering the potential to generate billions of dollars in revenue for the United States by 2018.[22] In spite of the therapeutic and economic benefits, embryonic stem cell utility is tempered by the fact that destruction of the embryo is required during the stem cell production process.[23]

An alternative to embryonic stem cells is induced pluripotent stem (iPS) cells, which are adult skin cells that have been reprogrammed genetically to behave like embryonic stem cells.[24] However the disadvantage of using iPS cells is that clinical application is not yet an option for humans because the use of retrovirus vectors to modify the cells creates a risk of cancer development.[25] A recent study using mice was conducted

20. *See* Elizabeth Svoboda, *The Essential Guide to Stem Cells*, POPSCI.COM, June 1, 2009, *archived at* http://www.webcitation.org/5uRGvLExl (social conservatives opposed to destroying embryos for stem cell research); *see also* Terence P. Jeffery, *Obama Signs Law Banning Federal Embryo Research Two Days After Signing Executive Order to OK It,* CNSNEWS.COM, Mar. 12, 2009, *archived at* http://www.webcitation.org/5sv6KG8qV (discussing recent executive order signed by President Obama involving federal funding for embryonic stem cell research and current legal restrictions).

21. *See* NATIONAL GEOGRAPHIC, *supra* note 15, at 257 (discussing the potential medical benefits of using embryonic stem cells). Since embryonic stem cells are pluripotent they can theoretically develop into any of the 210 cellular tissues in the human body. *Id.*

22. *See* Svoboda, *supra* note 20, at 2 (discussing expected annual revenue from stem cell therapies to be eight billion dollars by 2018).

23. *See* NATIONAL GEOGRAPHIC, *supra* note 15, at 257 (discussing the ethical dilemma behind the use of embryonic stem cells).

24. *See* Svoboda, *supra* note 20, at 1 (discussing various terms used in stem cell research); NATIONAL GEOGRAPHIC, *supra* note 15, at 257 (explaining noncontroversial alternatives to embryonic stem cells).

25. *See* Junying Yu, et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells,* 318 SCI. 1917, 1919, *archived at* http://www.webcitation.org/5uRH1Hlk0 (explaining that "before the cells can be used in the clinic, additional work is required to avoid vectors that integrate into the genome, potentially introducing mutations at the insertion site.").

to create iPS cells without the use of retroviruses, but the use of this technique on human iPS cells is still being tested.[26]

B. U.S. Stem Cell Law

In response to *Roe v Wade,*[27] members of Congress addressed concerns of exploiting aborted embryos and fetuses by placing a temporary suspension on federal funding of research that involved the destruction of human fetuses in 1974.[28] There was a political shift with regard to embryonic research in 1993 when a Democratic-controlled Congress was accompanied by Democratic President Bill Clinton.[29] President Clinton supported the NIH's use of federal research funds for embryos left over from in vitro-fertilization procedures.[30] Before a proposal could be approved, Congressional power swung back to the Republicans.[31] As a result, the Dickey Amendment was included in the budget

26. Matthias Stadtfeld et al., *Induced Pluripotent Stem Cells Generated Without Viral Integration*, 322 SCI. 945, 945, 949 (2008), *archived at* http://www.webcitation.org/5uRH5vV4J (discussing generation of induced pluripotent stem cells from mouse fibroblast and liver cells using nonintegrating adenoviruses expressing Oct4, Sox2, Klf4, and c-Myc)*;* Yuval Levin, *Stem Cell Advance*, THE NATIONAL REVIEW ONLINE, Sept. 25, 2008, *archived at* http://www.webcitation.org/5sv6SbCuO (discussing the development of iPS cells without use of a retrovirus).

27. 410 U.S. 113 (1973) (holding that a woman had a fundamental right to an abortion).

28. *See* BELLOMO, *supra* note 7, at 88 (discussing 1974 moratorium on federal funding of research using human fetuses). However, Congress did allow research involving human fetuses or living embryos if the purpose of the research was to enhance or ensure the fetus' chance of survival. *Id.* During the temporary suspension of embryonic research in 1974, Congress established The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to draft guidelines regarding human embryonic research. *Id.* at 88-89. In 1975, the commission issued its final report, appointing a national Ethics Advisory Board to propose standards for federally approved research protocols involving human embryos that would be eligible to be federally funded. *Id.*

29. *See* BELLOMO, *supra* note 7, at 90 (discussing a shift in the political climate during the early 1990s). The Democratic majority in Congress enacted the National Institute of Health (NIH) Revitalization Act which rescinded approval for research from the now obsolete Ethics Advisory Board. *Id.* The NIH advisory panel "recommended that human embryo research should, within a recognized framework of ethical safeguards, be deemed eligible for federal funding." *Id.*

30. *See* BELLOMO, *supra* note 7, at 90-91.

31. *See* BELLOMO, *supra* note 7, at 90-91.

bill which laid out certain restrictions on the type of embryonic research and cell lines that may be created for research purposes.[32] The Dickey Amendment was authored by Representative Jay Dickey, and is a provision to the NIH budget bill that is still in effect today.[33]

Although many lawsuits were filed seeking answers to questions involving the rights of human embryos with regards to due process and equal protection, they were dismissed as moot for procedural problems once President Bush took office.[34] Thus, the federal questions regarding an embryo's right to due process and equal protection have yet to be answered by the federal courts.[35] In 2001, the Bush Administration instituted a ban on federal funding for embryonic stem cell research that created a scientific and political uproar.[36] This policy limited federal funding to about sixty stem cell lines that had been created prior to August 9, 2001.[37] These federal restrictions led to certain state initiatives, such as the *California Stem Cell Research and Cures Initiative* (Proposition 71).[38] The California proposition

32. *See* Balanced Budget Downpayment Act 1, Pub. L. No. 104-99, § 128, 110 Stat. 26 (1996) [hereinafter Balanced Budget Downpayment Act] ("None of the funds…may be used for—(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…")*; see also* 42 U.S.C. § 289(g) (2008) (setting out the Public Health and Welfare's restrictions on fetal research).

33. *See* BELLOMO, *supra* note 7, at 90-91 (discussing the history of the Dickey Amendment).

34. *See* Doe v. Shalala*,* 122 F. App'x 600, 601 (2004) (holding the action was rendered moot by subsequent adoption of new federal policy). Advocacy groups filed cases on behalf of frozen human embryos to seek a declaration that embryos were protected under the Constitution. *Id.* They also sought an injunction against embryonic stem cell experimentation. *Id.*

35. *See id*. at 604 (declining to address the Constitutionality of the policy in favor of dismissing the case due to mootness).

36. *See President Discusses Stem Cell Research*, OFFICE OF THE PRESS SECRETARY, WHITE HOUSE, Aug. 9, 2001, [hereinafter *Address to Nation*] (announcing policy that limited federal funding for research on ESCs); *see also* Claudia Kalb, *A New Stem Cell Era,* NEWSWEEK, Mar. 9, 2009, *archived at* http://www.webcitation.org/5tGDwwtyA (highlighting how the Bush policy was intended to be a compromise, but scientists were frustrated by the limitations placed on embryonic stem cell research).

37. BELLOMO, *supra* note 7, at 66, 94 (discussing President Bush's limitation on federal funding for stem cell research).

38. BELLOMO, *supra* note 7, at 66 (discussing California's response to

established stem cell research as a state constitutional right, granting $3 billion to research funding over the next ten years.[39] Further, Proposition 71 specifically made embryonic stem cell research the top priority of the state funds.[40] While the states have the authority to pass their own laws that permit embryonic stem cell research with state funds, the importance of federal funding was greatly stressed by scientists.[41]

In 2009 President Obama lifted the Bush Administration's ban on embryonic stem cell research.[42] The scientific victory was short lived when days later President Obama signed an annual appropriations bill, which included the Dickey Amendment and its restriction on the cell lines used for stem cell research.[43] Despite these legal restrictions, President Obama directed the NIH to issue new stem cell research guidelines which allowed funding of research involving human embryos "that were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose," and "were donated by individuals who sought reproductive treatment...and who gave voluntary written consent."[44]

President Bush's policy).

39. BELLOMO, *supra* note 7, at 66-67 (outlining Proposition 71).

40. BELLOMO, *supra* note 7, at 66-67.

41. *See Frequently Asked Questions – Stem cells and the law*, EUROSTEMCELL, *archived at* http://www.webcitation.org/5tGENL7AI (follow "What does the law say about human embryonic stem cell research in the US? " hyperlink) (last visited Mar. 28, 2010) (explaining the limitation of federal funding on stem cell research). Many states modified their legislation in response to Bush's embryonic stem cell policy including California, Massachusetts, and Connecticut. *Id.; see also* Kalb, *supra* note 36 (describing the frustration and difficulty in separating research funded by private and/or government money). "One of the most disconcerting aspects, researchers say, has been the negative effect on collaboration, a hallmark of the scientific process. Researchers supported by private money haven't been able to team up with scientists funded by the government, potentially holding back new insights and advances." *Id.*

42. *See* "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells," Exec. Order No. 13,505,74, Fed. Reg. 10,677 (Mar. 9, 2009), *archived at* http://www.webcitation.org/5uRHBeJwg [hereinafter Removing Barriers] (revoking Executive Order 13435 to allow for the federal funding of stem cell research); *see also* Jeffery, *supra* note 20.

43. *See* Jeffery, *supra* note 20 (reporting the inclusion of the Dickey Amendment into the appropriations bill).

44. National Institutes of Health: National Institutes of Health Guidelines on

The revised guidelines were soon challenged in court as being contrary to the Dickey Amendment.[45] After hearing the plaintiffs' arguments against the guidelines, Chief Judge Lamberth of the District Court for the District of Columbia issued an injunction barring federal funding for embryonic stem cell research.[46] While the Department of Justice successfully requested the U.S. Circuit Court of Appeals to stay the injunction while the court reviews the case, research projects will be threatened if the Appeals Court affirms the lower court's ruling.[47] Despite the recent executive grant of federal funding for research, the Dickey Amendment proves to be an obstacle that scientists must maneuver around while seeking to advance the therapeutic potential of stem cells.[48]

C. Foreign Embryonic Stem Cell Law

As the United States hesitates to support this advancement in science, other countries with greater research options are threatening to surpass the developments of U.S. researchers.[49] The United Kingdom created the Human

Human Stem Cell Research, *archived at* http://www.webcitation.org/5sv6lCNJH (outlining NIH guidelines in implementing executive order 13505).

45. *See* Removing Barriers, *supra* note 42 (revoking presidential statement of 2001 and orders to expand NIH support of human stem cell research); *see also* Sherley v. Sebelius, 704 F. Supp. 2d 63, 65-69 (D.D.C. 2010) (adult stem cell researchers filed suit to enjoin the Secretary of Health and Human Services (HHS) from adopting the new stem cell research guidelines).

46. *See Sherley*, 704 F. Supp. 2d at 70-73 (holding the Dickey Amendment is not ambiguous and the court must 'give effect to the unambiguously expressed intent of Congress' to prohibit federal funding of research where a human embryo is destroyed).

47. *See* Rob Stein, *Appeals Court Lifts Ban on Stem Cell Funding*, WASH. POST, Sept. 9, 2010, *archived at* http://www.webcitation.org/5sv7bsxFn (reporting that a three-judge panel of the U.S. Circuit Court of Appeals granted request to stay injunction); *see also* Will Doran, *Embryonic Stem Cell Research Threatened by Ban,* THE DAILY TAR HEEL, *archived at* http://www.webcitation.org/5sv7hTVQZ (noting researchers could have their research permanently halted by the injunction and that pausing this type of research is disruptive and crippling).

48. *See Sherley,* 704 F. Supp. 2d at 73 (finding Dickey Amendment prevents the use of federal funds for certain types of stem cell research).

49. *See* BELLOMO, *supra* note 7, at 116 (quoting Professor John D. Gearheart of the John Hopkins Medical School when he said that "[t]here is a feeling we have got to do something rapidly or we are going to be really out of the ball

Fertilisation and Embryology Authority (HFEA) after passing the 1990 Human Fertilisation and Embryology Act.[50] The statutory functions of the HFEA include supervision of in vitro fertilization clinics, monitoring research facilities involved with human embryos, regulating storage of sperm, eggs, and embryos, and maintaining research licenses held by clinics.[51] The role of the HFEA is to regulate research in addition to providing guidance, advice, and information to the public and researchers.[52] The world's first stem cell bank was established in Britain under the direction of the HFEA, where they are currently seeking to categorize all of the embryonic stem cell lines used around the globe.[53] Some exciting advancements have been made in this field of research under the HFEA, including a recent study performed by Professor Alison Murdoch at Newcastle University.[54] Professor Murdoch used a nuclear transfer process to develop embryonic cell lines derived from the inner cell mass (ICM) of five to seven day old blastocysts that are predicted to be very useful in treating various diseases.[55]

Singapore established the Bioethics Advisory Committee (BAC) in 2000 in order to address the various legal, ethical, and social issues stemming from biomedical research.[56] Even though

game.").

50. *See Our Role as Regulator*, HUM. FERTILISATION AND EMBRYOLOGY AUTH., *archived at* http://www.webcitation.org/5tV0NAdMr (discussing the history of HEFA).

51. *See Our Role as Regulator*, *supra* note 50 (discussing the role of HEFA).

52. *See Our Role to Provide Guidance and Advice,* HUM. FERTILISATION AND EMBRYOLOGY AUTH., *at* http://www.webcitation.org/5tV1GmF6x (explaining HEFA's guidance and advisory role).

53. *See* BELLOMO, *supra* note 7, at 112 (describing the United Kingdom's approach to stem cell research).

54. *See* Miodrag Stojkovic, et al., *Derivation of Human Embryonic Stem Cells From Day-8 Blastocysts Recovered After Three-Step In Vitro Culture*, 22 STEM CELLS 790, 790 (2004), *archived at* http://www.webcitation.org/5tV1chRF6 (discussing a recent development in human embryonic stem cell research); *see also* BELLOMO, *supra* note 7, at 113.

55. *See* Stojkovic *supra* note 54, at 790 (describing culture conditions for developing human embryonic stem cells from two-day embryos); *see also* BELLOMO, *supra* note 7, at 113. The goal is to develop patient-specific stem cells to treat diseases. *Id*. In 2005, Murdoch's research team developed the United Kingdom's first human nuclear transfer-derived embryo cells, which were targeted for the treatment of diabetes. *Id.*

56. *See Home,* BIOETHICS ADVISORY COMMITTEE, *archived at*

there are no legislative restrictions on hESC research in Singapore, researchers rely on the policy guidelines published by the BAC.[57] The BAC is endorsed by the government and takes a consensus approach to their organization, encouraging public input regarding research decisions and guidelines.[58] The role of the BAC is to provide advice and recommendations to the Steering Committee of Life Sciences, who then offer policy guidelines in regards to biomedical research.[59] With the government investing over $1.8 billion in biotechnology, the Biopolis medical research center has attracted scientists from all over including Alan Colman, Edison Liu Tak-Bun, and Sir David P. Lane.[60]

http://www.webcitation.org/5sv7qVsu7 (discussing the purpose of BAC).

57. *See* Alan Colman, *Stem Cell Research in Singapore*, 132 CELL 519, 520 (2008); *see Medicines Act* [*Singapore*],GENETICS AND PUBLIC POLICY CENTER, *archived at* http://www.webcitation.org/5tV360koN.
The BAC has published several reports (the Advancing the Framework of Ethics Governance for Human Research 2003 and the Research Involving Human Subjects: Guidelines for IRBs 2004) which examine the current system of ethical governance in Singapore, provide recommendations on the constitution and roles of the IRB's in the context of clinical research, and to provide recommendations regarding future development of Singapore's ethical governance of clinical research.
Medicines Act [*Singapore*], *supra*.

58. *See About BAC*, BIOETHICS ADVISORY COMMITTEE, *archived at* http://www.webcitation.org/5tV3YDw3o, (follow "About Us" hyperlink; then follow "Who We Are" hyperlink) [hereinafter *BAC "Who We Are"*] (describing the organizational structure of BAC and their desire for public input).

59. *See About BAC, supra* note 58*; see also Steering Committee on Life Sciences-Terms of Reference*, NAT'L RES. FOUND., *archived at* http://www.webcitation.org/5sv7xZIEx.
Terms of Reference: To give prominence to the development of the Life Sciences sector in Singapore; to coordinate the activities of ministries such as Trade and Industry, Education and Health in R&D, industry development, healthcare and education to support the growth of the Life Sciences sector; and to provide policy guidance in addressing health, ethical and legal concerns which may arise from biomedical research, healthcare and industry development.
Id.

60. BELLOMO, *supra* note 7, at 113-14 (discussing the large degree of financial support from the Singaporean government); *see* Wayne Arnold, *Singapore Acts as Haven for Stem Cell Research,* NY TIMES, Aug. 17, 2006, at 3-4, *archived at* http://www.webcitation.org/5sv831fRQ [hereinafter Arnold] (noting that Alan Colman helped clone the sheep Dolly in 1996, Edison Liu Tak-Bun is from the National Cancer Institute, and Sir David P. Lane is renowned for his cancer research with the p53 tumor suppressing gene).

While Singapore seeks to become the next stem cell center, China is pouring its resources into stem cell research.[61] In 2001, the Beijing Ministry of Health Medical Ethics Committee, along with the Southern Chinese Human Genome Research Centre Ethical, Legal, and Social Issues Committee (ELSI), instituted ethical research restrictions that are far more liberal than the United States.[62] China's guidelines allow for the purchase of human embryos intended for research along with human cloning for therapeutic purposes, providing scientists with a very favorable environment for stem cell research.[63] The Chinese government contributed $200 million to Dr. Cao Yilin's Tissue Engineering Research Center, the total cost reaching $250 million.[64] If the United States refuses to adequately provide its scientists with an environment for this type of research to flourish, it will happen elsewhere and unfortunately the United States will not be able to reap the economic or patent benefits from that success.[65]

D. The Next Phase of Stem Cell Research

The need for Congress to revisit the Dickey Amendment is critical to the advancement of stem cell research in the United States.[66] The current restrictions are blocking possible avenues of therapeutic success because scientists are restricted to a small

61. *See* Lianming Liao, et al., *Stem Cell Research in China*, 362 PHIL. TRANS. R. SOC. B. 1107, 1107 (2007) [hereinafter Liao] (discussing how China has increased its, efforts on embryonic stem cell research).

62. *Compare* Liao, *supra* note *61, with* Balanced Budget Downpayment Act, § 128, 110 Stat. at 26 (comparing the differences in U.S. and Chinese regulations of hESCs). "The hESCs described in the guidelines include stem cells derived from donated human embryos, those originated from germ cells and those obtained from somatic cell nuclear transfer." Liao, *supra* note 61, at 1108.

63. Liao, *supra* note 61, at 1107-08.

64. *See* BELLOMO, *supra* note 7, at 115 (comparing U.S. funding of stem cell research to that of China).

65. *See* BELLOMO, *supra* note 7, at 114 (discussing the growing and rapidly developing field of stem cell research in Pacific Rim nations); Arnold, *supra* note 60 (discussing U.S. scientists relocating to Singapore, due to U.S. restrictions on stem cell research); Liao, *supra* note 61, at 1107 (discussing China's aggressive support in developing stem cell research).

66. *See* Sheryl Gay Stolberg, *Obama Is Leaving Some Stem Cell Issues to Congress*, N.Y. TIMES, Mar. 9, 2009, *archived at* http://www.webcitation.org/5tbK0kGoH (explaining that federally funded researchers will still be unable to create their own stem lines because of the restrictions imposed by the Dickey Amendment).

number of cell lines available for research.[67] The need to avoid controversial, divisive scientific methods cannot drive researchers because the progression of the biomedical field requires the freedom to pursue all of the research options available.[68]

While this type of medical science must be explored responsibly, the opinion of what constitutes morally acceptable stem cell research varies drastically across the country.[69] As the debate continues unresolved, every year hundreds of thousands of "poor quality" embryos are discarded at fertility clinics that could be used to create viable embryonic stem cell lines.[70] A recent study at Children's Hospital Boston demonstrated that early-arrested embryos were capable of yielding human embryonic stem cells.[71] Nevertheless, federal funding cannot be used to conduct research on these embryos because the Dickey Amendment strictly prohibits the intentional destruction of embryos for research purposes.[72] With this law in place, federal embryonic stem cell researchers will be prevented from using excess embryos discarded from in vitro fertilization (IVF) clinics,

67. Jeffery, *supra* note 20 (commenting on the statements of President Obama that lifting the limitations on research can lead to new therapies that could benefit society).

68. Jeffery, *supra* note 20 (discussing the Dickey Amendment's hindrance on beneficial research).

69. *See* BELLOMO, *supra* note 7, at 66-7 (speaking to differences between California and federal approaches to stem cell research).

70. *Embryos Discarded During IVF Create Stem Cell Lines,* US NEWS, Jan. 28, 2008, *archived at* http://www.webcitation.org/5sv89Gqdb (discussing the derivation of a stem cell line from poor-quality embryos discarded at in vitro fertility clinics); s*ee also* Paul H. Lerou et al., *Human Embryonic Stem Cell Derivation From Poor-Quality Embryos,* 26 NATURE BIOTECH. 212, 212 (2008), *archived at* http://www.webcitation.org/5tbNCOw7W (defining "poor-quality" embryos as those that are deemed "clinically useless based on poor morphology and a low likelihood of generating viable pregnancies."). Those embryos are typically discarded as "medical waste." *Id.*

71. *See* Lerou et al., *supra* note 70, at 212 (reporting results of deriving hESCs from different grades of poor-quality embryos).

72. *See* Balanced Budget Downpayment Act, *supra* note 32, at 34 (restricting use of federal funds for research where embryo is intentionally destroyed); *see also Sherley*, 704 F. Supp. 2d at 73 (stating the intent of the Dickey Amendment).

and thus will be unable to create new cell lines or have access to the embryonic stem cells their work requires.[73]

For those that believe life begins at conception, collecting stem cells that destroy the embryo is the equivalent of killing a human being.[74] From a legal standpoint they feel embryos should have access to due process and equal protection under the 14th Amendment.[75] Even though the moral status of embryos is undecided, the Supreme Court has previously declared that a fetus does not enjoy protection as a "person" under the law.[76] Regardless of the disputes over the moral and legal status of an embryo, discarding poor-quality IVF embryos is wasteful, leaving some people to argue that this resource should be utilized and not thrown away.[77]

III. Facts

Multiple levels of government regulate stem cell research.[78] At the federal level, the Executive and Legislative

73. *See* Stolberg, *supra* note 66 (explaining that "because of the Dickey-Wicker amendment, federal researchers would still be unable to create their own stem cell lines.").

74. *See Ethical Issues in Human Stem Cell Research: Volume 1 Report and Recommendation of the National Bioethics Advisory Commission*, NAT'L BIOETHICS ADVISORY COMM'N, 50 (1999), *archived at* http://www.webcitation.org/5tbPBsV9i ("The fundamental argument of those who oppose the destruction of human embryos is that these embryos are human beings and, as such, have a right to life.").

75. *See Human Embryo Research: All Sides to the Disputes*, RELIGIOUSTOLERALANCE.ORG, *archived at* http://www.webcitation.org/5uAoUKEE7:

Thus, an embryo is viewed as a human being with all of the rights of an adult. Experiments which subject an ovum to any significant risk are the ethical equivalent of the infamous medical experiments that were inflicted on unwilling and uninformed victims in Nazi death camps. Ends do not justify the means. Thus, no matter how helpful to mankind embryo research might potentially be, it cannot be done if the embryo is eventually killed or subjected to a significant risk.

Id.

76. *See Roe*, 410 U.S. at 158 ("[T]he word 'person,' as used in the Fourteenth Amendment, does not include the unborn.").

77. *See Embryos Discarded During IVF Create Stem Cell Lines*, *supra* note 70 (reporting embryos that cannot be used clinically for in vitro fertilization can be a source used to derive embryonic stem cells).

78. *See* Lauren Thuy Nguyen, *The Fate of Stem Cell Research and a Proposal for Future Legislative Regulation,* 46 SANTA CLARA L. REV., 419, 426-27 (2006)

branches control spending, research guidelines, and cell-line restrictions.[79] However, federal jurisdiction is not exclusive, which means states also have the power to enact laws regulating stem cell research using state funds.[80]

A. Federal Regulation

While the President of the United States has the power to set the federal government's policy for human embryonic stem cell research, the U.S. Constitution grants Congress with the authority to override Presidential policy by enacting federal laws.[81] The issue of federal funding and regulation of embryology research began in the 1970's with in vitro fertilization.[82] A federal rule was implemented in 1975 stating that the Department of Health and Human Services would not fund any research involving human in vitro fertilization (HHS) unless it had been reviewed by the Ethics Advisory Board (EAB).[83] Later, in 1979, the EAB stated it was "ethically acceptable to provide federal funding for embryo research under certain circumstances."[84] This recommendation was ignored by

(discussing various levels of federal regulation).

79. *See* Nguyen, *supra* note 78, at 425-27 (2006) (outlining federal government's role in regulating stem cell research); Owen C.B. Hughes, et al., *United States Regulation of Stem Cell Research: Recasting Government's Role and Questions to be Resolved,* 37 HOFSTRA L. REV. 383, 400-01 (2008) (discussing state and federal regulations of stem cell research).

80. *See* Nguyen, *supra* note 79, at 433 (highlighting state's ability to regulate stem cell research). Some states have banned the destruction of hESCs for research purposes, and others have enacted laws that support such research. *Id.* Until Congress passes a law that forbids state funded hESC research, states will have the authority to fund stem cell research that permits or limits the destruction of human embryos. *Id.*

81. *See* Nguyen, *supra* note 79, at 426-27 (illustrating congressional legislative abilities over the executive branch); U.S.CONST. art. I, §7, cl. 2 (noting the approval or veto of bills).

82. *See* Hughes, *supra* note 79, at 401 (explaining the origins behind funding for fields of embryology).

83. *See* O. Carter Snead, *The Pedagogical Significance of the Bush Stem Cell Policy: A Window into Bioethical Regulation in the United States,* 5 YALE J. HEALTH POL'Y L. & ETHICS 491, 493 (2005) (discussing the history of regulation of in vitro fertilization).

84. *See* Snead, *supra* note 83, at 493.

HHS, and eventually the rule requiring EAB approval was repealed in 1993.[85]

It was at this time that Congress chose to regulate stem cell research by attaching the Dickey Amendment to the 1996 Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act that precluded federal funds for "the creation of a human embryo or embryos for research purposes; or 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."[86] The Dickey Amendment has been re-enacted in the appropriations acts every year since 1997.[87]

The Food and Drug Administration (FDA) exercises federal control over individuals that conduct research on human subject. The FDA regulates stem cell research aimed at developing stem cells into drug products for general use, while the NIH regulates research that is in compliance with the President's research policy.[88] After scientists first derived human embryonic stem celss, the HHS decided that the cells were "not a human embryo within the statutory definition," and thus did not fall within the Dickey Amendment.[89] After this announcement,

85. *See* Snead, *supra* note 83, at 493.

86. Balanced Budget Downpayment Act, *supra* note 32, at 34; *see also* 45 C.F.R. § 46.204(a)(2) (2010) (describing activities directed toward fetuses in utero as subjects); 42 U.S.C. § 289 (g) (specifically noting part (a), which prohibits the Secretary from supporting "any research or experimentation…on a nonviable living human fetus"); *see also* Snead, *supra* note 83, at 493-94. Even though research proposals for projects involving human in vitro fertilization no longer needed Ethics Advisory Board (EAB) approval for federal funding, before any proposals could be made, the new Republican-majority Congress drafted the Dickey Amendment. *Id.*

87. *See* JUDITH A. JOHNSON & ERIN D. WILLIAMS, CONG. RESEARCH SERV., RL31015, STEM CELL RESEARCH—CRS REPORT FOR CONGRESS, 362 (2005) (discussing the federal regulatory landscape of the Dickey Amendment).

88. *Id.* (explaining the functions of the FDA and NIH in stem cell research).

89. *See* Piotr Rewerski, *The Need for a New U.S. Stem Cell Research Policy: A Comparative Look at International Stem Cell Research Laws,* 2007 U. ILL. J.L. TECH. & POL'Y 415, 418-19 (2007) (quoting JUDITH A. JOHNSON & ERIN WILLIAMS, CONG. RESEARCH SERV., RL 31015, STEM CELL RESEARCH (2004)). "An embryo is defined as an organism that when implanted in the uterus is capable of becoming a human being. A stem cell cannot become a human being, even if transferred into the uterus." *Id.*

the NIH decided to fund research involving stem cells once it received acceptable guidelines..[90] However, President Bush rejected the HHS position and NIH guidelines when he made his announcement that federal funds would only be used to support research using existing stem cell lines.[91]

B. State Regulation

States have the authority to enact their own legislation and regulation regarding embryonic stem cell research.[92] This has led to a spectrum of state laws, including states that prohibit state funding of stem cell research, such as Nebraska, as well as states that use large amounts of state funds for research, such as Wisconsin.[93] Until Congress passes definitive legislation on the issue, the executive and administrative agencies will continue to influence research policy and guidelines, while the states will continue to implement inconsistent regulatory schemes.[94] Although the need for open debate that includes moral, scientific, and political issues is evident, Congress' institutional limitations make it difficult to effectively address the complex and divisive subject of embryonic stem cell research.[95]

90. *See* Rewerski, *supra* note 90, at 419 (explaining that the final draft of the NIH guidelines were published in the Federal Registrar and the guidelines allowed federal funding of stem cells "derived from human embryos that were created for the purposes of fertility treatment and were in excess of clinical need.").

91. *See* Nguyen, *supra* note 79, at 425 (noting restrictions for federal funds).

92. *See* Rewerski, *supra* note 89, at 420 (explaining that federal law does not ban states from funding and regulating stem cell research).

93. *See* Rewerski, *supra* note 89, at 420 (highlighting varied state positions on stem cell research).

94. *See* BELLOMO, *supra* note 7, at 66-67 (discussing the California initiative to fund stem cell research in response to the lack of federal funding).

95. *See* Ryan Fujikawa, *Federal Funding of Human Embryonic Stem Cell Research: An Institutional Examination,* 78 S. CAL. L. REV. 1075, 1109 (2005) (detailing issues of Bush's stem cell research policy and congressional limits when enacting definitive legislation).
Given the level of bipartisan support, Congress is the logical forum for debating stem cell research policy. Unfortunately, Congress has been unable to accommodate such a debate, primarily because the transaction costs of building a bipartisan coalition to combat the President's institutionalized policies are too high and the internal pressure for change is insufficient. In the absence of congressional action, the President has resisted bipartisan political pressures and maintained his moral separation from any scientific or political

IV. Analysis

The Dickey Amendment is an outdated law that no longer reflects modern scientific understanding, the current political and ethical climate, or popular opinion. Revising the Dickey Amendment and implementing an administrative program similar to Great Britain's HFEA could remove the overly restrictive embryonic research policies, while maintaining sufficient regulation over the delicate issue of stem cell research.[96]

A. The Dickey Amendment

At the time the Dickey Amendment was included in the budget bill, the concept of therapeutic stem cell research had not yet been developed. Although the Dickey Amendment was first voted into law in 1996, stem cells were not successfully isolated until two years later in 1998.[97] To apply a regulatory law that was enacted before the research protocol was even discovered is not practical nor is it favorable for scientific research and advancement. The policy behind the Dickey Amendment developed at a time the stem cell debate was focused on cloning, in vitro fertilization, and somatic nuclear transfer (SCNT).[98] The Executive branch released a fact sheet that misrepresented important distinctions between these terms and misled the

arguments. This institutional framework that places stem cell policy primarily in the hands of the executive thus raises the cost of political coalition building in Congress, further handicapping the goal of an informed process to formulate hES policy. Congress's silence on human cloning is likewise revealing, in that it essentially defers to the executive and administrative agencies, even on seemingly clear-cut issues. Congress's silence has given the executive the necessary latitude to exercise its own institutional capabilities and frame the debate.
Id.

96. *See* BELLOMO, *supra* note 7, at 112 (the benefits of the UK's approach to stem cell regulation).

97. *See* Balanced Budget Downpayment Act, *supra* note 32, at 34 (enacting Dickey Amendment); Thomson et al., *supra* note 4, at 1145- 47 (describing 1998 study results on stem cell isolation).

98. *See* Hughes et al., *supra* note 79, at 401-02. One reason in vitro fertilization is related to hESC research is that hESCs can be derived from excess pre-implantation embryos that were created for fertility reasons but never used. *Id*.

public by confusing issues of vastly different areas of research.[99] Ideally, regulations based on a clear understanding of scientific advancements are the key to regulating research so that the moral issues are accurate, rather than distorted. Congress should be willing to adapt their laws to reflect the evolution of science and make appropriate alterations when necessary to support ethical scientific progress.[100] In order to adapt to new breakthroughs and to reflect current knowledge, regulations and laws governing research should be malleable, not rigid and immoveable.[101]

The Dickey Amendment's absolute ban on embryo destruction for research purposes makes it impossible for scientists to use federal money to create stem cell lines.[102] Researchers cannot develop therapeutic stem cell treatments without access to viable stem cell lines.[103] Although private investments and some state funds can be used to create embryonic stem cell lines, complications arise when researchers also receive federal grants.[104] The Dickey Amendment states that

99. *See* Hughes et al., *supra* note 79, at 401-02. As the debate regarding hESCs arose, important distinctions between "research embryos produced" and "SCNT-produced blastocysts" became unclear, and terms such as "human cloning," "human embryonic stem cells," and "somatic cell nuclear transfer," were blurred after the executive branch issued the "2001 Fact Sheet" on hESC research. *Id.* This confusion made it impossible to construct an honest, open debate about stem cell research. *Id.*

100. *See* BELLOMO, *supra* note 7, at 112 (discussing the HFEA's role to regulate stem cell research on a case by case basis); *see also Embryos Discarded During IVF Create Stem Cell Lines*, *supra* note 70 (commenting on how a new scientific breakthrough is less controversial from an ethical standpoint).

101. *See* BELLOMO, *supra* note 7, at 112; *see also Embryos Discarded During IVF Create Stem Cell Lines*, *supra* note 70.

102. *See* Balanced Budget Downpayment Act, *supra* note 32, at 34 (establishing funding restrictions); 42 U.S.C. § 289 (g), *supra* note 32 (codifying Secretary's rights and requirements); s*ee also* Stolberg, *supra* note 66 (explaining federally funded researchers are unable to create their own stem lines because of the restrictions).

103. *See* BELLOMO, *supra* note 7, at 31 (addressing the limited functionality of certain stem cell types); NATIONAL GEOGRAPHIC, *supra* note 15, at 257 (discussing the potential of stem cell research as dependant on the availability of embryonic stem cells).

104. *See* Diane T. Duffy, *Background and Legal Issues Related to Stem Cell Research,* ALMANAC OF POLICY ISSUES (2002), *archived at* http://www.webcitation.org/5sv8OKK1V (noting stem cell research can be paid for by private funding, not federal funding); Kalb, *supra* note 36

"[n]one of the funds...may be used for...research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death."[105] This type of language places unreasonable restrictions on researchers that receive federal funding.[106] For example, even when private funding is used to create a new stem cell line, the privately created cells cannot be used in projects that included money from the federal government.[107]

The overly-restrictive language of the Dickey Amendment makes embryonic stem cell research difficult to pursue. One solution is that Congress could revise the Dickey Amendment to allow for limited research applications and protocols that involved specific embryos.[108] For example, Congress could include an exception that allowed federal research on embryos labeled "poor quality" at fertility clinics, but only under strict regulation and federal oversight.[109] This would provide scientists with the ability to access stem cells for therapeutic research purposes while protecting human embryos from unethical research and experimentation.[110]

Another legislative option is to discard the Dickey Amendment entirely. One contention is that any government

(discussing that scientists must use different lab equipment for privately and federally funded research). Some research facilities have decided to build entirely separate lab spaces in order to comply with the funding restrictions. *Id.*

105. Balanced Budget Downpayment Act, *supra* note 32, at 34.

106. *See* Katharine Q. Seelye, *The President's Decision: The Overview; Bush Gives His Backing for Limited Research on Existing Stem Cells,* N.Y. TIMES Aug. 10, 2001, *archived at* http://www.webcitation.org/5tfgMCrbU (discussing how the stem cell lines allowed under the Dickey Amendment are inadequate to address the needs of researchers to reach their full scientific potential).

107. *See* Kalb, *supra* note 36 (highlighting the burden scientists face when collaborating privately funded research projects with federally funded projects).

108. *See* BELLOMO, *supra* note 7, at 112-13 (identifying the benefits of flexible stem cell regulations in the United Kingdom).

109. *See Embryos Discarded During IVF Create Stem Cell Lines*, *supra* note 70 (discussing the scientific benefits of using discarded or poor quality embryos).

110. *See* Seelye, *supra* note 107 (claiming use of already discarded embryos does not contain a strong ethical stigma).

regulation of scientific research is unwanted and unnecessary.[111] Removal of research restrictions would promote the creation of new stem cell lines and allow access to numerous lines currently unavailable.[112] However, complete de-regulation of stem cell research could result in unethical acquisition of embryonic stem cells, such as extracting stem cells from a fetus without parental consent.[113] Although removal of the current restrictions would eliminate bureaucratic obstacles and could facilitate more opportunities for therapeutic success, this action is extreme and would not likely receive popular support.[114] Abandoning all regulation has potentially dangerous consequences, such as extracting cells without consent, but maintaining regulations that are too restrictive threaten the advancement of biomedical research.[115] In order to promote research while maintaining sufficient oversight, Congress needs to consider revising the Dickey Amendment.[116]

Whether the Dickey Amendment is revised or discarded, one thing is certain: relying on executive orders, NIH guideline revisions, and judicial rulings will result in inconsistent and conflicting legal actions.[117] Without legislative action

111. *See* Lymari Morales, *Majority of Americans Likely Support Stem Cell Decision,* GALLUP, Mar. 9, 2009, *archived at* http://www.webcitation.org/5sv8TkP0j (asserting that fourteen percent of Americans interviewed wanted to place no restrictions on government funding).

112. *See* Stolberg, *supra* note 66 (discussing how lifting the restrictions of the Dickey Amendment will allow federally funded research on hundreds of unavailable stem cell lines as well as ones yet to be created).

113. *See Human Embryo Research: All Sides to the Disputes*, *supra* note 75 (discussing the ethical and religious concerns over untethered stem cell research).

114. *See* Stolberg, *supra* note 66 (reporting that the Obama administration's widespread allowance for stem cell research has incited opposition).

115. *See Human Embryo Research: All Sides to the Disputes*, *supra* note 75 (discussing ethical concerns over stem cell research); *see* Stolberg, *supra* note 66 (defining harms of overly restrictive regulations on stem cell research).

116. *See* Stolberg, *supra* note 66 (discussing the prospect of repealing the Dickey Amendment).

117. *See Address to Nation, supra* note 36 (announcing President Bush's restrictive approach to stem cell research); Removing Barriers, *supra* note 42 (offering President Obama's conflicting view); *see also* Sherley v. Sebelius, 704 F.Supp.2d 63, 71 (stating the NIH guidelines violate the Dickey Amendment by funding ESC research where an embryo is destroyed).

demonstrating a clear, unambiguous expression of congressional intent to expand stem cell research, federal funding for the destruction of a human embryo will continue to be prohibited.

B. Ethical Issues

There are two major competing moral ideologies that arise out of procedures involving the destruction of human embryos for research. The first is the belief that human life begins at conception and it is wrong to destroy that life in order to advance scientific understanding and medical treatment.[118] In contrast, the second ideology respects human life, while also recognizing that the legal status of an embryo is not equal to that of a fully developed human being.[119] According to this reasoning, it would be immoral to disregard certain avenues for the advancement of embryonic stem cell research, which could potentially be used to treat millions of people suffering from various diseases.[120]

Both arguments have valid concerns and beliefs; one is focused on the interests of the embryo and the other on the interests of people seeking stem cell treatments. The problem with the Dickey Amendment is that it fails to acknowledge situations where people seeking treatment may outweigh the embryo's interests.[121] The persuasion of the argument for protecting the embryo is diminished when it involves "poor quality" embryos assigned to be thrown away at fertility clinics.[122] The ethical concerns of using embryonic stem cells

118. *See* Kathi E. Hanna, *Cloning/Embryonic Stem Cells*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, *archived at* www.webcitation.org/5sv8ZKt22 (focusing on ethical concerns regarding the isolation of human stem cells from embryos and deriving stem cells from cloned embryos).

119. *See* Hanna, *supra* note 118.

120. *See* Hanna, *supra* note 118.

121. *See* Stolberg, *supra* note 66 (discussing the benefits of stem cell research that are foreclosed upon by the Dickey Amendment).

122. *See* Lerou et al., *supra* note 70, at 212 (classifying 'poor quality' embryos from in vitro fertilization as medical waste). Poor-quality embryos are not given an opportunity to be utilized in IVF techniques because they do not meet specified standards of viability. *Id.* Therefore, the argument that an embryo has the right to life is immaterial because poor-quality embryos are usually discarded as "medical waste" regardless of the well-being of the embryo. *Id.*

from human embryos that are discarded from a fertility clinic are not as persuasive as those concerns of using cloned embryos created solely for the purpose of being destroyed for research.[123]

Even if the Dickey Amendment is not revised or rejected, researchers might be able to argue that using discarded embryos is not destroying them when used "for research purposes" and avoid the amendment's restrictive language.[124] Once an embryo is labeled a "poor quality" embryo, its destruction is no longer related to research purposes, but for failing clinic standards, which might place that embryo outside the restrictive regulatory language.[125] When authorizing federal funding for stem cell research in August of 2001, President Bush reasoned "the life and death decision [had] already been made," and therefore no moral line would be crossed.[126] This reasoning could be applied to the argument for using "poor quality" embryos in federally funded research since the life or death decision has been made for those embryos being discarded at fertility clinics.[127] There are also early arrested embryos that are discarded once they are removed from the mother that could be used for deriving stem cell lines.[128] To simply throw these embryos away is wasteful, especially when the cells could be used to create useful stem cell lines.[129]

An alternative interpretation of the Dickey Amendment could allow federal funding for stem cells collected from "poor quality" embryos as well as early arrested embryos.[130] But, as

123. *See* Lerou et al., *supra* note 70, at 212.
124. *Embryos Discarded During IVF Create Stem Cell Lines, supra* note 70 (describing the process of discarding embryos).
125. *See Embryos Discarded During IVF Create Stem Cell Lines, supra* note 70 (discussing that "poor quality" stem cells are derived from IVF procedures, and could be a valuable asset in research).
126. Seelye, *supra* note 106 (discussing President Bush's policy for funding stem cell research).
127. *See* Seelye, *supra* note 106(discussing embryonic stem cell research can be morally acceptable where stem cells already discarded).
128. *See* S. Gavrilov et al., *Non-viable human embryos as a source of viable cells for embryonic stem cell derivation*, 18 REPROD. BIOMED. ONLINE, 301 (2009) (detailing process of extraction of embryos from similar processes used in genetic testing).
129. *See Embryos Discarded During IVF Create Stem Cell Lines, supra* note 70 (describing the potential uses of discarded embryos from IVF).
130. *See Sherley*, 704 F. Supp. 2d at 67-69 (discussing the defendant's

evidenced by the ruling in *Sherley*, courts are not willing to adopt a broader interpretation of the Dickey Amendment.[131] Therefore an express legislative amendment to the Dickey Amendment is necessary in order to ensure definite federal funding of research involving the use of "poor quality" and early arrested embryos as sources of embryonic stem cells.[132]

Alternatives to embryonic stem cell-based therapy, such as adult stem cells and iPS cells, support the argument that embryonic stem cell research should be abandoned because of the difficult moral issues involved.[133] These alternatives, however, have certain deficiencies that are absent from embryonic stem cells.[134] For example, adult stem cells are

interpretation of the Dickey Amendment and the 1999 NIH guidelines).

131. *See Sherley*, 704 F. Supp.2d. at 67-68. Defendants have maintained since 1999 that the Dickey Amendment does not apply to ESC research "because ESC's are not embryos as defined by the statute." *Id.* at 67. "Defendants argue that the ESC research is not research in which a human embryo is destroyed because ESC research does not involve embryos nor result in their destruction. This argument rests in defendants' interpretation of 'research,' as used in the Dickey-Wicker Amendment, to mean 'a piece of research.'" *Id.* at 71. The District Court rejected this argument stating:

ESC research is clearly research in which an embryo is destroyed. To conduct ESC research, ESC's must be derived from an embryo. The process of deriving ESCs from an embryo results in the destruction of the embryo. . . . Despite defendants' attempt to separate the derivation of ESCs from research on the ESCs, the two cannot be separated.

Id. at 71.

Judge Lamberth went on to hold that "If one step or 'piece of research' of an ESC research project results in the destruction of an embryo, the *entire* project is precluded from receiving federal funding by the Dickey-Wicker Amendment." (emphasis added) *Id.* at 71. The Justice Department is afraid that applying this order will not only affect research authorized by President Obama and the new NIH guidelines, but also research authorized by President Bush. *See* Jesse J. Holland, *Feds Appeal Order Blocking Stem Cell Research*, PHYSORG.COM, Sept. 1, 2010, *archived at* http://www.webcitation.org/5tfjxkaMN.

132. *See Sherley*, 704 F. Supp. 2d at 67-68 (affirming the strict interpretation of the Dickey Amendment and rejecting the defendant's alternative interpretation of the Dickey Amendment).

133. *See* Richard M. Doerflinger, *The Ethics of Funding Embryonic Stem Cell Research: A Catholic Viewpoint,* 9 KENNEDY INSTITUTE OF ETHICS J. 137, 137 (1999) (noting that alternative approaches suggest that embryonic stem cells are less significant than proponents indicate); *see also* Zuk et al., *supra* note 18, at 4279 (researching adult-derived stem cells); *see also* Svoboda, *supra* note 20, at 1 (discussing induced pluripotent stem cells).

134. *See* Zuk et al., *supra* note 18, at 4292-93 (characterizing differences between adult stem cells and embryonic stem cells).

limited in cell type differentiation, whereas embryonic stem cells are not limited because they are pluripotent.[135] Utilizing adult stem cells limits the number of possible therapeutic applications available to researchers because the cells develop into fewer cell types.[136] Another obstacle for researchers is that adult stem cells are difficult to isolate in developed tissue and culture, whereas embryonic stem cells are easily cultured for replacement therapies.[137]

Using induced pluripotent stem (iPS) cells is another promising alternative that has limited therapeutic potential.[138] This reprogrammed adult cell is better suited for disease development research than therapeutic application because reprogramming a cell's genome is correlated with health problems in cloned animals.[139] Currently the retrovirus vectors used to reprogram the cells lead to cancer and therefore cannot be used clinically.[140] Personalization issues involved with reprogramming cells for each individual would make FDA approval of the therapeutic protocol very unlikely.[141]

135. *See Stem Cell Basics: What Are the Similarities and Differences Between Embryonic and Adult Stem Cells,* STEM CELL INFORMATION: THE NATIONAL INSTITUTES OF HEALTH RESOURCE FOR STEM CELL RESEARCH, Mar. 9, 2009, *archived at* http://www.webcitation.org/5sv8jtKYm [hereinafter *Stem Cell Basics*] (distinguishing human embryonic and adult stem cells).

136. *See* Zuk et al., *supra* note 18, at 4279 (stating limitations in clinical use of adult stem cells).

137. *See Stem Cell Basics*, *supra* note 135 (highlighting challenges of adult stem cell cultivation).

Embryonic stem cells can be grown relatively easily in culture. Adult stem cells are rare in mature tissues, so isolating these cells from an adult tissue is challenging, and methods to expand their numbers in cell culture have not yet been worked out. This is an important distinction, as large numbers of cells are needed for stem cell replacement therapies.

Id.

138. *See* Svoboda, *supra* note 20, at 1 (defining induced pluripotent stem cells).

139. *See* Steven S. Clark, *Induced Pluripotent Stem Cells Steal Limelight from Embryonic Stem Cells*, WISCONSIN TECHNOLOGY NETWORK, Jan. 5, 2009, *archived at* http://www.webcitation.org/5sv8uqaR8 (commenting that Dolly the sheep suffered from arthritis and lung disease and was eventually euthanized).

140. *See* Yu et al., *supra* note 25, at 1917-20 (describing risk of mutation in currently existing cell programming techniques) .

141. *See* Clark, *supra* note 139. The article discusses administrative barrier to clinical use of iPS cells noting that:

The possibility of alternative sources of stem cells does not indicate that these other sources are viable options for clinical research and therapeutic applications. Morality concerns should be addressed reasonably and promising research should not be abandoned. The next section will address how ethical issues can be handled through careful regulation and government oversight in order to respect the competing moral interests of the embryo, scientific community, and those hoping for a breakthrough in stem cell-based therapies.

C. Alternative Embryonic Stem Cell Law

Compared to the research policies of the United Kingdom, Singapore, and China, the United States places far more restrictions on embryonic stem cells.[142] Foreign stem cell laws offer alternative research guidelines that could improve the United States' current legislative approach to embryonic stem cells.[143] In the United Kingdom the government-created Human Fertilisation and Embryology Authority ("HFEA") is an independent regulatory body monitoring research that involves human embryos.[144] The HFEA even has the power to approve the creation of human embryos specifically for research purposes.[145] The legislative framework is another useful feature of the HFEA, designed to be flexible in order to adapt to various circumstances

[T]he extent to which a person's genome is reset can vary from person to person, and this could mean that each person will require an individualized reprogramming regimen in order to create iPS cells for therapeutic use. However, it is unlikely that the Food and Drug Administration would approve such an individualized protocol because the agency likes strict uniformity and conformity in therapeutic protocols, not different protocols for different people.
Id.

142. *See* Childress, *supra* note 9, at 162 (describing United Kingdom's stem cell research policy); Arnold, *supra* note 60 (detailing Singapore's emergence as haven for stem cell research); Liao, *supra* note 61, at 1111 (discussing status of stem cell research in China).

143. *See* Childress, *supra* note 9, at 162 ("The U.K.'s strict regulation of reproductive technologies . . . and embryo research appears to have created a context for a positive response to the possibilities of human stem cell research").

144. *See* Childress, *supra* note 9, at 162 (stating function of HFEA).

145. *See* Childress, *supra* note 9, at 162 (stating authority of HFEA).

and advancements in science.[146] With an executive regulatory body similar to the HFEA, the United States could provide research guidelines and government oversight catered specifically to embryonic stem cell research.[147] An administrative approach would allow for targeted federal funding of stem cell research while providing more flexible and appropriate controls and limitations that would ensure the highest standards of ethical research integrity.[148]

In Singapore, the biomedical field has very few restrictions.[149] Not only may scientists extract stem cells from aborted fetuses and discarded embryos, but the government permits embryo cloning for the production of stem cells.[150] Lenient restrictions on hESC research are the result of the BAC's liberal research policies and willingness to receive public input and modify their guidelines.[151] The United States could adopt a less restrictive approach to stem cell research by appointing a committee similar to the BAC.[152] A sub-committee, mandated by Congress and endorsed by the NIH could focus specifically on hESCs.[153] Research guidelines would be more adaptable to scientific progress, better reflect majority opinion, and result in greater clinical potential of hESCs.[154] In Singapore, the

146. *See About the Human Fertilisation and Embryology Authority*, HUM. FERTILISATION AND EMBRYOLOGY AUTH., 5-6 (2009), *archived at* http://www.webcitation.org/5sv95OUgP (describing HFEA's authority). The Secretary of State has the ability to issue secondary legislation when appropriate, whereas the HFEA has the power to issue "Directions" and set aside statutory conditions, issue additional conditions for licenses, provide further guidance for new technologies, and require notification and approval of new methods for conducting a licensed activity. *Id.*

147. *See* BELLOMO, *supra* note 7, at 112-113 (discussing the benefits for the HEFA).

148. *See* BELLOMO, *supra* note 7, at 112-113 (opining the flexible British approach to stem cell funding and regulation is more conducive to beneficial results).

149. *See* BELLOMO, *supra* note 7, at 113. In order to be competitive in the therapeutic stem cell race, Singapore has established some of the world's "most lenient restrictions on biomedical research." *Id.*

150. *See* Arnold, *supra* note 60, at 2 (explaining Singapore's relaxed standards).

151. *See BAC "Who We Are," supra* note 58 (seeking public input on its work).

152. *See BAC "Who We Are*," *supra* note 58 (discussing the BAC).

153. *See BAC "Who We Are," supra* note 58.

154. *See* Colman, *supra* note 57, at 520 (pointing to success in Singapore and

combination of the BAC's broad guidelines and generous government funding has lead to successful preclinical trials involving patients that received stem cell transplants to repair cartilage damage.[155] Because of this lenient approach to hESC research, Singapore is currently well-positioned to translate the success of stem cell therapy in the laboratory to actual clinical application.[156] Until the United States adopts a less restrictive research policy, other countries will continue to exceed them in resources, funding, and therapeutic success.[157]

Expanding the United States' policy on hESC research does not have to go as far as China's liberal guidelines in order for research to flourish. In China, researchers can purchase embryos created for therapeutic research purposes by human cloning techniques, a research approach that is extremely controversial in the United States.[158] While this technique does provide China with access to numerous stem cell lines, ethical issues regarding human cloning do not have to be associated with stem cell research.[159] Primarily the United States' policy leans toward guidelines governing the development and research of human stem cells.[160] However, over-extensive regulations can be harmful to the progress of biomedical research.[161] Embryonic stem cell policy decisions should be based on good science and

United Kingdom where guidelines regulate research).

155. *See* Arnold, *supra* note 60, at 2 (describing Singapore's lenient standards); *See e.g.* KEVIN B.L. LEE et al., *Injectable Mesenchymal Stem Cell Therapy for Large Cartilage Defects—a Porcine Model,* 25 STEM CELLS 11, 2964 (2007) (observing study in which pigs received autologous mesenchymal stem cell transplants to affect cartilage repair). The cell-treated groups demonstrated improved cartilage both histologically and morphologically at six and twelve weeks compared with both control groups. *Id.*

156. *See* Arnold, *supra* note 60, at 1 (explaining Singapore's Company's claim to make stem cell lines for clinical tests).

157. *See* Colman, *supra* note 57, at 520 (highlighting the United States' lagging position due to its politically conservative approach).

158. *See* Liao, *supra* note 61, at 1107 (discussing China's acceptance of sale of embryos for therapeutic purposes but reluctance for commercial purposes).

159. *See* Lerou et al., *supra* note 70, at 212 (noting that during in vitro fertilization early-arrested embryos can yield human embryonic stem cells).

160. *See* Colman, *supra* note 57, at 520-21 (contrasting US with less regulated countries).

161. *See* Colman, *supra* note 57, at 520-21 (observing stem cell research thrives in many other countries).

high ethical standards, with an objective of rational and sensitive legislative oversight.

Federally funded research using "poor quality" embryos will likely only be conducted if there is a direct legislative act.[162] Congressional guidelines should specify that only those embryos being discarded for poor clinical standards can be utilized for research purposes.[163] Allowing donors to voluntarily donate, without any form of inducement, excess embryos from fertility clinics would greatly facilitate research purposes.[164] Congress should draft a donation provision into the fertility clinic consent form to allow individual donors the opportunity to determine the ultimate fate of their embryo's tissue.[165] The consent form should include options to: 1) donate excess in vitro fertilization embryos to other subfertile couples, 2) have excess embryos discarded, or 3) donate excess embryos for stem cell research.[166] In revising the current hESC research policy, Congress does not have to include an option for couples to create embryos solely for the purpose of research, but utilizing excess embryos that are being thrown away is a viable alternative the United States is failing to consider. Using excess embryos for research that have been donated from fertility clinics is not as ethically challenging as human cloning and the idea of human embryo farms.[167]

162. *See Sherley,* 704 F.Supp.2d at 64-69 (highlighting different presidential policies and NIH's failure to revise research guidelines to expand embryonic stem cell research in accordance with Dickey Amendment).

163. *See* Weigiang Liu et al., *Derivation and Characterization of Human Embroyonic Stem Cell Lines from Poor Quality Embryos*, 36 J. GENETICS & GENOMICS 229, 229 (acknowledging that poor quality embryos are good sources for deriving hESCs).

164. *See* Nguyen, *supra* note 78, at 445-46 (proposing requiring consent from donors at infertility clinics).

165. *See* Nguyen, *supra* note 78, at 445-46 (suggesting disclosure guidelines given to donors at infertility clinics).

166. *See* Kerstin Bjuresten & Outi Hovatta, *Donation of Embryos for Stem Cell Research-How Many Couples Consent?*, 18 HUM. REPROD. No. 6, 1353, 1355 (2003) (concluding that if given the option 92% of couples would donate their embryos).

167. *See* Bjuresten, *supra* note 166, at 1355 (noting that less than one percent of couples at infertility clinic raised ethical concerns about donating).

The United States would benefit greatly by adopting an administrative program similar to the HFEA in Great Britain.[168] A regulatory body could monitor and control research guidelines..[169] This could allow Congressional expansion of current research policy regarding hESCs while ensuring the biomedical field maintains an adequate ethical standard.[170] For example, an agency equivalent to the HFEA in the United States could license federally-funded facilities to use specific types of human embryos for experimentation, conduct investigations of the licensed research facilities to ensure it meets high standards, provide researchers with advice, and provide the public with accurate information.[171] An administrative agency framework could protect ethical research standards while simultaneously promoting hESC research.[172] The biomedical field would benefit immensely from a program designed specifically for regulating projects involving hESCs.[173] Congress itself is not the ideal regulatory body for a scientific field that is quickly advancing and in need of accommodating, evolving, and adaptable research guidelines.[174] One major benefit of creating an independent regulatory body is the ability to provide federal funds for advanced stem cell research within a flexible legal framework.

V. Conclusion

Science will continue to push the boundaries of understanding and possibility. In a field that is rapidly evolving, the best method of administrative control is through a small

168. *See* BELLOMO, *supra* note 7, at 112-113 (explaining the benefits of the HEFA).
169. *See* Rewerski, *supra* note 90, at 421 (offering United Kingdom's Human Fertilisation and Embryology Authority as example of regulatory body).
170. *See* Rewerski, *supra* note 90, at 421-22 (pointing to British success in expanding in an ethical way).
171. *See* Rewerski, *supra* note 90, at 421 (outlining scope of United Kingdom's Human Fertilisation and Embryology Authority's activities).
172. *See* Fujikawa, *supra* note 95, at 1087 (pointing to NIH guidelines as an attempt to advance federal funding in an ethical and legal manner).
173. *See* Rewerski, *supra* note 90, at 422-23 (offering Ethical Guiding Principles as possible reason for China's extensive and successful stem cell industry).
174. *See* Fujikawa, *supra* note 95, at 1109-10 (stressing that institutional limits of Congress make it an ineffective regulatory body).

regulatory body created to handle the delicate ethical issues and complicated science involved with stem cell therapy. Current legislative hESC laws have significantly impaired scientific progress and achievement in the United States. This has allowed some foreign countries to make impressive advancements in the biomedical field and in some cases surpass the United States in funding, support, and clinical success. Congress should revise the Dickey Amendment and statutorily create an administrative body and system of self-regulation, providing a flexible regulatory framework that would remove the existing restrictive federal research guidelines. While the biotech industry should not proceed unregulated, legislative guidelines must represent well-reasoned decisions. These administrative guidelines must be based on current scientific theories and social opinion, not arbitrary laws that are outdated and unfavorable.