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STEMMING THE TIDE OF STEM CELL RESEARCH: THE BUSH COMPROMISE

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I. INTRODUCTION

In 1998, a researcher at the University of Wisconsin made an incredible discovery that may lead to cures for a variety of debilitating ailments: the power of stem cells.¹ Scientists believe that stem cell utilization could lead to cures for diseases affecting over 128 million Americans.² Stem cell research has shown promise in curing heart disease, diabetes, Parkinson's disease, regenerating the brain tissue in stroke victims, and returning nervous system control to victims of paralysis.³ Israeli scientists have successfully transformed stem cells into immature heart-tissue cells.⁴ More recently, a woman from South Korea was able to walk again after twenty years of paralysis, after receiving stem cell therapy.⁵

* J.D., May 2005.

1. James A. Thompson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCI. 1145, 1145-47 (1998) (discussing the new-found ability to harvest, and maintain in a laboratory, human embryonic stem cells).

2. Press Release, The White House, Fact Sheet: Embryonic Stem Cell Research, (Aug. 9, 2001) [hereinafter Fact sheet: Embryonic Stem Cell Research], <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html> (detailing the potential of embryonic stem cells to cure a multitude of debilitating diseases). For a detailed discussion of the potential of stem cells to serve as a testing ground for pharmaceutical companies, see also Shirley J. Wright, *Human Embryonic Stem-Cell Research: Science and Ethics*, 87 AM. SCIENTIST 352 (1999); an abstract is available at <http://www.amsci.org/amsci/articles/99articles/Wright.html> (last visited May 29, 2005).

3. See generally Gabriel S. Gross, Comment: *Federally Funding Human Embryonic Stem Cell Research: An Administrative Analysis*, 2000 WIS. L. REV. 855 (2000) (detailing the potential of embryonic stem cells to cure a multitude of debilitating diseases).

4. Bill Hoffmann, *Doctors Turn Stem Cells to Heart Tissue*, N.Y. POST, Aug. 2, 2001, at 19 (explaining that newly grown heart cells derived from embryonic stem cells could be injected into a non-functioning area of the heart to replace cells that have died as the result of a heart attack). When one suffers a heart attack, the area of the heart that does not receive blood dies and becomes scar tissue. *Id.* Stem cells could theoretically replace those dead heart cells. *Id.*

5. Maria Vitale Gallagher, *Paralyzed South Korean Woman Walks Thanks to Adult Stem Cell*, at <http://home.christianity.com/scienceministries/>

This Comment will focus on the classification of embryonic stem cells and how that classification affects federal funding for stem cell research. More specifically, it will propose that particular stem cells should be classified as “human tissue,” not as a “human being.” Part II will provide a brief, technical introduction to the nature of stem cells, and will describe what researchers have been able to accomplish using stem cells and the potential for future medical breakthroughs. Part III will begin with a primer on the National Institutes of Health’s guidelines for federal funding of human embryonic stem cell research, and will follow with a discussion of President Bush’s Policy Address of August 9, 2001.⁶ It will then discuss how this policy affects federal funding for stem cell research.

Part IV will examine the inherent conflicts in classifying an embryo in one of three ways: as a “person”; as mere “human tissue”; and as “human tissue with the potential for human life.” This Comment will also examine the Nuremberg Code, which has been the ethical standard for conducting research on human subjects since shortly after World War II. Part IV will also explain the current status of federal funding for stem cell research and explore why the status of an embryo determines the availability of research grants as well as formation of public opinion. Finally, Part V of this Comment will propose that embryonic stem cells be officially classified as “human tissue” rather than a “human being,” and that the use of stem cells in medical treatment should qualify as a “tissue transplant.”

II. BACKGROUND

A. A Technical Introduction to Stem Cells

Stem cells are human cells that “have the ability to divide for indefinite periods in culture and to give rise to specialized cells.”⁷

107079.html (last visited May 29, 2005).

6. Press Release, The White House, Remarks by the President on Stem Cell Research (Aug. 9, 2001) [hereinafter Remarks by the President on Stem Cell Research], <http://www.whitehouse.gov/news/releases/2001/08/print/20010809-2.html>. President Bush’s address set the policy foundations for all federal funding of embryonic stem cell research and simultaneously set off heated debates throughout the nation. See Edward Epstein, *Feinstein Offers Measure to OK Curative Cloning / Senate Committee Debates Use of Fetal Stem Cells for Research*, S.F. CHRON., Feb. 6, 2002, at A3 (noting that cloning issue was debated in the Senate). A Senate Judiciary Committee recently considered a bill by California Senator Diane Feinstein that would authorize cloning of human embryos only for the purpose of stem cell research, not to reproduce a human being. *Id.*

7. Consuelo G. Erwin, Note: *Embryonic Stem Cell Research: One Small Step for Science or One Giant Leap Back for Mankind?*, 2003 U. ILL. L. REV. 211, 213 (2003) (discussing the ability of human stem cells to replicate and

Stem cells develop in three different stages. In the first stage, the stem cell is known as a totipotent cell.⁸ In the second, it develops into a pluripotent cell.⁹ Finally, the cell becomes a multipotent cell, the most specialized of the stem cells.¹⁰

Stem cells exist in two varieties: adult and embryonic.¹¹ Adult stem cells are multipotent and are harvested from adult tissue such as adult neural cells, bone marrow, live-birth umbilical cords, and placental blood.¹² The category of embryonic stem cells includes both totipotent and pluripotent cells and are harvested from a human embryo.¹³ They are more useful to researchers than adult stem cells because they are less specialized and therefore maintain the ability to develop into any type of human tissue.¹⁴

1. Totipotent vs. Pluripotent Stem Cells

When a sperm fertilizes an egg,¹⁵ the resulting cell begins to multiply.¹⁶ Before exceeding the eight-cell stage of development

specialize as a result of the process of differentiation, and quoting Nat'l Insts. of Health, *Stem Cells: A Primer*, <http://www.madrimasd.org/cienciaysociedad/ateneo/dossier/celulasmadre/primer.htm> (May 2000) [hereinafter *Stem Cells: A Primer*]).

8. *Id.*

9. *Id.*

10. *Id.* at 213-14. Scientists prefer to conduct research on the embryonic pluripotent cells rather than on the adult multipotent cells. The reason is that unlike the pluripotent cells, the multipotent cells have already begun to specialize and consequently cannot transform into any cell in the adult human body. *Id.*

11. *Id.* at 214.

12. *Id.* at 214-15. (explaining that while the stem cells derived from adult human tissue may not damage the donor, the amount of research that can be done with them is limited because of their inability to replicate indefinitely, and citing David P. Gushee, *A Matter of Life and Death: The Biotech Revolution*, CHRISTIANITY TODAY, Oct. 1, 2001, at 34).

13. *Stem Cells: A Primer*, *supra* note 7.

14. Fact Sheet: Embryonic Stem Cell Research, *supra* note 2. Scientific research using adult stem cells also suggests that unlike embryonic stem cells, which can reproduced indefinitely in a lab, adult stem cells divide a finite number of times, limiting their usefulness. *Before the Senate Comm. on Appropriations, Subcomm. on Labor, Health and Human Services and Education*, 106th Cong. (Apr. 26, 2000) [hereinafter NIH Statement] (statement of Allen M. Spiegel, M.D., Director, National Institute of Diabetes and Digestive and Kidney Diseases, and Gerald D. Fischbach, M.D., Director, National Institute of Neurological Disorders and Stroke), <http://stemcells.nih.gov/policy/statements/state.asp>.

15. See Gross, *supra* note 3, at 856-57 (explaining that prior to "The Bush Compromise," most fertilized eggs used in stem cell research were donated by couples who were attempting to conceive through in-vitro fertilization techniques, were successful, and no longer required the use of the extra cryogenically frozen ova).

16. See Erwin, *supra* note 7, at 213-14 (providing a brief explanation of the process of fertilization and how that process creates the pluripotent cells used for embryonic stem cell research). "Approximately four days after fertilization,

(approximately four to five days after fertilization), all embryonic cells are termed "totipotent."¹⁷ Totipotent cells have the potential to develop into any cell-type in the human body.¹⁸ In addition, any single totipotent cell has the ability to develop into a mature embryo.¹⁹ These totipotent cells eventually begin to specialize and develop into pluripotent stem cells through the process of differentiation.²⁰

As the fertilized egg continues to divide and multiply, the totipotent cells transform into pluripotent cells.²¹ In order to conduct research, these cells are extracted from the center of the resultant cell mass known as a blastocyst.²² In a laboratory, pluripotent cells maintain the ability to transform into any type of human tissue and regenerate indefinitely.²³ Unfortunately, the process renders the remaining embryonic cells nonviable.²⁴ It is this unfortunate consequence of embryonic stem cell harvesting that has become a moral hotbed of contention between government officials and scientists.²⁵

2. Adult Stem Cells vs. Embryonic Stem Cells

Adult stem cells are more specialized than embryonic stem

this totipotent cell begins to form a hollow sphere of cells called a blastocyst, which contains an inner cell mass." *Id.* at 214. This "inner cell mass" is made up of the pluripotent cells that are harvested to conduct stem cell research. *Id.*

17. Jason R. Braswell, *Federal Funding of Human Embryo Stem Cell Research: Advocating a Broader Approach*, 78 CHI.-KENT. L. REV. 423, 425-26 (explaining that complex organisms such as humans are made up hundreds of types of cells that number in the millions, and that all of these diverse cells originate as embryonic totipotent cells, and citing BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 36 (3d ed. 1994)).

18. *See id.* at 425 (explaining that these totipotent cells, once they become pluripotent, can be used either to replicate an existing cell in an adult human body, or if left alone, develop into a "complete" embryo).

19. *Id.*

20. *Id.* at 426.

21. *Stem Cells: A Primer*, *supra* note 7.

22. *See* NAT'L INST. OF HEALTH, *STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS*, 1 (2001), *available at* <http://stemcells.nih.gov/info/scireport/PDFs/fullrptstem.pdf> (explaining that the stem cell is derived from the blastocyst stage).

23. *See* Erwin, *supra* note 7, at 213 (describing the potential benefits of studying even a single line of pluripotent stem cells).

24. *See* Gross, *supra* note 3, at 856 (explaining that while the potential benefits to be derived from stem cell research are undeniable, a great controversy still exists because it destroys a potential human being).

25. *See* Scott Davison, *Influencing NIH Policy over Embryonic Stem-Cell Research: An Administrative Tug-of-War Between Congress and the President*, 22 J. NAT'L ASS'N OF ADMIN. L. JUDGES 405, 414-16 (2002) (describing how even after "The Bush Compromise" Congress continued to draft its own solution to the stem cell debate).

cells.²⁶ This specialization limits their usefulness in research.²⁷ Because adult (or multipotent cells) have already completed the process of differentiation, they are more specialized prior to being harvested than pluripotent cells, and therefore do not retain the ability to transform into any cell in the human body.²⁸

Embryonic stem cells are harvested from a human embryo at the beginning stages of differentiation.²⁹ Therefore, they have the potential to regenerate any tissue in an adult human body.³⁰ This area of research is known as “regenerative research.”³¹

Three different sources currently exist to obtain embryonic stem cells. The first is a donated frozen embryo, originally devised for in-vitro fertilization.³² The second source is the reproductive areas from a donated aborted fetus.³³ Most of the human stem cells used in research today are harvested in one of these two manners.³⁴ Most researchers prefer stem cells harvested in one of these two ways because they are consistently pluripotent, and because techniques already exist to facilitate their isolation and propagation.³⁵ The third source is the cloning of human stem cells.³⁶

B. The National Institutes of Health's Interpretation

The National Institutes of Health (“NIH”) is an administrative agency under the control of the Department of Health and Human Services (“DHHS”), which oversees federal

26. See Jason H. Casell, *Lengthening The Stem: Allowing Federally Funded Researchers to Derive Human Pluripotent Stem Cells from Embryos*, 34 U. MICH. J.L. REFORM 547, 551-52 (2001) (describing the limited ability of adult stem cells to divide, reducing their usefulness in producing sufficient “numbers of well-characterized cells for therapies”).

27. *Id.*

28. Fact Sheet: Embryonic Stem Cell Research, *supra* note 2.

29. Marta Brodsky, *The Viability of Our Humanity: Will the Supreme Court's Abortion Jurisprudence Survive the Challenge of Embryonic Stem Cell Research?*, 76 ST. JOHN'S L. REV. 225, 235 (2002).

30. See *id.* (explaining that theoretically, because embryonic stem cells are extracted prior to differentiation, they could regenerate any dysfunctional part of the body into which they are injected).

31. *Id.* at 230 (explaining that for the first time scientists are able to regenerate otherwise unusable human tissue—thus the term regenerative research).

32. See *id.* at 235 (citing *Stem Cells: A Primer*, *supra* note 7).

33. *Id.*

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

35. Christine Kirk, *Research Guidelines: NIH Issues Guidelines for Federally Funded Stem Cell Research*, 28 J.L. MED. & ETHICS 411 (2000).

36. See *Stem Cells: A Primer*, *supra* note 7 (describing a “somatic cell nuclear transfer” (“SCNT”), which is the fusion of two cells that subsequently begin to divide and eventually mutate into a blastocyst).

funding for stem cell research.³⁷ The NIH “interprets congressional law, complies with executive orders from the President, and creates standards for organizations to obtain federal funding for many types of biomedical research.”³⁸ On August 25, 2000, the NIH published its guidelines for federally funded stem cell research in the *National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells*.³⁹ The NIH’s goal in publishing these guidelines is to “ensure that NIH-funded research . . . is conducted in an ethical and legal manner.”⁴⁰

These guidelines must be followed by all NIH-funded stem cell researchers.⁴¹ NIH funds can only be used for research on embryonic stem cells derived from: (1) embryos created for fertility treatment in excess of clinical need; or (2) fetal tissue used in accordance with the guidelines and all applicable laws and regulations.⁴²

The NIH received approximately 50,000 comments on the guidelines during the public comment phase.⁴³ These comments came from sources as diverse as private citizens, scientists, members of Congress,⁴⁴ and religious organizations.⁴⁵ The views

37. Davison, *supra* note 25, at 409 (describing how the NIH is the agency that formulates guidelines for federally funded research based on policy laid out by the President).

38. *Id.*

39. See Kirk, *supra* note 35, at 411-12 (pointing out that prior to 2001, the NIH, along with the DHHS, approved funding for embryonic stem cell research because the congressional ban on “human embryo research” did not apply to embryonic stem cell research). See also Consolidated Appropriations Act of 2000, Pub. L. No. 106-113, § 510(b), 113 Stat. 1501, 1501A-275 (defining “human embryo or embryos” as including “any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this [Consolidated Appropriations] Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells”); Davison, *supra* note 25, at 412 n.38.

40. See *Before the Senate Comm. on Appropriations, Subcomm. on Labor, Health and Human Services and Education*, 106th Cong. (Sep. 7, 2000) (statement of Gerald D. Fischbach, M.D., Director, National Institute of Neurological Disorders and Stroke, and Allen M. Spiegel, M.D., Director, National Institute of Diabetes and Digestive and Kidney Diseases), available at http://www.ninds.nih.gov/news_and_events/congressional_testimony/testimony_stemcell_090700.htm.

41. National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. at 51,975.

42. *Id.*

43. See Kirk, *supra* note 35, at 411 (explaining that the incredible potential of stem cell research has sparked widespread public interest in a wide cross-section of the population).

44. See Brodsky, *supra* note 29, at 238 (citing *Stem Cell Research, Before the Senate Comm. on Health, Education, Labor and Pensions*, 107th Cong. (2001), <http://thomas.loc.gov/home/sencom.html> (describing the statement of typically conservative, “pro-life” Senator Arlen Specter who nonetheless

expressed in these comments were as diverse as the people who penned them. Some writers believed that no federal guidelines were necessary, while others believed the research was in violation of the DHHS appropriations law prohibiting human embryonic research.⁴⁶

C. President Bush's Policy Address of August 9, 2001

The idea of federal funding for embryonic research was a contentious issue long before stem cells were discovered.⁴⁷ President Reagan banned embryonic research during his administration,⁴⁸ and his successor, George Bush Sr., upheld the ban throughout his presidency.⁴⁹ President Clinton, on his first day in office, lifted the ban on fetal tissue research.⁵⁰ Then, George W. Bush reinstated the moratorium on federal funding for embryonic research only days after taking office.⁵¹

supports the use of embryonic stem cell research). Senator Specter wants Americans to "choose a path that does not impede the progress of science; that gives us the best chance to help those who may benefit from stem cell research." *Id.*

45. *Id.* at 239-42. The debate over stem cell research is not limited to scientists and the legislature, but it is also a contentious moral issue that involves both public and private entities. *Id.*

46. *Id.* The views on federally funded stem cell research range from the liberal view, held by many scientists, that no federal guidelines are necessary, to the conservative religious view, which focuses predominately on the moral implications of fetal tissue research. *Id.*

47. See Davison, *supra* note 25, at 410-15 (explaining the largely partisan political battle that has taken place over the past twenty years between different Presidents and Congresses over federally funding fetal tissue research).

48. *Id.* at 410. President Reagan, during his administration, believed that federal funding for any research using fetal tissue "would encourage abortion and indirectly implicate taxpayers for the increase." *Id.* Since that time President Reagan has contracted Alzheimer's disease, which is potentially curable using stem cell technology. Consequently, his wife, Nancy, has become one of the most vocal lobbyists on Capitol Hill for federal funding of stem cell research. See Braswell, *supra* note 17, at 428-29.

49. See generally Davison, *supra* note 25, at 410 (demonstrating how Republican Presidents, upholding the "pro-life view" of fetal tissue research, have historically maintained a ban on federal funding for fetal tissue research). In fact, since the inception of fetal tissue research, Presidential policy on federal funding has been drawn consistently along political party lines. *Id.*

50. *Id.* at 410-11 (describing the policy differences on fetal tissue research between Republican and Democratic Presidents, and between respective Presidents and Congresses as well).

51. *Id.* at 413-15. President Bush accomplished this feat during his policy address of August 9, 2001. *Id.* Prior to "The Bush Compromise" address, a debate had been brewing in Congress over the status of federal funding for stem cell research. See Gross, *supra* note 3, at 860 (quoting Arkansas Representative Jay Dickey's feelings that federally funded stem cell research "makes the government an accomplice in something that Congress has stated

Over the next several months, the news of advancements in privately funded stem cell research put intense pressure on the President to permit federal funding for stem cell research.⁵² On August 9, 2001, in what would become known as “The Bush Compromise,” President Bush addressed the nation and outlined his new policy toward funding stem cell research.⁵³ While not a total departure from the traditional Republican position of advocating a complete ban on all funding, the resulting policy opened the door, if ever so slightly, for federal funding of embryonic stem cell research.⁵⁴

D. Immediate Implications of “The Bush Compromise”

Effective August 9, 2001 at 9:00 p.m. EST, the NIH guidelines of 2000 were effectively suspended by President Bush’s new policy.⁵⁵ The new guidelines approve federal funding for stem cell research provided that: (1) “the derivation process was initiated prior to 9:00 p.m. Eastern Daylight Time on August 9, 2001”; (2) the stem-cells are derived from an embryo that was created for reproductive purposes and is no longer needed; (3) the donation of the embryo was obtained with the informed consent of the

specifically it doesn’t want anything to do with, the termination of an embryo”).

52. See Braswell, *supra* note 17, at 428-29 (describing the lobbying efforts of prominent American citizens such as Nancy Reagan lobbying for people inflicted with Alzheimer’s disease; Christopher Reeve appearing on behalf of victims of spinal chord injuries; Mary Tyler Moore on behalf of diabetes patients; and Michael J. Fox crusading for those afflicted with Parkinson’s disease).

53. Remarks by the President on Stem Cell Research, *supra* note 6. The President’s policy statement became known as “The “Bush Compromise” because for the first time, a President was straddling the line between conservative and liberal views on stem cell research while creating policy on federal funding. See Davison, *supra* note 25, at 413 (allowing research to go forward on existing cell lines, but freezing the creation of any new lines, the President attempted to please the scientific community while not offending any “pro-life” constituents).

54. See Davison, *supra* note 25, at 414-15. While not allowing research on stem cells harvested past the date of the policy statement, the new policy paved the way for research on existing stem cell lines. *Id.* In addition, the President created “The President’s Council on Bioethics” to monitor stem cell research. *Id.*

55. Press Release, National Institutes of Health, NIH Guide: Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Embryonic Stem Cells (Nov. 7, 2001), available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-007.html>. It is the duty of the NIH to interpret executive policy and implement guidelines to see the policy is carried out. See Davison, *supra* note 25, at 409 (describing the role of the NIH as an administrative agency within the Department of Health and Human Services that “interprets congressional law, complies with executive orders from the President and creates standards for organizations to obtain federal funding for many types of biomedical research”).

biological parents; and (4) the donation must not have involved financial inducements.⁵⁶

In some ways, the President's new policy was less constrictive than the traditional Republican pro-life view of stem cell research. First, President Bush recognized the possibility that a "five-day-old cluster of cells" is "not an embryo, not yet an individual, but a pre-embryo."⁵⁷ While at first glance this may appear to simply be an exercise in semantics, this minute differentiation is the balance upon which all federal funding teeters. Second, the President allowed for federal funding of over sixty pre-existing stem cell lines.⁵⁸ This is important because it allowed some federally funded research and thus discouraged a mass exodus of scientific minds from the United States⁵⁹ to countries that do not restrict this type of research.⁶⁰

III. ANALYSIS

The debate on embryonic stem cell research centers upon the classification of stem cells as either "human tissue" or a "human being." Under current federal policy outlined in "The Bush Compromise" and detailed in the NIH's resulting guidelines,

56. Press Release, National Institutes of Health, National Institutes of Health (NIH) Update on Existing Human Embryonic Stem Cells (Aug. 27, 2001) [hereinafter NIH Update], <http://stemcells.nih.gov/policy/statements/082701list.asp>. The new guidelines, as written in response to "The Bush Compromise," were very similar to the guidelines released by the NIH a year earlier. *Id.* The only significant change was the requirement that only existing stem cell lines be used for stem cell research.

57. Remarks by the President on Stem Cell Research, *supra* note 6.

58. See Braswell, *supra* note 17, at 432 (explaining that for embryonic stem cell lines to qualify for federal funding, according to "The Bush Compromise," the lines "must also have been derived from embryos that were created for fertility treatments, but are no longer needed, and the embryos have come from couples that gave their informed consent free of any financial inducements"). The NIH initially approved sixty-four human stem cell lines before increasing the number to seventy-eight. *Id.*

59. *Id.* at 439-40 (describing simply that scientists, frustrated by a lack of federal funding for their research, will leave the country and simply go where the government imposes fewer restraints). For example, Dr. Roger Pederson was conducting promising stem cell research just prior to the "Bush Compromise." *Id.* Directly following Bush's policy statement, Dr. Pederson announced that he would be emigrating to the United Kingdom to complete his research, where the government had recently announced that it approved the usage of thousands of unused embryos donated by couples attempting in-vitro fertilization. *Id.*

60. See Ben Knight, *Australia Ahead in Stem Cell Research*, at <http://www.abc.net.au/> (Oct. 10, 2003) (quoting one source as saying that "Australia is fast becoming an international leader in the field of stem cell research. While legislators in Europe and the U.S. continue to restrict embryonic stem cell research, Australia is seen as comparatively liberal"). Knight describes Australia as "poised to pick up new researchers, and research, that might otherwise have been done overseas." *Id.*

embryonic stem cell research will not receive federal funding as long as the stem cells are classified as a "human being." This current policy has origins in both international opinion and United States judicial interpretation.⁶¹

This analysis will first explain the historic origins of regulation on human research by dissecting the Nuremberg Code,⁶² which was one of the earliest attempts at setting ethical standards for medical research on human beings. An examination of both the United States Supreme Court⁶³ and state supreme court⁶⁴ decisions interpreting the conflict between classifying an embryo as a "person" or "property" will follow. Legislative enactments⁶⁵ and proposals⁶⁶ on the subject will be explored next. Finally, there will be a review of the current status of federal funding for embryonic stem cell research.

A. *The Misguided Application of the Nuremberg Code*

The Nuremberg Code is a set of ethical principles developed by an American war tribunal following World War II.⁶⁷ It was created in response to the atrocities committed by Nazi doctors who experimented on human subjects.⁶⁸ Many of these experiments led to the death of the subjects.⁶⁹ These doctors were

61. See e.g., Jay Katz, *Human Sacrifice and Human Experimentation: Reflections at Nuremberg*, 22 YALE J. INT'L L. 401, 406-07 (1997) (describing the history of conflicting medical principles governing human research); *Roe v. Wade*, 410 U.S. 113 (1973).

62. See Katz, *supra* note 61, at 405 (explaining that during World War II, Nazi doctors performed a battery of tests on prisoners that often were sadistic and fatal).

63. See *Roe v. Wade*, 410 U.S. at 154-56 (holding that a mother's right to privacy outweighs the legal rights of a fetus in the early stages of pregnancy); *Planned Parenthood v. Casey*, 505 U.S. 833, 846 (1992) (affirming its holding in *Roe v. Wade* that viability is the benchmark by which fetal rights should be measured).

64. See generally *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992); *Kass v. Kass*, 696 N.E.2d 174 (N.Y. 1998).

65. See Davison, *supra* note 25, at 420 (citing *Specter Stem Cell Bill Likely Lost to Bush Compromise Contentment*, THE BLUE SHEET, Aug. 15, 2001, at 33).

66. See generally *id.* (detailing various proposals from members of the House and Senate to facilitate embryonic stem cell research either in direct conflict with current White House policy, or as a way around White House policy).

67. Katz, *supra* note 61, at 406.

68. See Erwin, *supra* note 7, at 216 (describing various experiments performed on prisoners such as submersion in freezing water for hours at a time, exposure to biowarfare agents, castration and sterilization, and citing Thomas John Babbo, *Begging the Question: Fetal Tissue Research, the Protection of Human Subjects, and the Banality of Human Life*, 3 DEPAUL J. HEALTH CARE L. 383, 387 (2000)).

69. Babbo, *supra* note 68, at 387.

prosecuted by a three-judge tribunal in *United States v. Brandt*.⁷⁰

The Nazis defended their experimentation on prisoners by arguing that it was conducted during wartime, that they were simply following orders, and that their subjects would have died anyway.⁷¹ The tribunal felt that the Nazi doctors believed that medical advancement was more important than the lives of their subjects.⁷² The defendants were convicted of murder, and the tribunal produced what would become known as the Nuremberg Code.⁷³ The Code consists of ten rules, four of which are pertinent to the practice of stem cell research.⁷⁴

The first pertinent standard is that “the voluntary consent of

70. Erwin, *supra* note 7, at 216 (quoting the prosecutor in *United States v. Brandt* as saying that the defendants “are on trial for murder It is only the fact that these crimes committed in part as a result of medical experiments on human beings that make this case somewhat unique”).

71. Babbo, *supra* note 68, at 401-02.

72. *Id.* at 402.

73. *Id.* at 387-88.

74. See Katz, *supra* note 61, at 412-13 (explaining that many people feel that the resulting Nuremberg Code was only useful as applied to the atrocities committed by the Nazi doctors and did not have constructive applications beyond the Nuremberg trials). The ten rules are:

1. The voluntary consent of the human subject is absolutely essential

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons

9. [T]he human subject should be at liberty to bring the experiment to and end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. [T]he scientist in charge must be prepared to terminate the experiment at any stage, if she has probable cause to believe [that] the experiment is likely to result in injury, disability, or death to the experimental subject.

Babbo, *supra* note 68, at 385 n.8.

the human subject is absolutely essential” for research on a human subject.⁷⁵ The second is that research on a human subject should only be conducted if no other viable alternative exists.⁷⁶ The third is that a researcher may only conduct research with a high probability of death to the human subject if the researcher himself is also a subject.⁷⁷ The final pertinent standard is that the likelihood of danger resulting from the research cannot be greater than the problem to be solved.⁷⁸ Since the Nuremberg Code was unveiled, it has become the foundation upon which many other ethical codes have been built.⁷⁹

Even though the Nuremberg tribunal did not have human embryos in mind when they formulated their standards, embryonic stem cell research fits within the ethical standards of the resulting Nuremberg Code.⁸⁰ The first pertinent standard, voluntary consent of the subject, is satisfied when the stem cell donor gives his or her consent to the research.⁸¹ Some scholars, however, take a more literalist approach, and contend that because the four-to-five day-old fetus is unable to consent to testing itself, stem cell research invariably fails to meet this first standard.⁸²

The second standard, viability of alternatives, is satisfied by virtue of the fact that no other treatments are currently available to treat the estimated 128 million diseased Americans who might be cured through the use of embryonic stem cells.⁸³

The third, which deals with the death of the “human subject,” is satisfied because an embryonic stem cell has not been afforded

75. Babbo, *supra* note 68, at 385 n.8.

76. *Id.* See generally Fact Sheet: Embryonic Stem Cell Research, *supra* note 2. Scientific research using adult stem cells also suggests that unlike embryonic stem cells, which can reproduce indefinitely in a lab, adult stem cells divide a finite number of times, limiting their usefulness and alternatives for various research. NIH Statement, *supra* note 14.

77. Babbo, *supra* note 68, at 385 n.8.

78. *Id.*

79. *Id.* at 394.

80. However, James Dobson, founder of the Fundamentalist Christian Group “Focus on the Family,” believes that the freedom given to researchers working with embryonic stem cells is comparable to the atrocities committed by Nazi scientists during World War II. James Meek, *Gloves off in Reagan Stem War*, N.Y. DAILY NEWS, June 14, 2004, <http://www.nydailynews.com/news/story/202726p-174914c.html>.

81. See *Stem Cells: A Primer*, *supra* note 7 (stating that a majority of embryonic stem cells used in research are in fact donated from couples that attempted, or planned to attempt, in-vitro fertilization procedures).

82. See Erwin, *supra* note 7, at 238 (stating that an embryo is incapable of giving informed consent).

83. See Fact Sheet: Embryonic Stem Cell Research, *supra* note 2 (detailing the potential of embryonic stem cells to cure a multitude of debilitating diseases). See also Wright, *supra* note 2 (detailing the potential of stem cells to serve as a testing ground for pharmaceutical companies).

the status of "human being" by the United States Supreme Court, the state supreme courts, or the legislature.⁸⁴

The final standard, the likelihood of injury in relation to the problem to be solved, is satisfied as well. Although the embryo used is no longer viable after its pluripotent cells are harvested, many of these embryos are donated specifically for research, and the potential to be derived from their use greatly outweighs the consequence.⁸⁵

While the Nuremberg Code has greatly influenced American policy toward medical research, it is not legal precedent, and therefore one must look to case law to properly analyze the ethical concerns over stem cell research.

B. *Roe v. Wade*

In 1973, the United States Supreme Court decided the landmark abortion rights case of *Roe v. Wade*. In reaching its decision, the Court had to balance the state's interest in protecting the unborn, the interests of the unborn, and a woman's right to privacy.⁸⁶ It held that the interest in maintaining a woman's right to privacy during the first trimester of pregnancy was greater than that of protecting the fetus while it was not yet viable.⁸⁷ In fact, according to the *Roe* Court, the interest of the fetus itself does not surpass its mother's until the *third trimester*.⁸⁸ More importantly, the Court weighed in on the classification of an early-stage fetus.

The Court relied upon the specific wording of the Constitution for its ruling.⁸⁹ It noted that where the word "person" is used in the Fourteenth Amendment, it refers to "persons *born* or naturalized in the United States."⁹⁰ The Court held that the word "person," as used in the Fourteenth Amendment, did not include

84. See, e.g., *Roe v. Wade*, 410 U.S. 113 (1973); *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992); *Kass v. Kass*, 696 N.E.2d 174 (N.Y. 1998).

85. See Casell, *supra* note 26, at 547 (explaining that embryonic stem cell research has shown promise in curing Parkinson's disease, Alzheimer's disease, diabetes, and other neurological disorders).

86. *Roe v. Wade*, 410 U.S. at 155-56.

87. *Id.* at 163. The Court held:

[F]or the period of pregnancy prior to this "compelling" point, the attending physician, in consultation with his patient, is free to determine, without regulation by the State, that, in his medical judgment the patient's pregnancy should be terminated With respect to the State's important and legitimate interest in potential life, the "compelling" point is at viability.

Id.

88. See *id.* at 160 (agreeing with certain physicians and their scientific colleagues that life begins at viability, which is usually placed at seven months (twenty-eight weeks) into gestation).

89. *Id.* at 157 (listing where the word "person" is used in the Constitution and stating that it has constitutional application only postnatally).

90. *Id.* (emphasis added).

the unborn, and that the legal interests of a fetus increased as the fetus reached viability.⁹¹ If an unborn fetus does not meet the constitutional definition of a "person," then it must be some form of property interest.

Nineteen years later, the Supreme Court upheld *Roe v. Wade* in *Planned Parenthood v. Casey*.⁹² In *Planned Parenthood*, Justice O'Connor firmly restated the main point of the Court's decision almost two decades earlier: the government is not to interfere with a woman's choice to terminate an embryo prior to viability.⁹³ The Court further held that "[o]nly where state regulation imposes an undue burden on a woman's ability to make this decision does the power of the state reach into the heart of the liberty protected by the Due Process Clause."⁹⁴

C. Other Compelling Decisions

Currently, there are three different ways to classify an embryo.⁹⁵ The first way is as a "person" with all the rights attributable to a living, viable, human being.⁹⁶ The second is as "human tissue" with the legal status of a property interest until viability.⁹⁷ The third falls somewhere between these two categories, and under it an embryo is deemed human tissue with the potential for human life.⁹⁸

The first classification is not an option after the Supreme Court's decision in *Roe v. Wade*.⁹⁹ The Court specifically noted that

91. *Id.* at 158–59 (explaining that, while not before the end of the first trimester, "it is reasonable and appropriate for a State to decide that at some point in time another interest, that of health of the mother or that of potential human life, becomes significantly involved").

92. 505 U.S. 833, 876 (1992) (upholding a woman's privacy rights laid out in *Roe v. Wade*, but rejecting that Court's use of a rigid trimester formula: "there is a substantial state interest in potential life throughout pregnancy," although this interest bears a direct relationship to the length of the pregnancy).

93. *Id.* at 833.

94. *Id.* at 874.

95. *Davis v. Davis*, 842 S.W.2d 588, 596 (Tenn. 1992) (citing *Report on the Ethics Committee of the American Fertility Society*, 53 J. AM. FERTILITY SOC'Y 24S, 35S (1990)).

96. *Id.* See also Erwin, *supra* note 7, at 221 (explaining the three generally accepted categories for legally classifying embryos, and citing Dónal P. O'Mathúna, *Personhood: Stem Cell Research and the Moral Status of Human Embryos*, <http://www.all.org/abac/dpo001.htm> (last visited May 29, 2005)).

97. *Id.* See also *Roe v. Wade*, 410 U.S. at 141 (setting forth the principle that a fetus does not have the same rights as a living person at least until it is viable).

98. *Id.*; Erwin, *supra* note 7, at 221; *Davis*, 842 S.W.2d at 596.

99. See *Roe v. Wade*, 410 U.S. at 157–60 (giving different examples of why an embryo is not a "person" in the legal sense including: the use of the word "person" in the Constitution, the Stoics' belief that life began at birth, various prominent religious groups' belief in the same, and the generally accepted

a human fetus does not fit within the definition of a constitutional person.¹⁰⁰ Therefore, the Court held, at the earliest stage of fetal development, the mother's right to privacy in making her own decisions outweighed the interests of the fetus. The Court also suggested that a fetus' rights developed as it matured, and so while a newly conceived embryo had almost no individual rights, a fetus in the third trimester of gestation had almost the same rights as a fully developed human being.¹⁰¹

In *Kass v. Kass*, the New York Court of Appeals applied contract principles to the question of ownership of in-vitro embryos.¹⁰² In *Kass*, a divorced couple had frozen five embryos prior to their divorce.¹⁰³ Maureen Kass wanted the embryos implanted in order to become pregnant.¹⁰⁴ Mr. Kass did not wish to raise a child with his former spouse, and subsequently produced an informed consent agreement the two had signed prior to donating their reproductive material which stated that the couple would donate any unused embryos for scientific research.¹⁰⁵

Instead of recognizing the rights of the embryos, the court employed contract principles to settle the matter and treated the embryos as property of the couple.¹⁰⁶ While the court recognized a certain dignity associated with an embryo, it refused to attach any rights beyond that of personal property, fitting its decision within the parameters of the second category for embryonic classification.¹⁰⁷ The court ordered that the embryos be donated to science.¹⁰⁸

principle in the medical community that life begins at viability).

100. *Id.* at 157. The word "person" is used in the Fourteenth Amendment, in the listing of qualifications for Representatives and Senators, in the Apportionment Clause, in the Migration and Importation provision, in the Electors provisions, and in the Fifth, Twelfth, and Twenty-Second Amendments. *Id.* No prenatal application exists in any of these usages. *Id.*

101. *Id.* at 162-63 (describing the state's "separate and distinct" interests in protecting the rights of a pregnant woman and its interest in protecting the potentiality of human life). Each of these interests increases as the woman approaches term, and at a point during pregnancy, each becomes "compelling." *Id.*

102. 696 N.E.2d 174, 181 (N.Y. 1998) (enforcing a contractual agreement as to the disposition of unused cryogenically frozen embryos created by a couple who had subsequently divorced).

103. *Id.* at 175.

104. *Id.*

105. *Id.* at 177. See also *id.* at 180-81 (adopting the three-step test developed and employed by the *Davis* court in Tennessee: (1) what are the preferences of the progenitors? (2) if none, what prior agreement concerning the disposition of the preembryos has been made? (3) if none, what are the relative interests of the parties in either using or not using the preembryos?).

106. See *id.* at 181 (deciding that the frozen embryos were property without legal rights of their own).

107. *Id.*

108. *Id.* at 179-80. The Court stated that, in applying the *Davis* framework,

In another important case, *Davis v. Davis*, the Tennessee Supreme Court declared that an embryo preserved for in-vitro fertilization fit within the third category, qualifying only as human tissue with the potential to become a human life.¹⁰⁹ In that case, a married couple had preserved early stage embryos for in-vitro fertilization.¹¹⁰ After they were divorced, the wife wanted to donate the embryos to infertile couples while the husband wished for them to be destroyed.¹¹¹

The court held that the embryos were neither a person in the constitutional sense nor merely property.¹¹² They instead occupied an abstract category somewhere between the two that deserved special interest because of their potential to develop into a complete human being.¹¹³

Most importantly however, for purposes of discussing the ethical concerns over stem cell research, the court in *Davis v. Davis* distinguished an embryo from a "preembryo."¹¹⁴ This distinction is crucial in obtaining federal funding for embryonic stem cell research using donated in-vitro embryos under the current White House policy.¹¹⁵ The Supreme Court has yet to hear

it had two choices: it could follow the recommendations suggested by the American Fertility Society's Ethics Committee calling for donation of the embryos to science, or it could follow the contract between the couple involved. *Id.* at 181. In this case, those two choices led to the same outcome. *Id.*

109. 842 S.W.2d 588, 596 (Tenn. 1992) (holding that a frozen embryo was the joint property of both donors, and with the proper consent of both parties could be donated to science).

110. *Id.* at 592 (describing cryopreservation, in which multiple embryos are donated by a particular couple, and those that are not immediately used are frozen for future use).

111. *Id.* The trial court treated this particular battle as if it were a custody battle over children. *Id.* at 594. It also held that donation of embryos to an anonymous infertile couple "would rob [Mr. Davis] twice—his procreational autonomy would be defeated and his relationship with his offspring would be prohibited." *Id.* at 604. The Court overruled the decision of the trial court which treated this controversy as a custody battle and held: "Preembryos are not, strictly speaking, either 'persons' or 'property,' but occupy an interim category that entitles them to special respect because of their potential for human life." *Id.* at 597.

112. *Id.*

113. *Id.*

114. 842 S.W.2d at 593-95 (explaining the difference between an "embryo" and a "preembryo," but noting that this distinction was not the only issue bearing upon the court's decision). The court also was quick to point out that an embryo could not be a "person," according to Tennessee statutes because a fetus does not become a person until birth. *Id.* at 594-95.

115. See NIH Update, *supra* note 56 (publishing guidelines for future embryonic stem cell research). Research is permitted so long as: (1) "the derivation process . . . was initiated prior to 9:00 p.m. . . . on August 9, 2001"; (2) "the stem-cells are derived from an embryo that was created for reproductive purposes" and is no longer needed; (3) donation of the embryo is obtained through informed consent of the biological parents; and (4) that

a case dealing with the status of an in-vitro embryo.

D. Legislative Enactments on Embryonic Status

Many of our legislators have made it clear that the potential benefits of embryonic stem cell research outweigh the moral cost.¹¹⁶ As a result, a Senate subcommittee has proposed a bill that would allow an exception to “The Bush Compromise.”¹¹⁷ The bill would allow further research on donated embryos only if the embryos would certainly have been destroyed had they not been donated to science. The bill also contains rigorous guidelines requiring informed consent of the donors in order to please pro-life constituents and bioethicists.¹¹⁸

In another effort to sidestep the constraints of “The Bush Compromise,” the Senate Judiciary Committee recently proposed a bill sponsored by Senator Diane Feinstein that would allow cloning of human embryos only for purposes of research.¹¹⁹ It is clear from the aforementioned proposals that members of both the House and Senate view “The Bush Compromise” as constrictive.¹²⁰

E. States Take Action

Several states, most notably California, have taken action that effectively side-steps the restrictive mandates of “The Bush Compromise.”¹²¹ Voters in California were presented with “Proposition 71” on the November 2004 ballot.¹²² Proposition 71 proposed that the State of California sell \$3 billion in bonds and then distribute close to \$300 million per year for ten years to researchers for embryonic stem cell research.¹²³ Voters approved

donation must not have involved financial inducements. *Id.*

116. Davison, *supra* note 25, at 420.

117. *Id.* at 420-21 (explaining that several factors are leading members of the House and Senate to endorse stem cell research, especially their own aging membership and their aging constituents).

118. *See id.* (describing the balancing act that members of Congress must perform to push for advances in medical research while not offending their more conservative constituents).

119. Epstein, *supra* note 6.

120. Andrea Stone & Dan Vergano, *Congress Looks Again at Stem-Cell Research*, USA TODAY, June 8, 2004, http://www.usatoday.com/news/health/2004-06-08-stem-cell-research_x.htm (reporting that in June of 2004, Senate Majority Leader Bill Frist, a medical doctor, suggested that the three-year-old Bush policy should be reviewed). Fifty-eight members of the Senate, including fourteen Republicans, signed a letter to President Bush urging him to liberalize his policy toward stem cell research. *Id.*

121. *See* Ceci Connolly, *California Puts Stem Cells to a Popular Test—\$3 Billion Plan Would Bypass Bush Policy*, WASH. POST, Oct. 25, 2004, at A01, available at <http://www.biotechgov.org/news/5709> (describing the origins and substance of “Proposition 71”).

122. *Id.*

123. *California Gives Go-Ahead to Stem Cell Research: Proposition 71*

the measure by a margin of fifty-one to forty-nine percent.

New Jersey Governor James E. McGreevey signed a bill that permits embryonic stem cell research within that state and provides \$5 million in state funding to researchers annually.¹²⁴ In November of 2004, Wisconsin Governor Jim Doyle announced a plan to provide \$750 million to build an embryonic stem cell research institute on the University of Wisconsin-Madison campus.¹²⁵

IV. PROPOSAL

As previously stated, over 128 million Americans could possibly be cured of debilitating ailments by developing embryonic stem cell treatments.¹²⁶ It is well known that when controversial research receives federal funding, it not only gains fiscal support, but it also gains support in the court of public opinion.¹²⁷ If embryonic stem cell research is to receive untethered federal funding within the current parameters of White House policy and the resulting NIH guidelines,¹²⁸ its classification of embryos as "human beings" must change to that of "human tissue."

This Comment will first propose that a change of classification of embryonic stem cells from "human beings" to "human tissue" must take place via an act of Congress.¹²⁹ Second, it will propose that this act contain a four-part test that must be met by any couple wishing to donate their embryonic tissue for research.¹³⁰ And third, if such an act of Congress were to become law, then President Bush should act to create a new federal agency for the sole purpose of regulating subsequent research.

Congress must act in order to effect a change in the classification of embryonic stem cells used in stem cell research.

Provides \$3 Billion State Funding Over Next Decade, at <http://www.msnbc.msn.com/id/6384390> (Nov. 3, 2004).

124. See Connolly, *supra* note 121 (describing how various states are now passing "safe harbor" legislation allowing embryonic stem cell research).

125. Stacy Forster & Patrick Marley, *Stem-Cell Proposal Makes Some Bristle*, MILWAUKEE J. SENTINEL, Nov. 21, 2004, <http://www.jsonline.com/news/state/nov04/277209.asp>.

126. See Fact Sheet: Embryonic Stem Cell Research, *supra* note 2 (detailing the potential of embryonic stem cells to cure a multitude of debilitating diseases).

127. See Casell, *supra* note 26, at 570 (explaining that one way to drum up popular support for a proposed piece of legislation is employing celebrities to speak on the cause).

128. NIH Update, *supra* note 56.

129. U.S. CONST. art. I, § 7, cl. 2.

130. This four-part test will include requirements that any embryos used in stem cell research be: (1) donated by the biological parents, (2) with the informed consent of both biological parents, (3) without compensation beyond hospital costs, and (4) a mandatory forty-eight-hour "cooling-off" period for any couple trying to donate embryonic tissue.

Congressional action relieves President Bush of the responsibility of proposing new legislation in the face of Republican opposition.¹³¹ It also would allow him to avoid the consequences of disturbing the delicate balance currently maintained under "The Bush Compromise."¹³² Also, if the issue is fully debated by legislators in both the House of Representatives and the Senate, constituents may begin to reconsider the idea of federal funding for embryonic stem cell research without further action from the President.¹³³ One cannot expect the President to sign a piece of legislation in conflict with his previously held position,¹³⁴ and upon such a contentious issue, unless public support for the measure is considerable.

This act should require that both the couples wishing to donate embryonic tissue and the research foundations performing the research meet a four-part test. The goal of this test is to create a balance between facilitating research while maintaining the sanctity of life, without undermining the rights of donors in relation to a five-day-old cell mass.¹³⁵

The first part of this test requires that all embryonic tissue used for stem cell research be donated by both biological parents. The goal of this requirement is to avoid the creation of a "black market" for embryonic stem cell tissue. Many opposed to embryonic research (such as the religious right) are concerned that researchers will disturb the sanctity of life.¹³⁶ Without the assurance that no one is paid for embryonic tissue, overzealous researchers or struggling young couples might try to take advantage of the new law. Hopefully, opponents of previous bills¹³⁷

131. Davison, *supra* note 25, at 410-13.

132. See Braswell, *supra* note 17, at 433 (explaining that while not completely satisfied, a large majority of the House of Representatives would like to see at least *some* stem cell research, in line with the Bush policy statement).

133. See Davison, *supra* note 25, at 425 (explaining that critics of stem cell research frequently cite human cloning research to demonstrate that even when the public thinks it has a compromise, scientists will find a way to push the moral envelope).

134. Even though the President announced his plan to withhold federal funding with the exception of stem cell lines already in existence, he did state (in reference to embryos not used in in-vitro fertilization) "if they're going to be destroyed anyway, shouldn't they be used for a greater good, for research that has the potential to save and improve other lives?" Remarks by the President on Stem Cell Research, *supra* note 6.

135. See *Roe v. Wade*, 410 U.S. at 160 (holding that the interest of the state in maintaining a woman's privacy outweighs that of a non-viable fetus before the twenty-eighth week of gestation).

136. See Wright, *supra* note 2 (reiterating statements made at the National Conference of Catholic Bishops).

137. See Nelle S. Paegel, Notes and Comments: *Use of Stem Cells in Biotechnological Research*, 22 WHITTIER L. REV. 1183, 1186 (2001) (citing *Senators Debate Cell Research Lawmaker Compares Using Material from*

will be appeased by the refusal of the government to let embryonic tissue become simply a "property interest" to be bought and sold like any other publicly traded commodity.¹³⁸

The second requirement, similar to one of the NIH's current guidelines, is the informed consent of both biological parents.¹³⁹ The objective is two-fold: to avoid any disagreements between couples donating embryos not used for in-vitro fertilization, and to prevent lengthy court battles over custody of previously donated embryonic tissue.¹⁴⁰

The third prong of the test is that no compensation may be given to couples donating embryos beyond basic hospital costs. Obviously, this prong would need to be developed further by doctors and researchers to create a workable definition of "basic."¹⁴¹ However, research as promising as this should not be hindered by the inability to attract donors because the relatively slight cost of donation to the federal government is cost-prohibitive to individuals.

The fourth and final prong of this test is a mandatory forty-eight-hour "cooling-off period." The objective here is to dissuade undecided couples from making a decision that they might regret and choose to litigate in the future.¹⁴² In cases of donating unused in-vitro embryonic tissue, one might foresee a case where a couple receiving fertility treatment, upon finally conceiving a child of their own, might disregard any unused embryos only to realize afterwards the implications of their decision.¹⁴³ Congress might also require that donors attend a meeting with a licensed

Discarded Embryos to Nazism; Scientists Say Approach is Crucial, AUGUSTA CHRON., Apr. 27, 2000, at A07). Paegel quoted Senator Sam Brownback (R-Kan) as comparing embryo destruction for science to Nazi contentions: "This sounds . . . like what happened in World War II . . . these people are going to be killed, why not experiment on them." *Id.*

138. *Davis v. Davis*, 842 S.W.2d 588, 596 (Tenn. 1992) (explaining that one method of classifying embryonic tissue used in research is as simple "property interest," without any rights of a constitutional person).

139. The second prong of this Comment's proposed test corresponds to the third prong of the current NIH Guidelines for federal funding of embryonic stem cell research. NIH Update, *supra* note 56.

140. A good example of the type of litigation that will be avoided under this plan can be seen in *Kass v. Kass*, where a divorced woman unsuccessfully attempted to be fertilized with embryos saved by the couple prior to their divorce proceeding. 696 N.E.2d 174, 181-82 (N.Y. 1998).

141. Under this proposal, federal funding would not cover the entire process of in-vitro fertilization and donation. Rather, once a couple decided to donate embryonic tissue, only an incremental portion of their total cost, representing the costs to donate, would be reimbursed by federal funds.

142. An important concern of most legislation is to create laws that will not be the subject of future litigation.

143. It is clear that the only method of embryonic tissue research that could pass this test is the donation of unused embryonic tissue from the in-vitro fertilization process. *Stem Cells: A Primer*, *supra* note 7.

psychologist prior to donation, similar to the process employed at many abortion clinics.

Assuming a law is passed classifying embryonic stem cells as "human tissue," the third part of this proposal recommends that the federal government then act to establish an agency to monitor subsequent stem cell research. This agency would work under the NIH and assist with disbursement of federal funds and ensure that the four-part test detailed earlier in this proposal is followed.¹⁴⁴

This new agency could be made up of doctors, researchers, and politicians from both sides of the aisle,¹⁴⁵ to ensure that all viewpoints have a voice in deciding who gets federal dollars. It might also provide counseling services for couples considering whether to donate unused embryos. Just as the NIH's duty is to create guidelines by interpreting White House policy,¹⁴⁶ this new agency would interpret and enforce congressional mandates on embryonic stem cell research.

V. CONCLUSION

The suggested legislation would not violate the Fourteenth Amendment Due Process Clause definition of "person" as interpreted by the current Court.¹⁴⁷ Furthermore, declaring a five day-old embryo to be "human tissue" falls within the ethical guidelines laid out in the Nuremberg Code¹⁴⁸ and would not be in direct conflict with the major decisions of the United States Supreme Court or state supreme courts.¹⁴⁹

And, as far as current federal policy is concerned, "The Bush Compromise"—President Bush's statement that a "five-day-old cluster of cells" is "not an embryo, not yet an individual, but a pre-embryo"—was surely meant to leave open a window of opportunity for further research.¹⁵⁰

144. See Davison, *supra* note 25, at 407 (describing the role of the NIH as an administrative agency within the Department of Health and Human Services).

145. See *id.* at 410-16 (explaining the largely partisan political battle that has taken place over the past twenty years between different Presidents and Congress over federally funding fetal tissue research).

146. See *id.* at 409 (explaining the NIH's role in interpreting both executive orders and congressional law).

147. See *Roe v. Wade*, 410 U.S. at 156-58 (holding that the Constitution, by referencing "persons born or naturalized in the United States," was not encompassing the unborn).

148. See Babbo, *supra* note 68, at 385 n.8. For a list of the rules, see *supra* note 74.

149. See *e.g.*, *Roe v. Wade*, 410 U.S. at 158 (holding a non-viable fetus is not a person in the constitutional sense); *Kass v. Kass*, 696 N.E.2d 174, 181 (N.Y. 1998) (holding an embryo is human tissue with a property interest); *Davis v. Davis*, 842 S.W.2d 588, 593 (Tenn. 1992) (distinguishing an embryo from a pre-embryo).

150. Remarks by the President on Stem Cell Research, *supra* note 6.

When considering this proposal, one might be tempted to ask how the federal government could afford to pay for the donation of embryonic tissue for stem cell research, and how it could weather the storm of controversy sure to follow the passage of this proposed act? But with 128 million Americans suffering from debilitating illnesses that could possibly be cured by the use of embryonic stem cells, a better question would be: How could it not?