EMBRYONIC STEM CELL RESEARCH: WILL PRESIDENT BUSH'S LIMITATION ON FEDERAL FUNDING PUT THE UNITED STATES AT A DISADVANTAGE? A COMPARISON BETWEEN U.S. AND INTERNATIONAL LAW

I. INTRODUCTION

In an age where technological and medical advances are developing at exponential rates, the law may shape or follow advances.[1] Embryonic stem cell research is one rapidly emerging area in which the law may shape or follow advances.[2] Although the use of fetal tissue for medical research is not a new idea,[3] recent discoveries and advances, such as human genome mapping and human cloning, have forced most developed nations to re-evaluate their laws on genetic testing.[4] Each

1. *See* James E. Bowman, *Symposium Genetics and the Law: the Ethical, Legal, and Social Implications of Genetic Technology and Biomedical Ethics: The Road to Eugenics*, 3 U. CHI. L. SCH. ROUNDTABLE 491, 495–96, 501 (1996).

2. *See* Charles F. De Jager, Note, *The Development of Regulatory Standards for Gene Therapy in the European Union*, 18 FORDHAM INT'L L.J. 1303, 1311 (1995).

3. Jason H. Casell, Note, *Lengthening the Stem: Allowing Federally Funded Researchers to Derive Human Pluripotent Stem Cells From Embryos*, 34 U. MICH. J.L. REFORM 547, 548 (2001). "Extensive use of fetal tissue for medical research in the United States began in the 1950s when Dr. Jonas Salk used human fetal kidney cells to develop the polio vaccine." *Id*.

4. *See* De Jager, *supra* note 2, at 1311–12; Timothy Caulfield, *Clones,*

nation's scientific community must wait for approval, guidance, or funding to continue genetic research.[5] The wait is not a silent one, however, as an international debate over biotechnology regulation and morality rages.[6]

In the United States, the legal status of the human embryo has been a widely debated and highly political topic since the U.S. Supreme Court decision in *Roe v. Wade*.[7] In *Roe*, the Court held that a woman had the right to terminate her pregnancy in the first trimester based on a fundamental privacy right.[8] *Roe* dealt with the embryo in the context of abortion.[9] Outside the abortion context, the Supreme Court has not prevented the government from protecting embryos.[10] Thirty years after *Roe*, the legal status of the embryo remains unclear.[11] The issue of embryonic stem cell research has become so hotly contested and politically important that President George W. Bush discussed it in his first prime-time presidential address on August 17, 2001.[12] The presidential address and President Bush's later decision to modify existing policy on embryonic research evoked debate among key players on both sides of the issue.[13] Many

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Controversy, and Criminal Law: A Comment on the Proposal for Legislation Governing Assisted Human Reproduction, 39 ALBERTA L. REV. 335, 336 (noting that Canada may soon have to enact laws specifically addressing the concerns of reproductive genetics).

5. De Jager, *supra* note 2, at 1304–05.

6. Caulfield, *supra* note 4, at 335. Biotechnology is the engineering and technology of the interaction between human and machines. Leslie Cataldo, Note, *A Dynasty Weaned From Biotechnology: The Emerging Face of China*, 26 SYRACUSE J. INT'L L. & COM. 151, 151 (1998).

7. Roe v. Wade, 410 U.S. 113 (1973); *see* Casell, *supra* note 3, at 549.

8. *Roe*, 410 U.S. at 152–53; *see* Casell, *supra* note 3, at 564.

9. *See Roe*, 410 U.S. at 131–32.

10. *On Human Embryos and Medical Research: An Appeal for Ethically Responsible Science and Public Policy*, 16 ISSUES L. & MED. 261, 263–64 (2001) [hereinafter *On Human Embryos and Medical Research*].

11. *See* Rorie Sherman, *Embryo Cases: Different Views*, NAT'L L.J., Oct. 2, 1989, at 21.

12. Nancy Gibbs & Michael Duffy, *We Must Proceed With Great Care*, TIME, Aug. 20, 2001, at 14.

13. *See, e.g.*, Mike Pezzella, *Few Satisfied with Bush Stem Cell Compromise*, BIOTECH. NEWSWATCH, Aug. 20, 2001, at 1 (stating that President Bush's decision to allow limited federal funding of stem cell research has set off debate among scientists, ethicists, clergy, and politicians); Harry Austin, *Captive to an Empty Promise*, CHATTANOOGA TIMES, Aug. 18, 2001, at B6 (asserting that President Bush's hair-

conservatives who advocate a total funding ban, such as the Catholic Church and anti-abortion groups, have accused President Bush of breaking his campaign promise to prohibit federal funding of research involving the destruction of living embryos.[14] Taking another view, some scientists, citizens, and lawmakers supported Democratic efforts to reverse President Bush's decision and make embryonic stem cells more available for research.[15] Scientists fear that limitations on federal funding will keep them from realizing the huge potential of stem cell research.[16]

This Comment examines the current laws regulating stem cell research, both in the United States and internationally, and how disparities between nations' laws affect relevant technological, scientific, and medical developments. Part II provides a brief overview of stem cell research science, discusses the beneficial uses of the research, and explores the ethical debate surrounding the issue. Part III examines the current laws pertaining to genetic research in the United States, considering President Bush's decision regarding federal funding, and compares U.S. laws to those of other countries, including China, Japan, Germany, Australia, Great Britain, and Israel. Part IV considers the effects of disparities among the laws of the various nations, focusing particularly on the effects of President Bush's decision to limit federal funding of embryonic stem cell research. This Comment's conclusion is that the United States will be seriously disadvantaged, technologically and economically, if its laws fail to allow and encourage U.S. scientists to fully explore the potential of stem cell research.

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splitting position just opened the debate, not closed it).

14. Mitch Frank, *The Bush Decision*, TIME, Aug. 20, 2001, at 18. *But see* James A. Barnes, *The Art of Compromise*, NAT'L J., Aug. 18, 2001, at 2632.

15. Jeff Pillets, *Scientists Challenge Stem Cell Limits, Join Legislators in Call for Reversal*, RECORD (New Jersey), Aug. 17, 2001, at A1.

16. Sharon Begley, et al., *Did the President Go Far Enough?*, NEWSWEEK, Aug. 20, 2001, at 16 (reporting that many scientists believe the limits that President Bush's decision placed on stem cell research could severely inhibit life-saving medical advances).

II. THE SCIENCE OF STEM CELL RESEARCH

A. What are Stem Cells?

Stem cells have been called "the essence of an embryo."[17] They are biological building blocks that serve as the common ancestry of all 210 different kinds of tissue in the human body.[18] Stem cells grow and specialize to form the heart, skin, and other organs.[19] "Cell lines" are derived by removing cells from a body, then isolating and culturing them on a medium.[20] They are called cell lines because they "come from, and give rise to, other cells along a similar hereditary lineage."[21] Creating cell lines has become something of an art form because it is relatively difficult to develop and grow them in a laboratory from human cell samples.[22]

One type of stem cell research is adult stem cell research.[23] Stem cells have been found in human blood, bone marrow, nerves, and organs.[24] Some researchers indicate stem cells can be extracted from fat removed by liposuction.[25] Other stem cell sources include the human placenta, blood from umbilical cords,[26] and fetal tissue from terminated pregnancies.[27]

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17. Tim Friend, *Stem-Cell Debate Mixes Science, Religion, Politics*, USA TODAY, Aug. 8, 2001, at A7.

18. *See* Paul Recer, *Stem-Cell Research: Too Little is Known to Abandon It*; *'Lots of Promise': Pope says that Discoveries from Adult Stem Cells Eliminate the Need for Embryonic Cells*, TELEGRAPH HERALD (Dubuque, Iowa), Aug. 30, 2000, at A7; *On Human Embryos and Medical Research, supra* note 10, at 261.

19. Paul Recer, *supra* note 18, at A7.

20. Christopher Scott Pennisi, Note, *More on Moore: A Novel Strategy for Compensating the Human Sources of Patentable Cell-Line Inventions Based on Existing Law*, 11 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 747, 748 (2001).

21. *Id*.

22. *Id*.

23. Andrew Pollack, *The Stem Cell Debate; Scientists Seek Ways to Rebuild the Body, Bypassing the Embryos*, N.Y. TIMES, Dec. 18, 2001, at F6.

24. Frank, *supra* note 14, at 18; *see* Friend, *supra* note 17.

25. Pollack, *supra* note 23, at F6.

26. *Id*.

27. National Institutes of Health, Office of the Director, *Stem Cells: A Primer*, 4–5, May 2000, *at* http://www.nih.gov/news/stemcell/primer.pdf (last visited Mar. 15, 2003) [hereinafter *Stem Cells: A Primer*].

Embryonic stem cell research is the most promising, but also the most controversial type of research, because it involves the destruction of human embryos.[28] There are two methods of developing embryonic stem cell lines that scientists use for research: isolation of stem cells directly from an embryo[29] and cell nuclear transfer, also known as embryo-cloning.[30]

Embryonic stem cells, as the name would indicate, come from human embryos in a very early developmental stage.[31] When an egg is fertilized by a sperm, a process that takes about twenty-four hours,[32] the result is a single cell that is totipotent, meaning it has the potential to form an entire organism.[33] That single cell divides continuously, forming identical totipotent cells, that, in turn, divide.[34]

Approximately four days into this development process, the cells begin the specialization process.[35] About six days into development, they begin to form a sphere, called a blastocyst, which consists of approximately one hundred cells.[36] It is at this point that stem cells first appear.[37] Approximately nine days into development, the blastocyst splits into two layers of cells.[38] The

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28. Kate Foster, *Chinese Scientists Have Cloned Human Embryos*, SCOTSMAN, Mar. 7, 2002, at 8; s*ee also* Pollack, *supra* note 23, at F6 (discussing the exploration of alternatives to embryonic stem cell research as an effort to avoid ethical controversy caused by destruction of the human embryo).

29. *Stem Cells: A Primer*, *supra* note 27, at 4–5.

30. *Stem Cells: Australia Can Show the Way*, AUSTL. FIN. REV., Mar. 9, 2002, at 50. Cell nuclear transfer is the process by which an egg cell has its nucleus removed and is then fused with another cell, other than sperm or egg, and allowed to divide. Chang Ai-Lien, *Stem-Cell Trials Give Hope To Children*, STRAITS TIMES (Singapore), Aug. 17, 2001, at H14.

31. *The Science of Stem Cells*, *Embryonic Stem Cell Research at UW-Madison*, *at* http://www.news.wisc.edu/packages/stemcells (last visited Mar. 15, 2003).

32. *The Stem Cell Debate; The Embryonic Journey and Its Milestones*, N.Y. TIMES, Dec. 18, 2001, at F4 [hereinafter *The Stem Cell Debate*].

33. *Stem Cells: A Primer*, *supra* note 27, at 1. The resulting single cell is most commonly called the "zygote." Mildred L. Shumard, *'Contraceptive' or Abortion Pill?*, SARASOTA HERALD-TRIB., July 15, 1999, at 14A.

34. *Stem Cells: A Primer*, *supra* note 27, at 1.

35. *Id*.

36. Steve Connor, *Scientific Pioneers: How the Research Could Help to Treat Incurable Diseases*, INDEPENDENT, Feb. 28, 2002, at 3.

37. *Id*.

38. *The Stem Cell Debate, supra* note 32, at F4.

outer layer of cells develops into a placenta and other cells essential to fetal development.[39] The inner layer consists of pluripotent cells.[40] Scientists desire this inner layer of cells for embryonic stem cell research.[41] Timing is critical because researchers want to retrieve the cells after the blastocyst is formed, but before the inner layer of cells begins turning into specialized cells, such as skin or heart cells.[42] Although stem cells can be found throughout human development, even during adulthood, studies show they lose their versatility over time.[43]

B. The Potential Benefits

Scientists are eager to pursue embryonic stem cell research because they believe that stem cells can be used to help improve the health of approximately 128 million Americans afflicted with various diseases.[44] Although most of the work done to date is preliminary and privately funded, scientists believe stem cells have the potential to treat Alzheimer's and Parkinson's diseases, spinal cord injuries, heart disease, and multiple sclerosis.[45] Insulin-producing pancreatic beta cells could be transplanted into diabetic patients.[46] Cardiac muscle cells could be infused into a heart damaged by a heart attack.[47] Some scientists speculate that stem cells could be used to create entire organs for transplant into patients who may otherwise die while

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39. *Stem Cells: A Primer*, *supra* note 27, at 1.

40. *Id*. Pluripotent cells are different from totipotent cells in that pluripotent cells can develop into nearly every kind of cell that makes up a human being, but cannot form a placenta, and cannot survive alone in a womb. *Id*.

41. *See id.*

42. Clare Wilson, *Cutting Edge; What's the Most Exciting Area of Organ Bioengineering? You Might be Surprised by the Answer*, NEW SCIENTIST, Aug. 10, 2002, at 32.

43. *Id*.

44. Office of the Press Secretary, Fact Sheet: Embryonic Stem Cell Research, the White House, *at* http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html (Aug. 9, 2001) [hereinafter Fact Sheet].

45. President George W. Bush, Address to the Nation on Stem Cell Research from Crawford, Texas (Aug. 9, 2001), *in* 37 PUB. PAPERS 32 (Aug. 13, 2001) [hereinafter President Bush Address].

46. Fact Sheet, *supra* note 44.

47. *Id*.

waiting for a donated organ.[48]

Scientists and researchers are not the only ones who are excited and hopeful about the potential benefits of stem cell research.[49] Millions of people across the world afflicted with life-threatening illnesses and injuries are suddenly faced with the prospect of potential treatments, and wait anxiously for medical breakthroughs.[50] Some, such as Michael J. Fox and other celebrities, have lobbied Congress in support of increased funding for research.[51]

C. The Ethical Debate

Although people of different national, religious, and philosophical backgrounds disagree whether embryonic stem cell research is ethical, there are two main points of controversy regarding the science. The first involves the destruction of an embryo in light of the value of human life and the legal status of the embryo.[52] The second arises from a blurring and overlapping of the concepts and procedures of stem cell research and human cloning.[53]

1. The First Ethical Debate: Destruction of the Embryo

Stem cells are extracted from the embryo between nine and eleven days after fertilization.[54] Extracting the stem cells destroys the embryo.[55] Therefore, the debate surrounding the destruction of the embryo parallels the abortion debate about

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48. Steven Komarow, *Germany Awaits U.S. Action on Stem Cells; Controversial Research is Testing Moral Lessons for Hitler's Reign*, USA TODAY, Aug. 9, 2001, at A5.

49. *See* Kate Foster & Jason Beattie, *Scot to Pioneer Embryo Research*, SCOTSMAN, Feb. 28, 2002, at 5 (discussing Christopher Reeve, who hopes stem cell research may eventually enable spinal cord tissue replacement that would enable him to walk again).

50. *See* Lou Waters & Eileen O'Connor, *Michael J. Fox Urges Congress to Approve Stem Cell Research*, CNN TODAY, Sept. 14, 2000, Transcript #00091410V13, *available at* LEXIS, News Library, CNN File.

51. *Id*.

52. Friend, *supra* note 17, at A7.

53. Marilynn Marchione, *Cloning, Stem Cells Must Be Kept Separate*, MILWAUKEE J. SENTINEL, Aug. 13, 2001, at 1G.

54. *The Stem Cell Debate, supra* note 32, at F4.

55. *Stem Cells: Australia Can Show the Way*, *supra* note 30, at 50.

whether life actually begins at conception, viability, birth, or somewhere in between.[56] Because the Catholic Church, pro-life activists, and other religious groups believe that life starts at conception, they oppose embryonic stem cell research.[57] These groups argue that benefiting from the destruction of a human embryo is "no less a crime than abortion."[58]

But what if the embryos would be destroyed anyway? Standard in vitro fertilization practices already create a surplus of human embryos.[59] In fact, there are currently tens of thousands of frozen embryos waiting to either be "adopted, discarded or donated to researchers relying on private funding."[60] President Bush asked "if [the embryos are] 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?"[61] While the question seems simple and the answer obvious, some may reply that because a human embryo is going to be destroyed, experimenting on it or exploiting it as a natural resource is not justified.[62] However, those who support the sanctity of human life cannot ignore the potential that stem cells offer to improve lives.[63] As New York Democratic Representative Jerrold Nadler said during a House of Representatives hearing, "[w]e must not say to millions of sick or injured human beings, 'go ahead and die, stay paralyzed, because we believe . . . the clump of cells is more important than you are.'"[64]

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56. *See The Stem Cell Debate*, *supra* note 32, at F4.

57. *Id.* It should be noted, however, that opposition to abortion does not necessarily equal opposition to stem cell research. Republican Senator Orrin Hatch, for example, is a leading opponent of abortion, yet he supports stem cell research, saying "no baby was ever born in a petri dish." *Id.*

58. Richard Lacayo, *How Bush Got There: Months of Debate—and One Lucky Break—Led to the President's Compromise. The Inside Story*, TIME, Aug. 20, 2001, at 17.

59. Fact Sheet, *supra* note 44.

60. "*Frankenstein" Scientists Who Use Embryos to Grow Organs*, STRAITS TIMES (Singapore), Dec. 16, 2000, at 15.

61. President Bush Address, *supra* note 45.

62. *Id*.

63. Casell, *supra* note 3, at 569.

64. Nancy Gibbs, *Cloning: Where Do You Draw the Line?; The House Vote to Ban All Human Cloning was the First Skirmish in the Research Wars to Come. Next Up: Stem Cells*, TIME, Aug. 13, 2001, at 20.

Another argument offered to oppose embryonic stem cell research emphasizes the alternatives to destroying an embryo to obtain stem cells.[65] One alternative is the use of adult stem cells.[66] Adult stem cells, like embryonic stem cells, are unspecialized and can renew themselves.[67] Adult stem cells can also become specialized to form any of the tissues that originate from stem cells.[68] However, it appears that the full potential of adult stem cells is much more limited than that of embryonic stem cells.[69]

First, adult stem cells may not exist for all tissues.[70] They are also harder to isolate and purify than embryonic stem cells.[71] Additionally, adult stem cells may be able to divide only a limited number of times, which reduces their utility in producing adequate numbers of well-characterized cells for therapies.[72] Scientists have not successfully grown large numbers of adult stem cells in culture.[73] Further, adult stem cells may be more susceptible to disease than embryonic stem cells.[74] "Fetal tissue is preferred to adult tissue because fetal cells maintain their plasticity, change shape to place themselves in the correct location, are able to integrate and grow in new surroundings, and are less immunogenic than adult cells, making rejection less likely."[75]

A new finding creates another twist in the debate.[76] Scientists found a new source of embryonic stem cells in unfertilized monkey eggs. The eggs were "tricked" into dividing as if they were fertilized by sperm, a process known as

65. Recer, *supra* note 18, at A7.
66. Pollack, *supra* note 23, at F6.
67. Fact Sheet, *supra* note 44.
68. *Id.*
69. Casell, *supra* note 3, at 551.
70. Pollack, *supra* note 23, at F6.
71. *Id*.
72. Casell, *supra* note 3, at 551–52.
73. Pollack, *supra* note 23, at F6.
74. Casell, *supra* note 3, at 552.
75. *Id*. at 548–49.
76. *Complex Division; Research Changes Debate over Stem Cells*, COLUMBUS DISPATCH, Feb. 8, 2002, at 12A. The scientists are employed by Advanced Cell Technology of Worcester, Massachusetts. *Id*.

parthenogenesis.[77] Before the fertilization process, an egg sheds one of its two sets of chromosomes to make room for a new set from a visiting sperm.[78] Scientists "tricked" an unfertilized egg to reclaim the shed chromosomes and develop with a double set as if it were fertilized.[79] These eggs developed to the blastocyst stage, where scientists removed the stem cells and coaxed them to differentiate.[80]

This development, while exciting, raises several issues. For example, although scientists were able to retrieve stem cells that were coaxed to form specialized cells, it is uncertain whether the cells can produce viable tissue.[81] Additionally, although the process was successful using monkeys—an animal considered close to humans—scientists do not know if the technique will work on humans.[82] If the process does work on humans, its utility will be limited to replicating women's cell lines.[83] The embryo would be made solely of female chromosomes, because the egg is not fertilized with sperm.[84] Finally, the destruction of the embryo remains in issue. The pseudo-embryo created by parthenogenesis, called a parthenote, has no chance of being carried to term by humans[85] because men and women put different imprints on genes by using both the egg's and sperm's sets of chromosomes.[86] With only a female

77. Laura Beil, *Stem Cell Advance Reported; Growth Without Need For Embryo Might Ease Ethics Concerns*, DALLAS MORNING NEWS, Feb. 1, 2002, at 1A. Although rare, parthenogenesis occurs naturally in some animals and insects, such as certain snakes, turkeys, and aphids. *Complex Division; Research Changes Debate over Stem Cells*, *supra* note 76, at 12A.

78. Nicholas Wade, *New Stem Cell Source Called Possible*, N.Y. TIMES, Feb. 1, 2002, at A23.

79. *Id*.

80. Beil, *supra* note 77, at 1A; *Complex Division; Research Changes Debate Over Stem Cells*, *supra* note 76, at 12A. Previously, the process had been successfully performed on the unfertilized eggs of mice. Beil, *supra* note 77, at 1A.

81. Wade, *supra* note 78, at A23.

82. Beil, *supra* note 77, at 1A.

83. *Id*.

84. *See* Wade, *supra* note 78, at A23.

85. *Id*. The embryo formed through this process has been analogized to a naturally occurring pregnancy complication wherein the egg's chromosomes are lost and the sperm's chromosomes double up. *Id*.

86. *Id*.

imprint, the embryo will not develop properly and cannot be carried to term.[87] There is, therefore, debate whether destroying a parthenote constitutes the taking of a human life.[88] While a consensus has not been reached on the issue, one thing is clear: science will continue to advance even if the debate stagnates.[89]

As a final note, some argue that, even if embryonic stem cell research takes place, federal funding should not be used for projects that some find morally objectionable.[90] However, it is unreasonable to subject funding decisions to the whims of dissenting citizens or to allow those who oppose certain public goods to shirk from funding them.[91] "Having to pay for programs with which we ethically disagree is one consequence of living in a democracy."[92]

2. The Second Ethical Debate: Cloning

The issue of stem cell research is often clouded by misunderstanding, due in part to a blurred distinction between stem cell research and human reproductive cloning, a process that most people oppose.[93] The realization that human cloning was attainable became apparent on February 22, 1997, with the debut of a sheep named Dolly.[94] Dolly was cloned from the single cell of an adult sheep, making her the genetic twin of that organism.[95] Scientists subsequently recreated the experiment, proving that Dolly was not a fluke.[96] In fact, techniques have

87. *Id*.

88. *See* Beil, *supra* note 77, at 1A (presenting the varying viewpoints surrounding parthenotes and personhood).

89. *See id.* (reporting scientific experiments planned regardless of the debate surrounding stem cell research and cloning).

90. Ronald M. Green, *Stopping Embryo Research*, 9 HEALTH MATRIX 235, 247 (1999).

91. *Id*.

92. *Id*.

93. *See* Marchione, *supra* note 53, at 1G (explaining the differences between cloning and stem cell research).

94. Adam Greene, Note, *The World After Dolly: International Regulation of Human Cloning*, 33 GEO. WASH. INT'L L. REV. 341, 341 (2001).

95. *Id*.

96. *Id*.

been developed that make cloning even more efficient.[97] Without proper regulation, it is only a matter of time before someone clones a human.[98] Fortunately, countries are drafting such legislation.[99] The U.S. House of Representatives passed legislation banning human cloning, including cloning of human embryos for medical research.[100] The U.S. Senate is considering similar legislation.[101] Violators of the pending legislation could face ten-year prison terms and million-dollar fines.[102] Twenty-nine European nations have signed a treaty that completely bans research on human cloning.[103] In 1998, the Israeli government enacted a five-year ban on human cloning.[104]

While the prospect of human cloning can be frightening, it must be remembered that cloning is an issue separate from stem cell research. Although embryonic stem cells can differentiate into specific tissues, human reproductive cloning involves full genetic replication of an entire organism.[105] Studies show that,

97. *Id*.

98. *Id*. The Raelians, a religious cult who believe humans are clones of extraterrestrials, claim to have already cloned three humans. Elizabeth Weise, *Clonaid Says New Clone from Dead Baby; Company Has Refused to Provide Evidence and Faces Skepticism*, USA TODAY, Jan. 24, 2003, at A3. However, these claims are unsubstantiated and widely believed to be a hoax. *Id*.

99. *See* Greene, *supra* note 94, at 352–56 (describing in detail the policy and debate over legislation in nations around the globe).

100. Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. § 302 (2003) (passed Feb. 22, 2003).

101. Human Cloning Prohibition Act of 2003, S. 245, 108th Cong. § 498D (2003); *see Senate Considers Ban Affecting Human Embryos,* WASH. POST, Jan. 30, 2003, at A9 (summarizing recent U.S. Congressional attempts to ban human cloning).

102. H.R. 534, § 302; S. 245, § 498D.

103. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, Dec. 1, 1998, Europ. T.S. No. 168. These nations include: Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Moldova, Netherlands, Norway, Poland, Portugal, Romania, San Mariano, Slovakia, Slovenia, Spain, Sweden, Switzerland, and Turkey. Counsel of Europe, *Chart of Signatures and Ratifications of a Treaty*, *at* http://conventions.coe.int/Treaty/EN/searchsig.asp? NT=168&CM=&DF= (last modified March 15, 2003).

104. *World View*, AUGUSTA CHRON., Aug. 10, 2001, at A6; Nina Gilbert, *Knesset Bans Human Cloning for Five Years*, JERUSALEM POST, Dec. 30, 1998, *available at* 1998 WL 6539642.

105. Marchione, *supra* note 53, at 1G. Clones are created by replacing an egg's

despite the general opposition to human cloning, most people support research performed on surplus embryos at infertility clinics.[106]

Despite the distinction between cloning and stem cell research, a gray area exists between cloning embryos and individual human stem cells.[107] The cloning of human embryos solely for the purpose of generating stem cells is called "therapeutic cloning."[108] It is different from reproductive cloning because reproductive cloning involves cloning an embryo that is allowed to develop to term, resulting in a duplicate organism.[109] Although therapeutic cloning does not involve the same, surreal, science-fiction notions as human cloning, many scientists still oppose therapeutic cloning as impractical and overly hindered by ethical debate.[110] For example, the Right to Life Committee condemns the practice as "creating human embryos for the sole purpose of killing them and harvesting their cells."[111] Congress has strictly forbidden the use of any federal money for research involving human embryo cloning.[112]

Other scientists believe that guidelines prohibiting therapeutic cloning will prove too restrictive.[113] During therapeutic cloning, a human embryo is cloned by taking a cell from the body and combining it with a separate egg cell with its

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genes with another cell's genes. Amanda Onion, *Researchers Defend Plans to Clone People—Despite Opposition, Fertility Specialists Say a U.S. Ban Would Be Futile*, ABCNEWS.COM, Aug. 7, 2001, http://abcnews.go.com/sections/scitech/DailyNews/cloninghearing010807.html.

106. Marchione, *supra* note 53, at 1G.

107. This process is already being performed. In November 2001, Advanced Cell Technology, a research company located in Worcester, Massachusetts, announced that it had cloned the first human embryo. Jeff Donn, *Human Embryo Cloning Draws Fire*, OAK RIDGER ONLINE, Nov. 26, 2001, *available at* http://www.oakridger.com/stories/112601/stt_1126010046. html.

108. Xiangzhong "Jerry" Yang & Cindy Tian, *Don't Ban Therapeutic Cloning*, HARTFORD COURANT, Dec. 2, 2001, at C3.

109. *Id*.

110. Marchione, *supra* note 53, at 1G.

111. Donn, *supra* note 107.

112. Consolidated Appropriations Act of 2001, Pub. L. No. 106-554, 114 Stat. 2763, §510(a)(1) (2000).

113. Suzanne Morrison, *New Rules on Stem Cells; Research Permitted on 'Surplus' Human Embryos but Cloning Still Banned*, HAMILTON SPECTATOR, Mar. 5, 2002, at A11.

DNA removed.[114] The resulting embryo contains only the cell donor's genetic material.[115] Scientists believe this embryo could grow stem cells that would be "compatible with the original donor."[116] One purpose of this process would be to make individually customized cells, tissues, or organs that could be implanted into patients.[117] Because the cells would come from an embryo having the patient's own genes, they would not be attacked by the patient's immune system.[118]

III. THE CURRENT STATUS OF THE LAW

A. The United States

In August 2001, President Bush announced his long-awaited decision on federal funding of stem cell research.[119] He decided to allow funding for research on stem cell lines that were already in existence as of August 9, 2001.[120] Further restrictions require that the lines must have been derived: "(1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; [and] (3) without any financial inducements to the donors."[121] Therefore, federal funding will support research using existing qualified embryonic stem cell lines, but will not fund the creation of new stem cell lines or any research performed on those lines.[122] President Bush's rationale was that there were over sixty qualifying genetically diverse stem cell lines,[123] for which the life and death decision had

114. Deborah Cassrels, *Research and Destroy*, COURIER MAIL (Queensland, Australia), Dec. 1, 2001, at 27.

115. *Id*.

116. *Id*.

117. Marchione, *supra* note 53, at 1G; *see also* Komarow, *supra* note 48, at 5A.

118. Komarow, *supra* note 48, at 5A.

119. President Bush Address, *supra* note 45 (providing the full text of Bush's presidential address).

120. *Id.*

121. Fact Sheet, *supra* note 44.

122. Gibbs & Duffy, *supra* note 12, at 14.

123. President Bush Address, *supra* note 45. Many scientists question the existence of sixty-five stem cell lines and whether many are actually viable and who owns the patents. *See* Lacayo, *supra* note 58; *see* Tech Live, *Stem Cell Debate Shifts to Patents: Geron and the University of Wisconsin Hold Patents Over All Approved Stem*

already been made.[124] Additionally, the federal government is also funding research on "umbilical cord, placenta, adult, and animal stem cells."[125]

It is important to note that President Bush's decision does not affect private funding for embryonic stem cell research.[126] Private industry is exempt from President Bush's decision if it does not accept federal funds for its stem cell work.[127] Unfortunately, private funding may not be enough. Biotechnology research requires more capital than other entrepreneurial industries.[128] Furthermore, due to President Bush's decision, "embryonic stem cell research in the private sector is not subject to federal monitoring or ethical requirements."[129] These problems may place the United States in a disparate position internationally.[130]

B. International Laws

1. Great Britain

Great Britain was the first nation to pass a law allowing limited human cloning for the purpose of cloning stem cells from human embryos.[131] The law was passed in January 2001, amending the Human Fertilization and Embryology Act of

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Cells, *at* http://www.techtv.com/news/print/0,23102,3343323,00.html (originally posted Aug. 20, 2001). The intellectual property aspect of stem cell lines is a separate issue that will not be discussed in this Comment.

124. President Bush Address, *supra* note 45.

125. *Id*.

126. *See* Lacayo, *supra* note 58.

127. Arthur Caplan, *Embryonic Cloning Feat Points to Problems with Bush Policy*, *at* http://bioethics.net/msnbc.php?task=view&articleID=530 (posted Nov. 26, 2001).

128. Ralph E. "Chris" Christofferson, *Biotech Needs a Little Coaxing, Colorado Has Plenty to Offer, But Hasn't Put Priority on Providing Financial Incentives*, ROCKY MOUNTAIN NEWS, May 12, 2001, at 2C. "[O]ut-of-pocket costs to develop a new therapeutic agent are at least $100 million per product . . . ." *Id*.

129. Casell, *supra* note 3, at 568.

130. *See infra* Part IV.

131. *After Vigorous Debate Great Britain Becomes First Nation to Legalize Cloning Stem Cells from Human Embryos*, TRANSPLANT NEWS, Jan. 31, 2001 [hereinafter *After Vigorous Debate*].

1990.[132] It passed despite vehement and vocal opposition from religious leaders.[133] After seven hours of debate in Parliament, proponents of the measures prevailed by a vote of 212 to 92.[134] Guarantees that a committee of experts would closely examine ethical and scientific aspects of the issue won over opponents and allowed the victory.[135] It should be noted that human cloning in Great Britain remains illegal.[136] Furthermore, regulations mandate that any embryo involved in stem cell research cannot be used after fourteen days.[137]

Proponents of embryonic stem cell research in Great Britain are enthusiastic about the new law; they believe it will give the country a lead in the field, both academically and commercially.[138] Biotechnology executives believe that, with the funding climate in the United Kingdom, there is substantial venture capital for projects involving stem cell research.[139]

2. Australia

Australia has not passed federal legislation regulating stem cell research.[140] Stem cell research is legal in some parts of the country, but legislation differs throughout the six states and two

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132. *Id*. The Human Fertilisation and Embryology Act contained prohibitions against all human cloning. Greene, *supra* note 94, at 352; Human Fertilisation and Embryology Act, 1990, C.37 (Eng.) The Human Fertilisation and Embryology (Research Purposes), Regulations (2001) SI 2001/188, *available at* http://www.legislation.hmso.gov.uk/si/si2001/20010188.htm.

133. *See After Vigorous Debate, supra* note 131. "Stem-cell supporters have benefited from the relative weakness of the religious right." Romesh Ratnesar et al., *A Better Harvest; Looser Laws Have Helped European Scientists Seize the Lead in Creating Life-Saving Stem-Cell Therapies*, TIME, Aug. 13, 2001, at 42.

134. *After Vigorous Debate, supra* note 131. This came after the order passed through the House of Commons by a majority 2 to 1 vote late last year. *Id*.

135. *Id*.

136. *Id.*

137. *Embryo Cloning Approved in UK*, CHRISTIAN CENTURY, Feb. 19, 2001, at 13.

138. Sylvia Pfeifer, *Britain Takes Lead on Stem Cells*, SUNDAY BUS. (London), Dec. 24, 2000, at 8. (noting that the Wellcome Trust spends between £500 million and £600 million per year on biomedical research).

139. *Id*.

140. *Australia Agrees on National Human Cloning Ban*, TRANSPLANT NEWS, June 15, 2001.

territories.[141] For example, Tasmania,[142] Victoria,[143] Western Australia[144] and South Australia[145] have laws regulating cloning and stem cell research.[146] The Federal Cabinet, faced with a proposal to ban the use of embryo cells, decided the ban would not be appropriate without further consultation.[147]

Australia's national and state governments have jointly agreed to develop uniform legislation that bans human cloning, but allows human stem cell cloning for medical research.[148] The Council of Australian Governments has indicated that it would work toward such national regulations on cloning and stem cell research by June 2002.[149] According to Australian Prime Minister John Howard, health ministers will decide on a national approach to the issue after conferring with scientists, medical researchers, and citizens.[150] The compromise was necessary because federal and state health ministers were unable to reach a consensus on stem cell research.[151]

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141. *World View*, *supra* note 104, at A6.

142. Gene Technology Act., 2001, No. 53 (Tas.), http://www.thelaw.tax.gov.au/fullview/53++2001+GS159@EN+0000000000.

143. Gene Technology Act, 2001, No.67 (Vic.), http://www.dms.dpc.vic.gov.au/sb/2001_Act/A00904.html. A bill is currently pending in the Parliament of Victoria to amend the Gene Technology Act of 2001. Victoria, *Parliamentary Debates*, Legislative Assembly, Feb. 27, 2003, 234–37 (reading Health Legislation (Research Involving Human Embryos & Prohibition of Human Cloning) Bill 2003 (Vic.) (pending)).

144. Human Reproductive Technology Act, 1991, Preamble (W. Austl.), *available at* http://www.slp.wa.gov.au/statutes/swans.nsf/be018944e381736482567bd0008c67c/f74bf1105930945f48256c3d002fb143.

145. Reproductive Technology (Code of Ethical Research Practice) Regs, 1995, pt. 2 (S. Austl.), *available at* http://www.parlaiment.sa.gov.au.

146. Louise Dodson & Darren Gray, *Embryo Ban Hits Research*, THE AGE (Melbourne, Australia), Feb. 26, 2002, at 1. Outside of Victoria, Western Australia, and South Australia, use of surplus embryos from in vitro fertilization is prohibited in Australia because it destroys the embryo. Sean Parnell et al., *Embryo Stem Cell Ban Put On Hold*, COURIER MAIL (Queensland, Australia.), Feb. 27, 2002, at 10.

147. Parnell et al., *supra* note 146, at 10.

148. *Australia Agrees on National Human Cloning Ban*, *supra* note 140.

149. Dodson & Gray, *supra* note 146, at 1.

150. *Australia Agrees on National Human Cloning Ban*, *supra* note 140.

151. *World View*, *supra* note 104, at A6.

3. China

In China, the Ministry of Health officially announced in November 2000, that the Chinese government would allow embryonic stem cell research for treatment and prevention of disease, as long as such research is rational and effectively monitored.[152] However, all human cloning experimentation is strictly forbidden.[153] Many Chinese scientists are urging lawmakers to quickly enact legislation completely banning reproductive cloning to prevent misuse of technology.[154] The sentiment of those scientists, however, is not shared by all,[155] as teams of Chinese scientists have reportedly cloned dozens of human embryos.[156]

The Chinese government has made it clear that it wants its biomedical industry on par with the West.[157] It has established extensive state programs to further that goal, pouring in millions of dollars for research projects.[158]

4. Japan

Biotechnology is particularly controversial in "Japan, a home to virtually all of the world's major religions."[159] Nevertheless, in August 2001, a Japanese Cabinet panel approved strict guidelines for stem cell research.[160] One provision states that "embryonic cells used in research would be taken only from those made for fertility treatment that would

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152. *China Opposes Human Cloning, to Allow Monitored Stem Cell Research*, Xinhua News Agency (Beijing), Nov. 29, 2001, *translated in* BBC WORLDWIDE MONITORING, *available at* LEXIS, News Library, BBCMIR File.

153. *Id.*

154. *Id*.

155. *See* Hugh Dougherty, *China: We've Been Cloning Embryos for Two Years*, PRESS ASS'N (New York), Mar. 6, 2002.

156. *Id*.

157. Cataldo, *supra* note 6, at 160.

158. *Id*.

159. *See* Craig M. Borowski, *Human Cloning Research in Japan: A Study in Science, Culture, Morality and Patent Law*, 9 IND. INT'L & COMP. L. REV. 505, 518, 524 (1999); *see also Research Guidelines Approved in Japan, U.S. President Bush Okays Limited Funding*, BLOOD WKLY., Aug. 23, 2001 [hereinafter *Research Guidelines Approved in Japan*].

160. *Research Guidelines Approved in Japan, supra* note 159.

otherwise be discarded."[161] Like the United States, where federal funding is limited to research involving currently existing cell lines, the Japanese government will not allow the creation of embryos specifically for stem cell research.[162] The guidelines also specifically ban research aimed at finding potential medical applications or any other use of stem cells.[163] The provision means that scientists will only be allowed to conduct basic research.[164]

Additionally, like the United States, the Japanese government has placed a ban on human cloning research.[165] The ban is particularly important because Japanese institutes are leaders in cloning research, regularly cloning cows and other animals on a regular basis.[166]

5. Germany

As in Japan, biotechnology is an extremely controversial topic in Germany.[167] There, the debate has been fueled and shaped by memories of Hitler's Third Reich quest for a pure race and horrific experiments conducted on human beings by Nazi doctors.[168] German President Johannes Rau advises that Germany's history should be considered by everyone involved in modern research regulation, not only in Germany, but throughout the world.[169] Keeping these fears in mind, Germany's government is considering allowing research on embryonic stem

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161. *Id.*

162. *World View*, *supra* note 104, at A6; Gibbs & Duffy, *supra* note 12, at 14.

163. Dennis Normile, *Japan to Allow Stem Cell Research*, SCIENCE NOW (July 31, 2001) *at* http://bric.postech.ac.kr/science/97now/01_7now/010731a.html.

164. *See id.*

165. *World View*, *supra* note 104, at A6.

166. *Research Guidelines Approved in Japan*, *supra* note 159.

167. *Schroeder Tells German Parliament to Back Embryo Stem Cell Imports*, DEUTSCHE PRESSE-AGENTUR (Berlin), Jan. 29, 2002 (calling embryonic stem cell research a "highly emotional" issue), *available at* LEXIS, News Library, DPA File.

168. *See* Guy Raz, *Debate in Germany's Government Whether to Allow Research on Stem Cells from Human Embryos*, Statements on National Public Radio, Aug. 1, 2001, *at* http://nl.newbank.com.

169. *Germany Allows Import of Embryonic Stem Cells*, BLOOD WKLY, June 28, 2001, at 9–10.

cells.[170] German officials have indicated that the country's ultimate decision could be influenced by the direction taken by the United States.[171]

Currently, German law restricts laboratory use of embryos to in vitro fertilization.[172] Any embryos not implanted in a womb must be either discarded or frozen for later use.[173] Specifically, Germany's 1949 constitution effectively bans embryonic stem cell research by protecting human embryos from harm.[174] It is unclear, however, whether it is a violation to conduct research on embryonic stem cells imported from other countries.[175] Wolfgang Clement, Governor of North Rhine-Westphalia, Germany, has allowed stem cell research on embryonic stem cells imported from Israel.[176] His rationale is that no embryos are actually destroyed in Germany.[177] "[O]nly the frozen stem cells will be brought into the country. Under the German constitution, only embryos, not the stem cells, are protected."[178]

6. Canada

While Canada has not passed legislation regulating cloning or stem cell research, the federally financed Canadian Institutes for Health Research (CIHR) has proposed regulations that would provide public financing for stem cell research.[179] Scientists will be allowed to use leftover embryos from fertility clinics if the donor couples involved give their consent.[180] Under

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170. *See* Raz*, supra* note 168.

171. Komarow, *supra* note 48, at 5A.

172. *Id*.

173. *Id*.

174. Raz*, supra* note 168.

175. *Schroeder tells German Parliament to Back Embryo Stem Cell Imports*, *supra* note 167 (indicating that while German law is clear on its protection of the embryo, it is silent on the import of embryo stem cells).

176. *Germany Allows Import of Embryonic Stem Cells*, *supra* note 169, at 9–10.

177. Raz, *supra* note 168.

178. *Id*.

179. *Canada Takes Middle Path on Stem-Cell Study*, N.Y. TIMES, Mar. 5, 2002, at A5.

180. Suzanne Morrison, *New Rules on Stem Cells; Research Permitted on 'Surplus' Human Embryos but Cloning Still Banned*, HAMILTON SPECTATOR, Mar. 5, 2002, at A11.

the proposed regulations, scientists would be prohibited from creating embryos solely for research purposes.[181] Cloning of human embryos would also be banned.[182]

Until the Canadian Parliament passes legislation regarding stem cell research, the proposed regulations will serve as guidelines for CIHR financing of research projects.[183] While lengthy parliamentary hearings and debates are expected to result from the proposed regulations, regulation may ultimately be left to the CIHR.[184]

7. Israel

Currently, there is no law regulating stem cell research in Israel; however, in 1999, the Knesset passed the Anti-Genetic Intervention Law, prohibiting human cloning for five years.[185]

8. Singapore

In Singapore, there is currently no stem cell research legislation; however, scientists working with stem cells welcome proposed regulations based on the recommendations of the Bioethics Advisory Committee.[186] The proposed recommendations ban human cloning, but do not address the possibility of creating embryos to harvest stem cells.[187] The proposals would also require stem cells be taken only from embryos less than fourteen days old, where organs have not begun development.[188]

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181. *Canada Takes Middle Path on Stem-Cell Study*, *supra* note 179, at A5.

182. Morrison, *supra* note 180, at A11.

183. *Canada Bans Embryonic Cloning, but Allows Research on Fetal Stem Cells*, AGENCE FRANCE PRESSE, Mar. 4, 2002, *available at* LEXIS, News Library, AFP File.

184. *Id*.

185. Gilbert, *supra* note 104; World View, *supra* note 104, at A6.

186. Chan Kay Min, *Stat Board Right Move; Stem-Cell Researchers*, STRAITS TIMES (Singapore), Jan. 14, 2002, at H8.

187. *Id*.

188. *Id*.

9. Other Countries

Stem cell research in India is conducted quietly and with little opposition.[189] There are currently no laws there prohibiting such research.[190] The Indian Department of Biotechnology recently approved a program for stem cell research and "hopes that a significant amount of funding is available for this purpose in the next five-year plan."[191] In contrast, "Brazil, like much of Latin America, prohibits embryonic stem cell research."[192] In Finland, research is permitted on embryos leftover from fertility treatments; however, embryos cannot be created solely for research purposes.[193] In Taiwan, the government has banned human cloning, but is likely to allow limited embryonic stem cell research.[194]

IV. THE CURRENT STATE OF STEM CELL REGULATION IN THE UNITED STATES POSES PROBLEMS WITHIN THE COUNTRY AND FOR THE COUNTRY ON AN INTERNATIONAL BASIS

The disparities among the laws of the various countries could have a profound impact on embryonic stem cell research, particularly in the United States. Specifically, the rigidity of the current U.S. policy may cost the United States its best and brightest researchers as well as its grip on a newly developing industry that promises new life to a sagging economy. Additionally, the lack of federal regulations governing stem cell research may create disparities among the states. Finally, without adequate federal uniformity and international uniformity in regulation of embryonic stem cell research, there is a potential for abuse. Creating solutions to these problems requires immediate action by the U.S. government.

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189. *The Stem Cell Debate, supra* note 32, at F4.

190. *Id*.

191. *Stem Cells and Ethics*, HINDU (INDIA), Aug. 16, 2001, *available at* http://www.hinduonnet.com/thehindu/2001/08/16/stories/05162512.htm.

192. *The Stem Cell Debate, supra* note 32, at F4.

193. *Different Stances in Law*, TIMES HIGHER EDUC. SUPP., Mar. 8, 2002, at 14.

194. *Id*.

A. The Disparities Between Countries in Stem Cell Laws Could Put the United States at a Technological and Economic Disadvantage

Although the biotechnology industry has noble goals, it is profit driven.[195] Today, science is a global endeavor.[196] Thus, if the United States attempts to impede research in the name of theology, it will only move the research, and the accompanying technological and economic benefits, elsewhere.[198] Indeed, the possible benefits of stem cell research may completely transform health care and stimulate economic growth in the process.[199] The catch, unfortunately for the United States, is that those benefits will accrue to the countries "where the policies and funding encourage, rather than hobble, the stem cell enterprise."[200] Any attempt to stifle stem cell research could be devastating to this country, where the world's best and brightest have traditionally been drawn by U.S. research universities and corporations.[201]

Some academic scientists and researchers are already forced to conduct their stem cell work off-campus because schools want to ensure that their federal funding does not pay for "even one piece of paper associated with stem cell work."[202] This problem, and others experienced by researchers in the United States, indicates that researchers may conduct their work in a more hospitable environment.[203] Biotechnology requires billions of dollars for research, experimentation, and clinical trials.[204] Haile Debas, M.D., dean of the University of California at San

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195. Pennisi, *supra* note 20, at 749.

196. Robert Kuttner, *A Global Market Isn't as Easy as it Looks*, BUS. WK., Sept. 3, 2001, at 26.

197. *Id*.

198. *See id*.

199. *Following Bush Decision, US Stem Cell Patient Battle Begins, UK Set to Benefit?,* MARKETLETTER, Aug. 20, 2001, *available at* 2001 WL 9080233 [hereinafter *Following Bush Decision*].

200. *Id*.

201. Kuttner, *supra* note 196, at 26.

202. *US Stem Cell Researcher Defects to Britain to Continue Work with Public Support*, TRANSPLANT NEWS, July 27, 2001, *available at* 2001 WL 12314039 [hereinafter *US Stem Cell Researcher Defects*].

203. *Following Bush Decision, supra* note 199.

204. Cassrels, *supra* note 114, at 27.

Francisco School of Medicine stated that "[i]f federal support for stem cell research is not forthcoming, the risk exists that talented scientists will leave academic centers to seek opportunities in the private sector or even overseas."[205] This prospect is not a far-off risk. For example Roger Pedersen of the University of California at San Francisco, one of the leaders in U.S. stem cell research,[206] recently announced his plans to relocate to Cambridge University located in Britain.[207] He decided to move to Cambridge mainly "because of his increasing frustration at the prospects for public funding in the USA."[208] It appears that the result of President Bush's decision will not reflect his desire to save the "life" of the embryo where the life and death decision was not made prior to August 9, 2001.[209] His decision will simply drive the science to other countries.[210]

The locus of scientific development related to embryonic stem cell research seems to have jumped "the pond." Based on the disparities between U.S. and foreign laws, the environment in Europe is more welcoming to those interested in embryonic stem cell research.[211] Great Britain, particularly, with no restrictions on stem cell research has a far more encouraging environment than the United States.[212]

President Bush's decision will not affect just academic researchers. Specifically, one consequence of the decision will be that nearly all new stem cell research is proprietary.[213] This reality means that researchers wanting to use newly developed technologies and stem cell lines other than those qualifying for federal funding will be forced to license them from patent holders.[214] This will slow research, making it more costly. This is

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205. *US Stem Cell Researcher Defects*, *supra* note 202.
206. Kuttner, *supra* note 196, at 26.
207. *Following Bush Decision*, *supra* note 199.
208. *Id*.
209. *See* Begley et al., *supra* note 16, at 16.
210. Kuttner, *supra* note 196, at 26.
211. Ratnesar et al., *supra* note 133, at 42.
212. Kuttner, *supra* note 196, at 26.
213. *Id*.
214. *Id*.
215. *Id*.

in stark contrast to the environment in Great Britain, where stem cell research is publicly funded and will be made widely available, lowering the cost of research.[216]

One method Great Britain can use to attract researchers and scientists is the country's plans for the world's first embryonic stem cell bank.[217] The bank will store master stem cells.[218] As of 2001, the British hoped to have the bank operational "in about a year. . . ."[219]

It is no secret that U.S. law on stem cell research will give Great Britain, and possibly other countries, a huge technological and economic advantage over the United States.[220] It appears to be widely anticipated by members of the relevant scientific communities abroad.[221] There have been reports of "giddy talk of an influx of American brainpower and investment if the U.S. enforces stringent stem-cell rules."[222] For example, Trevor Jones, chairman of a British biopharmaceutical company, believes that a U.S. ban on therapeutic cloning, combined with President Bush's new restrictions on federal funding of embryonic stem cell research "will benefit [Great Britain's] academic research base in the stem cell field."[223] "[Great Britain] is going to be a more secure environment in which to conduct most areas of embryo research," adds Simon Best, chief executive of Ardana Biosciences in Edinburgh.[224] Best reports that he has taken calls from four U.S. companies seeking advice on how to go about conducting their research in Great Britain.[225] He believes "[t]here's going to be a lot of attraction for U.S. companies and

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216. *See Following Bush Decision*, *supra* note 199.

217. *Id*.

218. *Id*.

219. *Id.* According to two London-based newspapers, published in 2002, the British were still hoping to open the stem cell banks "within a year." *See* Jeremy Laurance, *Stem Cell Bank Will be Open Within a Year*, INDEP. (London), Sept. 10, 2002, at 2; Mark Henderson, *Stem Cell Scientists Given Pounds 40M Boost*, TIMES (London), Dec. 10, 2002, at 12.

220. *See* Ratnesar et al., *supra* note 133, at 42.

221. *Id*.

222. *Id*.

223. *Following Bush Decision*, *supra* note 199.

224. *US Stem Cell Researcher Defects*, *supra* note 202.

225. *Id*.

academics to see if they could and should do more work here."[226]

However, the prospect of losing some of the best scientific community members is not solely a U.S. fear. German companies, subject to regulations even more onerous than U.S. regulations, have expressed concerns over British competition.[227]

Any loss of technological advantages may be followed by economic losses, particularly in the biotechnology field.[228] Biotechnology's costs, product development time, and risks differentiate it from other entrepreneurial industries.[229] Because of these characteristics, substantial investments are required over long periods of time before benefits are fully realized.[230] However, those who make such investments "will reap major long-term economic benefits and advantages."[231]

B. Lack of Uniform Regulations in the United States and the International Community Corresponds to a Loss of Ethical Oversight of Stem Cell Research

While the disparity among the laws of various nations portends technological and economic consequences for the United States, an even more frightening prospect is that without uniform international regulation of embryonic stem cell research, there is potential for abuse.[232] Because President Bush's decision only affects federally funded research projects, private funding of projects involving embryonic stem cell research is left untouched.[235] This situation opens the door for biotechnology corporations.[236] Unencumbered by federal monitoring or ethical requirements,[237]scientists wishing to

226. Ratnesar et al., *supra* note 133, at 42.
227. Komarow, *supra* note 48, at 5A.
228. *See* Christofferson, *supra* note 128, at 2C.
229. *Id*.
230. *Id*.
231. *Id.*
232. *See* Cassrels, *supra* note 114, at 27.
233. *See* Gibbs & Duffy, *supra* note 12, at 14.
234. Casell, *supra* note 3, at 568.
235. *See* Gibbs & Duffy, *supra* note 12, at 14.
236. Green, *supra* note 90, at 243.
237. Casell, *supra* note 3, at 568.

bypass federal regulations may turn to venture capital for funding.[238]

An extreme example of private unregulated research is Panos Zavos, U.S. fertility specialist, and Severino Antinori, Italian cloning researcher.[239] The two researchers "plan to impregnate up to 200 women volunteers with cloned embryos . . . in an undisclosed Mediterranean nation."[240]

More benign examples include Geron Corp in Menlo Park, California, and Advanced Cell Technology in Worcester, Massachusetts, two U.S. companies that are privately funding embryonic stem cell research and are making impressive progress.[242] The work of each company may be ethically questionable.[243] Each company has gone to great lengths to assure the public "that there was ethical oversight of its work."[244] Geron, for example, formed its own review board for the sole purpose of establishing ethical research guidelines for the corporation.[245] While the formation of such a board is admirable, it must be remembered that Geron is under no obligation to abide by the guidelines.[246] Even more important, other research corporations continue to work without the guidance of an ethical review board.[247] There is no doubt that commercial interest in embryonic stem cell research will continue to flourish, considering the rate of scientific development[248] and President Bush's decision to withhold federal funding for this research "means a corresponding loss of federal ethical oversight."[250]

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238. Green, *supra* note 90, at 243–44.

239. Cassrels, *supra* note 114.

240. *Id*.

241. Casell, *supra* note 3, at 568.

242. Green, *supra* note 90, at 243–44.

243. *See id*. (discussing the corporations' experiments such as the creation of transgenic embryos—the insertion of the nuclei of human somatic cells into enucleated cow cells).

244. *Id.* at 244.

245. *Id*.

246. *Id*.

247. *Id*.

248. *Id*.

249. *Id*.

250. *Id*.

C. *Lack of Federal Legislation Creates Disparities Between State Laws Within the United States.*

Fear of ethical abuses of stem cell research domestically and internationally will persist.[251] However, ethical considerations are not the only problem with the lack of federal legislation. Specifically, without such legislation, individual states may regulate stem cell research.[252] Consequently, the current disparities among countries also may arise among the states. Several states have already enacted legislation regarding stem cell research prohibiting experimentation on embryos outside the womb.[253] These states include Louisiana, Maine, Massachusetts, Michigan, Minnesota, Pennsylvania, Rhode Island, and Utah.[254] In Wisconsin, legislation has been introduced that would completely outlaw embryonic stem cell research.[255] Andrew Cohn, spokesman for the Wisconsin Alumni Research Foundation, argues that legislation making it a felony to conduct embryonic stem cell research will hurt the university in "retaining faculty, . . . encouraging businesses to get involved in stem cell research, and hurt[ing] the progress of making discoveries to cure some of the world's most devastating diseases."[256]

D. *Solving the Potential Problems Involves Immediate Action by the U.S. Government*

One step the U.S. government can take to ensure uniform stem cell research laws is to assist in the creation of an international regulatory board with authority to enforce internationally agreed-upon guidelines.[257] Without such a regulatory body, the potential for unethical use of new

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251. Green, *supra* note 90, at 241.

252. *Id*.

253. *On Human Embryos and Medical Research*, *supra* note 10, at 263–64.

254. *Id*.

255. Dennis Chaptman and Marilynn Marchione, *Bill Would Ban Some Stem Cell Studies; 2 Legislators Push to Outlaw Embryonic Cell Work; UW Official Criticizes Idea*, MILWAUKEE J. SENTINEL, Dec. 12, 2001, at 1B.

256. *Id*. (quoting Andrew Cohn discussing the proposed legislation).

257. *See* Greene, *supra* note 94, at 362.

technology is inevitable.[258]

Other countries have openly expressed eagerness to adhere to an international policy in lieu of creating their own.[259] The United States must support the formation of a regulatory body to oversee such policies for several reasons.[260] First, The United States has the largest biotechnology industry, and is traditionally a world leader in the field.[261] Second, the U.S. government has extensive experience fostering cooperation on global security matters.[262] Third, the United States has the credibility to be a leader in global biotechnology policy.[263]

Before the United States can assist in the formation of an international regulatory body, however, it must enact legislation to uniformly regulate research domestically. Without national regulation, disparities among the states will parallel current disparities among nations.[265] In the absence of federal action, some states have enacted state laws to fill this void.[266] The hour is near for the federal government to step in and pre-empt the states.[267]

V. CONCLUSION

Preliminary indications suggest that embryonic stem cell research may hold the key to treating millions of people across the world who are suffering and dying. The U.S. government must expand the federal funding guidelines set forth in President Bush's address. The United States will be technologically and economically disadvantaged if its laws do not allow and encourage scientists to fully explore the potential of stem cell research.[268] The United States cannot afford to lose

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258. Cassrels, *supra* note 114.
259. *Id*.; *see also*, Komarow, *supra* note 48.
260. Greene, *supra* note 94, at 362.
261. *Id*. at 361.
262. *Id*.
263. *Id.*
264. *Id*.; *see* Komarow, *supra* note 48.
265. *See On Human Embryos and Medical Research*, *supra* note 10, at 263–64.
266. *Id*.
267. *See id*.
268. *US Stem Cell Researcher Defects to Britain to Continue Work with Public*

its best scientists and researchers to other countries that will not only allow, but also encourage and fund their research. President Bush acknowledged that

> [f]ederal dollars help attract the best and brightest scientists. . . . The United States has a long and proud record of leading the world toward advances in science and medicine that improve human life. And the United States has a long and proud record of upholding the highest standards of ethics as we expand the limits of science and knowledge.[269]

Although the United States can retain her scientists and maintain her stature as the world leader in biotechnology by offering encouragement to her scientists and researchers; she should not lose sight of the greater goal: encouraging successful research to save and improve human lives. Additionally, the United States must take a leading role to ensure that embryonic stem cell research is conducted ethically, both domestically and abroad. This must be effectuated by harmonizing domestic legislation with the rest of the world.

Although the debate about when "life begins" continues, it is more important than ever to realize that it is not only the life of the embryo that must be considered; consideration must also be given to those already living. Consider the emotional wording of a sign displayed by one woman campaigning outside the U.S. Capitol: "Stem Cell Research IS Pro Life—My daughter's life!"[270]

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Support, *supra* note 202; *Following Bush Decision*, *supra* note 199.

269. President Bush Address, *supra* note 45.

270. Lacayo, *supra* note 58, at 18.

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