

# THE NEED FOR A NEW U.S. STEM CELL RESEARCH POLICY: A COMPARATIVE LOOK AT INTERNATIONAL STEM CELL RESEARCH LAWS

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## I. INTRODUCTION

On July 19, 2006, President Bush used his veto power for the first time since taking office, rejecting Congress's attempt to lift funding restrictions on human embryonic stem cell research.<sup>1</sup> This thwarted efforts to reverse the current policy that severely restricts federal funding for embryonic stem cell research and only allows funding for research on stem cell lines created before the ban.<sup>2</sup> The news killed the hopes of millions of Americans suffering from debilitating diseases and hoping for a cure derived from embryonic stem cell research. During a hearing before the Subcommittee on Labor, Health and Human Services, James Cordy, founder of the Parkinson's Alliance, sat holding up an hourglass.<sup>3</sup> He stated:

I use this hourglass . . . to make two points: first to help those who do not have Parkinson's [to] appreciate the relentless and ruthless progression of this disease . . . Second this hourglass also reminds everyone that we who have Parkinson's as well as many other diseases are in a race against time.<sup>4</sup>

However, while President Bush's veto was devastating to supporters of stem cell research, it was good news for other countries attempting to overtake the United States' leadership role in the biotechnology industry.<sup>5</sup>

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1. Charles Babington, *Stem Cell Bill Gets Bush's First Veto*, WASH. POST, July 20, 2006, at A1.

2. JUDITH A. JOHNSON & ERIN WILLIAMS, CRS REPORT FOR CONGRESS: STEM CELL RESEARCH 2 (2004).

3. *Federal Funding for Stem Cell Research: Hearing Before the Subcomm. on Appropriations*, 108th Cong. 29-30 (2003) [hereinafter *Hearing*] (statement of James Cordy, Founder, Parkinson's Alliance).

4. *Id.* at 29-30.

5. *Id.* at 25 (statement of Dr. Roy Ogle) ("I want to reiterate the comment on our comparative disadvantage with other countries where they have more cell lines. It is clear that we are constrained in ways that other scientists in Europe and Asia are not. I know for a fact that China is making embryonic stem cell

This Recent Development compares the United States' restrictive policy on stem cell research with the moderate but well-functioning regulation of this same research in the United Kingdom and the permissive policy for stem cell research in China. The general policies of the European Union and Latin America are also considered, and the United Nations' failed attempt to create a unified international treaty regarding stem cell research is discussed. This Recent Development then describes the economic importance of stem cell research in the United States and advocates a more flexible federal policy as well as international guidelines. Finally, this Recent Development proposes using the United Nations as a platform for the creation of an international treaty on stem cell research and insists that the United States play an active role in the formation of this legislation.

Part II gives a background of stem cell research and the ethical issues implicated. Part III compares the federal and state regulation of stem cell research in the United States with that in the United Nations and China. Part IV describes the European Union's policy and the general trends in Latin America. Part V explains the United Nations' attempt to create an international treaty on stem cell research. Part VI discusses the economics of stem cell research. Part VII recommends that the United States play an active role in drafting international legislation relating to stem cell research, and suggests that the United Nations is the most fitting platform for this type of endeavor.

## II. THE SCIENCE, ETHICS, AND PURPOSE OF STEM CELL RESEARCH

Scientists believe that stem cell research may help to develop new treatments for the most serious diseases and radically transform the way human disease is treated and cured. Stem cells have three main characteristics: (1) they can renew themselves through cell division; (2) they are unspecialized; and (3) they can become specialized to perform specific functions.<sup>6</sup> The two main types of stem cells are adult and embryonic.<sup>7</sup> Because arguments offered against the use of embryonic stem cells cite the use of adult stem cells as an alternative,<sup>8</sup> the differences between the two should be highlighted.

Embryonic stem cells can form any cell in the body.<sup>9</sup> They maintain their plasticity, change shape to place themselves in the correct location, and they are capable of integrating and growing in new surroundings.<sup>10</sup> These types of

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research the cornerstone of their biotech industry . . . . So we need to keep up in this area. We need to be the leaders.").

6. University of Michigan Comprehensive Cancer Center, Cancer Stem Cells Research, [http://www.cancer.med.umich.edu/research/stem\\_cells\\_research.shtml](http://www.cancer.med.umich.edu/research/stem_cells_research.shtml) (last visited Nov. 14, 2007).

7. *Id.*

8. Christine Vestal, *Embryonic Stem Cell Research Divides States*, STATELINE.ORG, June 21, 2007, <http://www.stateline.org/live/details/story?contentId=218416>.

9. Heather Fowler, *Misapplied Ethical Considerations: U.S. Federal Stem Cell Mandates Lack Global Focus and Market Foresight*, 36 CORNELL INT'L L.J. 521, 526 (2004).

10. Denise Stevens, *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*, 25

cells are also less immunogenic than adult stem cells, which makes them less likely to be rejected by the human body.<sup>11</sup> Embryonic stem cells are self-renewing and can repopulate themselves in an undifferentiated state.<sup>12</sup> Embryonic stem are harvested from various sources, including: (1) human fetal tissue after an abortion; (2) excess embryos created for *in vitro* fertilization that are left over and voluntarily donated; (3) embryos created through *in vitro* fertilization for the sole purpose of medical research; and (4) human embryos created through somatic cell nuclear transfer where an adult human cell nucleus is moved into an enucleated human egg.<sup>13</sup> This last technique is also called therapeutic cloning.<sup>14</sup> In contrast, adult stem cells are found in adult tissues but do not exist for all tissues.<sup>15</sup> They are also more difficult than embryonic stem cells to isolate and purify and can only divide a limited number of times.<sup>16</sup> Furthermore, each adult stem cell is specialized for a certain tissue and has the limited ability to form a cell type for that specific tissue only.<sup>17</sup> Finally, adult stem cells cannot maintain long-term, self-renewing capacities.<sup>18</sup>

Ethical issues arise from the fact that when stem cells are extracted from an embryo, that embryo is destroyed. For many religious organizations human life begins at conception, and there is no acceptable reason for taking such a life.<sup>19</sup> For others, an embryo should be accorded moral weight.<sup>20</sup> This moral weight, however, should be weighed against the prospect of saving, prolonging, or improving others' lives.<sup>21</sup> Proponents of stem cell research argue that it is preferable to use embryos that cannot develop or grow beyond a certain stage, or that will be discarded unless they are used for research.<sup>22</sup> In addition, a debate exists over whether embryos should be cloned solely for the purpose of research. Opponents of therapeutic cloning argue that even if extra embryos created for reproductive purposes should be used for stem cell research, embryos should never be created through somatic cell nuclear transfer for that purpose.<sup>23</sup>

Stem cell research has the potential to help cure millions of people with many different diseases. This groundbreaking research could provide insight

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HOUS. J. INT'L L. 623, 632 (2003).

11. *Id.*

12. Fowler, *supra* note 9, at 526.

13. *Id.* at 527-31.

14. *Id.* at 527.

15. Stevens, *supra* note 10, at 632.

16. *Id.*

17. Fowler, *supra* note 9, at 526.

18. *Id.*

19. JOHNSON & WILLIAMS, *supra* note 2, at 26.

20. *See id.* (stating that "moral weight" falls below the level of human life).

21. *Id.*

22. Embryonic Stem Cells: Research at the University of Wisconsin-Madison, [http://www.news.wisc.edu/packages/stemcells/bac\\_report2.html](http://www.news.wisc.edu/packages/stemcells/bac_report2.html) (last visited Jan. 8, 2008); *see id.* (reasoning that there are an estimated 400,000 leftover embryos created for *in vitro* fertilization stored at fertility banks that can be either used for stem cell research or discarded).

23. *See* JOHNSON & WILLIAMS, *supra* note 2, at 2 (stating that there is a middle ground between using leftover embryos and creating embryos solely for research purposes).

into the causes of birth defects, genetic abnormalities, and other diseases. Stem cells can be used to produce large quantities of cells for the testing of new drugs,<sup>24</sup> which would be safer than the current practice of testing on human subjects. In addition, they can be transplanted into the body to cure diseases, such as diabetes and Parkinson's disease, and to heal injuries, such as those involving the spinal cord.<sup>25</sup> Furthermore, stem cells could be used to treat the damage caused by the side effects of medical procedures like chemotherapy.<sup>26</sup>

The cost-saving effects of these potential treatments would be enormous. Parkinson's disease costs the United States \$6 billion annually, while strokes cost \$45 billion, spinal cord injuries \$10 billion, epilepsy \$3 billion, Alzheimer's \$100 billion, and multiple sclerosis \$10 billion per year. Cardiovascular disease costs the United States a whopping \$325 billion annually.<sup>27</sup>

### III. COMPARING POLICIES WORLDWIDE

The United States' policy regarding stem cell research is one of the most restrictive among industrialized countries. The United Kingdom employs moderate stem cell legislation. China's policy is one of the least restrictive in the world.

#### A. *United States' Stem Cell Policy*

##### 1. *Federal Policy*

Before 2001, no federal funds had been used for stem cell research on cells derived from either human embryos or fetal tissue.<sup>28</sup> Since 1997, the Dickey Amendment has prohibited the Department of Health and Human Services ("HHS") from funding the creation of human embryos for research purposes or research in which human embryos are destroyed.<sup>29</sup> After human embryonic stem cells were derived in 1998, the National Institute of Health ("NIH") requested a legal opinion from the HHS on whether federal funds could be used to support embryonic stem cell research or whether the Dickey Amendment prohibited such use.<sup>30</sup>

In 1999, the HHS found that embryonic stem cells did not fall under the

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24. *Id.* at 5.

25. *Id.* at 2.

26. *Id.* at 2-3.

27. ROBERT LANZA, PRIVATE V. PUBLIC FUNDING OF STEM CELL RESEARCH: A PERSONAL LOOK AT WHAT IT REALLY MEANS 5 (Mar. 9, 2005), available at [http://www.aei.org/docLib/20050309\\_Lanza.pdf](http://www.aei.org/docLib/20050309_Lanza.pdf).

28. JOHNSON & WILLIAMS, *supra* note 2, at 3.

29. *Id.* The Dickey Amendment prohibits funds from being used in research that creates human embryos, and in research where human embryos are harmed or face the risk of being harmed. KU Medical Center, Stem Cell Research 101, <http://www.kumc.edu/stemcell/toolkit4.html> (last visited Mar. 8, 2008).

30. KU Medical Center, *supra* note 29.

Dickey Amendment because “such cells are not a human embryo within the statutory definition.”<sup>31</sup> An embryo is defined as an organism that when implanted in the uterus is capable of becoming a human being.<sup>32</sup> A stem cell cannot become a human being, even if transferred into the uterus.<sup>33</sup> After this decision by the HHS, the NIH disclosed that it planned to fund research using stem cells once appropriate guidelines were created.<sup>34</sup> These guidelines were later published in the Federal Register, and permitted federal funds to be used only if the cells were derived from human embryos that were created for the purposes of fertility treatment and were in excess of clinical need.<sup>35</sup> The NIH also prohibited funding for the following areas:

(1) research in which human stem cells are utilized to create or contribute to a human embryo; (2) research in which human stem cells are combined with an animal embryo; (3) research in which human stem cells are used for reproductive cloning of a human; (4) research in which human stem cells are *derived* using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; (5) research *utilizing* human stem cells that were derived using somatic cell nuclear transfer; and (6) research utilizing stem cells that were derived from human embryos created for research purposes, rather than for infertility treatment.<sup>36</sup>

However, on August 9, 2001, President Bush announced that federal funds would only be used to support research using existing stem cell lines where the life and death decision had already been made.<sup>37</sup> The federal government would support research involving stem cells from sources such as umbilical cord blood, placentas, and adult and animal tissues.<sup>38</sup> Existing stem cell lines were cleared for funding if they were: “derived (1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducement to the donors.”<sup>39</sup> Under these constraints, only twenty-one of the original seventy-eight human embryonic stem cell lines were eligible for federal funding.<sup>40</sup>

Stem cells are also regulated to a certain degree by various federal agencies, most notably the NIH and the Food and Drug Administration.<sup>41</sup> The Food and Drug Administration—which ensures the safety and efficacy of food, drugs, medical devices and cosmetics—regulates stem cell research aimed at the development of any “product” subject to its approval.<sup>42</sup> The NIH, the

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31. JOHNSON & WILLIAMS, *supra* note 2, at 4.

32. KU Medical Center, *supra* note 29.

33. JOHNSON & WILLIAMS, *supra* note 2, at 4.

34. *Id.*

35. *Id.* at 4-5.

36. *Id.* at 5.

37. KU Medical Center, *supra* note 29.

38. JOHNSON & WILLIAMS, *supra* note 2, at 6.

39. *Id.*

40. *Id.* at 8.

41. *Id.* at 6-7.

42. Dina Gould Halme & David A. Kessler, *FDA Regulation of Stem-Cell-Based Therapies*, 355 NEW ENG. J. MED. 1730, 1730-35 (2006), available at <http://content.nejm.org/cgi/content/full/355/16/1730>.

medical and behavioral research agency within the HHS, regulates stem cell research that it funds in compliance with President Bush's 2001 policy.<sup>43</sup> To do so, the NIH has created a Human Embryonic Stem Cell Registry that lists the human embryonic stem cell lines that meet the eligibility criteria as outlined in the Bush Administration's stem cell policy.<sup>44</sup> There is also a slight trend toward self-regulation. The American Society for Reproductive Medicine and the Society for Assisted Reproductive Technologies have both promulgated guidelines for stem cell research.<sup>45</sup> However, oversight is lacking due to the groups' limited ability to monitor and enforce compliance rules.

## 2. State Policies

The ban on federal funding does not prevent state funding of embryonic stem cell research.<sup>46</sup> States are allowed to create their own legislation and regulation regarding such research.<sup>47</sup> For example, Nebraska prohibits state funding for stem cell research.<sup>48</sup> Kansas restricts its funding to exclude research that would be contrary to federal law.<sup>49</sup> South Dakota prohibits all "nontherapeutic research that destroys a human embryo."<sup>50</sup> Louisiana is the most restrictive because it prohibits the intentional use and destruction of embryos under any circumstances.<sup>51</sup> Louisiana's stem cell research statute also defines an embryo not implanted in a woman's uterus as a "juridical person."<sup>52</sup>

Other states, such as California, Illinois, New Jersey, and Wisconsin, have proposed or committed large amounts of state funds to encourage stem cell research. California has the most ambitious stem cell funding program.<sup>53</sup> California supports embryonic stem cell research through Proposition 71, which commits \$3 billion dollars in research funding to be distributed in increments of approximately \$300 million over ten years.<sup>54</sup> Proposition 71 was approved by voters on November 2, 2004 and established a state

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43. JOHNSON & WILLIAMS, *supra* note 2, at 7.

44. *Id.*; NIH Human Embryonic Stem Cell Registry, <http://stemcells.nih.gov/research/registry> (last visited Nov. 12, 2007).

45. NATHAN BEAVER & MATTHEW MULKEEN, UNDER THE MICROSCOPE: THE INTERNATIONAL BUSINESS AND LEGAL ISSUES SURROUNDING THE STEM CELL INITIATIVE 18 (Sept. 8 2005), [http://www.foley.com/files/tbl\\_s31Publications/FileUpload137/2919/stem%20Cell%20Presentation%20-%20BioJapan2005%20\(2\).pdf](http://www.foley.com/files/tbl_s31Publications/FileUpload137/2919/stem%20Cell%20Presentation%20-%20BioJapan2005%20(2).pdf); ASRM, Ethical Considerations of Assisted Reproductive Technologies, <http://www.asrm.org/Media/Ethics/ethicsmain.html> (last visited Nov. 12, 2007).

46. See JOHNSON & WILLIAMS, *supra* note 2, at 13 (asserting that state decisions regarding funding of stem cell research are independent from federal decisions denying funding).

47. *Id.*

48. NEB. REV. STAT. § 71-7606 (2007).

49. JOHNSON & WILLIAMS, *supra* note 2, at 13.

50. S.D. CODIFIED LAWS § 34-14-16 (2007).

51. Allison Newhart, *The Intersection of Law and Medicine: The Case for Providing Federal Funding for Embryonic Stem Cell Research*, 49 VILL. L. REV. 329, 340 (2004).

52. LA. REV. STAT. ANN. § 9:129 (2007).

53. Sara Beardsley, *A World of Approaches to Stem Cells*, SCI. AM., June 27, 2005, <http://sciam.com/article.cfm?articleID=00086741-2DB7-12BC-ADB783414B7F014C>.

54. *Id.*

constitutional right to pursue embryonic stem cell research.<sup>55</sup> It allows somatic cell nuclear transfer (therapeutic cloning) but prohibits human reproductive cloning.<sup>56</sup>

In February of 2007, the California Institute for Regenerative Medicine (“California Institute”) became the United States’ largest financial backer of stem cell research by granting approximately \$45 million to about twenty state universities and nonprofit research laboratories for such research.<sup>57</sup> This far outdid the national government’s annual contribution of approximately \$25 million.<sup>58</sup> In March, the California Institute donated another \$80 million in research grants to established stem cell scientists.<sup>59</sup>

### B. United Kingdom’s Stem Cell Policy

The United Kingdom is one of the few countries that has introduced specific legislation enabling the use of human embryos for stem cell research.<sup>60</sup> The United Kingdom’s system of regulations operates under the Human Fertilisation and Embryology Act (“HFE Act”), which was passed in 1990.<sup>61</sup> The HFE Act established a seventeen-member Human Fertilisation and Embryology Authority appointed by the Minister for Health.<sup>62</sup> The group is charged with granting and maintaining licenses authorizing embryonic research by both public and private entities.<sup>63</sup> The use of embryos must be necessary for the research, and the research must be necessary or desirable and consistent with prescribed purposes.<sup>64</sup> Furthermore, the HFE Act permits therapeutic cloning but prohibits the use of embryos after the appearance of the primitive streak (normally after fourteen days).<sup>65</sup> Embryos created *in vitro* can be used with the consent of each person whose gametes were used in the creation of the embryo.<sup>66</sup> Finally, the HFE Act creates criminal penalties for violators.<sup>67</sup>

In 2001, the United Kingdom passed the Human Fertilisation and

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55. CAL. CONST. art. XXXV (effective Nov. 3, 2004).

56. *Id.* at §§ 3, 5.

57. *California Stem Cell Agency Awards Nearly \$45M in Research Grants*, INT’L HERALD TRIB., Feb. 16, 2007, <http://www.iht.com/articles/ap/2007/02/16/healthscience/NA-SCI-US-Stem-Cell-Grants.php>.

58. *Id.*

59. *Id.*

60. Beardsley, *supra* note 53.

61. *Id.*; Department of Health, Review of the Human Fertilisation and Embryology Act: A Public Consultation, [http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH\\_4123863](http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4123863) (last visited Nov. 12, 2007).

62. BEAVER & MULKEEN, *supra* note 45, at 9.

63. Office of Public Sector Information: Human Fertilisation and Embryology Act 1990 (c. 37), [http://www.opsi.gov.uk/acts/acts1990/ukpga\\_19900037\\_en\\_1#pb3-11g8](http://www.opsi.gov.uk/acts/acts1990/ukpga_19900037_en_1#pb3-11g8) (last visited Jan. 8, 2007).

64. *Id.*

65. *Id.* The primitive streak is defined as “active proliferation of the cells, loss of the basement membrane separating the epiblast and subjacent endoderm, migration of epiblastic cells and intermingling of the epiblast and endoderm cells. The primitive groove and node also appear at approximately this stage.” Embryo: Primitive Streak, <http://www.ana.ed.ac.uk/database/humat/notes/embryo/ectoderm/primstr.htm> (last visited Nov. 14, 2007).

66. BEAVER & MULKEEN, *supra* note 45, at 10.

67. *Id.*

Embryology Research Purpose Regulations to encompass the new advances in the field.<sup>68</sup> This regulation extended the terms of the 1990 Act to permit three new purposes for research using human embryos.<sup>69</sup> These include: (1) increasing knowledge about the development of embryos; (2) increasing knowledge about serious diseases; and (3) enabling any such knowledge to be applied in developing treatments for serious diseases.<sup>70</sup>

In 2002, the United Kingdom Stem Cell Bank (“Bank”) opened; the Bank is funded by the Medical Research Council and Biotechnology and Biological Sciences Research Council.<sup>71</sup> The main objectives of the Bank are to establish reliable banks of stem cell lines for researchers, to assess the stem cell lines’ performance at different passage levels, to ensure research opportunities for scientists while at the same time protecting the intellectual property rights of the donors, and to provide stem cells appropriate for clinical use.<sup>72</sup>

### C. China’s Stem Cell Policy

China has Asia’s most extensive stem cell research industry. Its emphasis is on performing clinical trials for adult stem cell therapies.<sup>73</sup> The country has at least three hundred stem cell researchers at approximately thirty institutions nationwide.<sup>74</sup> As one delegate from the U.K. Department of Trade sent to China to observe China’s development in the field stated, “[t]he facilities were, in every case we saw, equipped, funded and staffed to the levels at least as good—in most cases better—than equivalent cent[ers] in the [United Kingdom].”<sup>75</sup> In addition, China allows the production of new stem cell lines.<sup>76</sup> Therapeutic cloning is also legal there.<sup>77</sup> Between three hundred and four hundred researchers work on stem cells in China, and public and private spending on such research amounts to approximately \$40 million.<sup>78</sup>

Although there is no law that governs stem cell research in China, the Ministry of Health endorses it in its recommendations.<sup>79</sup> Chinese scientists work under the Ethical Guiding Principles on Human Embryonic Stem Cell

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68. Human Fertilisation and Embryology Authority, Regulation of Research on Human Embryos, [http://www.hfea.gov.uk/docs/Licensing\\_the\\_use\\_of\\_Human\\_Embryos.pdf](http://www.hfea.gov.uk/docs/Licensing_the_use_of_Human_Embryos.pdf) (last visited Mar. 9, 2008).

69. *Id.*

70. *Id.*

71. Lyn Healy et al., *The UK Stem Cell Bank: Its Role as a Public Research Resource Centre Providing Access to Well-Characterised Seed Stocks of Human Stem Cell Lines*, 57 *ADVANCED DRUG DELIVERY REV.* 1981, 1982 (2005), available at [http://www.sciencedirect.com/science?\\_ob=ArticleURL&\\_udi=B6T3R-4HHVX2-2&\\_user=10&\\_coverDate=12%2F12%2F2005&\\_rdoc=1&\\_fmt=summary&\\_orig=browse&\\_sort=d&view=c&\\_acct=C000050221&\\_version=1&\\_urlVersion=0&\\_userid=10&md5=f56c1c0ce19136eab2b3d6d46b5091d3](http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6T3R-4HHVX2-2&_user=10&_coverDate=12%2F12%2F2005&_rdoc=1&_fmt=summary&_orig=browse&_sort=d&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=f56c1c0ce19136eab2b3d6d46b5091d3); Medical Research Council, Ethics and Research Governance, <http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/index.htm> (last visited Nov. 14, 2007).

72. Lyn Healy et al., *supra* note 71, at 1983.

73. Clive Cookson, *Country Report: CHINA*, *SCI. AM.*, June 27, 2005, <http://www.sciam.com/article.cfm?articleID=00092B38-2E51-12BC-ADB783414B7F014C>.

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.*

78. Beardsley, *supra* note 53.

79. *Id.*

Research promulgated in 2003.<sup>80</sup> These permissive guidelines do not create any legal or criminal ramifications for violations.<sup>81</sup> In principle, they ban human reproductive cloning and hybridizing human germ cells with germ cells of any other species.<sup>82</sup> In addition, they require each institution performing stem cell research to create an ethics committee.<sup>83</sup> However, the guidelines allow stem cell research involving therapeutic cloning, the use of embryos from abortions, and the use of leftover embryos from *in vitro* fertilization as long as the embryos are cultured for less than fourteen days.<sup>84</sup> A more flexible ethical philosophy seems to help explain China's less restrictive policy on stem cell research.<sup>85</sup>

#### IV. TRENDS IN THE EUROPEAN UNION AND LATIN AMERICA

##### A. *The European Union and the Council of Europe*

The European Union as a body may fund research on embryonic stem cells regardless of the date of their creation.<sup>86</sup> Although legislation in the European Union is unclear regarding therapeutic cloning, it seemingly prohibits this form of stem cell formation.<sup>87</sup> However, research involving stem cells created from aborted embryos is allowed, as is, impliedly, research using embryos remaining after *in vitro* fertilization treatment.<sup>88</sup> Different policies exist within each member country of the European Union. For example, France permits the creation of new stem cell lines from *in vitro* fertilization embryos, and public funding for this type of research was \$4 million as of 2005.<sup>89</sup> In Germany, the policy is similar to that of the United States in that only research on stem cell lines created before 2002 is legal.<sup>90</sup> Finland permits

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80. Ministry of Health, People's Republic of China, *Ethical Guiding Principles on Human Embryonic Stem Cell Research*, Dec. 24, 2003, available at [http://www.chinaphs.org/bioethics/regulations\\_&\\_laws.htm#TOC113106142](http://www.chinaphs.org/bioethics/regulations_&_laws.htm#TOC113106142).

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

85. As to China's ethical views on embryonic stem cell research, they are partially explained by Professor Renzong Qiu. Yanguang Wang, *Chinese Ethical Views on Embryo Stem (ES) Cell Research*, in *ASIAN BIOETHICS IN THE 21ST CENTURY* 3.1, (2003), available at <http://eubios.info/ABC4/abc4049.htm>. Professor Qiu believes that in accord with the Confucian view, a person begins with birth. *Id.* Therefore, a human embryo is not a person, and abortion or the destruction of an embryo in order to extract stem cells should not be seen as the taking of a life. *Id.* However, although an embryo is not a person, it is a human biological life and should be accorded due respect. *Id.* If there is not a sufficient reason, it should not be destroyed or manipulated. *Id.* Trying to save or better a large number of human personal lives through stem cell research can be viewed as a sufficient reason. *Id.*

86. Beardsley, *supra* note 53.

87. *Id.*

88. *Id.*

89. *Id.* The European Union allows the production of new stem cell lines from unused *in vitro* fertilization embryos, but member countries have differing laws in this respect. *Id.*

90. *Id.*; BBC News, *EU Split Over Stem Cell Research*, <http://news.bbc.co.uk/2/hi/health/3055103.stm> (last visited Jan. 8, 2008).

research involving *in vitro* fertilization embryos.<sup>91</sup> Finally, Italy has a very restrictive policy, which it is considering modifying.<sup>92</sup> Funding from the European Union for stem cell research has been only \$650,000 over the past three years.<sup>93</sup> The European Union does not plan to increase funding for stem cell research projects, even though its total research budget will soon double.<sup>94</sup>

The Council of Europe, which was founded in 1949 and is composed of forty-seven member countries<sup>95</sup> aiming to develop common democratic principles based on the European Convention on Human Rights, has introduced the European Convention on Human Rights and Biomedicine (“European Convention”).<sup>96</sup> Thirty-one of the forty-seven member states have signed this ambiguous legislation, and fifteen countries have ratified it.<sup>97</sup> The European Convention provides that where a member state’s law allows research involving embryos, that law should also provide for the protection of the embryo.<sup>98</sup> It prohibits the creation of human embryos for research purposes.<sup>99</sup> The legislation does not take a clear position on therapeutic cloning but seemingly prohibits this form of stem cell creation.<sup>100</sup> However, research on stem cells created from aborted embryos is allowed as is, impliedly, research on embryos remaining after *in vitro* fertilization treatment.<sup>101</sup>

### B. Latin America

Most national policies in Latin America regarding stem cell research are restrictive.<sup>102</sup> This is mainly due to the fact that most Latin American countries have predominantly Catholic populations, and this religion gives a high moral weight to the embryo.<sup>103</sup> The Declaration of Human Rights of the American States (“Declaration”) provides that “every person has the right to

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91. BBC News, *supra* note 90.

92. Beardsley, *supra* note 53.

93. *Id.*

94. *Id.*

95. Council of Europe, The Council of Europe’s Member States, [http://www.coe.int/T/E/Com/About\\_Coe/Member\\_States/default.asp](http://www.coe.int/T/E/Com/About_Coe/Member_States/default.asp) (last visited Nov. 14, 2007).

96. Convention on Human Rights and Biomedicine, Apr. 4, 1997, E.T.S. 164, available at <http://conventions.coe.int/treaty/en/treaties/html/164.htm>. Interestingly enough, the Convention provides that: [p]arties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

*Id.*

97. Richard Gardner & Tim Watson, *A patchwork of Laws*, SCI. AM., June 27, 2005, <http://www.sciam.com/article.cfm?articleID=00031AB9-D9A9-12B9-969983414B7F0000>.

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. Rosario M. Isasi et al., *Research Ethics: Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia, and Africa*, 32 J.L. MED. & ETHICS 626, 630 (2004).

103. *Id.*

have his life respected.”<sup>104</sup> It further states that “[t]his right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life.”<sup>105</sup> The Declaration has been interpreted by many of the countries in the region to grant personhood to the embryo.<sup>106</sup> Therefore, they have drafted prohibitive legislation pertaining to the manipulation of embryonic cells.<sup>107</sup>

Examples of these policies can be found in the Ecuadorian Constitution, which prohibits research on human embryos; in an Argentinean Presidential Decree prohibiting the cloning of human cells to create human beings; and in Peruvian and Colombian legislation prohibiting fertilizing a human ovum with no intent to procreate.<sup>108</sup> Panama’s National Assembly went even further by creating legislation that makes it a criminal act to provide funds for stem cell research, whether they are from a public or private source.<sup>109</sup> Mexico exemplifies the tension between restrictive stem cell research policies based on religious beliefs or pressures, and the potential economic and scientific gains of stem cell research.<sup>110</sup> Mexico’s legislation prohibits human cloning but allows embryonic research.<sup>111</sup> In 2001, the Mexican President established the National Committee for the Human Genome to coordinate policies and actions on research and technological development.<sup>112</sup> At the same time, the President also created the National Bioethics Committee, in charge of prescribing ethical guidelines for all scientific research in Mexico.<sup>113</sup> Therefore, the future of embryonic research is uncertain in Mexico. Another country with a restrictive policy regarding stem cell research, but with a heavy investment in biotechnology, is Brazil.<sup>114</sup> In Brazil, the national law on Biosafety and Genetically Modified Organisms “can be interpreted to ban human cloning, prohibiting human reproductive and therapeutic cloning as well as HES research.”<sup>115</sup>

These examples demonstrate the tension between religion and economic policy. The policies of Latin American countries dominated by Catholicism aim to protect the human embryo, but their governments also recognize the enormous economic and social gains that can be achieved through the pursuit of medical advances using embryonic stem cell research.

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104. *Id.*

105. *Id.* at 629.

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.* at 631.

111. Center for Genetics and Society, Other Countries: National Policies on Human Genetic Modification: A Preliminary Survey, <http://geneticsandsociety.org/article.php?id=304> (last visited Feb. 24, 2008).

112. Isasi et al., *Research Ethics*, *supra* note 102, at 631.

113. *Id.*

114. *Id.*

115. *Id.*

## V. THE UNITED NATIONS' ATTEMPT TO CREATE STEM CELL POLICY

In 2001, the United Nations agreed to include the item "International Convention against the Reproductive Cloning of Human Beings" on its agenda.<sup>116</sup> This led to the creation of an Ad Hoc Committee to draft the language of an international treaty banning the reproductive cloning of human beings.<sup>117</sup> Other negotiations, regarding different types of cloning and human genetic technologies, were to follow in a separate convention.<sup>118</sup> Such a simple task—seemingly supported by every country represented at the convention—proved impossible.<sup>119</sup>

Soon a disagreement arose, and the United States created a separate proposal that would ban both reproductive cloning and research cloning in a single treaty.<sup>120</sup> The United States argued that the international community could not enact a treaty that only included a partial ban and did not outlaw research cloning.<sup>121</sup> This led to the United States and Costa Rica leading a forty-country coalition that effectively destroyed the effort to ban only the reproductive cloning of human beings.<sup>122</sup>

In searching for a solution to the impasse, South Korea proposed a two-tiered approach.<sup>123</sup> South Korea suggested that the convention ban human reproductive cloning and also draft optional provisions banning therapeutic and experimental cloning.<sup>124</sup> However, the United States coalition disregarded even this reasonable proposal.<sup>125</sup> Finally, due to the rifts between the different groups, the Coalition of the Islamic Conference proposed a motion to postpone the deliberations for a period of two years, until 2005, to enable the parties to study the issue in more detail and to reach a consensus.<sup>126</sup> This resulted in postponed deliberations and the creation of an ambiguous political statement that appears to prohibit all forms of cloning.<sup>127</sup> Because this declaration is non-binding, it has no effect on countries that wish to pursue any type of stem cell research and/or therapeutic cloning.<sup>128</sup>

## VI. THE STEM CELL MARKET AND ECONOMICS

The global stem cell market was valued at \$18.5 billion in 2001 and is

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116. Rosario M. Isasi & George J. Annas, *Arbitrage, Bioethics, and Cloning: The ABCs of Gestating a United Nations Cloning Convention*, 35 CASE W. RES. J. INT'L L. 397, 403-04 (2003).

117. *Id.*

118. *Id.*

119. *Id.* at 414.

120. *Id.* at 408; Report of the Working Group, Ad Hoc Committee on the International Convention Against the Reproductive Cloning of Human Beings, U.N. Doc. A/C.6/57/L.4 (Sept. 30, 2002).

121. Isasi & Annas, *supra* note 116, at 408.

122. *Id.* at 410-12.

123. *Id.* at 409.

124. *Id.*

125. *See id.* at 410 (stating that the United States was unwilling to negotiate a compromise).

126. *Id.* at 412-13.

127. Gardner & Watson, *supra* note 97.

128. *Id.*

anticipated to grow to approximately \$80 billion by 2010, with the greatest growth expected in Europe and Asia.<sup>129</sup> Accounting firm Ernst & Young reported that the total value of Europe's publicly quoted biotech companies more than doubled to approximately \$104 billion from 1999 to 2000.<sup>130</sup> In 2003, there were 113 tissue-engineering companies in Europe, fifty-four of which were directly related to stem cell research.<sup>131</sup> As of 2004, there were ten privately held stem cell companies in the United Kingdom.<sup>132</sup> Recently, the United Kingdom's first globally accessible stem cell bank opened in Hertfordshire.<sup>133</sup> At the same time, the Newcastle Centre for Life applied for and received a license for somatic nuclear cell transfer research.<sup>134</sup> Shockingly, in the United States, the market value of biotech companies fell by \$30 billion from 1999 to 2000.<sup>135</sup> Only ten private firms were actively involved in embryonic stem cell research, spending a total of \$70 million.<sup>136</sup>

The United States' federal ban on funds for embryonic stem cell research has placed it among the most restrictive countries worldwide within the industry. Although the United States has historically lead the biotechnology industry, the current Bush Administration's position places American scientists at a great disadvantage internationally. Because California is one of the leading states in terms of research funding, many scientists have relocated there.<sup>137</sup> However, once California has absorbed its maximum sustainable quantity of American scientists, the remainder will leave the United States to work in foreign countries. In fact, this phenomenon is already beginning.<sup>138</sup> Many top scientists have left the United States to continue their research in Europe and Asia.<sup>139</sup>

Brain drain is not the only problem caused by the current federal policy. The policy will result in the loss of the United States' edge in an industry that is growing at an enormous pace and could hold the future for treatments worth billions or even trillions of dollars. Other countries, namely China, have embraced embryonic stem cell research to capture the enormous potential economic gains from becoming a market leader in the areas of development and treatment.<sup>140</sup> Therefore, China's non-restrictive stem cell research policies

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129. See JIANGSHENG DO ET AL., *STEM CELL MISSION TO CHINA, SINGAPORE, AND SOUTH KOREA* 10 (2004), available at [http://www.oti.globalwatchonline.com/online\\_pdfs/36206MR.pdf](http://www.oti.globalwatchonline.com/online_pdfs/36206MR.pdf) (stating that the largest growth in the stem-cell market is expected to occur outside of the United States in less restrictive regions).

130. *Id.*

131. *Id.*

132. *Id.*

133. *Id.*; BBC News, *UK opens pioneer stem cell bank*, <http://news.bbc.co.uk/2/hi/health/3055103.stm> (last visited Jan. 16, 2008).

134. DO ET AL., *supra* note 129, at 11.

135. *Id.*

136. *Id.*

137. See Johnson & Williams, *supra* note 2, at 13 (listing California as the first state to "expressly permit and encourage research involving the derivation of human embryonic stem cells and cloned embryos.").

138. Carrie Sturrock, *US Loses Stem Cell Researcher*, *CONTRA COSTA TIMES*, July 17, 2001, available at <http://cmbi.bjmu.edu.cn/news/0107/137.htm>.

139. *Id.*

140. Susan Brown, *China Challenges the West in Stem-Cell Research*, *CHINA STEM CELL NEWS*, Apr. 12, 2007, <http://www.stemcellschina.com/content/view/571/266/lang/en/> ("In the West's unease over experiments

could possibly lead to Americans traveling to China for treatments.

The fact that patients will travel to less-restrictive countries to receive treatment that is prohibited or unavailable in their home country is apparent from current trends in Europe and elsewhere.<sup>141</sup> This phenomenon has been termed “reproductive tourism” and is exemplified by Europeans traveling to neighboring countries to receive infertility treatment because it is prohibited or in some way regulated in their own country.<sup>142</sup> This is a problem in Europe due to inequality of access.<sup>143</sup> It is fundamentally unfair that only citizens of richer countries in the European Union can afford to receive treatment in another country.<sup>144</sup> On a global scale, another problem with reproductive tourism is that this type of activity often takes place in less industrialized countries where health standards are lower and risks to patients are higher.<sup>145</sup>

## VII. RECOMMENDATION

This section recommends a change in stem cell research policy. The first subsection discusses the grounds for change. The second subsection proposes the platform and methodology for such a change. Finally, the third subsection identifies the starting point for an international treaty.

### A. *The Grounds for Change*

Not only should the United States change its policy for economic purposes, but it should also consider that the world and scientists everywhere are searching for ethical and international guidelines under which to work. The United States is still the industry leader in biotechnology, and other countries look to the United States to take an active leadership role in creating such international policies. Whether this is through the United Nations or regional treaties, there is a definite need for action.

The scientific community’s desire for guidelines and access to embryonic stem-cell lines and the hope of hundreds of millions of patients around the world are best summarized by the following statement made by Dr. John Kessler to the U.S. Senate Committee on Appropriations:

I am a researcher who has devoted his entire professional life to developing techniques for regenerating the damaged nervous system. I am also the father of a 17-year-old daughter, Allison, who 2 years ago suffered a spinal cord injury that confined her to a wheelchair. So I am speaking to you today both as a scientist and a representative of the many families who want to see stem cell therapies reach their

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that destroy human embryos, China sees opportunity—a chance to assume a leading role in what many see as a promising line of research.”).

141. Guidon Pennings, *Legal Harmonization and Reproductive Tourism in Europe*, 19 HUM. REPROD. 2689, 2690 (2004), available at <http://humrep.oxfordjournals.org/cgi/reprint/19/12/2689>.

142. *Id.*

143. *Id.* at 2691.

144. *Id.*

145. *Id.*

potential.<sup>146</sup>

### B. *The Platform and Methodology*

The problem of regulating stem cell research is not unique to the United States. Given the fact that scientists can easily relocate among countries to continue their research, an international resolution of the issue is essential. An international platform, such as the United Nations, is the best place for this type of resolution to be addressed. Although the world community's initial effort to compose a treaty governing stem cell research was not fruitful,<sup>147</sup> states should make another regulatory attempt.

A better way for sovereign states to negotiate specific research regulations in the United Nations would be to begin with a working draft of the proposed legislation. States could then amend the text of this working draft after negotiating changes to the specific rules and regulations, without having to create each specific provision from scratch. Thus, the question becomes how to obtain an acceptable working draft. Should it be adopted from the legislation of one specific country? Which country's legislation should be used as the boilerplate, a country with restrictive regulations or a country that has adopted more moderate guidelines for stem-cell research?

### C. *The Starting Point*

The starting point for this international treaty already exists in the work of the Hinxton Group.<sup>148</sup> In 2004, members of the Stem Cell Policy and Ethics Program at the Johns Hopkins Berman Institute of Bioethics created a group of international and interdisciplinary experts to explore the challenges of ethical and policy differences in national regulations governing stem cell research.<sup>149</sup> The objectives of the Hinxton Group were to identify the main challenges that scientists, universities and others faced in collaborating on stem cell research, developing guidance for conduct that could become applicable across national boundaries and legal regimes, exploring data sharing in international research, exploring the issues of cell donation, and "identifying forward-looking strategies to foster the scientific and ethical integrity of research in a global context."<sup>150</sup>

The Hinxton Group's organization should be replicated in a permanent committee of the United Nations. This committee should consist of international scientists, regulators, philosophers, bioethicists, clinicians, and lawyers. The committee should develop a proposed international treaty.

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146. *Hearing, supra* note 3, at 22 (statement of Dr. John A. Kessler, Chairman, Davee Dep't of Neurology, Nw. U. Med. Sch.).

147. Isasi & Annas, *supra* note 116, at 413.

148. The Hinxton Group, About the Hinxton Group, <http://www.hinxtongroup.org/au.html> (last visited Nov. 14, 2007).

149. *Id.*

150. The Hinxton Group, Transnational Cooperation in Stem Cell Research, [http://www.hinxtongroup.org/au\\_trans.html](http://www.hinxtongroup.org/au_trans.html) (last visited Nov. 14, 2007).

Countries could then sign the treaty and be bound by it.

If a few of the industrialized nations ratified the treaty, it could gain popularity, and other countries could be persuaded to ratify it as well. Thus, the regulation of stem cell research could follow the path of the regulation of international trade as per the General Agreement on Tariffs and Trade and the World Trade Organization.<sup>151</sup> As novel issues emerge in the field, parties to the treaty could negotiate amendments to its language. Although no country would be forced to join the treaty, as the market for stem cell therapy grows, economic pressures would persuade many to do so. Moreover, countries could give teeth to the treaty by passing national legislation that restricts cooperation and information sharing with non-ratifying States.

This process would enable the United States to influence a treaty that would bind many other countries. Stem cell research is an issue that should be addressed globally in a uniform manner. Policies in other countries will eventually influence technology and citizens of the United States. Given the diverse makeup of the United States and the diverse ethical and moral stances of its population, it would be much easier politically for the United States to ratify this type of international treaty than to propose its own national legislation in Congress. The federal law could then be amended to reflect the regulations and rules contained in this international treaty.

#### VIII. CONCLUSION

It is apparent that stem cell research presents many difficulties in terms of national and international regulatory schemes. This is in large part due to the different ethical considerations that need to be addressed in the regulation of this type of research. The debate centers on the question of what moral weight stem cells should be accorded. Should stem cells be viewed as human life that needs be protected from any sort of research? Or should certain types of stem cells be used for research that will potentially better the lives of others and offer the hope of treatment of and cures for many diseases?

It is also apparent that the economic market for stem cell research is enormous and growing at a fast pace. The United States now finds itself among the most restrictive countries in terms of regulation of stem cell research. Although states such as California, New Jersey, Connecticut, Maryland, and Illinois are funding this type of research, the federal government needs to lift the 2001 ban on funding and adopt new laws and regulations to create a uniform national system that promotes ethical stem cell research.

In addition, an international set of laws regulating stem cells is necessary. The United States is not the only country struggling with the stem cell issue, and scientists conducting research as well as patients receiving stem cell treatment can easily travel between countries. Such international regulation

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151. World Trade Organization, The GATT Years: From Havana to Marrakesh, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/fact4\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm) (last visited Nov. 14, 2007).

would be best developed through the United Nations, where a working group or permanent committee should use the Hinxton Group's proposed objectives to develop a treaty that could be ratified by a number of nations. This would offer the United States an opportunity to take part in the effort to create legislation that would affect both its scientists choosing to work abroad and its citizens choosing to obtain treatment in other countries. It would also offer the United States an opportunity to ratify this treaty and to amend its federal law to accommodate it, with less political opposition than if it were solely created by Congress.

The fact that America's technological and medical superiority is being eroded by other countries, such as China, makes the need for this change in American federal law more urgent. To retain its leadership position, maintain its economic viability in this industry, and ensure the best healthcare possible for its citizens, the United States must act now and amend its regulation of stem cell research.