AMERICA'S STRUGGLE TO DEVELOP A CONSISTENT LEGAL APPROACH TO CONTROVERSIAL HUMAN EMBRYONIC STEM CELL RESEARCH AND THERAPEUTIC CLONING: ARE THE POLITICS GETTING IN THE WAY OF HOPE?

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INTRODUCTION

The secret to fame and importance in American society is often the ability to crossover into mainstream media and maintain a continuing presence. If that is the case, meet America's new rising stars: human embryonic stem cells. Once limited to the pages of Science, Nature, and other scientific journals, human embryonic stem cells now find themselves center stage in American politics. The death of former President Ronald Reagan from Alzheimer's disease in June 2004 and the death of Superman himself, Christopher Reeve, in October 2004, as well as the Bush-Kerry Presidential election have caused people all across America to discuss the scientific and ethical aspects of human embryonic stem cell research and therapeutic cloning. From President George W. Bush to Howard Stern, from the *New York Times* to People Magazine, human embryonic stem cells have America's attention.

Because human embryonic stem cell research and therapeutic cloning are so controversial, this note advocates that the United States should adopt a similar legal approach as the United Kingdom. The U.K. has decided the potential benefits that will result from human embryonic stem cell research outweigh the ethical problems. The promise of potential benefits has prompted the U.K. to provide public funds for both areas of research and, therefore, the British government is better able to monitor and regulate both procedures. The U.S., on the other hand, has banned public funding for human embryonic stem cell research and therapeutic cloning, but it has left private research largely unregulated. The U.S. government needs to increase public spending and impose more restrictions on human embryonic stem cell research

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and therapeutic cloning to prevent U.S. scientists from developing projects that go beyond what the public and legislators will be able to tolerate. If the citizenry's bounds of decency continue to be pushed by controversial genetic research, there is a risk that all types of human embryonic stem cell research and therapeutic cloning will be banned. Without public funding and regulation, therefore, the U.S. will be unable to fully realize the potential benefits of these two types of research.

Part I of this note evaluates human embryonic stem cell research, including an explanation of the potential benefits of this procedure and the ethical debates surrounding this type of research. Part I also identifies the legal approach to human embryonic stem cell research currently used in the U.S. Next, Part I addresses therapeutic cloning. First, therapeutic cloning is explained and then distinguished from reproductive cloning. Second, Part I discusses the ethical concerns that arise from therapeutic cloning. Third, Part I outlines the current U.S. legal approach to therapeutic cloning. Part II of this note explains the British approach to both of these controversial research procedures. Part III describes the state of unregulated, private genetic research in the U.S. Finally, Part IV proposes that the U.S. adopt a legal scheme similar to that in Britain regarding human embryonic stem cell research and therapeutic cloning.

I. EVALUATION OF HUMAN EMBRYONIC STEM CELL RESEARCH

Human embryonic stem cells have the potential to develop into many different cell types in the body.[1] The three classes of human stem cells are totipotent, multipotent, and pluripotent.[2] A fertilized egg is totipotent because it has reached its total potential and can develop into all different types of cells in the body.[3] Multipotent cells, meanwhile, are human stem cells that can develop into a small number of different cells in the body.[4] Finally, pluripotent human stem cells can develop into any type of cell but they cannot give rise to those cells needed to develop a fetus.[5]

Scientists believe that human embryonic stem cells have much greater developmental potential than adult stem cells because embryonic

1. National Institute of Health, *Stem Cell Information: Frequently Asked Question*, *at* http://stemcells.nih.gov/info/faqs.asp (last visited Nov. 13, 2004).

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.*

stem cells are thought to be pluripotent, while adult cells are thought to be multipotent.[6] Pluripotent stem cells are derived from either human embryos that are a few days old, called blastocysts, or from fetal tissue obtained from terminated pregnancies.[7] Stem cells derived from blastocysts or from fetal tissue are then used to cultivate stem cell lines.[8] Most stem cells originate from surplus embryos that were created for infertility research purposes from *in vitro* fertilization procedures.[9] These stem cells are then offered to scientists after a donor's informed consent is obtained.[10] It is important to highlight that human embryonic stem cells are not taken from eggs fertilized in a woman's body.[11]

These embryonic stem cell lines are essential for researchers because they are essentially immortal.[12] Once a cell line is established, unlimited cells can be created and then frozen for storage or distribution to other researchers.[13] Human embryonic stem cell lines developed in a laboratory are called cell cultures.[14] The cells divide and spread over a culture dish.[15] When the cells begin to outgrow the dish, researchers then replate the cells.[16] This process of relocating the cells into different plates is repeated for about six months and, at the end of this period, scientists use the healthy cells to establish a stem cell line.[17] A scientist can start with 30 original cells and end up with millions.[18] If the cells were not replated, they would clump together and form heart blood cells, muscle cells, nerve cells, or many other types of cells.[19]

A. Potential Benefits of Human Embryonic Stem Cells

Human stem cell lines are a vital resource for scientists because of their potential use in transplantation and treatment of diseases, screening new drugs, and understanding birth defects.[20] For instance, researchers

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6. National Institute of Health, *supra* note 1.
7. *Id.*; National Institute of Health, *Stem Cell Information: Stem Cell Basics*, http://stemcells.nih.gov/info/basics/basics3.asp (last visited Aug. 20, 2004).
8. National Institute of Health, *supra* note 1; National Institute of Health, *supra* note 7.
9. National Institute of Health, *supra* note 7.
10. *Id.*
11. *Id.*
12. *Id.*
13. *Id.*
14. National Institute of Health, *supra* note 7.
15. *Id.*
16. *Id.*
17. *Id.*
18. *Id.*
19. National Institute of Health, *supra* note 7.
20. *Id.*

point to the problems that currently face doctors when transplanting organs in a patient.[21] Doctors must overcome complications caused by the rejection of the new organ by a patient's immune system.[22] Researchers believe that human embryonic stem cell lines will be able to overcome this immune rejection in the future through gene therapy.[23] Currently, scientists are trying to overcome the technical challenges of how to control the evolution of pluripotent cells into specific cells in the body because scientists want these cells when they are at an initial and undefined stage. Another challenge faced by researchers is the danger that a patient's body could reject foreign, donor embryonic stem cells.[24]

Human embryonic stem cells may also be used to test new drugs.[25] The benefit of using pluripotent cell lines is that drugs could be tested in a wider range of cell types.[26] Again, the problem researchers face is how to control the development of these pluripotent cells into different cells in the body.[27]

In addition, human embryonic stem cells may prove invaluable to the treatment of some of the gravest medical conditions, such as cancer and birth defects, caused by abnormal cell division.[28] Once researchers understand what causes a human embryonic stem cell to evolve into a specific type of cell (i.e., muscle cell or nerve cell), then it may be possible to prevent abnormal cells from developing.[29]

Scientists estimate that human embryonic stem cells will make the greatest impact in regards to the generation of cells and tissues.[30] Donated organs and tissues are used to repair bad tissue, but the demand for new tissues and organs far outweigh the supply.[31] Researchers believe that human embryonic stem cells will become a renewable source of replacement and will be used to treat Parkinson's disease, Alzheimer's disease, spinal cord injuries, strokes, burns, heart disease, diabetes, and various forms of arthritis.[32]

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21. National Institute of Health, *supra* note 7.
22. *Id.*
23. *Id.*
24. *Id.*
25. *Id.*
26. National Institute of Health, *supra* note 7.
27. *Id.*
28. *Id.*
29. *Id.*
30. *Id.*
31. National Institute of Health, *supra* note 7.
32. *Id.*; *see also*, Cynthia Donley Young, Comment: *A Comparative Look at the U.S. and British Approaches to Stem Cell Research*, 65 ALB. L. REV. 830, 833 (2002).

B. Differences between Adult Stem Cells and Embryonic Stem Cells

The U.S. government permits testing on adult stem cells, which have turned out to be more useful than researchers initially thought.[33] There are, however, several important limitations regarding the use of these multipotent cells. Adult stem cells are often found only in small quantities and, therefore, it is difficult to isolate and purify these cells.[34] Also, there is evidence that adult cells have a lesser capacity than embryonic stem cells to multiply.[35] Researchers have been unsuccessful so far in creating an adult stem cell culture, and since large numbers of cells are required for stem cell replacement therapies, this is an important difference between adult and embryonic cells.[36] Lastly, "adult stem cells may contain more DNA abnormalities—caused by sunlight, toxins and errors in making more DNA copies during the course of a lifetime."[37] Consequently, researchers believe adult stem cells have a more limited application than embryonic stem cells.[38]

In addition, the primary role of adult stem cells differs from that of embryonic stem cells.[39] Adult cells work within the body to maintain and repair the tissue in which they are located.[40] Adult stem cells are believed to reside in a specific area of a tissue where they do not divide until division is triggered by disease or tissue damage.[41] The adult tissues that contain stem cells include the brain, blood, skeletal muscles, skin, and liver.[42] Thus, the potential use of adult stem cells may be restricted because they become cell types of their tissue of origin.[43] On the other hand, embryonic stem cells can give rise to all different types of tissue in the body.[44]

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33. National Institute of Health, *supra* note 7.

34. Denise Stevens, Comment: *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 HOUS. J. INT'L L. 623, 632 (2003).

35. National Institute of Health, *supra* note 7.

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. National Institute of Health, *supra* note 7.

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*

C. Ethical Concerns Regarding Human Embryonic Stem Cell Research

Although the potential benefits of embryonic stem cell research seem to outweigh the use of adult stem cells, the U.S. has failed to embrace this line of research because of the ethical concerns associated with the destruction of embryos.[45] Some opponents of human embryonic stem cell research argue that the moral status of a person begins at conception.[46] Since embryos are destroyed in the process, these opponents assert this type of research is immoral because a person or potential person is being denied life without due process of U.S. laws.[47] Furthermore, a person or potential person is being denied the proper level of respect embodied within the United Nations Declaration on Human Rights.[48] That Declaration provides that "everyone has a right to life, liberty and security of person."[49]

Also, opponents are concerned that doctors and women will work together to create embryos for the sole purpose of establishing a supply of stem cells.[50] This concern is heightened when a donor or doctor may have a relationship with a patient who could potentially benefit from human embryonic stem cell research.[51] For example, suppose that a doctor has a parent who is suffering from Parkinson's disease. This doctor has been doing extensive research and believes that embryonic stem cells are the solution to this terrible ailment. Suddenly, a woman enters the doctor's office and wants to discuss the termination of her pregnancy. The doctor chooses to make a more persuasive argument in favor of terminating the pregnancy and the woman follows this advice.

Another argument against the use of embryonic cells is that of anti-abortion activists. [52] They are concerned that the process of extracting cells from aborted fetuses will allow researchers to use fetal tissue and thus sway otherwise undecided women to pursue an abortion, by providing an argument in support of abortion.[53] Consequently, opponents of abortion are concerned that women will justify their decisions to terminate their pregnancies because the cells may make a

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45. Young, *supra* note 32, at 834.

46. *Id.* at 835.

47. *Id.*

48. James J. McCartney, *Essay: Embryonic Stem Cell Research and Respect for Human Life: Philosophical and Legal Reflections*, 65 ALB.L REV. 597, 602 (2002).

49. *Id.*

50. Young, *supra* note 32, at 836.

51. *Id.*

52. *Id.* at 836-37.

53. *Id.* at 836.

positive contribution to medical research.[54] Similarly, women may be even more likely to justify their decisions to terminate pregnancies when they know people who are ill and may be helped by human embryonic stem cell research.[55]

Proponents of stem cell research, however, disagree that the human embryo deserves the legal status due a fully formed human being.[56] Moreover, these same proponents believe that it would be immoral not to use embryos that would otherwise be destroyed since embryonic stem cells have the potential to cure and treat millions of Americans who are plagued by various health problems.[57] Furthermore, supporters of stem cell research assert that human embryonic stem cells derived from surplus embryos under *in vitro* fertilization procedures do not fit the technical definition of an embryo.[58] The is so because embryonic stem cells "do not have the capacity to develop into a human being even if transferred to the uterus, thus, their destruction in the course of research would not constitute the destruction of an embryo."[59]

Moreover, advocates of human embryonic stem cell research state that it is unlikely that "women contemplating abortion would be swayed by research."[60] In addition, lawmakers have taken steps to further insulate women from making pregnancy decisions based on sick family members and friends.[61] Laws prohibit women from designating a recipient of their embryonic cells.[62]

D. U.S. Legal Approach to Human Embryonic Stem Cell Research

The cloud of controversy that cloaks embryonic stem cell research, coupled with the unknown potential of these cells, has prevented the U.S. from formulating a consistent regulatory scheme.[63] While there are a few laws that affect government-funded research, private research, for the most part, has been left unregulated.[64] The Food and Drug Administration (FDA) has also been silent on what kind of restrictions

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54. *Id.* at 836-37.

55. Young, *supra* note 32.

56. National Human Genome Research Institute, *Cloning/Embryonic Stem Cells*, http://www.genome.gov/10004765 (last visited Nov 13, 2004).

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. Young, *supra* note 32, at 837.

62. *Id.*

63. *Id.* at 841.

64. *Id.*

should govern this research and states have passed laws that are both inconsistent and vague.[65] The problem may be that legislators lack the expertise to draft laws that capture the nuances of this area of research.[66] Terms like "embryo," "fertilization," and "cloning" need to be specifically defined. The laws of three different States that govern embryos have been found unconstitutional because they were too vague and did not provide proper notice to scientists on what conduct was regulated.[67]

As the field of human embryonic stem cell research advances and human clinical trials become a reality, the U.S. government will no longer have the luxury of a hands-off approach.[68] Federal funding of embryonic stem research is regulated through the Omnibus Consolidated and Emergency Supplemental Appropriations Act, which is an appropriations bill for the Department of Health and Human Services (DHHS).[69] This rider prohibits public funds from being used in research where embryos are destroyed or subjected to risk of injury that is greater than the risk for research performed on fetuses *in utero*.[70] The DHHS excludes research on stem cell lines because they are not considered organisms under the statutory definition.[71] As mentioned, these human embryonic stem cells do not have the capacity to form a human being even if they were transferred to a woman's uterus.[72]

Federal laws also regulate government-sponsored research involving fetal tissue.[73] Fetal tissue taken from terminated pregnancies can be used for therapeutic purposes as long as the donor's informed consent is obtained in accordance with 42 U.S.C. § 289g-1(b)(1).[74]

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65. Young, *supra* note 32; Letter from Bernard A. Schwetz, Acting Prinipal Deputy Commissioner Food and Drug Administration, to The Honorable Edward M. Kennedy, Senator, Stem Cells (Sept. 5, 2001), *at* http://www.fda.gov/oc/stemcells/kennedyltr.html (last visited Nov. 13, 2003).

66. Young, *supra* note 32, at 842.

67. *Id.* For a full discussion of state laws regulating embryonic stem cell research and therapeutic cloning, *see* Lori B. Andrews, *Legislators as Lobbyists: Proposed State Regulation of Embryonic Stem Cell Research, Therapeutic Cloning and Reproductive Cloning*, The President's Council on Bioethics Washington, D.C. (January 2004), *available at* http://www.bioethics.gov/reports/stemcell/appendix_e.html (last visited on Nov. 13, 2004).

68. Young, *supra* note 32, at 841.

69. *Id.* at 843-44.

70. *Id.* at 844.

71. *Id.*; *see also* National Human Genome Research Institute, *supra* note 56.

72. Young, *supra* note 32, at 844; *see also* National Human Genome Research Institute, *supra* note 57.

73. Young, *supra* note 32, at 845.

74. 42 U.S.C. §§ 289g-1(b)-(c) (2004); Young, *supra* note 32, at 845.

Consent must be in writing and the donor must be unaware of the identity of the tissue recipient.[75] The doctor must also submit a signed written statement that ensures the donor consented to the abortion and that the procedure was not impacted in any way by the potential for that fetus to facilitate future medical study.[76] In addition, the researcher who utilizes the fetal tissue must submit a written statement that he or she is aware that the tissue was extracted from an aborted fetus. Finally, that researcher must also indicate that she or he accepts the additional responsibilities attached to research procedures that involve fetal tissue and human embryonic cells.[77]

There are additional restrictions. For example, 42 U.S.C. 289g-2 prohibits the purchase of fetal tissue when interstate commerce is implicated.[78] Furthermore, each step must also be carried out in accordance with applicable state laws.[79] Violators of any of these statutory provisions may be subject to fines or imprisonment, with a maximum sentence of ten years in jail.[80]

The scope of this federal statute, however, is narrow.[81] These provisions govern the use of fetal tissue and embryonic stem cells derived from either aborted or stillborn pregnancies.[82] These sections, though, only apply to the transplantation of fetal tissue and embryonic cells into human beings.[83] As a result, these provisions may not be applicable to human embryonic stem cell research since testing is limited to the stem cells themselves, and they do not provide for transplantation of these cells into human subjects.[84] The language of these laws, therefore, permits federal funding of human embryonic stem cell research. The problem for researchers is that human embryonic stem cell research is governed, not by federal law, but by the President's policies.

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75. 42 U.S.C. §§ 289g-1(b)-(c) (2004); Young, *supra* note 32, at 845.
76. 42 U.S.C. §§ 289g-1(b)-(c) (2004); Young, *supra* note 32, at 845.
77. 42 U.S.C. §§ 289g-1(b)-(c) (2004); Young, *supra* note 32, at 845.
78. 42 U.S.C. § 289g-2 (2004); Young, *supra* note 32, at 845.
79. Young, *supra* note 32, at 845.
80. 42 U.S.C. § 289g-2 (2004); Young, *supra* note 32, at 845.
81. Young, *supra* note 32, at 845-46.
82. *Id.*
83. *Id.*
84. Human Genome Project Information, *Cloning Fact Sheet, at* http://www.ornl.gov/sci/ techresources/HumanGenome/elsi/cloning.shtml (last visited on Nov. 13, 2004).

E. President Bush's Stance on Human Embryonic Stem Cell Research

President Bush's policy, announced on August 9, 2001, was an attempt to reconcile the potential benefits of human embryonic stem cell research with the strong moral objections regarding the destruction of embryos.[85] President Bush decided to restrict federal funding to research on 60 stem cells lines that were already in existence to prevent further destruction of human embryos.[86]

The President assigned the National Institute of Health (NIH) to develop guidelines on how to allocate government money and to develop guidelines that preserve the President's stance on the use of embryos.[87] Federal funds, therefore, can only be used for research where embryonic stem cells were obtained with the donor's informed consent, from excess embryos under *in vitro* fertilization procedures, and without any financial incentives to taint the donors' decisions.[88] No federal monies may be given to research involving newly destroyed embryos, embryos created solely for research purposes or cloned human embryos.[89] According to a White House press release, President Bush believes that, "[f]ederal funding of medical research on these existing stem lines will promote the sanctity of life 'without undermining it' and will allow scientists to explore the potential of this research to benefit the lives of millions of people who suffer from [life-destroying] diseases."[90]

Critics of President Bush's policy claim that he overestimated the ability of scientists to rely on existing stem cell lines.[91] Not only are there a lot fewer stem cell lines than first thought, but researchers believe that many lines have been corrupted and are not useable.[92] Researchers are now awaiting whether or not "Congress will exercise its own power and mandate new rules for embryonic stem cell research; trumping Bush's plan and sending the NIH back to the drawing board once more."[93]

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85. White House Press Release, President George Bush, Embryonic Stem Cell Research, *at* http://www.d-trends.com/Government/stemcellbush.pdf (last visited on Nov. 13, 2004); *see also* Scott Davison, *Influencing NIH Policy over Embryonic Stem-Cell Research: An Administrative Tug-of-War Between Congress and the President*, 22 J. NAT'L ASS'N ADMIN. L. JUDGES 405, 414-17 (2002).

86. White House Press Release, *supra* note 85; Davison, *supra* note 85.

87. White House Press Release, *supra* note 85; Davison, *supra* note 85.

88. White House Press Release, *supra* note 85; Davison, *supra* note 85.

89. White House Press Release, *supra* note 85.

90. *Id.*

91. Davison, *supra* note 85, at 419.

92. *Id.* at 419-20; Letter from Bernard A. Schwetz, *supra* note 65.

93. Davison, *supra* note 85, at 410.

F. Introduction to Cloning

"Trace the lines of science, religion, ethics and politics and eventually they will intersect at one of the most divisive issues currently at play here: human cloning."[94] Cloning is a general term used to describe scientific procedures that make duplicates of biological material, and, in most cases, usually involve the duplication of genes and cells without the creation of entirely new specimens.[95] Therapeutic cloning duplicates human embryos, and then researchers extract stem cells from the cloned embryos to cultivate the cells into organs within a laboratory setting, away from women's uteruses. In the future, therapeutically-cloned organs may be used to replace diseased organs in patients or to test the effects of new drugs.

When a new specimen is created, the process is called reproductive cloning.[96] One example is the experiment that led to the formation of Dolly the sheep in 1996.[97] Dolly was the result of a process referred to as somatic cell nuclear transfer.[98] Dolly was, in fact, the genetic twin of another adult sheep.[99] Since there are, however, so many troubling aspects of reproductive cloning, it is important to distinguish it from therapeutic cloning.[100]

1. Overview of Reproductive Cloning

Reproductive cloning, the process used to create Dolly, is a procedure used to create an animal that has the same genetic makeup or DNA as another existing animal.[101] This process involves the removal of the nucleus of an egg and replacing it with the nucleus of a donor adult cell.[102] The reconstructed egg is then stimulated with chemicals or electric current to trigger cell division.[103] "Once the cloned embryo reaches a suitable stage, it is transferred to the uterus of a female host where it continues to develop until [its] birth."[104] Reproductive cloning is different from sexual reproduction because sexual reproduction is the

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94. Kirk Semple, *U.N. to Consider Whether to Ban Some, or All, Forms of Cloning of Human Embryos*, N.Y. TIMES, Nov. 3, 2003, at A11.

95. National Human Genome Research Institute, *supra* note 56.

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.*

100. National Human Genome Research Institute, *supra* note 56.

101. Human Genome Project Information, *supra* note 84.

102. *Id.*

103. *Id.*

104. *Id.*

process where an egg and sperm fuse to form a new organism.[105] In reproductive cloning, though, there is only one parent.[106] In the case of Dolly, it "was different because she [was] not genetically unique [although] genetically identical to [another] six-year old ewe."[107]

2. Scientific Uncertainties and Ethical Concerns Regarding Reproductive Cloning

Scientific uncertainties and ethical concerns have made the prospect of cloning humans very troubling, even within the scientific community.[108] Cloning studies are performed on sheep, cows, pigs, goats, and mice.[109] Very few of these cloning attempts have been successful so far.[110] Cloned animals often die *in utero*.[111] Cloned animals that do make it through birth often suffer severe birth defects.[112] In total, more than 90% of cloning attempts fail and more than 100 experiments can be required to produce one viable offspring.[113] In addition, host females may face serious risks, including death.[114]

Researchers are also concerned about the impact that the aging process will have on these cloned animals.[115] Cells are capable of a finite number of divisions.[116] Scientists are unsure what effect the aged nucleus has on these cloned animals.[117] Studies have shown that cloned animals die faster and are unhealthy in most cases.[118] Scientists are also concerned about whether these cells will mutate, thus giving rise to health problems, like cancer, in their offsprings.[119] In fact, Dolly, the celebrity sheep, lived to the age of 6.[120] She was put down by lethal injection in 2003 because she had been suffering from lung cancer and crippling arthritis.[121] Although Dolly's postmortem examination

105. Human Genome Project Information, *supra* note 84.
106. *Id.*
107. National Human Genome Research Institute, *supra* note 56.
108. Human Genome Project Information, *supra* note 84.
109. *Id.*
110. *Id.*
111. *Id.*
112. *Id.*
113. Human Genome Project Information, *supra* note 84.
114. *Id.*
115. National Human Genome Research Institute, *supra* note 56.
116. *Id.*
117. *Id.*
118. *Id.*
119. *Id.*
120. Human Genome Project Information, *supra* note 84.
121. *Id.*

indicated that, other than the cancer and arthritis, she was quite normal, most Finn Dorset sheep live to be 11 to 12 years of age.[122]

Most of the ethical objections to reproductive cloning are expressed in "playing God" arguments.[123] Opponents believe that researchers are upsetting the natural balance to life and that reproductive cloning would rob "a future individual of the right to a unique identity."[124] Interestingly, much of this concern regarding reproductive cloning is based on the public's misperception that a child can be created who would be identical to an existing person.[125] This fear is based on the theory of genetic determinism, which states that genes alone affect who an individual will become.[126] In reality, individuals are influenced by much more than just their genes.[127] "Each individual is, in fact, the result of a complex interaction between his or her genes and the environment within which she or he develops."[128]

The strongest argument against reproductive cloning encompasses familial and child welfare related considerations.[129] Proponents of reproductive cloning advertise the potential use of this procedure to provide couples, who could not normally have children, with an offspring clone carrying one of his or her parent's genes.[130] Critics, though, argue that cloning would lead to ambiguous familial relationships.[131] They argue that "[i]f the cell nucleus from the father were used, for example, the child would be the genetic son of its grandparents, the genetic sibling of its uncles and aunts and the genetic uncle of its cousins."[132] Furthermore, the situation becomes even more convoluted when parents want to replace a dead child with a clone.[133] Since both the genes and the environment shape a child's development, the clone would not be identical to the dead child.[134] Serious

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122. Human Genome Project Information, *supra* note 84.

123. National Human Genome Research Institute, *supra* note 56.

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.*

128. National Human Genome Research Institute, *supra* note 56.

129. The United Kingdom Parliament, *House of Lords Stem Cell Research Report*, Appendix 6.6, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8316.htm (last visited Nov. 13, 2004).

130. *Id.*

131. *Id.*

132. *Id.*

133. *Id.* at Appendix 6.7.

134. National Human Genome Research Institute, *supra* note 56.

repercussions are likely to emerge in such situations.[135] Parents, who expected to merely substitute the clone for their dead child, may be disappointed.[136] The cloned child, meanwhile, "would have to live with the unavoidable [fact] that it was intended to replace a lost child and was not brought into being for its own sake."[137]

This lack of understanding about reproductive cloning, coupled with the scientific uncertainties surrounding these experiments, have prompted most people to conclude that it would be unethical to create human clones at this point in time.[138]

G. Description of Therapeutic Cloning

Therapeutic cloning, on the other hand, is very different from reproductive cloning.[139] Therapeutic cloning, or embryo cloning, is the production of embryos for research.[140] The purpose of this research is to create embryos that grow to the blastocyst stage so that human embryonic stem cells can be extracted and used for developing therapies and treatments for human ailments.[141] Reproductive cloning, in contrast, would take the next step and actually implant the blastocysts in women's uteruses with the goal of creating babies.[142] Thus, the purposes of reproductive cloning and therapeutic cloning are very different.[143]

Human embryonic stem cells derived from cloned embryos would have the greatest potential to improve organ transplants.[144] As previously discussed, researchers were concerned that patients' immune systems would still reject a donor's embryonic stem cells.[145] If cloned cells were used, that risk would be greatly diminished.[146]

In November 2001, scientists from a biotechnology company in Massachusetts cloned the first human embryos for research.[147] They

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135. The United Kingdom Parliament, *supra* note 129, at Appendix 6.7.

136. *Id.*

137. *Id.*

138. The United Kingdom Parliament, *supra* note 129; Human Genome Project Information, *supra* note 84; National Human Genome Research Institute, *supra* note 56.

139. Human Genome Project Information, *supra* note 84.

140. *Id.*

141. *Id.*

142. *Id.*

143. *Id.*

144. Human Genome Project Information, *supra* note 84.

145. *Id.*

146. *Id.*

147. *Id.*

took eggs from women's ovaries.[148] Next, they removed the nuclei from those eggs and replaced them with skin cells.[149] Despite the limited results from this experiment, the potential use of cloned embryos as a source of embryonic cells can be a safe and acceptable alternative to current practices that can involve the use of cells extracted from aborted and stillborn fetuses.[150]

H. Objections to Therapeutic Cloning

Opponents of therapeutic cloning object to this procedure for several reasons.[151] First, opponents assert that embryos should not be created solely for research purposes.[152] Second, opponents argue that therapeutic cloning is "a step on the slippery slope to 'reproductive cloning.'"[153] Third, researchers have to battle opposition directed at therapeutic cloning because of the public's lack of knowledge about the fundamental differences between reproductive and therapeutic procedures.[154] "The difficulty in making a distinction between reproductive and therapeutic cloning is showing up most evidently in two competing Senate bills."[155] In 2003, Senate Majority Leader Bill Frist proposed a bill that would ban all forms of cloning.[156] The other bill, in contrast, banned reproductive cloning, while it allowed therapeutic cloning.[157]

It appears that there is often some degree of stigma attached to any cloning procedure, regardless whether its goal is to create baby clones or to extract human stem cells for therapeutic purposes.[158] Scientists were quick to denounce the announcement made in early 2003 by a religious Sect, the Raelians, that they had created the first human clone.[159] The group failed to provide any evidence in support of its claim and researchers in favor of therapeutic cloning were afraid that they would be unfairly lumped together with scientists who were

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148. Human Genome Project Information, *supra* note 84.

149. *Id.*

150. *Id.*

151. The United Kingdom Parliament, *supra* note 129, at § 5.5.

152. *Id.*

153. *Id.*

154. Gregory E. Kaebnick, *All Clones are Not the Same*, N.Y. TIMES, Jan. 2, 2003, at A17.

155. *Id.*

156. *Id.*

157. *Id.*

158. Gina Kolata, *The Promise of Therapeutic Cloning*, N.Y. TIMES, Jan. 5, 2003, § 4, at 7.

159. *Id.*

carrying out reproductive cloning experiments.[160] Scientists want to be clear that the Raelians were not engaging in therapeutic cloning research.[161] They declared that "[w]hat [the Raelians] said [they] did is reproductive cloning, which creates humans but has no role in curing disease."[162] They also exhorted the scientific community to "plead with the public, [to avoid being tarred] with the same brush."[163] Scientists are fearful that therapeutic research will continue to suffer setbacks unless the public becomes aware of the fundamental differences in these two types of cloning procedures.[164]

In November 2003, the *New York Times* reported that President Bush was supporting a United Nations proposal banning all types of cloning, including therapeutic cloning.[165] There were three competing resolutions and the U.S.'s position, while by far the most extreme, was backed by more than 100 countries.[166] Belgium advanced a more moderate proposal, banning only reproductive cloning, not therapeutic cloning.[167] This second plan was supported by approximately 20 countries.[168] Even though the U.N. has no authority to ban research itself, the nations that sign a treaty are expected to adhere to it.[169] The U.S. supports the position that a partial ban would "leave open the door to abuses, with the emergence of a black market in embryos provided by impoverished women."[170] Researchers, however, argue that a total ban would deprive signatory countries from reaping the benefits of therapeutic cloning procedures that are much less controversial and risky than reproductive cloning techniques since embryos are created in a lab, outside of women's uteruses.[171] The "U.S.-led drive for a broad global ban on all forms of human cloning" was eventually blocked by the U.N. general assembly's legal committee, which voted 80 to 79, with 15 abstentions, to defer drafting the treaty until 2005.[172]

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160. Kolata, *supra* note 158.

161. *Id.*

162. *Id.*

163. *Id.*

164. *Id.*

165. *A Fight at the U.N. Over Cloning*, N.Y. TIMES, Nov. 5, 2003, at A24; Semple, *supra* note 94.

166. Semple, *supra* note 94.

167. *Id.*

168. *Id.*

169. *Id.*

170. *Id.*

171. National Human Genome Research Institute, *supra* note 56.

172. Irwin Arieff, *US Loses UN Vote on All-Out Cloning Ban*, THE GUARDIAN, Nov. 7, 2003, *available at* http://www.guardian.co.uk/international/story/0,3604,1079871,00.html

I. U.S. Regulations on Cloning

The U.S. House of Representatives voted 265 to 162 in July 2001 to make any form of cloning a criminal offense.[173] One year later, President Bush announced his policy to restrict government funds to research involving preexisting embryonic stem cell lines.[174] Current bills before Congress vary from conservative versions prohibiting all types of cloning, like the Frist proposal, to moderate versions prohibiting reproductive cloning and imposing a moratorium on therapeutic cloning, to the most liberal proposal prohibiting reproductive cloning while permiting therapeutic cloning.[175] Currently, the Senate has not taken any action, and researchers expect the President to announce a moderate plan, which would prohibit reproductive cloning and impose a moratorium on therapeutic cloning.[176]

Gregory E. Kaebnick, a bioethics research associate at The Hastings Center wrote, "Distinctions that require explanations tend to get lost in public debate, and the controversy over cloning is a perfect example. There are two fundamentally different types of cloning—reproductive cloning and therapeutic cloning—but the distinction between them is in danger of getting lost. And if it does, it could be a severe blow to science."[177] Time will reveal whether or not researchers in the genetics field will be able to overcome the public's misperception of therapeutic cloning and convince legislators to permit this procedure. Otherwise, scientists will be unable to realize the full potential of human embryonic stem cell research.[178]

II. U.K. Regulatory Scheme Regarding Embryonic Stem Cell Research and Therapeutic Cloning

A. Introduction

The U.K.'s approach to human embryonic stem cell research and therapeutic cloning has evolved with emerging technologies and, as a result, has enabled that country to take advantage of these new fields of research while staying in tune with its citizenry.[179] The British

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(last visited Nov. 13, 2004).

173. National Human Genome Research Institute, *supra* note 56.

174. *Id.*

175. *Id.*

176. *Id.*

177. Kaebnick, *supra* note 154.

178. *Id.*

179. *See generally* The United Kingdom Parliament, *supra* note 129.

Parliament appointed the Warnock Committee [hereinafter the Committee] to report its findings about the ethics of human embryonic stem cell research.[180] The Committee started by considering what status should be granted to an early embryo.[181] The Committee "adopted a position between these opposing views, concluding that the early embryo has a special status but not one that justifies its being accorded absolute protection."[182] This view was reflected in the Human Fertilization and Embryology Act of 1990 [hereinafter the 1990 Act] that the Parliament eventually adopted.[183]

B. Warnock Committee Defines Status of an Early Embryo

The Committee first reasoned that persons must be respected so they cannot be treated as mere means.[184] The Committee attempted to accommodate various competing interests, including religious organizations, right-to-life advocates, members of the scientific community as well as many other groups.[185]

The Committee considered the basic arguments that right-to-life advocates assert. People who advocate that embryos also deserve the same protection that persons receive rely on the fact that embryos have the potential to become persons.[186] It seems to follow, according to proponents of this position, that the embryo is alive and must therefore have a right to life.[187]

The Committee, on the other hand, took into account arguments that embryos should not share the same status as persons.[188] First, babies have a "continuity of identity," between the baby and the adult it will one day become.[189] An embryo, meanwhile, does not have that same continuity.[190] A blastocyst can become a heart or an umbilical cord or divide to form twins.[191]

Second, the embryo, on its own, cannot survive.[192] "Although the

180. The United Kingdom Parliament, *supra* note 129, at § 4.
181. *Id.* at § 4.5.
182. *Id.*
183. The United Kingdom Parliament, *supra* note 129, at § 4.5.
184. *Id.* at § 4.7.
185. *Id.* at §§ 4, 5.
186. *Id.* at § 4.9.
187. *Id.*
188. The United Kingdom Parliament, *supra* note 129, at § 4.21.
189. *Id.* at § 4.9.
190. *Id.* at § 4.11.
191. *Id.* at § 4.11.
192. *Id.*

early embryo contains within it the full genetic potential of one or several human beings who may develop from it, it requires many other factors, particularly those provided by the maternal environment in the womb, to enable it to realise that potential."[193] Embryos, like tissues and cells are technically alive, but being alive does not necessarily mean an embryo is afforded a full right to life.[194]

Third, the Committee weighed in on the reaction that cultures have when an early embryo is lost.[195] It stated that "[a]lthough would-be parents may feel sad at the natural loss of early embryos before implantation, there is no public mourning ritual associated with it, nor is there for the loss of surplus embryos left over from IVF treatments."[196]

Fourth, the Committee evaluated current British legislation directed at research on human embryos.[197] Abortion has been legal for over 30 years in the U.K.[198] The Abortion Act permits the termination of pregnancies where fetuses are 24 weeks or less.[199] This legislation "reflects a gradation in the respect accorded to a fetus as it develops from the early embryo to its birth."[200] This law seems to echo the majority opinion. In addition, *in vitro* fertilization has been used for 25 years and has garnered much public support.[201] Since there is no way to avoid the creation of surplus embryos, some will be destroyed.[202] The Committee therefore concluded that "[t]o accord the early embryo the full protection accorded to a person would also be inconsistent with the use of IVF."[203]

Finally, there are many advocates who argue that the benefits of embryonic stem cell research and therapeutic cloning outweigh the evil of destroying embryos.[204] These procedures have the potential to treat many serious illnesses.[205] It follows that "respect for persons may take the form of developing treatments for serious degenerative diseases, and there can be few causes more worthwhile than to relieve the suffering

193. The United Kingdom Parliament, *supra* note 129, at § 4.11.
194. *Id.* at § 4.14.
195. The United Kingdom Parliament, *supra* note 129 at § 4.13.
196. *Id.* at § 4.13.
197. *Id.* at § 4.20.
198. *Id.*
199. *Id.* at § 4.20.
200. The United Kingdom Parliament, *supra* note 129, at § 4.20.
201. *Id.*
202. *Id.*
203. *Id.*
204. *Id.* at § 4.17.
205. The United Kingdom Parliament, *supra* note 129, at § 4.17.

caused by the diseases."[206] Although the Committee gives preference to embryos extracted from surplus embryos from *in vitro* fertilization procedures, the 1990 Act allows for the creation of embryos specifically for research purposes when "there is a demonstrable and exceptional need."[207] Thus, the Committee concluded that an embryo should have the status of a potential person, but they would not grant embryos an unconditional claim to protection since embryonic cells have the potential to facilitate so many important treatments.[208]

C. *Human Fertilization and Embryology Act of 1990*

The Committee's report led to the 1990 Act that is still relevant and supported by the majority of British citizens.[209] The Act requires that a fourteen-day limit from the time the embryo begins to develop be imposed on embryonic research.[210] This is because "[f]ourteen days has an objective justification insofar as it represents the stage at which the primitive streak, the precursor of the development of a nervous system, begins to appear."[211] The Act requires informed consent from the donors, outlaws payment for donations, places restrictions on the export of the embryos, and requires meticulous record-keeping to account for the creation and disposal of embryos.[212]

The U.K. regulatory scheme also established The Human Fertilisation and Embryology Authority (HFEA) to oversee the use of embryonic cells.[213] The HFEA has been successful because it has commandeered respect from both the medical and scientific communities, as well as the British citizenry.[214] The HFEA uses experts in the field to peer-review applications to ensure that the proposed use of embryos is in accordance with legislative requirements.[215] The HFEA then grants licenses to scientists to engage in embryonic stem cell research.[216] This agency also controls the development of new stem cell lines when it is satisfied that there are no suitable existing cell lines.[217]

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206. The United Kingdom Parliament, *supra* note 129, at § 4.17.
207. *Id.*
208. *Id.* at § 4.28.
209. *Id.* at §4.20.
210. *Id.* at § 4.22.
211. The United Kingdom Parliament, *supra* note 129, at § 4.20.
212. *Id.* at § 4.25.
213. *Id.* at § 8.
214. *Id.* at § 8.1.
215. *Id.* at § 8.2.
216. The United Kingdom Parliament, *supra* note 129, at § 8.6.
217. *Id.* at § 4.

Moreover, the HFEA worked with the British Department of Health and the Medical Research Council (MRC) to establish an embryonic stem cell bank to ensure the purity of these cells and to develop codes of conduct for the use of the bank.[218]

D. U.K. Restrictions on Reproductive and Therapeutic Cloning

In 2001, the British Parliament issued additional regulations under the Human Fertilization and Embryology Act of 1990 to address cloning.[219] The Parliament took into account the same factors that were present in the human embryonic stem cell research debate and concluded that therapeutic cloning should be permitted and reproductive cloning should be banned.[220]

The Parliament decided to address the two types of cloning in separate pieces of legislation.[221] First, the government passed the Human Reproductive Cloning Act of 2001 that banned reproductive cloning.[222] This law makes it a criminal offense for researchers to transplant a cloned embryo into a woman's uterus.[223]

Meanwhile, the Parliament had merely extended the 1990 Embryology Act to include therapeutic cloning.[224] This decision was met by much criticism.[225] Opponents of the 1990 Act argue that it should not be used to regulate therapeutic cloning because the legislation made no mention of cloning or cell nuclear transfers (CNR).[226]

The Parliament countered by stating that it extended the 1990 Act with the 2001 Regulations because the inclusion of therapeutic cloning aligned with the original purpose of the law.[227] The government reasoned that ten years ago researchers believed that cell nuclear replacement only had application in reproductive cloning.[228] Now scientists realize that this technique has application in therapeutic

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218. The United Kingdom Parliament, *supra* note 129, at §§ 8.26, 8.27.
219. *Id.* at § 5.1.
220. *Id.* at § 8.
220. *Id.*
221. *Id.*
222. The United Kingdom Parliament, *supra* note 129, at § 8.16.
223. *Id.* at § 8.16.
224. *Id.* at § 5.4.
225. *Id.* at § 5.5.
226. *Id.* at § 5.1.
227. The United Kingdom Parliament, *supra* note 129, at § 5.4.
228. *Id.* at § 5.9.

cloning.[229] The British government weighed the same factors that were present in the human embryonic stem cell research debate and concluded that the benefits of therapeutic cloning outweigh the ethical problems associated with this procedure.[230] Thus, the government imposed strict guidelines to limit the creation of cloned embryos to situations where "there is a demonstrable and exceptional need which cannot be met by the use of surplus embryos."[231] The Parliament concluded that therapeutic cloning is a vital research tool for scientists to further human embryonic stem cell research and, as a result, extended the 1990 Act to allow for this type of procedure.[232]

Even though the British Parliament has passed more legislation than the U.S. to regulate the use of embryonic cells, the U.K. maintains a much more open-minded approach to these controversial procedures.[233] In providing public funding, the British government has the luxury of installing an agency to oversee the use of embryos while being able to require meticulous record-keeping by researchers to account for every embryo.[234] The U.K. system is both well-managed and supportive, thus granting British citizens access to the benefits of embryonic stem cell research and therapeutic cloning.[235]

III. UNREGULATED, PRIVATE GENETIC RESEARCH IN THE U.S.

A. Introduction

The U.S. government needs to adopt an approach similar to the U.K.'s regulatory scheme in order to reap the potential benefits of human embryonic stem cell research and therapeutic cloning. The U.S. government has been too restrictive with appropriations of government funds for human embryonic stem cell research and therapeutic cloning.[236] At the same time, the government has so far provided only minimal guidelines for private research.[237]

Since the private research sector is largely unregulated, the government has essentially turned its back to the consequences of procedures that use human embryonic stem cells, which may challenge

229. The United Kingdom Parliament, *supra* note 129, at § 5.9.
230. *Id.* at § 5.4
231. *Id.* at § 5.14.
232. The United Kingdom Parliament, *supra* note 139, at § 5.14.
233. *Id.* at § 8.
234. *Id.*
235. *Id.*
236. White House Press Release, *supra* note 85.
237. *Id.*

what society is capable of tolerating at this time. A British online magazine included an editorial piece in 2003 that told the story of two brothers, Jamie and Charlie Whitaker.[238] Charlie is five-years old and suffers from a rare blood disorder that requires him to undergo painful blood transfusions and injections.[239] A promising treatment requires the transfusion of blood stem cells taken from an umbilical cord of a baby with a matching tissue type.[240]

Charlie's parents decided to have Jamie, a "saviour sibling," serve as a tissue match for his big brother.[241] Jamie was conceived via a process of fertilization, genetic testing and selection of embryos prior to pregnancy to ensure the likelihood that his tissue would be compatible with his older brother's.[242] This process is also referred to as designing babies. The boys' mother says that the family "combined having more [children] with helping Charlie."[243]

The British family turned to a Chicago clinic for help after the HFEA decided it would not grant the Whitakers permission to use *in vitro* fertilization and genetic testing since Charlie's condition was not known to be significantly influenced by genetic factors.[244] The British agency concluded that "[i]f there are benefits for the child to be created from a [tested] embryo. . .to avoid significant risk of serious disease, then. . .the balance of potential harm and potential good falls in a different place than if you are simply [testing] an embryo for the benefit of another person."[245] Even though the HFEA came under fire for not helping Charlie, the agency concluded that the risks were too great in this instance.[246] Furthermore, the agency felt that the process may be beyond what the British public will tolerate at that time.[247]

Therefore, the family set its sights on America where private sector scientists were willing to make this controversial leap.[248] So it happened that "the much-maligned American private sector, and a specific Chicago clinic in particular,. . .stepped in where others in the U.K.

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238. John Gillott, *IVF babies: Life Chances*, Spiked Science, *at* http://www.spiked-online.com/Articles/00000006DE17.htm (last visited Nov. 13, 2004).

239. *Id.*

240. *Id.*

241. Gillot, *supra* note 238

242. *Id.*

243. *Id.*

244. *Id.*

245. *Id.*

246. Gillot, *supra* note 238.

247. *Id.*

248. *Id.*

either could not or would not."[249] Since there are no laws restricting these human embryonic stem cell procedures in the private sector, no one stopped to involve the American citizenry in the public debate. No one discussed whether or not "designing" Jamie was too risky and whether or not the procedure went beyond the limits of what Americans are willing to tolerate.

B. Discussion of Techniques for Designing Babies

There are several different techniques for designing babies.[250] Some techniques serve important medical purposes.[251] First, embryos can be screened where the likelihood is high that an offspring will have a serious genetic disease.[252] Embryos that have the inherited condition are not implanted in the womb.[253] Second, embryos can also be screened for unknown diseases.[254] Again, only the healthy embryos are implanted.[255] Third, embryos can be screened to select the sex of a baby to prevent certain diseases that are only passed through the male line or the female line.[256]

Other, more controversial, techniques may also be possible in the future.[257] Scientists hope to one day fix defective or diseased embryos when they are at an early stage.[258] Therapeutic cloning could be utilized to replace a cell's defective DNA with healthy DNA.[259] This technique has not been carried out on humans yet.[260] An even more controversial technique would allow doctors to create a genetic profile for each embryo and parents could then select an embryo based on that profile.[261] This technique has no therapeutic value, but it is also not possible right now.[262] Perhaps the most controversial technique involves the genetic manipulation of embryos for cosmetic reasons.[263] In the future it may be

249. Gillot, *supra* note 238.
250. Center for the Study of Technology and Society, *Special Focus- Designer Babies*, http://www.tecsoc.org/biotech/focusbabies.htm (last visited Nov 13, 2004).
251. Center for the Study of Technology and Society, *supra* note 250.
252. *Id.*
253. *Id.*
254. *Id.*
255. *Id.*
256. Center for the Study of Technology and Society, *supra* note 250.
257. *Id.*
258. *Id.*
259. *Id.*
260. *Id.*
261. Center for the Study of Technology and Society, *supra* note 250.
262. *Id.*
263. *Id.*

possible for parents to choose the eye color, hair color, and height of their offspring.[264] Scientists point out, though, that other characteristics such as intelligence, athleticism, and beauty are ultimately determined by a child's environment, thus minimizing the effect of genetic manipulation on the development of the human being.[265]

C. Objections to Designing Babies

The basic arguments against "designing babies" involve the "looming shadow of eugenics- the practice of 'improving' the human gene pool by eliminating undesirables."[266] Critics assert that tampering with early embryos and stem cells may actually bring about unintended mutations to the gene pool.[267] Furthermore, opponents state that it is unethical to treat an embryo as a means to parents' happiness.[268] Likewise, economic pressures may be a factor when parents make design choices because "[i]nsurance companies, for instance, may refuse to cover a newborn with a condition that could have been corrected before birth, thus, forcing parents to design their child."[269]

Another major social concern is that these designing techniques will lead to a race of super humans who could discriminate against others without genetic enhancements.[270] Moreover, if these techniques are only available to the wealthy, the poor will be left to suffer through these inherited ailments.[271] Finally, many of these techniques can lead to the destruction of embryos either inside or outside a woman's womb, which is anathema to anti-abortion advocates.[272]

D. Implications of "Designing Techniques"

In a related story, the New York Times printed repeated ads for the Genetics and IVF Institute (GIVF) that openly marketed a eugenics procedure to let parents select the sex of their baby.[273] The ad offers the sex-selection procedure as a method of "balancing" the makeup of a

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264. Center for the Study of Technology and Society, *supra* note 250.
265. *Id.*
266. *Id.*
267. *Id.*
268. *Id.*
269. Center for the Study of Technology and Society, *supra* note 250.
270. *Id.*
271. *Id.*
272. *Id.*
273. Austin Ruse, *New York Times Ads Offer Designer Babies*, Wed., Oct. 8, 2003, NewsMax.com, *at* http://www.newsmax.com/archives/articles/2003/10/8/23812.shtml (last visited on Nov. 13, 2004).

family and allow for treatment of babies with gender-linked health problems.[274] The article also reported that in the U.K. there have been cases where mothers of babies with Down syndrome or simply surgically correctable ailments have been pressured by doctors "to abort their babies for the greater good of society."[275]

Opponents of this genetic testing procedure are hoping that legislators will take their warnings as a wakeup call.[276] Bill Albert, member of the Council of Disabled People, says that Americans need to "face up to what's going on and not say this is about choice [since] this is [really] about elimination."[277] Opponents believe that designing techniques would wipe out the disabled portion of our population.[278]

The novelty of these designing procedures and the public's lack of awareness have permitted private sector scientists to slip under the radar of government regulation. Since the U.S. does not have a strong regulatory structure in place to deal with embryonic stem cell research and therapeutic cloning, especially in the private sector, scientists may view the government's hands-off approach a license to run free with emerging techniques. Leslie Bender, an Associate Dean and Professor of Law and Women's Studies at Syracuse University College of Law, advocated in a journal article that the U.S. legislature needs to address these new reproductive techniques because the courts have been forced to settle disputes where there is little or no legal or policy guidance, resulting in frequent mistakes by the judiciary.[279] Researchers, meanwhile, are fearful that legislators will eventually react to these radical procedures and, without drawing distinctions between the various uses of embryos, will institute a complete ban or moratorium.[280]

IV. THE U.S. SHOULD ADOPT BRITAIN'S REGULATORY APPROACH TO HUMAN EMBRYONIC STEM CELL RESEARCH AND THERAPEUTIC CLONING

Thirty years after *Roe v. Wade*,[281] the U.S. has failed to come to terms with the debate over the legal status of an embryo.[282] Abortion is still a politically divisive issue in America, and it is unlikely that

274. Ruse, *supra* note 273.

275. *Id.*

276. *Id.*

277. *Id.*

278. *Id.*

279. Leslie Bender, *Genes, Parents, and Assisted Reproductive Technologies: ARTs, Mistakes, Sex, Race, & Law*, 12 COLUM. J. GENDER & L. 1, 13-14, 74-75 (2003).

280. National Human Genome Institute, *supra* note 56.

281. *Roe v.* Wade, 410 U.S. 113, 35 LEd. 2d 147, 93 S.Ct. 705 (1973).

282. Denise Stevens, *supra* note 34, at 625.

Congress will resolve it any time soon.[283] Most opposition to the use of embryonic cells in the U.S. revolves around "religious and ethical principles [that] play an influential role in lawmaking."[284]

The U.K., meanwhile, has adopted the view that it is difficult to justify an absolute prohibition on the destruction of early embryos while permitting abortion after a fetus has begun to develop.[285] In addition, the British Parliament relies on the fact that the majority of its citizens support embryonic stem cell research and therapeutic cloning. The U.K., through careful consideration and strict regulation, has been able to find an appropriate middle ground.

The U.S. government; however, has not been as successful at finding a consistent approach. On the one hand, the government has been too conservative in providing federal funds for embryonic research, mostly due to misunderstanding and blurry distinctions between embryonic stem cell procedures. On the other hand, the U.S. government has been too liberal in not providing more restrictions on private sector embryonic research. Another important challenge facing American legislators is the difficulty in transforming healthcare system to enable healthcare organizations to incorporate these new technologies.

Before his death, Christopher Reeve, the actor-turned-patient and advocate for embryonic stem cell research, gave a talk that cited polls showing 68 percent of Americans actually support all types of embryonic stem cell research.[286] In 1995, Reeve was injured in a horse riding accident that left him paralyzed.[287] He warned that politics in the U.S. were getting in the way of patient hope, claiming the U.S. government had become a roadblock between the American people and the life-saving therapies and treatments that resulted from embryonic cells.[288] He stated that countries, like the U.K., have "purified embryonic stem cell lines, ready for export around the world," and that the U.S. "must reclaim [her] preeminence."[289]

Without adequate federal funding there is a danger that U.S. academic researchers will leave and go to other countries to conduct

283. Denise Stevens, *supra* note 34, at 625.

284. Young, *supra* note 32, at 834.

285. The United Kingdom Parliament, *supra* note 129, at § 4.25.

286. Robin Rupli, *Actor Christopher Reeve, Scientists Review Progress of Stem Cell Research*, VOANEWS, *at* http://www.voanew.com/article (last visited on Nov. 13, 2004).

287. *Id.*

288. *Id.*

289. *Id.*

their research.[290] The economic reality is that "[a]lthough the biotechnology industry has noble goals, it is profit driven."[291] Not only will these other countries benefit from the contributions made by U.S. researchers, but they will also benefit economically when the U.S. is forced to pay for the use of their stem cell lines.[292]

It seems that the U.S. has no choice but to provide federal funds and put in place a regulatory structure aimed at a controlled facilitation of the use of embryonic cells. Recently, South Korean scientists announced that they successfully cloned human embryos extracted from embryonic stem cells and derived from eggs donated by Korean women.[293] The U.S. needs to come to terms with the use of embryonic stem cells or, otherwise, the U.S. will lose its preeminence in the scientific arena, the American public will lose out on the potential benefits of embryonic stem cell research and therapeutic cloning, and private sector scientists will continue to utilize genetic testing procedures that are out of sync with American values.

Regardless of how the U.S. government chooses to approach the use of embryonic cells, it is clear that a hands-off approach will not be tolerated for much longer as new techniques are rapidly emerging. In addition, the aging Congress continues to make proposals that federal monies should be used to fund embryonic stem cell research.[294] Congress may one day override the President's current prohibitory policy.[295] Also, states may continue to pass their own laws and, as a result, trigger the national government to reevaluate its own regulatory scheme.[296] New Jersey and California lawmakers recently passed legislation that made a "powerful statement against federal funding restrictions on such research."[297] Furthermore, inconsistent and vague state laws may also prompt the federal government to pass uniform national laws.[298] Once the U.S. government takes another stab at passing regulations concerning embryonic stem cell research and therapeutic cloning, it would be in the interest of all Americans if our legislators and President used the U.K.'s regulatory scheme as a model.

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290. Stevens, *supra* note 34, at 646.

291. *Id.*

292. *Id.* at 647-48.

293. *Scientists 'Cloned Human Embryos,'* CNN.COM, *available at* http://www.cnn.com/2004/HEALTH/02/12/science.clone (last visited Nov. 13, 2004).

294. Davison, *supra* note 84, at 419.

295. *Id.*

296. Laura Mansnerus, *New Jersey Lawmakers Set to Approve Embryonic Stem Cell Research*, N.Y. TIMES, Jan. 11, 2003, at B4.

297. *Id.*

298. Young, *supra* note 32, at 842.

CONCLUSION

Even though the U.K. has codified more rules on embryonic stem cell research and therapeutic cloning than the U.S., "these regulations reflect a more permissive attitude toward conducting and funding research."[299] President Bush's policy restricting federal funding for these types of research has made it impossible for the NIH to develop guidelines that "promote medical advancements and appropriately limit research under the authority of a conflicted federal government."[300] Congress, the President, and the American public lack enough information to make informed decisions and to distinguish beneficial therapies from those procedures that are considered too controversial. Consequently, the U.S. fails to make any significant breakthroughs in the fight against potential diseases and in the search reproductive treatments to be derived from embryonic stem cell research and therapeutic cloning.

299. Young, *supra* note 32, at 852.

300. Davison, *supra* note 85, at 427.