Misapplied Ethical Considerations: U.S. Federal Stem Cell Mandates Lack Global Focus and Market Foresight

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Misapplied Ethical Considerations: U.S. Federal Stem Cell Mandates Lack Global Focus and Market Foresight

Heather L. Fowler†

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† The author is a third-year law student at Cornell University. She would like to thank all those who disagreed with her, especially her Dad, because those arguments strengthened this paper. She would also like to thank her supporters, especially her Mom, for sticking up for her.
Introduction

"We have arrived at that brave new world that seemed so distant in 1932, when Aldous Huxley wrote about human beings created in test tubes," remarked President Bush as he announced new restrictions on federal funding of stem cell research. Embryonic stem cells are a unique class of cells that possesses the ability to differentiate into almost all of the cells and tissues of the human body. Scientists believe that stem cell research will enable them to find cures for many debilitating diseases. They envision a system of medicine where an Alzheimer's patient could regain his memory by replenishing his brain cells, or a person with kidney failure could revive her organs with new cells rather than a transplant. Scientists believe that this is the untapped power of the stem cell: the ability for patients to draw on their own body's cells and customize stem cells to heal their ailments. According to Dr. Harold Varmus, former Director of the National Institutes of Health (NIH), "there is almost no realm of medicine that might not be touched by this innovation . . . . It is not too unrealistic to say that this research has the potential to revolutionize the practice of medicine and improve the quality and length of life." Scientists involved with embryonic stem cell research say that they cannot ignore any research avenues because they do not know which cells work best as research mediums for particular diseases.

The legal history surrounding stem cell research demonstrates the U.S. federal government's reluctance to embrace this research. In 1994, the NIH's Embryo Research Panel recommended the use of federal funds to support research using human embryos. Congress did not agree with the recommendation, and enacted a federal law banning the use of appropriated federal funds for any research "in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury . . . greater than that allowed for research on fetuses in utero." The Depart-
ment of Health and Human Services (DHHS) reinterpreted the statute’s language in 1999 to find that it did not apply to stem cells.\(^\text{10}\) DHHS relied upon the statute’s definition of embryos as “organisms,” deciding that stem cells are not organisms and thus not embryos with respect to the law.\(^\text{11}\)

Concurrently, advances in the field of stem cell research\(^\text{12}\) led to increased debate as to whether such research was ethical.\(^\text{13}\) The primary ethical concern was the source of stem cells.\(^\text{14}\) Prior to 1998, scientists had used only animal embryos for embryonic stem cell research. But in 1998, Dr. James Thompson of the University of Wisconsin and Dr. John Gearhart of Johns Hopkins University each used privately funded laboratories to isolate and culture human embryonic stem cells for research.\(^\text{15}\) An ethical issue with using human stem cells arises because an embryo used for the sake of its stem cell tissue cannot develop to term, and is thereby denied the opportunity to become a human being.\(^\text{16}\) Thus, the argument goes, the potential of the embryo to become a human is devalued in favor of its immediate value as a source of tissue.\(^\text{17}\)

In response to these initial debates, President Clinton requested that the National Bioethics Advisory Committee (NBAC) review the ethical issues of stem cell research.\(^\text{18}\) The NBAC concluded that it was ethically permissible for the federal government to support research using stem cells

...
from (1) embryos left over from fertility treatments, and (2) cadaveric fetal tissue from elective abortions. Soon after, the NIH published guidelines to regulate stem cell research that supported the NBAC's conclusion. Bearing in mind that Congress had rejected its 1994 recommendation to use federal funds for research purposes, the NIH distinguished embryonic stem cells derived for research purposes and those used for research purposes. The NIH guidelines prohibited publicly funded scientists from employing the former type of stem cells.

The NIH guidelines were never fully implemented because President George W. Bush placed a moratorium on stem cell research soon after taking office. Then, on August 9, 2001, President Bush announced federal mandates that restricted the funding of stem cell research such that researchers could only use embryonic stem cell lines created prior to the announcement of the mandates. The NIH determined that sixty-four human embryonic stem cell lines existed at the time of the announcement.

Despite numerous complaints from the scientific community, these mandates remain in effect. The mandates have increased research delays
and brain drain\textsuperscript{29} in the United States. Many scientists fear that the limits on federal funding severely constrain their research abilities by making access to adequate stem cell lines a slow and frustrating process.\textsuperscript{30} Others have moved, or plan to move, their research to countries with less restrictive regulations on stem cell research.\textsuperscript{31}

This Note argues that the federal mandates restricting stem cell research inappropriately handle the ethical considerations of stem cell research by (1) reflecting the Bush administration's conservative views and pro-life beliefs, and (2) failing to consider both the social costs, such as the delay to current research, the sacrifice of medical advances, and the inevitable "brain drain" from the United States caused by these impediments, and the social benefits of stem cell research. Noting the influx of stem cell researchers to Singapore, where there are more liberal research laws,\textsuperscript{32} I will propose that the United States should adopt an approach for federally-funded embryonic stem cell research like that of Singapore, which is more global and progressive, but still closely regulates research boundaries.

Part I of this Note briefly summarizes stem cell biology and research use. Part II discusses the current state of stem cell research in the United States. Part III details Singapore's regulatory scheme for stem cell research. Part IV compares the U.S. and Singaporean approaches to the ethical considerations of stem cell research. Part V discusses the shortcomings of the Bush administration's mandates and the need to adopt an approach like that of Singapore, which incorporates ethical concerns into an analysis of the costs and benefits of stem cell research.

I. Stem Cells

Any given human being is never the same conglomerate of cells on a day-to-day basis but nevertheless remains the same person. This may seem

\textsuperscript{29} University negotiated for months with the owners of cell lines in India only to have the Indian government ban the export of the cells. \textit{See Statement of Curt I. Civin, supra} note 27, at 21. Roger Pendersen, who formerly worked at the University of California, San Francisco, but moved to Cambridge University in England to take advantage of more liberal stem cell research regulations, noted that the lack of U.S. federal support has "undoubtedly" delayed the benefits of research to patients with degenerative diseases. \textit{Status of the Implementation of the Federal Stem Cell Research Policy: Hearings Before the Subcomm. on Labor, Health & Human Servs., Educ., & Related Agencies of the Senate Comm. on Appropriations, 107th Cong. 12} (2002).

\textsuperscript{30} \textit{See Send in the Clones, THE EcONOMIST, Aug. 24, 2002, at 58.} (discussing the recent influx to researchers to Singapore to take advantage of new research facilities, large amounts of funding, and permissive stem cell research regulations).

\textsuperscript{31} \textit{See Statement of Curt I. Civin, supra} note 27, at 20; \textit{see also} Melissa Huang, \textit{Stem Cells Responsible for Medical Discoveries, Ethics Controversy, UNIVERSITY WIRE, Sept. 17, 2001} (quoting Ted Kennedy as stating that "many in the scientific community are concerned that the President's decision will delay development of cures for dread disease for many years, at the cost of countless lives and immeasurable suffering"); Kelly Hearn, \textit{New Stem Cell Lines Will be Needed, UNITED PRESS INT'L, Oct. 31, 2001} (expressing concern that "existing stem cell lines could accrue genetic abnormalities over time[,]" thus requiring new stem cell lines).

\textsuperscript{32} \textit{See id.; see also infra note 80.}
like an odd statement, at least until one considers that human beings are made up of trillions of cells which are constantly being replenished or repaired by other cells: stem cells. While most of the body’s cells are organized into specialized tissues and organs, stem cells are unspecialized and have the potential to become different cell types.33

There are two main types of stem cells: adult and embryonic. Adult stem cells are specific to certain tissues—usually bone marrow, skin, liver, and other organs—and have the limited ability to form certain cell types for only their assigned tissue.34 Embryonic stem cells can form virtually any cell in the body, because unlike adult stem cells, they are not differentiated for a specific tissue.35

Embryonic stem cells are unique in that they are self-renewing and can repopulate themselves while in an undifferentiated state.36 In contrast, adult stem cells are specialized and cannot maintain long-term, self-renewing capacities.37 The ability of embryonic stem cells to divide extensively has led some nonscientists to assert that researchers can simply use existing stem cell lines for their research.38 However, many scientists, and the NBAC, state that this is a misunderstanding of the science involved.39 They say that it is essential for scientists to repeatedly derive new embryonic stem cell lines because (1) the properties of the cells differ depending on the methods used to derive them, (2) embryonic stem cells are unstable cell types that cannot undergo mass production without sustaining irreversible changes,40 and (3) there remains a tremendous amount for scien-

33. See NBAC REPORT, supra note 4, at 1.
34. See Ariff Bongso, M.D., Human Embryonic Stem Cells—Science & Ethics, in ETHI-
CAL, LEGAL AND SOCIAL ISSUES IN HUMAN STEM CELL RESEARCH, REPRODUCTIVE AND THERA-
PEUTIC CLONING: A REPORT FROM THE BIOETHICS ADVISORY COMMITTEE SINGAPORE E3-6, E3-7 (2002); STEM CELL BASICS, supra note 3. Recent research has shown, however, that some adult stem cells, when transferred to another tissue, take on the characteristics of that tissue. See Juan R. Sanchez-Ramos et al., Expression of Neural Markers in Human Umbilical Cord Blood, 171 EXPERIMENTAL NEUROLOGY 109 (2001) (bone marrow cells to muscle cells and to nerve cells); A.L. Vescovi, R. Galli & A. Gritti, The Neural Stem Cells and Their Transdifferentiation Capacity, 55 BIOMEDICINE & PHARMACOTHERAPY 201, 203 (2001) (the reverse); Vaclav Ourednik et al., Segregation of Human Neural Stem Cells in the Developing Primate Forebrain, 293 SCI. 1820 (2001) (glial cells to nerve cells); Christopher R.R. Bjornson et al., Turning Brain into Blood: A Hematopoietic Fate Adopted by Adult Neural Stem Cells in Vivo, 283 SCI. 534 (1999) (neural stem cells to blood cells).
35. See STEM CELL BASICS, supra note 3.
36. See id.
37. See id.
38. See NBAC REPORT, supra note 4, at 19. It is President Bush’s view that the stem cell lines existing as of August 9, 2001 are sufficient to sustain stem cell research in the United States. See Bush Address, supra note 1, at 955-56.
39. See NBAC REPORT, supra note 4, at 19.
40. A study showed that existing stem cell lines commonly used by researchers have lost the ability to generate all mouse tissues. See A. Nagy et al., Derivation of Completely Cell Culture-Derived Mice from Early-Passage Embryonic Stem Cells, 90 PROCEEDINGS OF THE NAT’L ACADEMY OF SCI. USA, 8424 (1993). The researchers concluded, “[P]rolonged passage in culture reduces the potential of the ES-cell population as a whole . . . [T]he proportion of cells that retains full potential diminishes with extended passage.” Id. at 8427.
tists to learn about the derivation process.\textsuperscript{41}

Embryonic stem cells can be derived from four main sources: (1) human fetal tissue following an elective abortion (also called cadaveric tissue); (2) human embryos created by \textit{in vitro} fertilization (as a fertility treatment) that are in excess of fertility need and are voluntarily donated; (3) human embryos created by \textit{in vitro} fertilization where the sperm and eggs are donated for the sole purpose of providing research material; and (4) human embryos created asexually by a technique called 'somatic cell nuclear transfer,' which moves an adult human cell nucleus into an enucleated human egg (also called therapeutic cloning).\textsuperscript{42}

Scientists believe that human embryonic stem cells will revolutionize the treatment of many debilitating diseases. Today, doctors often use donated tissues and organs to replace destroyed or ailing tissue, but the need for tissues and organs far outweighs supply.\textsuperscript{43} Stem cells offer a possible renewable source of replacement cells and tissues to treat many diseases.\textsuperscript{44} Two factors contribute to these great therapeutic expectations: (1) the ability of embryonic stem cells to produce almost unlimited numbers of any cell in the body, and (2) the possibility that embryonic stem cells may be genetically engineered to prevent immune rejection by transplant recipients.\textsuperscript{45} Potential treatments include replacing insulin-producing cells in children with Type 1 diabetes,\textsuperscript{46} replacing dopamine-producing cells in individuals with Parkinson's disease,\textsuperscript{47} correcting diseases of the bone or cartilage, such as osteogenesis,\textsuperscript{48} replacing tissue damaged by radiation or chemotherapy cancer treatments,\textsuperscript{49} and restoring immunity in people with AIDS.\textsuperscript{50} Clinical treatments would involve direct injection of the embryonic stem cells into the diseased sites.\textsuperscript{51} It is conceivable that doctors could use embryonic stem cells to build new organs for transplantation.\textsuperscript{52}

\textsuperscript{41} See NBAC REPORT, supra note 4, at 20.
\textsuperscript{42} See id. at 1-2; Bongso, supra note 34, at E3-2.
\textsuperscript{43} See STEM CELL BASICS, supra note 3.
\textsuperscript{45} See Bongso, supra note 34, at E3-5.
\textsuperscript{46} See Suheir Assady et al., \textit{Insulin Production by Human Embryonic Stem Cells}, 50 DIABETES 1691 (2001).
\textsuperscript{48} See Barbara A. Huibregtse et al., \textit{Effect of Age and Sampling Site on the Chondro-Osteogenic Potential of Rabbit Marrow-derived Mesenchymal Progenitor Cells}, 18 J. ORTHOPAEDIC RESEARCH 18, 18-24 (2000).
\textsuperscript{51} See Bongso, supra note 34, at E3-6.
\textsuperscript{52} See id.
II. Status of Stem Cell Research in the United States

"As the discoveries of modern science create tremendous hope, they also lay vast ethical mine fields. As the genius of science extends the horizons of what we can do, we increasingly confront complex questions about what we should do . . . . So I have decided we must proceed with great care."

In 2001, President Bush stated that the federal government would not endorse or fund stem cell research that would result in further destruction of human embryos. As a result, scientists could either try to use one of the validated, existing stem cell lines, or establish two separate laboratories: one for federally-funded stem cell research and the one for privately-funded stem cell research. Most scientists find the latter route unfeasible because it creates duplication that is incredibly expensive and private funding sources have significantly decreased due to changes in the economy.

On the other hand, scientists who chose the former route complain that more than a year later, they still have not been able to locate or obtain viable stem cell lines to use for their research. They note that the problems hindering their ability to obtain cell lines include questions of who owns the line, scientists not wanting to share their lines with other researchers, companies demanding a piece of profits of future discoveries in exchange for cell lines, and the astronomical fees charged to obtain lines. Additionally, because little is known about the cell lines themselves, scientists must engage in time-consuming and frustrating processes to determine whether a particular cell line will advance their research. While the NIH has listed more eligible lines on its registry, only a fraction of these lines are accessible, and scientists are wary of the persistence and patience needed to obtain the cell lines.

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53. Bush Address, supra note 1, at 955 (emphasis added).
55. See id.
56. See id. (noting the added costs of obtaining two, rather than one, set of laboratory equipment and the time for scientists to commute between labs).
58. See id. at 20. (noting that while the NIH provided a list of stem cell lines that could be used in federally funded research, scientists quickly discovered that "none of these cell lines was available readily to us"). Dr. Civin states that he spent several months negotiating with an Indian company, Reliance Life Sciences, to obtain cell lines that, as required by his research needs, would not form blood cells and would grow rapidly. See id. at 21. The agreement was cancelled, however, in May 2002 when the Indian government put an indefinite hold on the export of stem cells. See id. Additionally, he recounts the story of a colleague who applied to receive a line of stem cells from Wisconsin in the Fall of 2001. See id. After a series of negotiations, a $5,000 fee, and a six-month wait, his colleague finally received the cells, only to discover that they grow exceedingly slowly—at one-tenth the rate of cells normally used. See id.
59. See id. (stating that the administrative burdens to obtain a cell line are unreasonable and that while researchers used to pay $50-100 for a cell line, they now have to pay $5,000 upfront).
60. See id.
61. See Scientists: Stem Cell Rules Halt Progress, supra note 27.
62. See id.
U.S. scientists are understandably frustrated with the slow pace the new regulations have forced them to assume. There is a broader concern that the United States, traditionally a leader in biomedical research, is falling behind and that the American people, who are usually the first in line for new medical treatments, will have to wait longer.

While most Americans believe that human stem cell research should continue, they probably do not realize that stem cell research is continuing at a much faster pace in other countries. Americans are also probably unaware that the "brain drain" caused by the outflow of U.S. scientists to other countries is a growing problem. Lured by the prospect of readily available stem cell lines that adequately fit their research needs and more favorable regulations of stem cell research that allow for a wider pool from which to select stem cells, leading U.S. stem cell researchers are moving their laboratories to other countries.

However, not all American states are content to watch as stem cell researchers struggle. On September 22, 2002, then Governor Gray Davis of California signed legislation that overrides the federal stem cell man-

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63. See statement of Curt I. Civin, supra note 27, at 22 (stating that "without our vigorous leadership in federally supported stem cell research, the pace of discoveries will be much slower than necessary.").

64. See id. (noting that "exciting new stem cell research" has been reported by China, Singapore, Australia, and the U.K.).

65. See id.


67. England faced a similar issue when prior to parliamentary approval of stem cell research, scientists noted that absent this approval they would leave the country to research abroad where stem cell research regulations were more lenient. See Melissa Kite, MPs Pressured Over Human Embryo Vote, THE TIMES (London), December 19, 2000, at 8.

68. See Statement of Curt I. Civin, supra note 27, at 22; see infra note 76.

69. Authorization to conduct research on human embryos has been left to the discretion of the states, subject to the approval of the U.S. Food and Drug Administration under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. See Dept. of Health and Human Services Protection of Human Subjects, 45 C.F.R. § 46 (2000).

70. See CAL. HEALTH & SAFETY CODE §§ 125115-125117 (2003). The Code reads:

Article 5. Stem Cell Research

125115. The policy of the State of California shall be as follows:

(a) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given.

(b) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells, including somatic cell nuclear transplantation, shall be reviewed by an approved institutional review board.

125116. (a) A physician, surgeon, or other health care provider delivering fertility treatment shall provide his or her patient with timely, relevant, and appropriate information to allow the individual to make an informed and voluntary choice regarding the disposition of any human embryos remaining following the fertility treatment.
dates\textsuperscript{71} and provides state support for scientists to create new cell lines for their research.\textsuperscript{72} The bill, which took effect January 1, 2003,\textsuperscript{73} allows researchers in California to use federal and state funds for their research, as long as the federal funds only support research using federally-approved cell lines.\textsuperscript{74} Using state funds, researchers may employ donated surplus embryos or create human embryos\textsuperscript{75} to support their research if an independent review board has approved the project.\textsuperscript{76}

III. Singapore's Stem Cell Law

"If we aspire to be a hub for the life sciences or biomedical sciences, we have got to be doing it in a way which is internationally acceptable. We should be morally clean and not to be seen doing things which others would not want to do..."\textsuperscript{77}

Singapore has made rapid progress in the field of stem cell research during the past two years. In 2001, when President Bush announced the

\textsuperscript{71}(b) Any individual to whom information is provided pursuant to subdivision (a) shall be presented with the option of storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research.

(c) Any individual who elects to donate embryos remaining after fertility treatments for research shall provide written consent.

\textsuperscript{125117.} (a) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.

(b) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.

(c) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.

\textsuperscript{71.} State autonomy in this field may soon end, as Senator Sam Brownback has introduced Senate Bill 1899, which, if enacted into law, would ban therapeutic cloning, reproductive cloning, and the importation of products produced by such processes into the United States with penalties of up to ten years in jail and fines of at least $1 million. Human Cloning Prohibition Act of 2001. S.1899, 107th Cong. 2d Sess. (2002). In addition, the National Academy of Sciences released a report in 2002 recommending that the United States create legislation to ban reproductive cloning. See Committee on Science, Engineering, and Public Policy, National Research Council, Scientific and Medical Aspects of Human Reproductive Cloning (2002).

\textsuperscript{72.} Jim Warren, Taking Aim at Washington, California Adopts Law Permitting Embryonic Stem Cell Research, TRANSPLANT NEWS, Sept. 27, 2002. The Bill articulates the state's rationale for the legislation: "California's biomedical industry is a critical component of the state's economy that provides employment in over 2,500 companies to over 225,000 Californians, pays $12.8 billion in wages and salaries, invests more than $2.1 billion in research, and reports nearly $7.8 billion in worldwide revenue, and would be significantly diminished by limitations imposed on stem cell research." Cal. Health & Safety Code §125116 (2003).

\textsuperscript{73.} See Warren, supra note 72.

\textsuperscript{74.} See Scientists: Stem Cell Rules Halt Progress, supra note 27 (verifying with Dr. Elias Zerhouni, director of the NIH, that researchers in California may use both federal and state funds).

\textsuperscript{75.} Researchers can create human embryos "from any source" including somatic cell transfer transplantation or cloning. Cal. Health & Safety Code § 125115(a) (2003).

\textsuperscript{76.} See Warren, supra note 72.

\textsuperscript{77.} See Singapore Bioethics Panel Recommends Approval of Stem Cell Research, TRANSPLANT NEWS, June 30, 2002 (quoting Lim Pin, chair of the Bioethics Advisory Committee) (emphasis added).
federal stem cell mandates, not a single university in Singapore taught advanced cellular biology and only one prominent researcher in Singapore, Ariff Bongso, studied stem cells. In 2002, Singapore invested in new biomedical research facilities including a 500-acre science park, set aside $2 billion for research in biomedical technology until 2005, and pledged $285 million for science scholarships. Singapore is rapidly realizing the fruits of these investments, as many major names in stem cell research have relocated their research laboratories to the country. Moreover, Singapore is already charting new territory with major advances in the stem cell market, notably by producing marketable, fully human, animal-free stem cell lines. Why is Singapore, a country that a few years ago had barely engaged in stem cell research, able to reap the benefits of a stem cell market when stem cell research in other countries is “crawling like a caterpillar?” In short, because Singapore has tapped the potential of progressive regulation of stem cell research.

Singapore’s Bioethics Advisory Committee (BAC) was commissioned in December 2000 to examine the ethical, legal, and social issues of biomedical science research in Singapore. In February 2001, the BAC created the Human Stem Cell Research (HSR) Subcommittee to study the ethical issues associated with human stem cell research. In addition, the BAC consulted with local interest groups and the public, examined interna-

78. See Send in the Clones, supra note 29, at 58. Bongso was the first scientist to isolate human stem cells, but failed to patent his technique, allowing American researchers to benefit from his work. See id.


80. Alan Coleman, the head researcher of the team that cloned the sheep Dolly, moved his research to Singapore in 2002 to take advantage of government funding. See Send in the Clones, supra note 29, at 58. James Tam, an American academic, was recruited by Singapore to act as dean of the new university research faculty. See id. Edison Liu, formerly a leading researcher at the National Cancer Institute in the U.S., is now head of Singapore’s Genome Institute. See id. Yoshiaki Ito and his research team recently left Kyoto University to join the Institute of Molecular and Cell Biology in Singapore. See id.

81. See First Fully Human Embryonic Stem Cell Line Created in Joint Singapore-Australia Venture, TRANSPLANT NEWS, Aug. 12, 2002. Ariff Bongso, funded by ES Cell International, created a new, totally animal-free cell line that used human skin cells as feeder cells, rather than mouse feeder cells. See id. There are plans to make animal-free cell lines, termed the “next gold standard in stem cells,” commercially available in the future. See id.


83. See Deputy Prime Minister and Minister for Defense Dr. Tony Tan Ken Yam, Speech at the Opening Ceremony of the Conference on “Beyond Determinism and Reductionism: Genetic Science and the Person” (July 17, 2002) [hereinafter Dr. Tan Speech], available at http://app10.internet.gov.sg/data/sprinter/pr/2002071702.htm). Dr. Tan states that the purpose of the BAC was to strike a balance between the competing interests of Singapore in achieving scientific advancement and protecting its people: “We need to allow biomedical science to develop and grow for the benefit of mankind and the continued progress of Singapore. At the same time, we need to debate and address the broader social and ethical issues squarely, and to put in place strong safeguards to protect the individual, public interest and the Singaporean society.” See id.

84. See id.
tional positions, and gathered written submissions on its website to understand public concerns and interests regarding stem cell research. On June 21, 2002, the BAC produced a comprehensive report that recommended a complete ban on human reproductive cloning and made eleven key recommendations for regulating human stem cell research and therapeutic cloning.

The BAC recommended that the government permit human stem cell research and therapeutic cloning under strict regulation. It proposed the creation of a regulatory body to license, control, and monitor human stem cell research in Singapore. In order to maintain respect for the human embryo, the guidelines permit embryonic stem cell research only when the researcher can show that there is "strong scientific merit in and potential medical benefit from" the proposed research.

The BAC recommendations also prioritize the source of stem cells available for research: (1) existing cell lines; (2) surplus embryos; and (3) creation of embryos. Researchers must first use existing stem cell lines because they provide a ready source that does not require further sacrifice of embryos. In light of the limited number of existing cell lines and the concern for possible immunological rejections, a researcher could also use surplus embryos under the recommendations. The BAC reasons that among the dispositional options available to surplus embryos—perishing or using them in research—research is an act of greater respect for the embryo. The BAC believes that scientists can adequately carry out research using existing stem cell lines and surplus embryos, but notes that there may be situations in which there is no acceptable alternative but creation of embryos. In this scenario, the researcher must demonstrate to a designated statutory body that the proposed research has strong scientific merit and a large potential medical benefit.

The Singaporean Government accepted the BAC's recommendations

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85. See id.
87. See id. at iv-vi (qualifying its recommendation by stating that human reproductive cloning should be prohibited).
88. See id. at 32-33.
89. See id. at v.
90. See id. The U.S. also permits federal funding of research using existing cell lines. See Bush Address, supra note 1, at 955-56.
91. See Ethical, Legal, and Social, supra note 86, at 25-26.
92. See id. at 26 (noting that while federal funding does not support the use of surplus embryos in the United States, the NBAC supported federal funding of such research in its report Ethical Issues in Human Stem Cell Research).
93. See id. at 26, 28.
94. See id. at 28. There is evidence that research embryos created through cloning may offer the great benefit of deriving stem cells that are genetically compatible with the person being treated, thereby avoiding the problems of rejection. See id.
95. See id. at 29.
and appointed the Ministry of Health to establish regulations to license, control, and monitor all human stem cell research in Singapore.97 Singapore's Parliament is expected to pass the recommendations into law in 2003.98

IV. Regulation of Stem Cell Research: A Comparison of the U.S. Approach with Singapore's Approach

Ethical considerations feature prominently in debates about the legality of stem cell research. They shape the laws promulgated by countries grappling to regulate stem cell research. In determining the limits of federal funding for stem cell research in the United States, the Bush administration focused almost entirely on ethical issues, incorporating its pro-life and faith-based views into the decision.99 In contrast, Singapore's BAC balanced ethical concerns with the potential public benefit from the research and the costs of restricting research, to determine the scope of the country's stem cell regulations.100 Thus, the BAC's approach closely resembles a cost-benefit analysis, while the Bush approach does not take into account non-religious considerations at all.

A comparison of these approaches, using the two fundamental ethical questions posed by the Bush administration, illustrates the shortcomings of the U.S. federal mandates. The two ethical questions are: (1) are embryos human life and therefore something to protect, and (2) if the embryos will perish anyway, should they be used in research to achieve a greater good?

A. Are Embryos Human Life?

The moral debate about the status of embryos revolves around the question of whether one should treat the embryo as a living person or as a potential life. From a strictly biological point of view, there is not a clear-cut point at which human life begins, as sperm and eggs are living things that fuse to form an embryo that potentially grows into a living person.101 Many scientists support the view that after fusion of the sperm and egg, the resulting blastocyst is not yet an embryo.102 This is because any particular cell in the blastocyst is just as likely to become part of the placenta, which is discarded at birth, as it is to become part of a "potential person."103 Ethics commissions in several countries, including the NIH Human Embryo Research panel in the United States, have approved research on the human embryo until it is fourteen days old.104 Before that time, there is no

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97. See id.; see also Dr. Tan Speech, supra note 81.
98. See Ai-Lien, supra note 96, at A-1.
99. See, e.g., Bush Address, supra note 1, at 954-56.
100. See ETHICAL, LEGAL & SOCIAL, supra note 86.
102. See id.
103. See Bongso, supra note 34, at E3-9.
104. See id.
"primitive streak," a structure that later becomes the brain and spinal cord, providing the possibility of pain or sentience. Thus, before fourteen days, some scientists call a blastocyst a "pre-embryo." Battling against the scientific viewpoint is the more religious belief that life begins at the moment of conception. In this view, the use of any human embryo for research purposes is unethical and unacceptable on the grounds that an embryo should, at all times, be accorded full human status.

While President Bush stated that he found widespread disagreement in his survey of the beliefs held by Americans as to whether an embryo is a human life, he concluded that federal funds should only be used for existing stem cell lines where "the life and death decision has already been made." President Bush thereby demonstrated his Administration's support for the view that an embryo should be treated as a human life, otherwise there would be no "life and death decision." In support of the federal mandates, the President stated that he is obliged "to foster and encourage respect for life in America and throughout the world."

Singapore's BAC addressed this same ethical issue and determined that an embryo "has a special status as a potential human being, but does not have the same status as a living child or adult." It holds this intermediate position on the ground that an embryo has undifferentiated tissues (and so cannot feel pain) and "its form and stage of development are not yet recognisably human." A living child or adult, however, carries "the investment of experience" and is self-aware; thus, their needs are more deserving of consideration than the needs of an embryo. The BAC noted that one must weigh respect for the embryo against potential benefits that may arise from research. Therefore, while the BAC supports embryonic stem cell research, it finds that this research "should take place..."
only when there is very strong scientific merit in, and potential medical benefit from, such research."\textsuperscript{116}

B. Should Embryonic Stem Cells Be Used for Research if They are Going to Be Destroyed Anyway?

To address this question, one must examine the various sources of embryonic stem cells individually, because the United States treats each source differently.

1. Stem Cells from Aborted Fetuses

Many view the derivation of embryonic stem cells from fetal tissues, and thus the ethical acceptability of using stem cells, as closely tied to the ethical acceptability of abortion. Singapore has addressed this issue by finding that elective abortions are permissible and by implementing a system to ensure that the decision to donate the tissue to research is made independent of the decision to abort.\textsuperscript{117} The United States, however, does not permit researchers to use embryos from aborted fetuses. This position is inconsistent with President Bush's statement that only the existing stem cell lines as of August 9, 2001 can be used because, "the life and death decision has already been made," in that the "life or death decision" has also already been made for an aborted fetus. President Bush is a staunch pro-life advocate and this decision may reflect his administration's views on abortion.\textsuperscript{118} At a pro-life rally in 2002, President Bush stated, "Our nation should set a great goal, that unborn children should be welcome in life and protected in law."\textsuperscript{119}

2. Surplus Embryos

Surplus embryos occur when, in the process of \textit{in vitro} fertilization, doctors match sperm and egg to create embryos outside the womb and more embryos are produced than are planted in the mother. These surplus embryos often remain frozen in laboratories until a couple decides whether to destroy them, allow them to be implanted in an adoptive mother, or donate them for research purposes. President Bush acknowledged that Americans hold varying views about whether it is ethical to allow couples to donate surplus embryos to science.\textsuperscript{120} He stated that some believe that donating the embryos to science allows them to be used for a greater purpose rather than just destroying their potential.\textsuperscript{121} Others believe it is better to destroy the embryos because experimentation does not justify

\textsuperscript{116} See id. at 25.
\textsuperscript{117} See id. at 22-23. Noting the contentious nature of the abortion issue, the BAC concluded that this use is allowed because under the Termination of Pregnancies Act, elective abortion is legal. See id.
\textsuperscript{118} See Yang, supra note 25 (noting that President Bush was "genuinely 'conflicted'" about providing any support for stem cell research given his position on abortion).
\textsuperscript{120} Bush Address, supra note 1, at 954.
\textsuperscript{121} See id.
death. Without stating so explicitly, the Bush administration demonstrated its support of the latter position by prohibiting researchers from using surplus embryos. The administration concluded that using surplus embryos would cross a "fundamental moral line" of making a life or death decision.

Singapore allows scientists to use surplus embryos for stem cell research because if only existing cell lines are used, research and the potential public benefit will be limited. The BAC determined that allowing researchers to use embryos created for fertility purposes rather than destroying them is an act of greater respect for these embryos. The BAC noted that the United Kingdom, and the NBAC report from the United States, support this position. To ensure that researchers do not abuse the rules permitting use of surplus embryos, Singapore maintains strict guidelines to obtain donor consent, prohibits trade in donated embryos, and created conscientious objection guidelines to allow persons with a conscientious objection to refrain from participating in research on human stem cells.

3. Creation of Embryos for Research

Scientists can create embryos solely for research purposes by a variety of techniques, including cloning. While some people see little difference between surplus embryos and embryos created for research, others support the use of surplus embryos but strongly oppose the creation of embryos solely for research. The Bush administration also strongly opposes the creation of embryos for research purposes, especially through cloning techniques. The Administration found that moral concerns should be the focus of this decision, rather than the need to find cures for

122. See id.
123. See id. at 955
124. See id.
125. See ETHICAL, LEGAL AND SOCIAL, supra note 86, at 26-27, para. 21-23.
126. See id. at v.
127. See id. at 26. The Nuffield Council on Bioethics analogized using surplus embryos for stem cells to tissue donation and thus found that this did not indicate a lack of respect for the embryos. Id.
128. See id. Although research on surplus embryos cannot be federally funded in the United States, the NBAC in a commissioned report released in September 1999, stated a contrary position: "Research that involves the destruction of embryos remaining after infertility treatments is permissible when there is good reason to believe that this destruction is necessary to develop cures for life-threatening or severely debilitating diseases when appropriate protections and oversight are in place in order to prevent abuse." See NBAC REPORT, supra note 4, at 52.
129. See ETHICAL, LEGAL AND SOCIAL, supra note 86, at 33-34.
130. Id. at 34.
131. Id. at 34-35.
132. Id. at 27.
133. See Bush Address, supra note 1, 955.
134. See id. ("I strongly oppose human cloning, as do most Americans. We recoil at the idea of growing human beings for spare body parts, or creating life for our convenience.").
diseases.135

Singapore's BAC noted that there is a fundamental difference between surplus embryos and embryos created solely for research.136 It balanced ethical concerns about the use of human embryos against the potential benefits of research.137 One potential benefit is the capability to derive stem cells that are immunologically compatible with the transplant recipient, which avoids possible problems of rejection.138 Use of created human embryos also enables scientists to determine how to reprogram adult cells to behave like embryonic stem cells.139 The fast pace of research development also creates a constant need for more research embryos.140 Despite these benefits, the BAC adopted the more conservative position that a researcher must show compelling reasons why the creation of embryos for research is necessary and why existing cell lines or surplus embryos are insufficient to meet this need.141 The reviewing statutory body must also find that the proposed project has strong scientific merit and a large potential medical benefit.142

C. Consideration of Alternative Sources for Stem Cells

Potential alternative sources for stem cells include adult stem cells, animal stem cells, and umbilical cord placenta. Both the United States143 and Singapore144 sanction federal funding for research that uses these sources. The largest controversy arises over whether adult stem cells could suffice as a research substitute for embryonic stem cells. Singapore noted that while some promising research is being conducted using adult stem cells, embryonic stem cells offer several properties, such as pluripotence,145 that make them a better research medium.146 The NIH similarly stated that pluripotence makes embryonic stem cells a superior medium, because adult stem cells can only mature into the cell types of their tissue of origin.147 The NIH found that larger numbers of embryonic stem cells can grow in a culture, whereas adult stem cells are rare and methods to expand their numbers have yet to be fully developed.148 The

135. See id. ("Even the most noble ends do not justify any means.").
136. See ETHICAL, LEGAL AND SOCIAL, supra note 86, at 27.
137. See id. at v.
138. See id.
139. See id.
140. See id. The BAC also notes that in response to the fast pace of research development, the United Kingdom, under the Human Fertilisation and Embryology Act 1990, allows the creation and use of human embryos for research purposes subject to a license. See id. at 28. This UK regime allows embryos to be created either by IVF or cloning techniques. See id.
141. See id. at 28-29.
142. See id. at 29.
143. See Bush Address, supra note 1, 955-56.
144. See ETHICAL, LEGAL AND SOCIAL, supra note 86, at 22-23.
145. Pluripotent means the potential to develop into any one of the many types of tissues found in the human body. See Juengst, supra note 8, at 3180.
146. See ETHICAL, LEGAL AND SOCIAL, supra note 86, at 23-24.
147. See STEM CELL BASICS, supra note 3.
148. See id.
Bush administration has failed to address the distinctions between adult and embryonic stem cells. President Bush conceded that though some scientists believe embryonic stem cells have unique potential, only adult stem cell research is entitled to "aggressive federal funding."

V. The Need for Reform in U.S. Stem Cell Regulation: Failings of the Current Approach

The Bush administration's regulation of stem cell research is in need of reform because (1) the mandates do not reflect the views and needs of the country but rather the administration's conservative views; and (2) the mandates do not reflect the potential costs and benefits of the research. If the United States had acknowledged and addressed the ethical considerations of stem cell research within the context of a cost-benefit analysis as Singapore did, it would likely have promulgated less restrictive regulations.

The Bush administration's restrictive mandates have widespread, debilitating effects on research. While U.S. scientists continue to struggle with their research, Singapore's regulations enable its scientists to achieve great advancements in biomedical science, send a message to the people of Singapore that the government values their health and well-being, and ensure that embryonic stem cell research continues in a highly controlled manner.

A. The Bush Administration's Focus on its Pro-Life and Faith-Based Views Biased Stem Cell Mandates Toward Greater Research Restriction

The Bush administration's approach to stem cell regulation was inappropriate. First, it removed a debate that properly belongs in the public forum into private chambers. Second, it subsequently imposed its views, which do not reflect the majority opinion, upon the country. The United States, a secular country that recognizes many different religious beliefs, commonly deals with regulatory decisions closely related to ethical debates in a public forum, where the diverse religious and philosophical viewpoints of Americans can be heard. Prior to the Bush administration's mandates, a number of government agencies considered the ethics of stem cell research by collecting opinions from the American people and referring to them in their own recommendations. The Bush administration, more than any

149. See Bush Address, supra note 1, 954. However, Bush acknowledged that "most scientists, at least today, believe that research on embryonic stem cells offer the most promise because these cells have the potential to develop in all of the tissues of the body." See id.

150. See id. at 955-56.

151. See Eric Juengst & Michael Fossel, The Ethics of Embryonic Stem Cells - Now and Forever, Cells Without End, 284 JAMA 3180, 3182-83 (2000). In 1994, the Human Embryo Research Panel formulated recommendations at the request of President Clinton. See id. In 1999, DHHS reinterpreted this information and the NBAC reviewed the ethical issues of stem cell research. See generally NBAC REPORT, supra note 4 (setting forth the NBAC's consideration of the scientific, medical, and legal issues relating to
other, has been resolutely "faith-based." President Bush reads his Bible regularly, makes religious references in speeches, and states his reliance on faith and God to guide his decisionmaking. Faith-based views and pro-life beliefs strongly influenced the administration's decision to impose restrictive regulations, and this is unfair to Americans who do not share these belief systems. In addition, even people who do share the views of the Bush administration wonder if the administration's strong focus on these beliefs is a mistake.

Furthermore, the federal stem cell mandates send a puzzling message to the world about the United States' interest in biomedical advancement. Arthur Caplan, director of the Bioethics Center at the University of Pennsylvania in Philadelphia, stated "[t]he rest of the world thinks of us as the leader in technology. So when we sound so fearful about biotechnology, people get puzzled."

1. The Effect of the Bush Administration's Pro-Life Stance

Cadaveric stem cell tissue would provide scientists with another source from which to derive stem cells, without making the "life or death" decision that President Bush set as the dividing line for federal support. The Bush administration's decision not to allow research using cadaveric tissue shortsightedly addresses the administration's anti-abortion views and not the potential benefits to Americans. There are numerous sources of support for this statement. First, elective abortions are legal in the United States and have been since 1973. Second, a recent poll showed that a majority of Americans support human embryonic stem cell research, and that even the majority of white Catholics polled supports the research.

Third, in a report commissioned by the Bush administration, the NIH sanctioned the use of cadaveric tissue for stem cell research. Finally, with procedural safeguards such as Singapore's, the United States could ensure that a woman makes the decision to abort separately from the donation decision.

2. The Effect of the Bush Administration's Faith-Based Analysis

For any country, religious beliefs are relevant to the regulation of stem cell research; religious leaders have been vocal in their views about the

human embryonic stem cell research). The NIH responded with its own recommendations based on this research. See id. at i-xi.

153. See id. at 30 (discussing the public concern over President Bush's aggressive pursuit of war with Iraq).
155. See Bush Address, supra note 1, at 955.
156. See Roe v. Wade, 410 U.S. 113 (1973) (legalizing abortion in all 50 states).
157. See Caldwell, supra note 66.
158. The Catholic Church's official position is pro-life. See id.
159. See id.
160. See NBAC REPORT, supra note 4, at 46-49.
161. See ETHICAL, LEGAL, AND SOCIAL, supra note 86, at 32-33.
morality or immorality of research that uses human embryos. In the
United States, President Bush used his own religious beliefs to support his
administration's decisions on the boundaries for stem cell research. Stating his belief that "human life is a sacred gift from our Creator," President Bush announced that the administration crafted federal stem cell research mandates so as not to cross a "fundamental moral line." Singapore's approach to addressing religion in research regulation differs markedly. The BAC examined the various religious viewpoints of Singaporeans and concluded that "Singapore is a secular state, and in the interests of religious tolerance and social harmony specific religious convictions cannot be the basis for determining policy." For those who, because of their beliefs, did not want to participate in research projects involving embryonic stem cells, Singapore created the Conscientious Objection Guidelines. The Bush administration should have employed an approach similar to Singapore's because, like Singapore, the United States is a secular nation, and not all Americans share the same support for faith-based decisionmaking.

162. See The Stem Cell Controversy: The Debate, ABC News, at http://abcnews.go.com/sections/politics/DailyNews/stem_cells_Bush010809.html; see also Sharon M. Parker, Bringing the "Gospel to Life" to American Jurisprudence: A Religious, Ethical, and Philosophical Critique of Federal Funding for Embryonic Stem Cell Research, 17 J. CONTEMP. HEALTH L. & POL'Y 771, 791-808 (2001) (discussing religious issues related to embryonic stem cell research). Pope John Paul II stated on July 23, 2001: "A free and virtuous society, which America aspires to be, must reject practices that devalue and violate human life at any stage from conception until natural death." See id. However, although the Catholic Church opposes stem cell research, individual Catholics have differed in their views on the subject. See NBAC REPORT, supra note 4, at 100. Some look at the early human embryo not as an individualized human entity with the settled potential to become a human person and thus find respectful research permissible. See id. Other major religions have strands that could potentially support fetal research. See Send in the Clones, supra note 29, at 58.

163. See Yang, supra note 25. In an interview with 20/20 about his regulations of federal funding for stem cell research, President Bush stated, "I reach out to God everyday, I pray everyday, I read the Bible everyday. . . . I think this is the kind of decision where it does require prayer." See id.

164. See Bush Address, supra note 1, at 955.

165. See id.

166. See Elliot, supra note 113, at E4-4.

167. See ETHICAL, LEGAL AND SOCIAL, supra note 86, at 34-35 ("With diverse views on the ethics of human stem cell research, it is envisaged that on moral or religious grounds, a segment of the research community and the public may not wish to be involved in such research or in a particular manner of such research. Such objections would be legitimate, given that Singapore is a multi-religious and pluralistic society. It is not the remit of the BAC to challenge or reconcile disagreements held from personal moral or religious convictions. As such, every individual should be allowed to make an informed choice on whether to participate in such research, given his or her beliefs. Hence, the legislative framework should provide for such a situation, in that no one should be under a duty to participate in any such research or manner of research, which would be authorised or permitted by the law, to which he has a conscientious objection.")
B. If the Bush Administration Had Engaged in a Cost-Benefit Analysis, Like that of Singapore, the U.S. Stem Cell Mandates Would Likely be Less Restrictive

For two decades, the executive branch of the U.S. federal government has espoused cost-benefit balancing as its official creed for health and safety regulations.168 This analysis requires both a quantitative and qualitative accounting of the effects of a regulation.169 The Government's rationale for using cost-benefit analysis is that regulation should promote social welfare,170 and that cost-benefit analysis provides an imperfect but useful proxy for inquiry into this social welfare question.171 Although the imperfection of cost-benefit analysis negates its applicability as a strict measure of the value of a regulation,172 high costs and low benefits may provide a signal to the Government that something is amiss in the regulation.173

The greatest challenge for cost-benefit analysis is the incorporation of unquantifiable costs or benefits of a regulation, such as the distributional effects of a regulation,174 the effect on scarce natural resources,175 and, importantly for stem cell research regulations, ethical considerations. Even when not all costs and benefits are quantifiable, the process of accounting for the consequences of a regulation is itself a useful tool to avoid potential distortions caused by emotional evaluations of a perceived risk.176 The comparison in Part IV of the Bush administration's approach to stem cell regulation with that of Singapore illustrates this point.

1. The Bush Administration Failed to Adequately Consider the Benefits of Stem Cell Research

Because of its focus on ethical issues raised by its pro-life and faith-based beliefs, the Bush administration failed to adequately consider the

171. See Hahn & Sunstein, supra note 168, at 1499.
173. See Hahn & Sunstein, supra note 168, at 1491.
174. See id. at 1525-27.
175. See Arrow, supra note 169, at 222.
176. See George F. Loewenstein et al., Risk as Feelings, 127 PSYCHOL. BULL. 267, 269 (2001) (stating that emotional responses can be greater than cognitive evaluations of risk, even where people are aware that risks are small).
potential benefits the American people may gain from stem cell research. President Bush stated that U.S. stem cell regulations are restrictive because the progress of stem cell research has not lived up to its initial expectations and the research "offers both great promise and great peril." The President's observations are not consistent with general opinion in the United States or abroad. In a report compiled at the Bush administration's request, the NIH concluded that stem cells from embryonic sources show tremendous promise for treating various diseases and conditions, and it recommended that research using both cadaveric tissue and surplus embryos should proceed. Countries with whom the United States is usually on par, if not ahead of, in scientific research, such as the United Kingdom, Singapore, Australia, Canada, and Japan, all sanction stem cell research using surplus embryos. With the exception of Australia, they all allow the creation of embryos for research under strict guidelines. The regulations of these countries are not unethical because they are less restrictive than those of the United States. Rather, the regulations demonstrate an accounting of the medical benefits that would accrue to their citizens, the economic benefits of being a leader in biomedical research, and the social benefits of sending a message to citizens that the government cares about their health and well-being. The Bush administration's message is quite different. While President Bush stated his concern that embryonic stem cell research will devalue human life, his administration's heavy research restrictions send a message to the American people that the U.S. government does not value their lives enough to ensure that all avenues for developing cures and treatments are open. What will happen when some country discovers a cure for multiple sclerosis; will the United States make that cure illegal because human embryonic stem cells were used in its research? Will the Bush administration tell the 400,000 American Multiple Sclerosis sufferers that they cannot cure their disease because it believes that the cure itself devalues human life?

2. The Bush Administration Failed to Adequately Consider the Costs of Restricting Stem Cell Research

The Bush administration failed to adequately consider the costs that its restrictive mandates would impose on biomedical research in the United States. For example, the United Kingdom's regulations are more permissive than the United States' because it considered that (1) requiring British scientists to import embryonic stem cells would make the research more expensive and time-consuming and could lead to obstacles in the progress

177. See Bush Address, supra note 1, at 955.
178. See NIH EXEC. SUMMARY, supra note 5, at ES-1, ES-10.
180. See Bush Address, supra note 1, at 955.
of potentially invaluable research; if these obstacles existed, British researchers would move to other countries with less restrictive attitudes toward stem cell research; and it was important to keep researchers in Britain so that its patients would have access to benefits from practices such as therapeutic cloning. The U.S. federal mandates do not protect Americans from the harms that the United Kingdom worried about. Americans have realized these harms as (1) scientists are complaining of research delays due to difficulty in accessing adequate cell lines; (2) U.S. researchers are moving to other countries with more permissive stem cell regulations; and (3) Americans worry that they will not have access to the medical treatments that stem cell research will offer. These effects of regulation have forced the United States, traditionally a leader in biomedical research, to sacrifice major medical advances. The President expressed his administration's belief that the sixty-four existing cell lines would lead to "breakthrough therapies and cures." However, since the President passed the stem cell mandates in August 2001, many scientists have petitioned the President for change because the regulations have crippled the progress of their research. The delays in research are prompting researchers to leave the United States to work in countries with more permissive stem cell regulations. Meanwhile, countries such as Singapore, whose regulations are more permissive, are realizing advancements at a rapid pace. The human embryonic stem cell industry is still in its formative stages and if the United States continues to restrict stem cell research and let other countries become leaders in stem cell research, it will relinquish control over the future direction of this industry.

If the Bush administration had adequately considered the great potential of stem cell research and the great harm that the United States would suffer if it is unable to actively pursue this research, it likely would have realized the need for more permissive regulations.

Conclusion

All Americans weigh the costs and benefits of their activities on a daily basis: the choice to drive a car knowing that the exhaust contributes to global warming; the choice to eat cereal or other packaged food, knowing that the packaging contributes to waste and waste disposal problems; and


183. See id.

184. See id.


186. See id. at 22.

187. See id.

188. See Bush Address, supra note 1, 955.


190. See id.

191. See Send in the Clones, supra note 29, at 58.
the choice to smoke a cigarette, knowing that the second-hand smoke may harm the health of others. The Bush administration also makes decisions that require balancing, such as whether or not to go to war against Iraq, with the knowledge that soldiers will die. While an administration will carefully consider its reasons to go to war, it does not choose not to go because it believes it is unethical to allow Americans to benefit from the death of soldiers. Instead, it likely engages in a thorough analysis that weighs all relevant costs and benefits of the situation before coming to a decision.

The Bush administration’s regulation of stem cell research is too restrictive because (1) the administration failed to put aside its pro-life and faith-based views in favor of the views and needs of the country at large; and (2) the administration failed to engage in a balanced analysis of the potential costs and benefits of the research, in addition to its analysis of the ethical considerations involved.

The Bush administration’s decision to restrict federal funding of stem cell research sends a message to the American people that it not only believes the use of embryos for research is unethical, but that it believes the potential benefit they will receive from the research does not outweigh this ethical consideration. Had the Bush administration relied less on its pro-life and faith-based views, and more on the scientific opinion, government reports, and research trends in other countries, it would have realized the enormous disadvantages that the restrictive mandates impose on the American people. If the Bush administration had balanced the costs and benefits of the research, it might have reached a different conclusion. The administration should have more support for its mandates than faith-based views and ethical arguments. The administration does a disservice to the American people by passing a regulation that does not adequately consider the costs and benefits of that regulation. The United States has consistently used the cost-benefit framework to make regulatory decisions, and the administration should not have treated stem cell research differently.

Contrary to President Bush’s assertion, we do not live in a brave new world, similar to that described by Aldous Huxley, where children are born in hatcheries with predetermined achievement potentials. Rather, we live in a country with the utmost respect for human life and the utmost appreciation for the achievement of the underdog. The essence of the stem cell debate is whether scientists can use embryos to improve the lives of the living—the views and lives of the American people deserve greater respect and consideration than the Bush administration’s inadequate decision-making process afforded them.

192. See Bush Address, supra note 1, at 955 ("We have arrived at that brave new world that seemed so distant in 1932, when Aldous Huxley wrote about human beings created in test tubes in what he called a 'hatchery.'").