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The States “Race” with the Federal Government for Stem Cell Research

Joanna K. Sax, Ph.D.*

I. INTRODUCTION

Indicative of the political divide among American citizens, stem cell research was one of the more hotly debated issues in the 2004 presidential election, with strong support professed by Ron Reagan at the Democratic National Convention.1 In the months leading up to the election, President George W. Bush and Senator John Kerry presented different views regarding the future of stem cell research in this country.2 Among Senator Kerry’s promises to America was a pledge to “lift the ban on federal funding of research on stem cell lines created after August 2001.”3

During the 2004 presidential race, President Bush expressed his views about the future of stem cell research as well. In response to a question posed about a particular scientific technique called somatic cell nuclear transfer, he stated:

I believe all human cloning is wrong, and a total ban on human cloning is necessary to ensure the protection of human life as the frontiers of science expand. Anything short of a comprehensive ban would be impossible to enforce and would permit human embryos to be created, developed, and destroyed solely for research purposes. I strongly support a comprehensive law against all human cloning.4

The results of the November 2004 election mean that President Bush’s

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3. Id.

4. Id. at 47-48.
positions on cloning and stem cell research will likely continue for the next four years in federally-supported laboratories. However, some states have recently taken steps to allow and even promote stem cell research.5

States often serve as laboratories for national policy, with each state experimenting with different approaches to a given issue. For example, recognizing the medical, scientific, and economic benefits of stem cell research, New Jersey and California passed legislation in 2004 to allow stem cell research within their states.6 Most notably, Californians voted in the November 2004 election for a $3 billion state referendum to fund stem cell research over the next ten years.7 Stem cell research may also be conducted with essentially no government oversight by using private funds.8

Other countries allow stem cell research under specific guidelines. For example, while Great Britain promotes therapeutic cloning, it does not allow scientists to keep embryos for growth past fourteen days, thus eliminating the potential for this technology to be used for human cloning.9 The British government created the UK Stem Cell Bank, to which scientists must submit every new embryonic stem cell line to be evaluated and maintained.10 In addition, research in Great Britain may soon be further regulated by the European Union, which has proposed guidelines to fund stem cell research in countries where it is legal.11

The goal of this paper is to analyze and explain the impact of state


6. Id.

7. California Stem Cell Research and Cures Act, 2004 Cal. Legis. Serv. Prop. 71 (West). (Voter "Proposition 71" put a proposal to the vote of the public to use publicly-backed bonds averaging $295 million annually over ten years to pay for stem cell research; the proposition was passed in the 2004 election).

8. George Q. Daley, Missed Opportunities in Embryonic Stem Cell Research, 351 N. ENG. J. MED. 627, 627 (Aug. 12, 2004) (noting that private funding is available but unpredictable for such research).


10. Rosenthal, supra note 9, at F6 ("Every new stem-cell line must be ceded to the national bank, where it is evaluated and maintained, and may not be transferred elsewhere without approval from a government steering committee.").

11. Associated Press, World Briefing Europe: European Union Proposes Stem Cell Rules, N.Y. TIMES, July 10, 2003, at A6 (noting that the European Union head office proposed guidelines for financing research on embryonic stem cells, but excluded any country where human embryonic stem cell research is forbidden).
legislation and funding on the future of stem cell research. Without federal law regulating stem cell research, funding by states and private organizations may spur competition to attract and retain leading scientists and industry in individual states. Alternatively, state-funded stem cell research may incite the federal government to react either positively or negatively to pre-empt state and private action. Traditionally, most support for scientific research comes in the form of grants from the National Institutes of Health (NIH).\textsuperscript{12} Due to the practical ban on stem cell research at the federal level, states have taken action to circumvent national biomedical policy. Literally, the states are serving as laboratories for both scientific research and policy decisions.

As a matter of public policy, the NIH should set uniform guidelines to allow stem cell research, including provisions for the establishment of new stem cell lines and funding for laboratories at the national level. There are three main reasons for this policy. First, the federal infrastructure to fund biomedical research is already established by the NIH. In order for the states to form mini-institutes of health, much of the initial state revenue would have to be allocated to fund the building of a state research institute and to set up the necessary infrastructure.\textsuperscript{13} This is a waste of public money when a functional national program already exists.

Second, competition among the states for using state money to fund research is not the ideal method for strong scientific progress. Under this model, with varying amounts of regulation between states, scientists in State A may not be able to collaborate with scientists in State B because State B prohibits stem cell research. A national policy, on the other hand, would allow scientists in different states to work with each other as well as with scientists around the world to promote stem cell research.

Third, the NIH has previously dealt with controversial research. In the 1970s, some people feared that recombinant DNA technology would lead to biowarfare.\textsuperscript{14} The NIH successfully established a committee to address concerns by limiting the use of the technology to biomedical research.\textsuperscript{15} A

\textsuperscript{12} Connie Bruck, \textit{Hollywood Science}, NEW YORKER, Oct 18, 2004, at 64 (describing the role of the NIH in the federal funding of scientific research); Nicholas Wade, \textit{Bush Policy on Human Stem Cells Faces New Challenges}, N.Y. TIMES, Mar. 4, 2004, at A18 (describing the "vast bulk of biomedical researchers" as supported by federal grants).

\textsuperscript{13} Jonathan Knight, \textit{Critics Slate Ethical Leeway in California Stem Cell Proposal}, 431 NATURE 232 (Sept. 16, 2004) (stating that California’s Proposition 71 will provide $3 billion for embryonic stem cell research and infrastructure, including the distribution of grants by the California Institute for Regenerative Medicine) [hereinafter Knight – Critics].

\textsuperscript{14} Bruck, supra note 12, at 67 ("In 1974, when [Berg] and his colleagues discovered how to engineer recombinant DNA, it provoked fears of rampant super-microbes that might be created by some errant laboratory.").

\textsuperscript{15} \textit{Id.} (discussing how the research was able to progress); Erika Check, \textit{Biologists See
similar committee could be established to oversee stem cell research and address concerns by ensuring that scientists only perform therapeutic research, not reproductive research.\textsuperscript{16} The promise of stem cell research is to help people afflicted with illnesses;\textsuperscript{17} this should be a federal policy because it affects citizens in every state and around the world.

Part II of this article explains the ethical divide surrounding the technique of establishing embryonic stem cell lines. By describing the scientific techniques used to establish stem cell lines and the potential to help patients with many different types of diseases, I hope to communicate that the promise of stem cell research is too great to be blocked by the current federal policy. In Part III, I describe the federal policies regarding stem cell research under Presidents Clinton and George W. Bush. To date, the progress of stem cell research at the federal level lies in decisions made by executive order.\textsuperscript{18} Congress has considered several bills regarding stem cell research, but the United States does not currently have federal law in this area.\textsuperscript{19}

In Part IV, I discuss initiatives, scientific and financial, undertaken by private investors and states to support stem cell research. Part V considers whether the state initiatives will create a state competition for researchers and industry, using state competition under corporate law as a guide. I argue that California may already be so far in the lead due to its concentrated biomedical environment that, combined with the commitment of $3 billion of state-funded stem cell research,\textsuperscript{20} traditional state-

\textsuperscript{16} Check, \textit{supra} note 15, at 431 ("Other researchers proposed that scientists set up a body similar to the Recombinant DNA Advisory Committee, which is run by the US National Institutes of Health (NIH), to review questions on stem-cell research.").

\textsuperscript{17} See, \textit{e.g.}, NIH Director's Statement on Research Using Stem Cells, Before the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies (Jan. 26, 1999) (Statement of Harold Varmus, M.D., Dir., Nat'l Inst. of Health), \textit{available at} http://stemcells.nih.gov/policy/statements/statement.asp [hereinafter NIH Director's Statement].


\textsuperscript{19} See, \textit{e.g.} Jeffrey Brainard, \textit{After Heated Debate, U.S. House Votes Again to Ban Cloning}, \textit{49 Chron. Higher Educ.} A24, A24 (Mar. 14, 2003) (describing a stem cell bill that was voted on in the House but does not have the votes to pass in the Senate); Denise Grady, \textit{Debate Over Cloning in U.S. Remains Intense}, \textit{N.Y. Times}, Feb. 12, 2004, at B12 ("[T]he United States has no federal laws regarding cloning, unlike Britain, which has banned reproductive cloning while allowing research on therapeutic cloning.").

\textsuperscript{20} California Stem Cell Research and Cures Act, \textit{supra} note 7.
competition models do not apply. Nevertheless, other states may still conduct stem cell research on a smaller scale, which calls for the implementation of uniform federal guidelines for stem cell research.

California’s initiative may invite the federal government to enact legislation to preempt state law in such a way as to either support or further hinder stem cell research; but if California is able to produce positive results in the near future and the public begins to see the possible benefits, it will be more difficult for the federal government to enact anti-stem cell legislation. Therefore, the “race” is on between California and the federal government to determine whether stem cell research will progress.

II. AN EXPLANATION OF STEM CELL RESEARCH

A. Overview

Scientists who work with stem cells derive them from two main sources, embryonic and adult cells. During embryogenesis, cells are partitioned into three layers, each subsequently giving rise to various tissues and organs, transforming during development into skin, muscle, cartilage, etc. While these embryonic cells offer the greatest potential to treat many human diseases, some adult tissues and organs retain stem cell dependence for repair and so may also provide a viable option for treating human ailments.

At the basic scientific level, stem cells offer great potential to treat many types of diseases because they can undergo multiple divisions while remaining undifferentiated in the laboratory. Upon stimulation, either physiologically or experimentally, stem cells are induced to differentiate into specific cell types, such as muscle.

Stem cells are classified along a spectrum defined by their ability to transform into different cell types. These include:

totipotent (able to give rise to all embryonic and extra-embryonic cell

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23. Id.
24. Id.
25. NIH Stem Cell Information, supra note 21.
26. Id.
27. Wagers & Weissman, supra note 22, at 639.
types), pluripotent (able to give rise to all cell types of the embryo proper), multipotent (able to give rise to a subset of cell lineages), oligopotent (able to give rise to a more restricted subset of cell lineages than multipotent stem cells), and unipotent (able to contribute only one mature cell type).  

Embryonic stem cells characteristically have more plasticity, meaning they fall towards the totipotent and pluripotent end of the spectrum, whereas adult stem cells may be more restrictive in their ability to differentiate into multiple cell types.

Most of the controversy surrounding stem cell research concerns the process of obtaining embryonic stem cells. Most notably, embryonic stem cells can be obtained through *in vitro* fertilization procedures. Some argue that it is morally and ethically wrong to create a human life only for the purpose of destroying it. Proponents of stem cell research argue that many fertilized eggs from fertility clinics will simply be destroyed anyway and so would be useful for research. Opponents respond that the fertilized egg has the potential for human life and cannot reconcile this view with the purposeful destruction of that potential life in a scientific laboratory. Proponents argue that human life has not yet begun in a petri dish. The debate goes back and forth but basically comes down to a division between those who believe that a fertilized egg should only give rise to a human

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28. *Id.*
29. *Id.* at 639-40 (describing characteristic differences between embryonic stem-cells and adult stem-cells).
30. Jason Scott Robert, *Model Systems in Stem Cell Biology*, 26 BIOESSAYS 1005, at 1005 (2004) (“Public debate over stem cell research has focused largely on scientific and ethical questions about the sources of stem cells-embryonic, fetal, and ‘adult’ (or tissue specific).”).
32. William Safire, *Reagan’s Next Victory*, N.Y. TIMES, June 7, 2004, at A27 (“Opponents say the harvesting of these cells destroys potential human life.”). *See also* John M. Broder & Andrew Pollack, *Californians to Vote on Stem Cell Research Funds*, N.Y. TIMES, Sept. 20, 2004, at A1 (describing that opponents to embryonic stem-cell research as believing that “researchers must destroy human embryos, an act that is abhorrent to some religious conservatives and opponents of abortion”).
33. *See Disease Insights from Stem Cells*, *supra* note 31, at 787 (“[T]he existing cell lines have all been derived from embryos left over from *in vitro* fertilization.”) emphasis added; Safire, *supra* note 32, at A27 (“[P]roponents say these are left over from in vitro banks and already destined for destruction, donated by people to whom 'pro life' also means saving the lives of suffering patients.”).
34. Robert, *supra* note 30, at 1005 (describing ethical concerns that “isolating cells from the inner mass destroys the embryo”).
being and those who believe that a discarded fertilized egg could be the key to helping people affected with a variety of diseases.

The second ethical debate in stem cell research surrounds the technique called somatic cell nuclear transfer. As will be described in more detail below, this technique involves the transfer of one person’s DNA into a fertilized egg that has had its DNA removed. This is essentially the technique used to create the cloned sheep “Dolly.” Opponents argue both that it is wrong to destroy a potential human life and that this technique can be used for human cloning. Proponents of stem cell research argue that this technique can be used to study genetic diseases from affected patients and that the egg will be destroyed within a few days of the DNA transfer.

To address the human cloning issue, one suggestion is to draw a line between therapeutic and reproductive cloning by following the policy in Great Britain, where eggs cannot be grown past fourteen days. Taken together, the main ethical divide is the technique for establishing an embryonic stem cell line. This paper will set out the techniques and potential benefits of stem cell research and hopefully elucidate that despite the ethical divide, many lives can be improved and saved by supporting stem cell research.

B. Why Study Stem Cells?

Three main properties of stem cells make them good candidates to treat multiple types of disease: (1) they can divide many times and still remain as undifferentiated cells, available to be later turned into a specific cell type such as muscle; (2) they are not specialized to any specific cell-type lineage; and (3) they can be induced to differentiate into a specific cell type. While work with mouse (murine) stem cells has progressed over the last twenty years, researchers have only been working with human stem

36. Disease Insights from Stem Cells, supra note 31, at 787 (“[T]here is opposition to SCNT because it involves the production of human embryos for research.”).
38. Laurie Goodstein & Denise Grady, Split on Clones of Embryos: Research vs. Reproduction, N.Y. TIMES, Feb. 13, 2004, at A22 (quoting opponents of somatic cell nuclear transfer on religious grounds as saying: ‘[w]e don’t sacrifice one human life in order to possible help another human life’; ‘[this research is] nothing short of cannibalism’; and ‘[Koreans produced] human embryos for the explicit purpose of fatally mining them.’).
39. Id. (noting that many, if not most, scientists support cloning to make embryonic stem cells: “Those cells are prized for research because of their potential to become almost any type of tissue, perhaps one day to be used to treat illnesses or injuries.”).
40. Young, supra note 9, at 849.
41. NIH STEM CELL INFORMATION, supra note 21.
cells since 1998. To date, researchers are interested in understanding the unique properties of stem cells and applying that knowledge to treat disease.

One disease that receives particular attention in the press is Parkinson's disease (PD), a neurodegenerative disease caused by the degeneration of a particular type of neuron called dopamine-producing neurons. In mouse models, scientists transplanted stem cells induced to differentiate into dopamine-producing neurons, which successfully improved motor function. The promise of applying a similar strategy in humans could lead to a stem cell-based treatment for affected humans.

Type I diabetes research also stands to benefit from the potential of stem cell research. The standard treatment for type I diabetes is to maintain a particular level of blood glucose through insulin injections. However, ideal blood glucose levels are difficult to achieve and patients suffer other complications including kidney failure, stroke, amputation, and seizures. In an attempt to find alternative approaches to treatment, researchers are hopeful that islet cell transplantation may provide a treatment to restore insulin-producing cells.

Other major areas of research that will potentially benefit from stem cell research include understanding the mechanisms of genetic diseases and drug discovery. For example, scientists could create cell lines with the same genetic lesions found in patients to study what goes wrong in the diseased cellular process and these cells could then be used to screen for molecules that stall or stop disease progression. Studies in murine stem cells do not provide appropriate material to model human disease because they often lack the capability to properly replicate human disease. Further, murine stem cells often cannot be replicated in a genetic manner because

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42 Id. See also Sylvia Kim, *Embryonic Stem Cell Research Controversy: Focus on the Private Sector and International Sphere*, 14 HASTINGS WOMEN'S L. J. 89, 89 (2003).
43 NIH STEM CELL INFORMATION, supra note 21.
44 Id.
46 Id.
47 Id. (stating that human pluripotent stem cells offer the best source of islet cells for treating and curing type I diabetes).
48 *Disease Insights from Stem Cells*, supra note 31, at 787 (explaining that stem cell research is important beyond "cell-replacement therapies," including "uncovering the mechanisms of genetic diseases, and in generating sources of normal and impaired tissues for use in drug discovery").
49 Id. (establishing an unlimited quantity of diseased tissue for use in experiments to understand the molecular mechanism of disease and "design high-throughput screens to identify molecules that halt disease progression").
some human ailments are too complex to be re-created in mouse models.

C. Embryonic Stem Cells

1. How Researchers Obtain Embryonic Stem Cells – A Basic Understanding of Scientific Technique

Embryonic stem cells are obtained from eggs that have been fertilized in vitro (i.e., in a test tube), not from eggs fertilized in a woman’s body. The fertilized egg is a totipotent cell that can give rise to an entire organism. Approximately three to four days after in vitro fertilization, the cell mass divides and forms a blastocyst containing multiple cells that are divided into three concentric circles. The innermost layer contains a group of approximately thirty pluripotent cells called the “inner cell mass.” This layer is isolated to grow the stem cells in tissue culture.

While each type of cell grown in a lab requires tweaking of the basic tissue culture system, the following process applies to most cell types. Cells are grown on plastic petri dishes in a liquid, nutrient-enriched medium containing sugar, salt, and other nutrients to feed the cells. As cells grow and divide, they fill up the petri dish and are then split into multiple dishes in a process known as “passaging.” Once established, they can be frozen

50. Id. (noting that while it is feasible to generate ES-cell lines from mouse models of human disease, the “underlying causes may be different from those of the human diseases they are supposed to represent. And many human diseases are so complex or poorly understood that mouse models do not exist for them.”).

51. Id.

52. Spiegel & Fischbach, supra note 45 (explaining that when a sperm fertilizes an egg, the product is a single totipotent stem cell that has the potential to form an entire organism). See also Helen Pearson, Early Embryos Fuel Hopes for Shortcut to Stem Cell Creation, 432 NATURE 4 (NOV. 4, 2004). The article describes a study where researchers grew stem cells out of a culture before it formed a blastocyst. Some researchers suggest that this new technique may quell some ethical concerns because researchers are not destroying an entire embryo. However, others suggest that opponents will remain steadfast in the belief that “stem cell lines can only be created by destroying a human embryo.”

53. NIH Stem Cell Information, supra note 21 (describing the culture conditions for stem cells).

54. Id. See also Robert, supra note 30, at 1005-06 (“After the third cell division, cells begin to specialize, and an inner cell mass (ICM) forms within the blastocyst. Cells removed from the ICM are pluripotent, having less [compared to totipotent], but nonetheless impressive, capacity for differentiation into various cell types (though pluripotent stem cells cannot form placenta, some believe they can form the embryo).”).

55. NIH Stem Cell Information, supra note 21 (“cell culture” is the technical term for growing cells in a laboratory).

56. Id.

57. Id.

58. Id.
and shipped to other laboratories for experimentation.\textsuperscript{59}

Embryonic stem cells require an extra step in the tissue culture process. The petri dish used to plate the “inner cell mass” is first coated with mouse feeder cells.\textsuperscript{60} The feeder cells provide a sticky surface to which the inner cell mass adheres, and also release important nutrients and growth factors to help the inner cell mass survive.\textsuperscript{61} Scientists presently are devising ways to use other means to plate the inner cell mass because they are worried about the transfer of murine viruses or other molecules into the stem cells to be used later in human patients.\textsuperscript{62}

2. How to Differentiate Embryonic Stem Cells

Once the pluripotent stem cell line is established and characterized as undifferentiated, cells can be used in experiments and can be stimulated to differentiate.\textsuperscript{63} Scientists differentiate the cells into muscle, blood, or nerve cells by changing the tissue culture conditions.\textsuperscript{64} For example, specific growth factors can be added to direct a cell to differentiate.\textsuperscript{65} Alternatively, scientists can genetically modify the cells by transfecting a specific gene into the nucleus or DNA of the cell, which will cause the stem cell to differentiate. These differentiated cells could then be used in human patients to treat a variety of diseases.\textsuperscript{66}

3. Another Way to Create Stem Cell Lines is by Somatic-Cell Nuclear Transfer

To study mechanisms of human diseases and generate cell lines for drug screening, scientists use somatic-cell nuclear transfer (SCNT) to create stem cell lines from patients.\textsuperscript{67} To create the “diseased” stem cell line, the

\begin{footnotesize}
\begin{enumerate}
\item Id. ("established" means cells are growing well in tissue culture).
\item Id.
\item NIH Stem Cell Information, supra note 21. (describing the laboratory conditions for embryonic stem cells).
\item Id.
\item Id. While establishing the stem cell line, scientists employ multiple tests to determine whether they have established a stem cell line. These include, (1) growing the cells for many months; (2) testing for specific cell surface that are only found on undifferentiated cells; (3) ensuring chromosomal stability; (4) determining the cells can withstand a freeze/thaw so they can be frozen and then grown again; and (5) testing whether the cells are pluripotent. Scientists do not have a consensus to experimentally test for many of the previous conditions.
\item Id.
\item Id.
\item Id. (describing how to differentiate a stem cell).
\item See Disease Insights from Stem Cells, supra note 31, at 787 ("With current technologies, generating new ES-cell lines from patients would require somatic-cell nuclear
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nucleus from a patient’s cells is extracted and injected into an enucleated egg. The egg is then stimulated to divide in vitro and form a blastocyst. After about five days of growth as described above, the inner cell mass is extracted and cultured in vitro and then “induced to form the diseased tissue.”

The SCNT process has received opposition due to the perception that it involves the production of human embryos for research, so it has been lumped into the same general category of “cloning” and is subject to regulation aimed mainly at preventing reproductive cloning.

**D. Adult Stem Cells**

Undifferentiated adult stem cells are found in “niches” in a variety of tissues and organs. Scientists believe the small number of adult stem cells found in a particular tissue is in place to maintain or repair the tissue in case of injury. Originally, scientists found two kinds of stem cells in the bone marrow; one gives rise to blood cells (hematopoietic stem cells), while the other gives rise to “bone, cartilage, fat, and fibrous connective tissue.” More recently, scientists discovered small numbers of adult stem cells in other tissues. These discoveries have led scientists to try to grow adult stem cells in tissue culture, characterize them, and attempt to differentiate them so they can be used to treat disease.

Scientists are presently studying a variety of issues to determine whether...
adult stem cells can be used to effectively treat disease. These issues include: (1) determining which tissues contain stem cells; (2) examining the source of adult stem cells; (3) differentiating in vivo and in vitro; and (4) studying how adult stem cells kick into action once injury has occurred. Recent studies suggest that adult stem cells may have more plasticity than previously believed, meaning that stem cells isolated from one tissue may be able to transform into cells of another tissue with the appropriate stimulation. However, studies in this area are in the infant stage.

E. A Comparison of Embryonic and Adult Stem Cells

Adult and embryonic stem cells each contain advantages and disadvantages for research. One example is that adult stem cells may already be further along in the differentiation process than embryonic stem cells, so they only differentiate into specific lineages. On the other hand, embryonic stem cells appear to have the plasticity to differentiate into all cell types. Low numbers of adult stem cells are found in each tissue and the tissue culture conditions for these cells are not yet optimized. Alternatively, embryonic stem cells are easily expandable in tissue culture conditions, which is important because large numbers of cells are required for experiments and therapies. A potential advantage of adult stem cells is that the recipient could use his or her own cells, thus avoiding any potential immunological rejection. However, it is unclear whether a patient would reject donor embryonic stem cells.

77. NIH STEM CELL INFORMATION, supra note 21 (describing a list of key questions surrounding adult stem cells).
78. Wagers & Weissman, supra note 22, at 639 (explaining that the suggestion that adult stem cells may trans-differentiate has in turn given rise to the concept of stem cell plasticity).
79. Id. at 644 (“Given the rarity with which events interpreted to represent “transdifferentiation” have been detected in vivo, and the intense controversy surrounding these findings, very stringent criteria should be required for the demonstration of a bona fide trans-differentiation event.”).
80. NIH STEM CELL INFORMATION, supra note 21 (describing the advantages and disadvantages of adult and embryonic stem cells). Robert, supra note 30, at 1007 (“[I]n order that hypotheses about the potential pluripotency of tissue-specific stem cells be neither prematurely accepted nor prematurely rejected, comparative studies must be (and are being) undertaken on all relevant types of stem cells. We do not want to conclude that ‘adult’ stem cells as such are or are not pluripotent until we have shown this for every tissue-specific stem cell system.”).
81. NIH STEM CELL INFORMATION, supra note 21.
82. Id. (describing the advantages and disadvantages of adult and embryonic stem cells).
83. Id.
F. Technical Bypass Options

In an attempt to bypass the embryo creation process, some researchers have proposed alternative methods for nuclear transfer that may circumvent the ethical dilemma surrounding experimental designs to obtain embryonic stem cells. In November 2004, the President's Council for Bioethics heard two proposals that might bypass the "destruction of an embryo" ethical dilemma. The first proposal would define an embryo as "nonviable before any cells are taken from it." The second alternative contained a proposal whereby the DNA is "jinxed" before being transferred into an egg. In this second method, DNA missing key developmental genes is used for the transfer into an enucleated egg using the SCNT technique. This would allow the cells to divide and form embryonic stem cells, but it would not allow an embryo to be formed and later "destroyed." To date, this technique is purely theoretical and it will take experimental progress to determine efficiency and feasibility. Other scientific proposals to sidestep the "destroyed embryo" ethical debate include: parthenogenesis (tricking an unfertilized egg into dividing by mimicking the effect of a sperm), use of defunct (i.e., nonviable) embryos created for in vitro fertilization, isolating a single cell from a pre-blastocyst or a blastocyst without destroying the entire blastocyst, and changing mature cells into pluripotent stem cells.

84. Constance Holden & Gretchen Vogel, A Technical Fix for an Ethical Bind?, 306 SCIENCE 2174, 2174 (Dec. 24, 2004) (discussing that new ways to create stem cell lines "would enable scientists to sidestep the ethical debate that has polarized the United States and triggered governments around the world to become involved to an unprecedented degree in regulating research.").
85. Id.
86. Id.
87. Id.
88. Id.
89. Holden & Gretchen, supra note 84 (stating that knocking out a key developmental gene before transferring the nucleus of a donor cell into an enucleated egg cell would allow for creation of a reprogrammed cell capable of forming ES cells but lacking the signals needed to form an organized embryo. "No embryo created . . . no embryo destroyed.").
90. Id. at 2175.
91. Id. at 2175-76 (discussing the experimental status and future prospects for a variety of alternative experimental procedures to obtain stem cells).
III. AN OVERVIEW OF RECENT NATIONAL AND STATE POLICY OF STEM CELL RESEARCH

The NIH contributes to the advancement of science through various programs, including those that train scientists and issue research grants. Increased funding in new avenues of promising research is important to help those affected with degenerative diseases and to continue the NIH's record of improving human health. In 1998, at President Clinton's request, the National Bioethics Advisory Commission reviewed medical and ethical issues related to human stem cell research and with the support of the Department of Health and Human Services, recommended that responsible funding of embryonic stem cell research be permitted. In a statement made to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Harold Varmus, Director of the NIH under President Clinton, explained the advantages of federally funded research:

There are a number of advantages to using public funding for research. Perhaps the most important reason is the fact that Federal involvement creates a more open research environment – with better exchange of ideas and data among scientists – more public engagement and more oversight. In addition, Federal support increases the fiscal resources and expands the pool of talented investigators – particularly in academia – both of which accelerate the tempo of scientific discovery.

In this address, Varmus explained three potential applications of stem cell research. First, scientific understanding of the normal function of cells and tissues provides insight into what is different and wrong in cell types that deviate from the healthy path. An example of this type of research is studies done by cancer researchers who compare normal and tumor cells to learn what changes transform a healthy cell into a cancer cell. Second, stem cells could be used in pharmacological screenings to study the

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92. See Bush and Kerry Offer Their Views on Science, supra note 2, at 51 (noting that in 2004, the NIH trained 1500 more scientists per year and issued 10,000 more research grants than it did in 1998).
94. Kim, supra note 42, at 99 (describing the history of the federal policy on stem cell research).
95. NIH Director's Statement, supra note 17.
96. Id. ("Studying normal cell and tissue development will provide an understanding of abnormal growth and development which, in turn, could lead to the discovery of new ways to prevent and treat birth defects and even cancer.").
97. Id.
potentially toxic effects of newly developed drugs. 98 Third, stem cells provide the potential to direct the specialization of these undifferentiated cells to be used for transplants. 99 Two particularly exciting areas falling within this last use include heart disease and type I diabetes. 100

Soon after the NIH published guidelines for conducting research with stem cells in the Federal Registrar, the scheduled review of pending grant applications on April 25, 2001, was postponed while President George W. Bush’s administration reviewed this area of research. 101 Then, in August of 2001, President Bush banned through executive order federal funding of stem cell research for all practical purposes. 102 President Bush based his decision on his personal “belief in the fundamental value and sanctity of human life.” 103 Following President Bush’s statement, the NIH announced that stem cell research would be funded only if the following criteria were met:

The derivation process (which begins with the destruction of the embryo) was initiated prior to 9:00 EDT on August 9, 2001. The stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed. Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements. 104

This policy banned federal funding for: “(1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose.” 105 Technically, the Bush administration is the first to

98. Id. (“Use of human pluripotent stem cells could allow researchers to study the beneficial and toxic effects of candidate drugs in many different cell types and potentially reduce the numbers of animal studies and human clinical trials required for drug development.”).

99. Id. (stating that the third and most obvious potential application of these human pluripotent stem cells is specialization of the cells into tissues that could be transplanted into patients for the purpose of repairing injury and pathological processes).

100. Id. (citing heart disease and type I diabetes as examples of the potential of stem cell research in treating disease).


103. Office of the Press Secretary, Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), available at http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html [hereinafter Fact Sheet]. See also President George W. Bush, supra note 102 (“My position on these issues is shaped by deeply held beliefs.”).

104. NIH’s Role in Federal Policy: Stem Cell Research, supra note 18.

105. Fact Sheet, supra note 103.
fund human embryonic stem cell research. To the non-scientifically trained American, this policy appeared to be a good compromise in the ethical debate surrounding stem cell research. However, to the trained scientist, this policy effectively banned stem cell research because it remains to be proven if any of the approximately sixty cell lines established prior to August 9, 2001, could actually be used to advance scientific research. In addition to his own moral beliefs, President Bush partly relied on advice given by the President's Council on Bioethics (PCB), a federal advisory committee headed by Leon Kass. Selected by the President and heads of departments, federal advisory committees are meant to provide expert and objective advice on various issues. However, many members of the scientific community feel that President Bush does not appoint or even dismisses committee members who do not share his personal beliefs.

A recent report by the Union of Concerned Scientists noted:

[T]here is a well-established pattern of suppression and distortions of scientific findings by high-ranking Bush administration political appointees across numerous federal agencies . . . [and] there is strong documentation of wide-ranging effort to manipulate the government's scientific advisory system to prevent the appearance of advice that might run counter to the administration's political agenda.

However, the Bush administration vehemently objects, asserting that no


107. Elias Zerhouni, Stem Cell Programs, 300 SCIENCE 911 (May 9, 2003) ("By early winter of 2001, 71 independent human embryonic stem cell derivations were identified on the NIH Human Embryonic Stem Cell Registry as eligible for research supported by federal funds.").

108. Robert Steinbrook, Science, Politics, and Federal Advisory Committees, 350 N. ENG. J. MED. 1454, 1454 (Apr. 1, 2004) ("Federal advisory committees are meant to provide independent, expert, and objective advice on policy, the funding of research, and other issues. Although their advice may be followed, or ignored, they do not make decisions."); Federal Advisory Committee Act, Pub. L. No. 92-463 (Oct. 6, 1972).

109. Steinbrook, supra note 108, at 1454 (noting that "candidates have reportedly been asked to state their views on specific topics, such as abortion, stem cell research, and human cloning.").

litmus test is used to appoint committee members.\textsuperscript{111}

President Bush recently came under criticism when he did not reappoint two stem cell research proponents, suggesting that dissent was not appreciated on the Council.\textsuperscript{112} One scientist, Elizabeth Blackburn, charged the administration with replacing pro-stem cell members with persons whose beliefs lie closely to those of Leon Kass.\textsuperscript{113} Furthermore, Blackburn worries that strong data regarding the promise of stem cell research is being purposefully left out of the Council’s report, suggesting bias against funding.\textsuperscript{114} Practically speaking, however, it may be almost impossible to separate advisory committees from politics.\textsuperscript{115} To address some of the recent criticisms, two reports from the General Accounting Office and the National Academies will examine issues including federal appointments, adequacy of the procedure to ensure scientifically sound advice, and quality of the peer review system.\textsuperscript{116}

In a hearing before the 108th Congress, Elias Zerhouni, Director of the NIH under President Bush, reported on the progress of stem cell research.\textsuperscript{117} In this address, Zerhouni reported that seventy-eight stem cell lines are “fully eligible for federal funding” and that eleven stem cell lines are “widely available for all researchers.”\textsuperscript{118} While a limited number of stem cell lines are available for federally funded research, even proponents of the

\textsuperscript{111} Id. at 1455 (noting that the Bush administration defends its actions); Aaron Zitner, Advisors Put Under A Microscope, L.A. TIMES, Dec. 23, 2003, at A1.

\textsuperscript{112} Steinbrook, supra note 108, at 1454. See also Elizabeth Blackburn, Bioethics and the Political Distortion of Biomedical Science, 350 N. ENG. J. MED. 1378, 1379 (Apr. 1, 2004) (discussing her personal experience of being asked to leave the President’s Council on Bioethics).

\textsuperscript{113} Blackburn, supra note 112, at 1379 (“The published views of the three new members differ sharply from mine and May’s and are much closer to those espoused by Kass. Furthermore, not one of the newly appointed members is a biomedical scientist.”).

\textsuperscript{114} Id. at 1380 (“[W]ork with animals increasingly suggests that research may result in therapies for diabetes, Parkinson’s disease, and spinal injuries among other conditions. Yet the best possible scientific information was not incorporated and communicated clearly in the council’s report, suggesting that the presentation was biased.”).

\textsuperscript{115} Steinbrook, supra note 108, at 1458 (quoting G. Calvin Mackenzie as stating, “[i]nsulating appointments to advisory committees from politics is just about an impossibility.”).

\textsuperscript{116} Id. at 1459 (noting that as a result of the controversies surrounding federal advisory committees, two potentially influential reports are forthcoming).


\textsuperscript{118} Id. See also Paul McHugh, Zygote and “Clonote”- The Ethical Use of Embryonic Stem Cells, 351 N. ENG. J. MED. 209, 209 (July 15, 2004) (noting that the NIH has made “15 to 20 human stem cell lines available for federally supported research.”).
current policy acknowledge that some technical barriers make the current forum for research even more challenging.\textsuperscript{119} The current stem cells lines "may be difficult to grow and differentiate"\textsuperscript{120} and the genetic origin and culture conditions of the established cell lines may affect scientific progress.\textsuperscript{121}

Members of the scientific community are extremely critical of the current stem cell policy. One scientist argues that the practical ban on stem cell research in this country will undermine the ability of our scientists to compete internationally.\textsuperscript{122} Should stem cell research later become unrestricted, we will then lack a work force prepared to work on potential breakthrough discoveries in other countries.\textsuperscript{123} Others argue that religious and political tests should not be used in determining scientific policy.\textsuperscript{124} Scientists also believe that current stem cell lines most likely have limited potential for use in clinical therapy due to mouse contamination.\textsuperscript{125}

Finally, we currently lack the ability to create cell lines to model diseases.\textsuperscript{126} In a survey taken at a stem cell research conference, a majority of researchers opined that there are not enough stem cell lines for research and that the current federal policy hinders research.\textsuperscript{127} Indeed, research in

\begin{footnotes}
\item[119.] Stem Cell Research, Hearing Before Senate Appropriations Subcommittee on Labor, Health and Human Services, and Education (Session 1), 108th Cong. (Statement of Ronald McKay) (May 22, 2003), available at \url{http://olpa.od.nih.gov/hearings/108/session1/testimonies/stemcell.asp} (last visited Nov. 2, 2005)
\item[120.] Id.
\item[121.] Id. (noting that many early stem cell lines were established by co-culturing the cells with mouse feeder cells).
\item[122.] Jeffrey M. Drazen, \textit{Embryonic Stem cell Research - The Case for Federal Funding}, 351 N. ENG. J. MED. 1789, 1789 ("If we continue to prevent federal funds from being used to support this research in the United States, the ability of our biomedical scientists to compete with other research teams throughout the world will be undermined.").
\item[123.] Id. ("[W]ithout the needed laboratory know-how, as a result of our current federal policy of permitting research with only a limited number of preexisting embryonic stem cell lines, these experiments [referring to a stem cell related breakthrough in another country] could take years to complete, and replication would be likely to happen outside the United States.").
\item[124.] David Baltimore, \textit{Science and the Bush Administration}, 305 SCIENCE 1873, 1873 (Sept. 24, 2004) ("In various ways, the scientific community in the United States-and in other nations as well-has expressed concerns about the way in which decisions about scientific issues have been subjected to political tests by the Bush administration.").
\item[125.] Daley, \textit{supra} note 8, at 627 ("All were cultured in contact with mouse cells and bovine serum, which renders them inferior to newer lines, derived under pristine conditions, for potential therapeutic applications.")
\item[126.] Id. ("More important questions can be addressed only by means of the lines modeling specific diseases, and therapies may best be pursued with lines genetically matched to specific patients through somatic-cell nuclear transfer.").
\item[127.] Amanda L. Drake et al., Letter to the Editor, \textit{Researcher Opinions on Human Embryonic Stem Cell Issues}, 122 J. INVESTIG. DERMATOLOGY 855, 855 (2004) (discussing the results of a survey taken to determine scientific opinions about the current state of stem
foreign countries has already addressed some of the concerns put forward by American scientists, including how to culture new stem cells lines not contaminated with mouse feeder cells. As previously noted, Great Britain recently implemented policies to encourage growth and progress in stem cell research, including opening a stem cell bank and issuing licenses to use cloning techniques, namely SCNT, to establish stem cell lines. Some argue the "scientific epicenter" for stem cell research is shifting overseas, where countries like Great Britain support the research under "strictly monitored conditions."

Several bills have been proposed by members of Congress, voted on in the House, or referred to committees. On February 27, 2003, the House voted in favor of a bill that would prohibit both therapeutic and reproductive cloning and include a criminal penalty for violation. About the same time, a number of senators introduced a bill that allowed therapeutic cloning, but banned reproductive cloning. While other bills remain either on the floor or in committee, Congress has yet to make a definitive statement on the future of stem cell research.

IV. PRIVATE INVESTORS AND INDIVIDUAL STATES ARE TAKING THE LEAD IN STEM CELL RESEARCH

Private organizations and individual states are implementing programs and funding to advance research. Researchers at Harvard University,
funded by private money, are opening a stem cell research center. In 2004 both New Jersey and California passed legislation allowing and/or funding stem cell research. Initiatives such as these show that some states so strongly believe in stem cell research, either for medical, political, or economic reasons, that they are willing to support research that the federal government is not willing to presently fund.

A. Privatization of Stem Cell Research

Recently, Harvard University announced its plan to open the Harvard Stem Cell Institute. In consideration of the ethical debate, the Harvard Stem Cell Research Committee will review research proposals for the Institute. The Institute proposes to contribute to research that may be done at laboratories outside of Harvard, establish core facilities to work with stem cells, and bring scientists together through seminars and symposiums. Proponents of the private institute believe that scientific progress in stem cell research and its application to disease will challenge the ethical opposition in favor of increased funding to help those affected with illnesses.

Earlier in 2004, Harvard researchers made seventeen embryonic stem cell lines available to other laboratories. While some acknowledge that the stem cell lines made available by the NIH may be enough to get the field started, private funding will be needed to produce additional cell lines and fund further research. Moreover, researchers working with the newly available cell lines from Harvard will require private funds to perform the research due to current federal prohibitions.

137. Powell, supra note 135.
138. Id. (discussing committee created to review research proposals for non-federally funded projects).
139. Id. (describing the goals of the Institute).
140. Harvard Plans Center to Grow Stem Cells, N.Y. TIMES, Mar. 1, 2004, at A18 (opining that with every success, Americans will not stand for scientists unable to work on diseases).
141. Editorial, The Privatization of Stem Cells, N.Y. TIMES, Mar. 9, 2004, at A24 (stating that private and state funding may be needed to expand research as new embryonic stem cell lines are made available).
142. Id. (noting that additional stem cell lines will be required for research to move forward).
143. Id. (noting that research on new stem cell lines will require private financing).
B. State Legislatures are Passing Bills to Allow and Fund Stem Cell Research

While some states such as Missouri and Kansas have specifically banned embryonic stem cell research, other states including New Jersey and California passed legislation allowing stem cell research. The motivation behind passing bills allowing stem cell research may be, in part, the hope of contributing to state economic growth.

1. New Jersey Passes Pro-Stem Cell Research Legislation

New Jersey recently passed stem cell research legislation and stated:

Open scientific inquiry and publicly funded research will be essential to realizing the promise of stem cell research and maintaining the State's leadership in biomedicine and biotechnology. Publicly funded stem cell research, conducted under established standards of open scientific exchange, peer review and public oversight, offers the most efficient and responsible means of fulfilling the promise of stem cells to provide regenerative medical therapies.

The New Jersey bill allows all types of stem cell research (including adult, embryonic, and SCNT), sets up an institutional review board to review stem cell research, and states that information will be presented to infertility patients about their options to donate unused embryos to research. While it was legal to perform stem cell research with private money prior to the passing of the New Jersey bill, the new bill "amounts to a proclamation in support of the science." Economic considerations of the state's biotechnology industry also played a role in the decision to pass stem cell legislation. The New Jersey bill states: "The biomedical industry is a critical and growing component of New Jersey's economy, and would be significantly diminished by
limitations imposed on stem cell research." In May 2004, Governor James McGreevey signed legislation establishing a "state-supported stem cell research facility" and about 200 researchers attending the forum said, "they hoped the institute would help New Jersey retain its status as a center for pharmaceutical and biotech research." In addition, state officials commented on the contribution of scientific research to the state economy, noting that, "120 biotech research businesses in New Jersey employed 8,000 people and created $1 billion in revenue for the state economy."

Supporters of the bill hope that the pro-stem cell legislation will attract scientists from around the world, as well as biotech and pharmaceutical industry to the state. For instance, after California passed pro-stem cell legislation in 2002, that state experienced an influx of researchers and received private funding for a Stanford University stem cell research center. New Jersey hopes for a similar investment trend.

2. California Passes a Referendum and $3 Billion in Funding for Stem Cell Research

California initially passed a bill allowing therapeutic stem cell research in 2002, but that bill was unfunded. Then, in 2004, Californians voted on and passed a stem cell referendum allowing embryonic stem cell research, adult stem cell research, and SCNT. That measure also required that all

151. John M. Broder & Andrew Pollack, Californians to Vote on Stem Cell Research Funds, N.Y. TIMES, Sept. 20, 2004, at A1 (reporting that Governor McGreevey signed the legislation establishing a state-supported stem cell research facility).
152. David Kochieniewski, McGreevey Signs Bill Creating Stem Cell Research Center, N.Y. TIMES, May 14, 2004, at B5; See also Laura Mansnerus, New Jersey Forges Ahead on Stem Cells, N.Y. TIMES, Feb. 21, 2004, at B1 (noting that the budget will provide $6.5 million for a research institute to be run by Rutgers University and the University of Medicine and Dentistry of New Jersey).
153. Kochieniewski, supra note 152, at B5.
154. Mansnerus, supra note 152, at B1 (noting that Dr. Wise Young and other researchers hoped to recruit about a dozen of "the best stem cell scientists in the world," which would cost about $25 million).
155. Laura Mansnerus, Stem Cell Law Welcomed by Researchers, N.Y. TIMES, Jan. 6, 2004, at B6 ("'If you were a biotech, would you invest millions of dollars and jobs in a state that might outlaw what you're doing?'").
156. Id.
158. CAL. HEALTH & SAFETY CODE § 125300(a) (West 2004) ("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.")).
research be reviewed by "an approved institutional review board." The California bill acknowledges the "promise for developing new medical therapies" and notes the effect on the California economy:

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.

Unlike New Jersey, however, California placed a $3 billion funding initiative on the November 2004 ballot to allow citizens to vote on providing public funding of stem cell research.

Proposition 71, backed by Governor Arnold Schwarzenegger, was a ballot initiative providing $3 billion for stem cell research over the next ten years. Robert Klein, a real-estate developer and major author and promoter of Proposition 71, stated that the $3 billion price tag was needed to mimic a national funding program. Klein argued that California, though already in financial trouble, could afford the initiative by putting the debt obligations off to the future by using bond proceeds to pay off the interest and partly relying on economic growth from the promise of stem cell research to help pay off the rest. Proposition 71 also establishes the California Institute for Regenerative Medicine, which will award research funding to grant applicants. The core clauses of the initiative were inserted into the California constitution and so will require a 70% legislative majority to make any changes, effectively eliminating legislative

163. Bruck, supra note 12, at 70 (quoting Klein's argument that "a billion would not sufficiently support what he has devised: a ten-to-thirteen year program moving from basic applied research to clinical trials to therapy development," and that it will take $3 Billion to run a substitute national program).
164. Id. (explaining how Klein proposed to fund Proposition 71).
165. Id. (explaining that the California Institute for Regenerative Medicine is to award the research grants, and will be governed by a twenty-nine-member board, consisting of representatives of universities, medical-research institutions, and patient-advocacy groups).
Interestingly, opponents of Proposition 71 included both pro-stem cell research groups and anti-stem cell organizations, albeit for different reasons. The more liberal camps that traditionally support progressive views regarding abortion rights argue that Proposition 71 "lacks adequate ethical safeguards against financial conflicts of interest." They argue the lack of legislative oversight will allow the Research Institute to "make its own rules about conflicts of interest and informed consent." Anti-stem cell research persons and organizations posit the same ethical dilemmas described at the national level, including ethical objections to the destruction of blastocysts and the potential for reproductive cloning. Besides ethical considerations, others argue that California is already so far in debt that this initiative is fiscally irresponsible.

Proponents of Proposition 71 argue the "initiative will more than pay for itself." Spending on buildings and research staff will generate tax revenue and, when combined with stimulation of the state’s biotechnology industry and better therapies that economize medical costs, the initiative costs will be covered. Proponents also contend that the proposal for the California Institute for Regenerative Medicine will provide the "highest possible level of accountability and will serve as a model of how science can be funded at the state level.”

Irv Weissman, one of the strongest proponents of Proposition 71, explained in a recent interview that passage of the proposition will enable California to attract some of the best scientists in the United States.

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166. Id. (noting that the initiative’s core clauses will be incorporated as an amendment to the California Constitution, thereby creating a constitutional right to conduct stem cell research in California); Jonathan Knight, War of Words Escalates in Run-Up to California’s Vote on Stem Cells, 430 NATURE 125, 125 (July 8, 2004) (explaining that Proposition 71 will not only establish a California Institute for Regenerative Medicine to distribute grant money through a review process, but also by amending the constitution and requiring a 70% legislative majority to make changes to the proposition, the initiative seeks to make California a haven for this research) [hereinafter Knight – War].

167. Knight – Schwarzenegger, supra note 162, at 888.

168. Id.

169. Knight – Critics, supra note 13, at 232.

170. Id. at 232.

171. Knight – Schwarzenegger, supra note 162, at 888.

172. Id.

173. Id. (“Spending on buildings and research staff alone will generate enough tax revenue to... cover the first five years’ interest on the bond. [T]he bond should stimulate the state’s biotechnology industry and give better therapies that will save tens of millions of dollars in medical costs each year.”).

174 Knight – Critics, supra note 13, at 232.

175 Bruck, supra note 12, at 78.
Weisman predicts that scientists will relocate to California, leaving other states at a competitive disadvantage, "and probably only then will the state legislatures and the federal government wake up to realize that California is stealing, for a song, these scientists and building a whole future."  

Another strong supporter of Proposition 71, former NIH director Harold Varmus, stated, "I think that the symbolic value of having some state doing [stem cell research] with public money, to embarrass the federal government and try to encourage it to get back in the game, would be very, very important." But Varmus expressed concerns that state-by-state funding initiatives are not an adequate substitute for NIH policies and funding and stated that he would like the federal government to change the current policy. The only way President Bush could undermine the future funding of stem cell research would be to pass federal law outlawing therapeutic cloning. A bill to this effect has already failed twice in the Senate, thus the chances of a federal ban passing look slim.

The promise of funded stem cell research in California may indeed lead prominent researchers in other parts of the country to move to there, thus weakening the potential for embryonic stem cell research in other states. Other states may therefore miss out on a huge economic opportunity if their researchers leave before the state legislatures pass pro-stem cell policy. To this end, some hypothesize that other states may follow California's lead. Indeed, the governors of both Wisconsin and New Jersey have since proposed spending millions of dollars on their state's biotech and biomedical research.

Even though the federal government is not funding laboratories that want to establish new stem cell lines, public money is still being used to promote

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176. *Id.*
177. *Id.* at 80.
178. *Id.* (stating that there really is no substitute for the NIH, and that it sets a bad precedent to solve the problems of the NIH through state funding).
179. The Stem-Cell State, 432 NATURE 131, 131 (Nov. 11, 2004) (noting that there is still a chance that President George Bush and his allies in Congress who oppose the research could undermine Proposition 71 with a federal ban in essential techniques such as 'therapeutic cloning,' but that such a bill has failed twice in the Senate already).
180. *Id.* (indicating that researchers outside California worry that Proposition 71 could weaken embryonic stem cell research elsewhere because while privately-funded research centers exist outside California, even senior researchers may find it difficult to pass up funding and lab space).
181. Jonathan Knight, Joys Match Fears as California Agrees to Stem Cell Proposal, 432 NATURE 135, 135 (Nov. 11, 2004) ("In response to such pressures, other states may consider stem-cell measures of their own, suggests Kevin Wilson, a spokesman for the American Society for Cell Biology... 'There could be a domino effect,' he predicts.").
this research at the state level. Researchers wishing to engage in frontier science have limited choices. They can either attempt to solicit private funding at the institute where they currently research or move to a state with a commitment to funding the research.

V. IMPLICATIONS OF STATE COMPETITION AND/OR FEDERAL INTERVENTION

A wide breadth of literature in corporate law concerns the relationship between state competition and federalism. Legal scholarship focuses on whether competition among states to attract corporations results in a "race-to-the-bottom" or "race-to-the-top." More recent scholarship argues that state competition to attract corporations does not exist due to Delaware’s dominant position in the market for incorporation. However, Delaware’s fear of federal regulation affects its policy.

Will the recent California stem cell legislation cause a similar effect by attracting leading scientists, biotech and pharmaceutical companies to move to California and leave other states? Due to its favorable legal infrastructure and biomedical policy contributing to "agglomeration economies," California may be so far in the lead that other states may only be able to conduct research on a much smaller scale. Put in another way, Proposition 71 may attract leading scientists to a state that already has favorable conditions for start-up biotech companies. Other states, such as New Jersey and Massachusetts, may continue to draft, pass, and fund pro-stem cell research policy in an attempt to emulate California so as to also profit from scientific innovation. However, these states may not be able to provide the same advantageous resources that already exist in California, thereby making it difficult to catch up.

The federal government, perhaps California’s most formidable opponent, may act to provide pro- or anti-stem cell policies or may choose to allow a state-regulated model to persist. A potential disadvantage under the state-regulated model is that scientists in different states cannot collaborate with one another if the state policies differ. Under a pro-stem cell federal policy,

187. Id. at 576.
all scientists will have the opportunity to work with one another. In addition, the federal government should enact policies to oversee responsible stem cell research before the states or researchers in the private sector conduct ethically questionable experiments. Moreover, the amount of federal dollars that can be appropriated to stem cell research far surpasses what individual states can afford and scientific progress will move faster if laboratories around the country all receive federal funding. On the other hand, although the federal government has not passed anti-stem cell legislation, California’s policy may cause a federal backlash. This state behavior may give anti-stem cell federal legislators the ammunition needed to convince borderline votes to pass legislation that preempts state law with a federal ban, which could halt stem cell research in this country for years to come.

A. State Competition Under Corporate Law

State policymakers are aware that different legal infrastructures can attract industry. Delaware currently provides the most attractive corporate laws for large corporations in the country. Underscoring the state-competition model for corporate law, some scholars argue that state laws lead to a race-to-the-bottom, where protections of management interests outweigh shareholder protections. Others argue that state competition leads to a race-to-the-top, where state laws protect shareholders’ interests because investors can sell their shares if managers do not perform optimally. Similar to corporate law, state policy that offers incentives to researchers and industry interested in stem cells will move scientists to states offering those opportunities. California not only currently offers the most freedom and resources to conduct stem cell research, the state’s businesses also stand to make a tremendous amount of money if stem cell research leads to the effective treatment of a variety of diseases.

188. See Bruck, supra note 12, at 64 (noting that the NIH’s budget in 2003 was $27.3 Billion, $190.7 million of which was allocated to adult stem cell research and $24.8 million to embryonic stem cell research).
189. Bebchuk & Hamdani, supra note 184, at 554.
191. Romano, supra note 183, at 711 (discussing the state competition literature, citing Winter, State Law, Shareholder Protection, and the Theory of the Corporation, 6 J. Legal Stud. 251, 255 (1977)).
192. Broder & Pollack, supra note 32, at A1 (noting that a study, financed by the initiative’s proponents, predicted that research would generate between $537 million and $1.1 billion in royalties to the state over the next 35 years).
1. The Potential Effects of Proposition 71 Do Not Follow the Race-to-the-Top or Race-to-the-Bottom State Competition Models

William Cary defines the race-to-the-bottom as a system where the legal infrastructure, enforced by the courts, allows an environment in which corporate management is able to benefit most from their decisions without regard to the needs of the shareholder. An important aspect of Cary’s argument for the race-to-the-bottom theory is the composition of the Delaware bench and the “relationship between politics, the bar, and the judiciary.”

Cary connected seven justices of the Supreme Court of Delaware from 1951 to 1974 to the drafting of Delaware corporate law. Indeed, Delaware’s Court of Chancery specializes in corporate law and publishes its opinions, thereby creating a body of corporate case law, meaning many corporations prefer to litigate in Delaware due to the case law history.

To analogize Proposition 71 to Cary’s race-to-the-bottom model, the shareholders are the citizens of California and management is represented by the proposition proponents and those who control the $3 billion of research money. A group called Doctors, Patients and Taxpayers for Fiscal Responsibility opposed Proposition 71, claiming that the people who stand to benefit the most are the venture capitalists and biotech companies who pushed the initiative forward.

Recently, Governor Schwarzenegger appointed Robert Klein as the new chairman of the Citizen’s Committee to oversee the newly formed Research Institute for Regenerative Medicine. Some critics of this appointment suggest that a more thorough candidate search should have been

194. Id. at 690-91 (“What is striking about the membership of the court in the last 23 years is that almost all the justices were drawn from the group responsible for the 1967 revision of the corporation law.”).
195. Id. See also Marcel Kahan & Ehud Kamar, The Myth of State Competition in Corporate Law, 55 Stan. L. Rev. 679, 708 (2002) (“A principal attraction of incorporating in Delaware is the high quality of its chancery court... and the opinions of the court are published in the state and regional reporter, and are available on commercial databases, creating a body of case law that provides guidance to practitioners.”).
196. Knight –WAR, supra note 166, at 125 (“The true winners... are the initiative’s sponsors. Most of the S2.6 million so far raised to support the ballot drive has come from venture capitalists and biotechnology entrepreneurs who stand to gain from its passage.”).
197. Carolyn Marshall, Financier To Lead Institute On Stem Cells, N.Y. Times, Dec. 18, 2004, at A13 (“The real estate developer who helped write and finance a ballot initiative to create a California stem cell institute was elected on Friday to a six-year term as chairman of the committee that oversees it.”); Safire, supra note 182, at A33 (“As the driving force behind the initiative to invest $3 billion in stem cell research over the next decade, the builder-financier [Robert Klein II] has just been nominated by Gov. Arnold Schwarzenegger to head the citizens’ committee overseeing the state’s Institute for Regenerative Medicine.”).
performed. It is unclear at this time whether those venture capitalists and biotech investors responsible for funding may be the same people receiving the grant money and profiting publicly and personally from Proposition 71, with some arguing that Proposition 71 is a form of corporate welfare.

Unlike Cary’s corporate law model, however, Proposition 71 will most likely not follow a state competition model that may lead to a race-to-the-bottom. First, if research funded by Proposition 71 does not produce clinical results in the next ten years, it seems unlikely that the voters of California will pass initiatives for additional funding. Second, biotech companies must consider their own shareholders and investors. Those companies receiving Proposition 71 funding will need to conduct innovative and successful research in order to obtain additional funding, retain their current shareholders, and attract new investors. The incentive to “earn” additional funding through successful research will translate to benefits for the shareholders, so that the profit-seeking motive will balance the interests between the managers and the shareholders. Thus, a second tier of manager-shareholder relations will control the potential for a race-to-the-bottom that could potentially harm the citizens of California.

Third, academic scientists will most likely operate under Proposition 71 as they do under NIH funding by writing competitive grant applications, receiving funding, and then applying the grant money to support research in their laboratories. While university professors do not answer to “shareholders,” the potential of additional funding motivates them to produce and publish quality research. Such an incentive will most likely encourage them to use Proposition 71 funding in the most scientifically optimal manner, without financial motivations that would hurt California’s citizens. Thus, the incentives to perform stem cell research in California, or any other state, would not create a race-to-the-bottom.

In opposition to Cary’s race-to-the-bottom theory, Ralph Winter argued that if management chose to incorporate (or reincorporate) in a state with interests adverse to the shareholder, then the “investors would require a higher return on capital to finance the business operating under the inferior legal regime.” In contrast, under a value-maximizing regime, biotech firms and industry would strike a balance between the hunger of management to dive into the lucrative pool of stem cell research with the interests and investments of the stockholders. While Winter’s corporate model may be applied to the management-shareholder relationship in

199. Bruck, supra note 12, at 77.
200. Romano, supra note 183, at 711 (summarizing Winter’s argument in response to Cary).
biotech companies as discussed above, most likely this relationship will not be the incentive for biomedical industries to re-locate to California. More likely, as discussed in more detail below, the pro-stem cell research policy, combined with the established scientific clusters such as Silicon Valley, will make it very difficult, if not impossible, for other states to compete with California.

2. Proposition 71 May Increase the Agglomeration of Biotech Industry in California

Once Proposition 71 passed, New Jersey immediately announced its intention to increase funding for stem cell research. The fear that industries may leave their home state to move to a state that permits stem cell research is very real. Thus, states may attempt to compete to retain and attract industry by using state revenue.

In an analogous system, Ronald Gilson argues that the differences in legal infrastructure in California and Massachusetts explain, in part, the reason for the success of California’s Silicon Valley and the decline of Boston’s Route 128. Building on Alfred Marshall’s concept of “agglomeration economies,” Gilson argues that Silicon Valley benefits from the lack of enforcement of covenants not to compete in California, thereby leading to employee mobility and more dynamic diffusion of knowledge of the industry. In response to employee mobility, Silicon Valley employers realized that in order to succeed they should adopt a strategy of cooperation and competition that leads to collaboration between universities and biotech companies, both large and small. On the other hand, because post-employment covenants not to compete seem to be regularly enforced in Massachusetts, employees in the high technology industries lack mobility, and thus corporations are encouraged to function on the less successful corporate and scientific model of vertical integration and internal innovation. Taken together, Gilson argues that the differences in legal infrastructure and subsequent externalities led to the

201. Gilson, supra note 186, at 577.
202. Id. at 576-78. (discussing how legal infrastructure impacts the dynamics of industrial districts, particularly those in high technology).
203. Id. at 608-09 (“Employees learned that they could leave; employers learned that they could not prevent high velocity employment and the resulting knowledge spillover. And that legal infrastructure caused employers, however reluctantly, to adopt a different strategy, one of cooperation and competition, that generated a dynamic process leading to Silicon Valley’s characteristic employee career pattern . . . .”).
204. Id. at 606 (discussing how Silicon Valley’s legal infrastructure yielded conditions able to support “a second-stage agglomeration economy,” allowing it thrive while Route 128’s infrastructure led to its decline).
success and decline of two similar industries situated in different states.

Proposition 71 gives California another advantage to attract and retain scientists and industry to its already expanding and successful biomedical industry. The collaborative biotech environment already established by the legal infrastructure as discussed above is fertile ground for an explosion of stem cell research now that the state is offering a large amount of research money. Indeed, California may already be so far ahead of other states that no other states, including New Jersey, will be able to compete. Thus, the "agglomeration economies" theory more aptly explains why California's position does not fit under a state "race" model as described above.

Many scholars, as noted below, suggest that Delaware no longer fits under a state-competition model, but is kept "in check" by fear of federal pre-emption. In general, the federal government does not intervene to regulate corporate law unless it feels that the states are not protecting their citizens. Passage of the Sarbanes-Oxley Act is a recent example of such federal intervention. The situation with California is slightly different, because normally the federal government is the principle leader of biomedical policy and funding. California, unhappy with the lack of federal funding for stem cell research, took its own initiative to implement policy and funding. But this type of state action could cause the federal government to pass stem cell legislation. If Congress decides to pass stem cell legislation, it could either support stem cell research or preemptively ban it and all state law, which would make the federal government the most formidable opponent to California's efforts.

B. Federal Involvement to Control State Behavior

Perhaps the larger issue with the states legislating stem cell research is the invitation for the federal government to take stronger steps to pre-empt state behavior.

For the majority of publicly funded biomedical research, the NIH undergoes public comment on its policy, sets a national standard, and institutes a peer-review process for grant review. Traditionally, the NIH

205. Bebchuk & Hamdami, supra note 184, at 604-05.
206. See id.
208. See Bruck, supra note 12, at 64 (explaining that traditionally decisions about federal funding have been made by the NIH, the "world’s leading medical-research institution, which awards more than forty thousand research grants each year.").
funds research grants regardless of the laboratory’s domicile. While private persons and organizations may donate money to fund research, the vast majority of basic science research stems from federal money.\(^{210}\) Moreover, state funding will not be able to reach the amount of money the federal government can invest into research.\(^{211}\) The NIH has tackled other difficult research issues, including recombinant DNA technology.\(^{212}\) However, stem cell research marks the first time that states have taken action to move forward with research that the federal government does not support. Here, California again may find that its strongest opponent is the federal government.

The federal government may decide to pass legislation on issues not addressed by state law or it may find a state law so egregious that it responds by passing federal legislation to pre-empt state law.\(^{213}\) For example, some scholars argue that Delaware’s corporate law is not encouraged by state competition, but rather is kept in check by the fear of federal action.\(^{214}\) While the federal government has not stepped in to mandate a national incorporation policy, it certainly enters the corporate realm on specific issues, most notably securities.\(^{215}\) Recent examples include the Enron and WorldCom corporate scandals, which led to the passage of the Sarbanes-Oxley Act, setting standards for such issues as managerial duties and the chain of command for authority within a corporation.\(^{216}\)

It may be irrelevant whether California will spawn state competition for researchers and industries if the federal government intervenes to displace the state policy. At the two extremes, the federal government could either change the current stem cell policy to reflect that of the Clinton era, seeking to establish policy, guidelines, and grants to fund stem cell research, or it

\(^{(last \ visited \ Oct. \ 30, \ 2005).}\)


\(^{211.}\) See Bruck, supra note 12, at 64.

\(^{212.}\) Id. at 67 (explaining that risks of allowing recombinant-DNA research seemed “frightening” before breakthroughs and benefits came about).

\(^{213.}\) Roe, supra note 185, at 601. (commenting that the federal government replaces and modifies state legislation if it finds offensive).

\(^{214.}\) Id. at 591-92 (arguing that even if corporate matters remain at the discretion of Delaware, the federal government has frequently taken away the state’s power to create corporate law); Bebchuk & Hamdani, supra note 184 (commenting that Delaware is so dominant in corporate law that other states are not a challenge to its position); Kahan & Kamar, supra note 195, at 685 (arguing state competition may have existed in the past and may exist in the future, but it does not exist right now).

\(^{215.}\) Roe, supra note 185, at 592.

\(^{216.}\) Id. at 598 (discussing how Sarbanes-Oxley demonstrates Congress’s willingness to pre-empt state corporate law).
could pass legislation banning all stem cell research and thereby pre-empt state policy.

1. The Federal Government Should Regulate and Fund Stem Cell Research

In 1998, the Clinton administration established that federal funds, via the NIH, could support research involving embryonic stem cells. This decision was not the first time the federal government took steps to advance controversial research through the NIH. An earlier example is the promotion of recombinant DNA technology. Initially, critics believed that synthesizing DNA could be used to create microbes that were dangerous to the public. However, a strict set of guidelines developed to shape recombinant DNA technology and this area of research provided many medical benefits, including the production of insulin.

Establishing national guidelines for progress in stem cell research can address most ethical controversies and ensure research is conducted responsibly. Without federal policy, an ethical investigation, similar to one conducted in South Korea, may be required in the United States. In February 2004, a group of Korean scientists published the results of a study where they obtained stem cells from a cloned human embryo using SCNT. The study was a first step towards the idea that a patient’s own cells may be used for treatment, thus avoiding an immune response. However, ethical issues soon came to light concerning how the South Korean research team obtained the eggs used in the experiments. It is unclear whether a Ph.D. candidate in the Korean lab donated her own eggs for the research. If true, some argue that women researchers will be pressured to donate their own eggs when, for the best interests of all involved, the donor and research should be at arms-length.

218. Id.
219. Id. (discussing Paul Berg's instrumental work in the 1970s promoting NIH guidelines for recombinant DNA technology).
221. Hwang, W.S. et al., Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived From a Cloned Blastocyst, 303 SCIENCE 1669, 1669-74 (Mar. 12, 2004); David Cyraninski, Crunch Time for Korea's Cloners, 429 NATURE 12, 13-14 (May 6, 2004) (describing the work of the Korean scientists) [hereinafter Crunch Time].
222. Crunch Time, supra note 221, at 13.
223. Id. (describing how a Ph.D. student in the lab initially said she donated her eggs and then later retracted the statement).
224. Id. (discussing how bioethicists are concerned that not maintaining such a boundary could give rise to researchers directly influencing donors).
One of the biggest concerns with the South Korean study was that the lab performed experiments without the government’s legal or ethical oversight.225 The Korean researchers argue they received approval by an institutional review board, but in a letter to Science in August 2004, the president of the Korean Bioethics Association, Sang-Yong Song, stated, “We believe that is premature to perform this research before these issues had been resolved . . . [and] [t]he Korean government is working to prepare regulations, guidelines, and review systems for biotechnology research in keeping with global standards.”226 A similar dispute could easily arise in the United States without national guidelines in place.

The individual states and the private sector are not technically governed by national ethical guidelines with respect to obtaining the stem cell material and the limitations on how research is conducted. However, organizations concerned with ethical and responsible stem cell research have issued proposed guidelines for use by privately-funded researchers,227 which could be used as persuasive evidence of accepted practice in any suits challenging researcher behavior. In addition, proponents of stem cell research arguably have incentives to conduct ethically responsible research so as not to antagonize the federal government to enact further anti-stem cell policy.

With individual states also enacting their own guidelines, research may be limited by interstate differences because a scientist in one state may be unable to collaborate with scientists in other states. For example, if State A allows scientists to work with newly established stem cell lines, while State B does not, joint research will be impaired. A national policy allowing stem cell research would alleviate this problem by providing guidelines that allow scientists in all states to collaborate with one another, as well potentially with international scientists. Increased interaction and collaboration would better promote the great potential for stem cell research to help patients.

State initiatives to promote stem cell research are laudable. However, unlocking the full potential of this research will require the type of long-term, broad financial support only the federal government can sustain. Research will progress more quickly and more people will potentially be helped if the NIH adopts the Clinton administration’s pro-stem cell research policy. The United States federal government should follow the lead of

226. Id. at 945.
Great Britain by implementing ethical and safety guidelines and funding the promotion of stem cell research.

Sound guidelines for supporting stem cell research include requiring non-compensatory consent for donation of fertilized eggs, limiting the time the blastocysts can be grown in a petri dish, and establishing a federal stem cell bank. In addition, the NIH offers a preexisting functional infrastructure to enact guidelines, fund peer-reviewed research grants, and establish a stem cell bank depository such that scientists among the states can collaborate with each other and also work with other scientists around the world. In this way, the United States will establish uniformity throughout the country when conducting stem cell research.

2. State Policy Promoting Stem Cell Research Could Potentially Cause Federal Retaliation and Halt Stem Cell Research

On August 9, 2001, President Bush announced his stem cell research policy that only stem cell lines created before that date could be used for federally-funded research and that no new stem cell lines could be created using federal funds.\(^228\) The House of Representatives passed a bill that criminalizes both therapeutic and reproductive cloning with punishment of a fine of at least $1 million and up to ten years in prison.\(^229\) This bill, however, does not have the votes to pass the Senate.\(^230\) Senator Orrin Hatch (R-UT) sponsored a bill in the Senate that would prohibit reproductive cloning but allow therapeutic cloning.\(^231\) This bill has not passed the Senate and President Bush says he would veto such a bill.\(^232\) To date, the government does not have federal law with respect to reproductive or therapeutic cloning technology.

If the anti-stem cell politicians in Washington gain momentum to legislatively ban stem cell research, one of the only things that can save pro-stem cell policy is a therapeutic breakthrough. If the public sees the promise of research to patients able to receive effective treatment using stem cell technology, then President Bush and other similarly-aligned politicians will have a hard time taking those treatments away from the American public. Research is an expensive, slow, and laborious process,
and the real "race" may be between individual states and the federal government.

VI. CONCLUSION

This article presents the current state of affairs for stem cell research by providing an overview of the research, explaining the ethical objections, describing the federal policy, and illustrating the state and private responses to the federal restrictions. In recognition of the practical federal ban on stem cell research, private investors and states took initiative to promote the scientific, medical, and economic potential of stem cell research. This dissent against federal policy may lead to state competition for researchers and industry, but more likely, it will induce a federal reaction. It is unclear at this time whether the federal government will enact policy to support the ethical promotion of therapeutic research or ban stem cell research, thus stifling progress in this country for years to come.