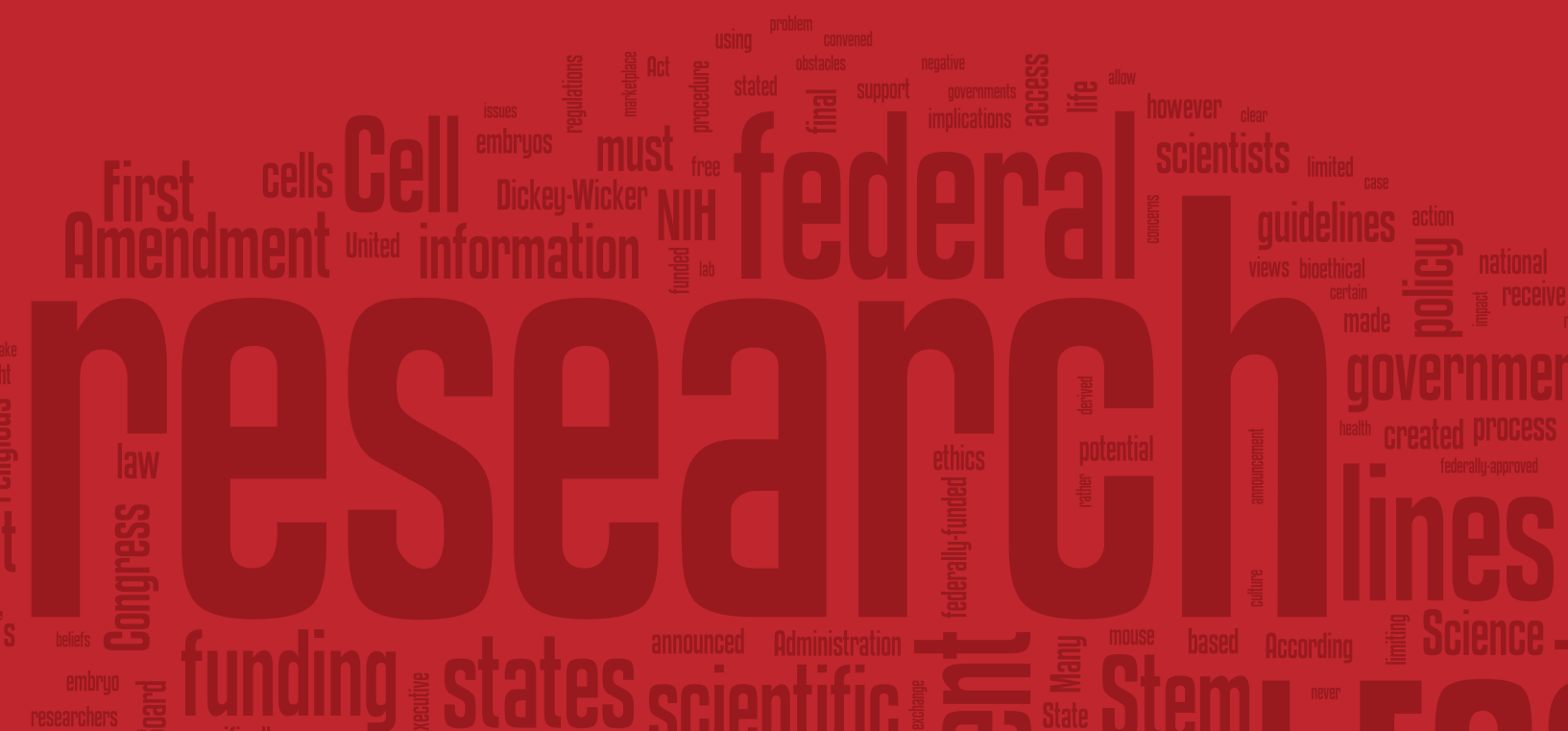




# CENSORING SCIENCE: A Stem Cell Story



*Censoring Science: A Stem Cell Story*

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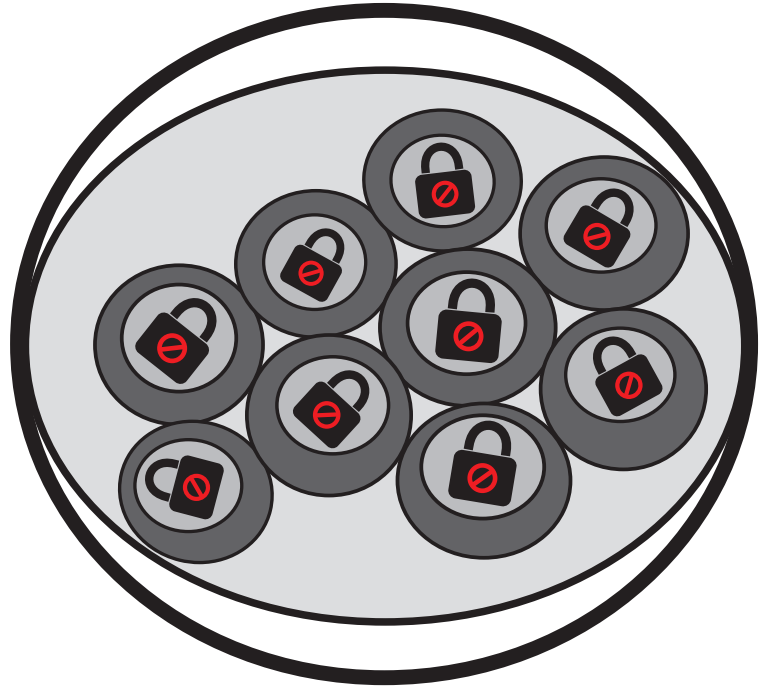
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*A popular Government, without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy; or, perhaps both. Knowledge will forever govern ignorance: And a people who mean to be their own Governors, must arm themselves with the power which knowledge gives.*

James Madison



## Censoring Science: A Stem Cell Story

**T**his is a tale of bold government overreaching. It is a cautionary tale, a reminder that the Constitution's First Amendment protections of the free exchange of ideas, the right to make one's views known to government, and the expectation of government transparency are only as strong as our demand for their implementation. The following is a case study of the suppression of scientific discovery put in motion by presidential fiat, unfettered by Congress, and embraced by leaders of various states. In making policy for human embryonic stem cell (hESC) research, the highest government officials, expressing the supremacy of religious views, have restricted the marketplace of ideas through actions that have denied the nation its right to political participation. As a result, the public has suffered real and long-lasting consequences.

James Madison, the fourth President of the United States and author of the First Amendment, believed that access to information was a fundamental condition to effective self governance.

A popular Government, without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy; or, perhaps both. Knowledge will forever govern ignorance: And a people who mean to be their own Governors, must arm themselves with the power which knowledge gives.<sup>1</sup>

According to philosopher Alexander Meiklejohn, the First Amendment at its core protects a free exchange of ideas specifically to allow for self-governance.<sup>2</sup> The right to receive information is critical to society's ability to make informed decisions. Meiklejohn wrote that scientific knowledge is one of the most crucial areas of thought from which voters derive "the capacity for sane and objective judgment." Specifically, he stated that "[t]he achievements of philosophy and the sciences in creating knowledge and understanding of men and their world must be made available, without abridgement, to every citizen."<sup>3</sup> In essence, the First Amendment, in order to function as intended in a democracy, must protect a right to receive information, a right to know.

The Supreme Court has recognized this First Amendment right to know. As the Court found in *Board of Education v. Pico*, "the right to receive ideas is a necessary predicate of the recipient's meaningful exercise of his own rights of speech, press and political freedom."<sup>4</sup> Justice Brennan's plurality opinion for the Court in *Pico* said:

Our precedents have focused "not only on the role of the First Amendment in fostering individual self-expression but also on its role in affording the public access to discussion,

**"And we have recognized that 'the State may not, consistently with the spirit of the First Amendment, contract the spectrum of available knowledge.' In keeping with this principle, we have held that in a variety of contexts 'the Constitution protects the right to receive information and ideas.'"**

**- Justice Brennan  
Board of Education v. Pico**

debate, and the dissemination of information and ideas." And we have recognized that "the State may not, consistently with the spirit of the First Amendment, contract the spectrum of available knowledge." In keeping with this principle, we have held that in a variety of contexts "the Constitution protects the right to receive information and ideas." (Internal citation omitted)<sup>5</sup>

Constitutionally protected free inquiry and expression in the fields of health and science currently are being abridged openly by the federal and some state governments. Those governments are obstructing scientific discovery by limiting the scope and type of certain research, and by impeding access to information about scientific developments. By disrupting the creation of new scientific information, those governments endanger the marketplace of ideas, threatening not only constitutional rights to freedom of speech, thought and inquiry, but also

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<sup>1</sup> 9 Writings of James Madison 103 (G. Hunt ed. 1910).

<sup>2</sup> Alexander Meiklejohn, "The First Amendment Is An Absolute," *The Supreme Court Review*, Vol. 1961 (1961): 245-246, 254.

<sup>3</sup> *Id.* at 257.

<sup>4</sup> *Board of Education v. Pico*, 457 U.S. 853, 867 (1982) (holding that the school board does not have an unfettered right to remove constitutionally protected books from school libraries in part because of the students' right to have access to a full range of information).

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<sup>5</sup> *Board of Education v. Pico*, 457 U.S. 866-67.

society's decision and policy-making processes that depend on reliable, valid information.

There surely are special and rare situations in which government legitimately may constrain the free exchange of ideas and when transparency is not the paramount objective. Under law, for example, government may withhold information that properly has been deemed classified for the purpose of protecting national security. Stem cell science does not present such a situation. To the contrary, President Bush's 2003 Executive Order which amended the law of classification of materials and extended far reaching powers of classification for national security purposes, specifically exempts "[b]asic scientific research information not clearly related to the national security . . ."<sup>6</sup>

The case study that follows is not one involving the security of the nation nor does it reflect a regrettable classification error. It is a matter of unlawful federal censorship of scientific discovery with a cascade of effects in states across the nation.

## Case Study: Stem Cell Research

Human embryonic stem cell (hESC) research is a field of science with significant bioethical implications.<sup>7</sup> Many believe that embryos, upon their

formation, have the status of human beings, so research on even very early embryos is imbued with moral and religious consequences. Add to that the fact that an embryo necessarily must be destroyed in the process of deriving stem cells, and it is clear why ethical issues are inevitably on the hESC research agenda. Notwithstanding these concerns – indeed, on account of them – the public has a right to know about the medical advances that potentially could arise from hESC research. The public has a right to express the range of views that will bring into balance respect for the pursuit of science and the nation's moral comfort. In an area where there are so many deeply held but differing religious and moral views, government should not by proclamation construct a narrow spectrum of available knowledge but rather should foster the "vital interchange of thought."<sup>8</sup>

Despite the clear value of public debate on this issue, President Bush neither issued a proposed hESC policy nor collected public comment on the subject. He abandoned federal regulatory procedure and his Administration violated federal statutory law, effectively choking off federal funding for robust but regulated hESC research. President Bush restricted the marketplace of ideas and openly based his decision to do so only on his ethical and religious beliefs.

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<sup>6</sup> Exec. Order No. 13292, 68 Fed. Reg. 15315 (March 28, 2003)

<sup>7</sup> There have been important recent advances in the development of induced pluripotent stem cells (iPS) that are derived from adult somatic cells. The new developments in iPS research hold scientific promise of future stem cell therapies that are free from the current ethical concerns associated with the use of hESCs. President Bush recognized the promise of iPS research in his Executive Order titled "Expanding Approved Stem Cell Lines in Ethically Responsible Ways." Exec. Order No. 13435, 72 Fed. Reg. 34591 (June 22, 2007). These developments do not, however, diminish the importance of continued hESC research. First, scientists continue to make important discoveries based on hESC research. A study published in the journal *Blood* in August 2008, for example, reports that scientists have developed red blood cells from hESCs, creating a potential solution to insufficient blood supply in the US. According to the *Wall Street Journal*, "[t]he result suggests that embryonic stem cells could someday supply type O-negative 'universal donor' red cells for transfusion." Associated Press, "Scientists Finds Way to Create Red Blood Cells," *Wall Street Journal*, August 20, 2008 at D2. Secondly, there are several major issues in iPS research that

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must be resolved before the stem cells could be considered appropriate for human therapies. One issue is that the retroviral vectors used to induce pluripotency may make the cells susceptible to cancer. In addition, "random insertion of retroviruses into the genome carries the risk of accidentally turning on or off some key gene inappropriately, perhaps later in development." *Nature Reports Stem Cells*, (May 1, 2008) at <http://www.nature.com/stemcells/2008/0805/080501/full/stemcells.2008.67.html> It would be short-sighted if the public were to support only iPS research in order to avoid ethical controversy.

<sup>8</sup> *Kleindienst v. Mandel*, 408 U.S. 753, 775 (1972) (Marshall, J. dissenting). (Upholding the statutory exclusion of an alien invited to participate in academic conferences in the US). In his dissent, Justice Marshall eloquently explained that "[t]he freedom to speak and the freedom to hear are inseparable; they are two sides of the same coin. . . . The activity of speakers becoming listeners and listeners becoming speakers in the vital interchange of thought is the 'means indispensable to the discovery and spread of political truth.' Its protection is 'a fundamental principle of the American government.' (Internal citations omitted).

Prior to President Bush's action on hESC research, ethics had been a major concern of scientific research and federal law. Congress grappled with the bioethical implications of fetal tissue research and the potential for federal agencies to impede such research through ethical objections raised by their agency heads. In 1993, Congress passed the National Institutes of Health (NIH) Revitalization Act (NIHRA), creating a system for vetting research about which ethical concerns had been advanced. Recognizing the potential for the Secretary of Health and Human Services to impede research that raised ethical questions, NIHRA stated that "if research has been recommended for approval...the Secretary may not withhold funds for the research because of ethical considerations" unless such withholding is first recommended by an advisory board convened to study such research.<sup>9,10</sup>

Acting in compliance with NIHRA, the Clinton administration convened an ethics board when NIH began to receive applications for funding of research involving human embryos. In 1994, the ethics board advised that research on human embryonic stem cells was, in many circumstances, ethically permissible.<sup>11</sup> Congress responded in the HHS 1996 budget by adopting the Dickey-Wicker Amendment which prohibited funding by HHS for research in which a human embryo was "created" or "destroyed"

for research purposes.<sup>12</sup> Despite the plain language of the Dickey-Wicker Amendment, its authors inadvertently created an opportunity that would allow for continued but limited hESC research. The budget amendment forbade only federal funding of the derivation of the hESC, a process that destroys the source embryo. Dickey-Wicker did not prohibit federal funding of research using hESC cells post-derivation so long as no federal funds were involved in the derivation process. NIH then developed hESC research guidelines that, after a formal public notice and comment period, were issued in final form in August 2000. Thereafter, the NIH began receiving requests for the funding of stem cell research in accordance with the Final Guidelines.<sup>13</sup>

NIHRA and the Dickey-Wicker Amendment illustrate and provide a backdrop for the dilemma President Bush faced upon coming into office. Proponents of hESC science focused on the strong potential of hESC research to discover therapies for injury and debilitating diseases, while detractors objected to the research, broadly stated, on the basis of their religious and moral convictions. President Bush responded to this challenge according to a specific set of religious values that he personally embraced.

Ignoring the directives in NIHRA which stipulate that funds may be withheld for ethical reasons only upon the recommendation of an ethics advisory

<sup>9</sup> 42 U.S.C.A. §289a-1(b). The National Institutes of Health is an agency within the U.S. Department of Health and Human Services and is, by far, the largest funder of biomedical research within the United States.

<sup>10</sup> In addition to protecting ethically-charged research in general, NIHRA also sought to maintain the possibility of research on human fetal tissue for therapeutic purposes. Section 113 of NIHRA established that human fetal tissue may be used, but only with informed consent of the donor. Subject to the condition that the tissue be donated with informed consent in accordance with the statute, NIHRA stated that "no official of the executive branch may impose a policy that the Department of Health and Human Services (HHS) is prohibited from conducting or supporting any research on the transplantation of fetal tissue for therapeutic purposes." National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, Sec. 113 (June 10, 1993). While fetal tissue research as defined in this section of NIHRA does not involve hESCs, it serves as an important precursor to the current stem cell debate.

<sup>11</sup> Yaniv Heled, "On Presidents, Agencies, and the Stem Cells Between Them: A Legal Analysis of President Bush's and The Federal Government's Policy on the Funding of Research Involving Human Embryonic Stem Cells," 60 Admin L. Rev. 65, 81 (Winter 2008).

<sup>12</sup> The Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, §128(2), 110 Stat. 26, 34 (1996). In relevant part, the Dickey-Wicker Amendment states: "None of the funds made available by Public Law 104-91 may be used for – (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)2 and 42 U.S.C. 289g(b). For purposes of this section, the phrase 'human embryo or embryos' shall include an organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this ACT, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human

<sup>13</sup> Heled, *supra* note 10 at 81.



***“None of the funds made available by Public Law 104-91 may be used for – (1) the creation of human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero...”***

**Dickey-Wicker Amendment  
The Balanced Budget Downpayment Act**

board, President Bush announced in the eighth month of his presidency that he was limiting federal funding for hESC research to stem cell lines already in existence, which, he said, numbered 60 cell lines.<sup>14</sup> In his announcement on stem cell research, delivered in his first direct televised address to America since his inauguration,<sup>15</sup> the President recognized that research on human embryonic, pluripotent stem cells held scientific promise. He also recognized that

rapid progress in this research will come only with federal funds. Federal dollars help attract the best and brightest scientists. They ensure new discoveries that are widely shared at the largest number of research facilities and that the research is directed toward the greatest public good.<sup>16</sup>

Despite the promise of hESC research and the importance of federal funding to fuel scientific discovery, the President, based on “a great deal of thought, prayer and reflection” offered his “position on these issues [which] is shaped by deeply held beliefs.” Though he believed, he said, in the “great promise” of this research,

I also believe human life is a sacred gift from our Creator. I worry about a culture that devalues life, and believe as your President I have an important obligation to foster and encourage respect for life in America and throughout the world. And while we’re all hopeful about the potential of this research, no one can be certain that the science will live up to the hope that it has generated.<sup>18</sup>

Based on his religious beliefs and the fact that he could not know for certain the outcome of prospective scientific research, President Bush limited federal funding to research on hESC lines derived prior to his statement. With this decision, he avoided the use of federal support for the future embryo-destroying process of deriving cell lines subsequent to the announcement of his position.

Typically, law is made by Congress passing and the President signing legislation. The Executive Branch then develops regulations for implementing the law by, as a first step, publishing a draft set of regulations in the Federal Register. As provided in the

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<sup>14</sup> At the time of the President’s speech, significantly fewer than 60 stem cell lines actually existed. See *infra* at page 9.

<sup>15</sup> Katherine Seelye and Frank Bruni, “A Long Process That Led to Bush Decision,” *New York Times*, (August 11, 2001) at A2.

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<sup>16</sup> President George W. Bush, “President Discusses Stem Cell Research,” (August 9, 2001) at <http://www.whitehouse.gov/news/releases/2001/08/print/20010809-2.html>.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

***I have given this issue a great deal of thought, prayer and considerable reflection...My position on these issues is shaped by deeply held beliefs...I believe human life is a sacred gift from our Creator. I worry about a culture that devalues life, and believe as your President I have an important obligation to foster and encourage respect for life in America and throughout the world. And while we're all hopeful about the potential of this research, no one***

***can be certain that the science will live up to the hope it has generated...I have made this decision with great care, and I pray it is the right one."***

**President George W. Bush  
"President Discusses  
Stem Cell Research"  
(August 9, 2001)**

Administrative Procedure Act (APA),<sup>19</sup> the public is invited to comment on the draft before adoption. The Executive Branch reviews the comments and produces a final set of regulations as well as an extensive summary of the comments and the government's response to them.

In announcing his final policy, President Bush abandoned all semblance of federal legal procedure. His decision was never vetted through the Administrative Procedure Act's regulation-creating process, nor was it ever embodied in an official Executive Order. Congress never took action to endorse or override it. Furthermore, the President's decision to restrict funding was made without the review of an ethics board as mandated by NIHRA.<sup>20</sup>

The televised speech simply became the rule. The newly appointed director of the NIH discarded the Final Guidelines which had been promulgated through the legally prescribed APA process.<sup>21</sup> The notice of withdrawal of the prior guidelines printed in the Federal Register stated only that "The President has determined the criteria that allow Federal Funding for research using existing embryonic stem cell lines...Thus, the NIH Guidelines as they relate to human pluripotent stem cells derived from human embryos are no longer needed." In that one action, the Final Guidelines of 2000, about which approximately 50,000 people had submitted comments, were replaced by no more than a televised announcement and a fact sheet available on the White House website.<sup>22</sup>

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<sup>19</sup> Administrative Procedure Act 5 U.S.C. 553 (1966).

<sup>20</sup> Heled, *supra* note 10 at 84, 92, 93.

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<sup>21</sup> Heled, *supra* note 10 at 85, 86.

<sup>22</sup> On the same day President Bush announced his hESC policy, he also released a fact sheet summarizing his position. See "Fact Sheet: Embryonic Stem Cell Research," (August 9, 2001) at <http://www.whitehouse.gov/news/releases/2001/08/print20010809-1.html>.

In addition to the fact that the President's informal action was a clear example of overreaching that was, at best, alarming<sup>23</sup> and at worst, illegal,<sup>24</sup> it also has had a significant negative impact on research about which the public has a right to know. First, the policy was based on misinformation. President Bush announced in his televised statement that more than 60 hESC lines already existed and would be available for federally-funded research. This inventory never has been realized. According to the NIH website, there currently are 21 hESC lines available for research up from 17 in 2004, and 1 in April 2002, a full eight months after the President announced his policy.<sup>25</sup> In explaining this discrepancy in the numbers of announced and available hESC lines, Elias Zerhouni, President Bush's Director of NIH from May 2002 through October 2008, wrote that "many of these derivations were in the early phases of

development and had not been expanded or characterized to the point where they could be readily distributed to the research community."<sup>26</sup> Apparently, only one third of the lines originally announced have now, seven years later, been made ready for research use. Unfortunately for researchers, the paucity of federally-approved hESC lines provides little genetic diversity, thus further inherently limiting the research value of these cell lines.<sup>27</sup>

Another problem with the federally-approved hESC lines is that about half of the cell lines grow slowly, making them "virtually unusable."<sup>28</sup> These cell lines have aged and developed genetic mutations, making them suitable only for limited types of research.<sup>29</sup> Additionally, these stem cell lines "were grown in poorly defined media conditions using dated protocols that make the cells difficult to thaw and grow in culture."<sup>30</sup>

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<sup>23</sup> According to Heled, "President Bush and his Administration, probably well aware of this situation, seem to have taken advantage of it in designing President Bush's Directive so as to ensure that its form would be impervious to judicial review. First, the President delivered his Address orally, on television, and it was never published in the Federal Register. The accompanying Fact Sheet was never published in any formal government publication. Second, neither the Address nor the Fact Sheet bears the signature of the President, and the Address does not include any specific operational instructions directed at executive officers, but is merely a vague pronouncement of moral preferences. Finally, the Address and Fact Sheet carry none of the conventional titles, which could have helped to classify them under one of the known forms of presidential directives (e.g., "executive order" or "memorandum"). Thus, President Bush's Directive does not seem to fall squarely under any of the known types of presidential directives. As a result, there are no formal or procedural requirements applicable to it, so it cannot suffer from any formal or procedural flaw, which might have affected its validity or enforceability." (Internal citations omitted). Heled, *supra* note 10 at 89-90.

<sup>24</sup> Heled argues that, under NIHRA, President Bush did not have the authority to withhold funding for hESC research on ethical grounds without the recommendation of an ethics advisory board. *Id.* at 91-110. Heled also argues that the Bush Administration was required to follow the notice and comment requirements of the APA since the announced policy on hESC research suspended the implementation of the duly promulgated Final Rule. *Id.* at Footnotes 3 and 95.

<sup>25</sup> National Institutes of Health, Stem Cell Information, Frequently Asked Questions (April 2008) at <http://stemcells.nih.gov/StemCells/Templates/StemCellConte>

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<sup>26</sup> Elias Zerhouni, "Stem Cell Programs," *SCIENCE* Vol 300 (May 9, 2003) at [www.sciencemag.org](http://www.sciencemag.org).

<sup>27</sup> Robert Streiffer, "Informed Consent and Federal Funding for Stem Cell Research," *Hastings Center Report* 38, no. 3 (2008): 40-47, 40.

<sup>28</sup> "The Lure of Stem Cell Lines," *Nature* 442, 336-337 (July 27, 2006) at <http://www.nature.com/nature/hournal/v442/n7101/full/442336a.html>.

<sup>29</sup> *Id.*; Claudia Dreifus, "A Conversation with – Douglas Melton; At Harvard's Stem Cell Center, the Barriers Run Deep and Wide," *New York Times*, (January 24, 2006).

<sup>30</sup> Streiffer, *supra* note 26 at 40.

Even more discouraging is the fact that the hESC lines available for federally-funded research are not appropriate for direct development into human therapies. The NIH website reports that the available hESC lines have been sustained in culture dishes with a “feeder layer” of mouse cells.<sup>31</sup> According to Donald Kennedy, Editor-in-Chief of Science from 2000-2008, “new lines are needed for research because all current ones were developed in the presence of mouse cells that provided needed growth factors, and thus may be contaminated with viruses or proteins from those mouse cells.”<sup>32</sup> Transplanting contaminated lines into humans potentially could introduce new mouse viruses to human beings.<sup>33</sup> Contaminated lines – the only lines available for federally funded research – thus cannot be used directly to create therapies for human use.<sup>34</sup>

The hESC lines themselves are not only scientifically unsound, but ethically deficient as well. A recently-published study has shown that the embryos from which the federally-approved hESCs

were derived were not obtained with appropriate informed consent of the embryo donors as required by the Administration’s own policy.<sup>35</sup> Ironically, the Bush Administration’s moral stance on hESC research has mandated that federally-funded research be done only on cell lines obtained under ethically-uncertain circumstances.

The fact that there are only twenty-one, flawed, hESC lines available for federally-funded research has significantly limited the work of scientists employed by the government. Unable to seek private funding, government scientists cannot conduct meaningful hESC research in federal laboratories.

Scientists who are not employed by the government have more options. Many have sought – and some have found – alternative sources of funding. The federal government’s restrictions, however, still have a significant negative impact on these scientists.<sup>36</sup> Non-federally-funded hESC research must be kept completely separate from

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<sup>31</sup> The National Institutes of Health, Stem Cell Information, Stem Cell Basics (February 2008) at <http://stemcells.nih.gov/info/basics/basics3.asp>.

<sup>32</sup> “Researchers Cite Stem Cell Shortage,” *CBS News* (July 20, 2008) at <http://www.cbsnews.com/stories/2003/05/09/tech/printable553079.shtml> (May 9, 2003).

<sup>33</sup> Streiffer, *supra* note 26 at 40; “The Lure of Stem-Cell Lines,” *supra* note 27.

<sup>34</sup> “The Lure of Stem-Cell Lines,” *supra* note 27; Dreifus, *supra* note 28.

<sup>35</sup> Streiffer, *supra* note 26. In his article, Mr. Streiffer argues that the federal government should make available federal-funding for research on newly-derived stem cell lines so that appropriate informed consent can be obtained from donors prior to use. In response to Mr. Streiffer’s article, Story Landis, director of the National Institute of Neurological Disorders and Stroke and chair of the NIH stem cell task force, stated that NIH does not plan to make any changes as a result of these ethical concerns. “Ethics Questions Add to Concerns About NIH Lines,” *SCIENCE*, Vol. 321 (August 8, 2008) at [www.sciencemag.org](http://www.sciencemag.org).

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<sup>36</sup> A recent article in *Cell Stem Cell* analyzes the connection between policies on hESC research and publication data. According to the study, “overperforming” countries with the highest level of research output were those with “permissive policy environments for hESC research.” The data reveal “significant underperformance” of hESC research production in the United States, which “suggests that federal funding restrictions may have influenced the amount of hESC research conducted by U.S. scientists, despite the presumably positive impact of the emergence of state support for this field.” Aaron D. Levine, “Identifying Under- and Overperforming Countries in Research Related to Human Embryonic Stem Cells,” *Cell Stem Cell*, Vol.2, Issue 6, Pages 521-524 (June 5, 2008). See also two July 2006 articles in *Nature* describing how research in Sweden and the United Kingdom has progressed due in part to national funding sources and support of research. “The Lure of Stem-Cell Lines,” *supra* note 27; Meredith Waldman and Alison Abbott, “Special Report: A long week in stem-cell politics,” *Nature*, 442, 335 (July, 27 2006) at <http://www.nature.com/nature/journal/v442/n7101/full/442335a.html>.

federally-funded studies in a laboratory to ensure that no federal funds are used to support hESC research using unapproved lines. Nothing in the hESC lab may be purchased with federal money, and no lab personnel or support staff may be paid for their hESC work through a federal grant.<sup>37</sup> The burden and expense of maintaining such separate-ness detracts from the resources that otherwise might be funneled into research itself. Faced with these constraints, numbers of US researchers have chosen to leave the United States to conduct their research abroad.<sup>38</sup>

The obstacles to hESC research affect not only established scientists, but also their trainees. Graduate and post-graduate students funded by NIH training grants are not able to conduct research with non-registry hESCs unless their salaries for that work are funded separately.<sup>39</sup> As trainees' access to mentors is dwindling and they recognize the obstacles to conducting hESC research, young scientists likely will be drawn to fields of study that are less

restricted. The next generation of scientists therefore is being deterred from specializing in this field.

It is not adequate for hESC research in the United States to be based primarily in laboratories that are able to raise non-federal money. The potential of hESC therapies will not be realized unless the research is robust and wide-spread. According to one Harvard researcher, "it's unlikely that one person or one lab will solve a problem as big as degenerative diseases, which is what stem cell researchers are trying to do. It takes a community of people in an area to solve a big problem. If you were trying to solve cancer at two places, no one would think that was enough."<sup>40</sup>

These impediments to scientific discovery all arise out of President Bush's personal belief that "human life is a sacred gift from our Creator," and that, as "President [he had] an important obligation to foster and encourage respect for life...". As a consequence, the creation of human embryonic stem cell lines essentially was declared an immoral act. The

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<sup>37</sup> Dreifus, *supra* note 28. See also Andrew Pollak, "\$271 Million for Research on Stem Cells in California," *New York Times* (May 8, 2008). Mr. Pollak describes in this article a satellite facility at the University of San Francisco, California designed to segregate non-registry hESC research as required by the Bush Administration's policy. The satellite lab had no backup generators and, when a storm caused power failures, all cell lines being grown in incubators were destroyed. According to a scientist working in the laboratory, "Several years of work literally went down the drain."

<sup>38</sup> Aaron D. Levine, "Research Policy and the Mobility of US Stem Cell Scientists," *Nature Biotechnology*, Vol. 24, No. 7 (July 2006). According to Mr. Levine, two surveys designed to assess reports of relocation of stem cell scientists "indicate that US stem cell scientist were significantly more likely than biomedical scientists working in less contentious fields to have received job offers to move to new positions in the 12 months preceding the survey. The difference was particularly pronounced for international positions, suggesting US stem cell scientists are disproportionately considering leaving the country. Job offers received by stem cell scientists were skewed toward countries and states with permissive stem cell research."

<sup>39</sup> Dreifus, *supra* note 28. See, e.g., the University of California, San Francisco Human Stem Cell Research Policy allowing students and trainees supported by federal funding to conduct non-registry hESC research only with written permission from the government and only if allowed by the

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terms of their specific grants. University of California, San Francisco, Human Stem Cell Registry Policy, Frequently Asked Questions (updated September 2006) at <http://www.research.ucsf.edu/SC/FAQ/scFAQ.asp>.

<sup>40</sup> Dreifus, *supra* note 28.

choice is presented as either valuing life or supporting research. That dichotomy has paralyzed even Congress. Representatives of pro-life constituents did not attempt to close the loophole left open by the Dickey-Wicker Amendment or to enact a law embodying President Bush's position. On the other hand, supporters of hESC research did not challenge the legality of the President's discussion and fact sheet, likely out of concern that strident moralists in Congress would react by closing entirely the loophole left by the Dickey-Wicker Amendment. The President's rhetoric created inaction, chilling not only research, as described above, but also political response.

Given this climate, most states also chose a strategy of inaction. The federal policy was itself so limiting, that states could avoid taking a position on the purported conflict between religion and science. Some states, however, did create additional restrictions that might present obstacles to conducting hESC research.<sup>41</sup> Two of those states, South Dakota

***The President's rhetoric created inaction, chilling not only research... but also political response.***

and Louisiana, specifically ban some form of hESC research and have even imposed criminal penalties on those who conduct such research.<sup>42</sup>

Some states that did support hESC research, on the other hand, created their own programs to do the work. Among the states that explicitly made hESC research legal,<sup>43</sup> many authorized significant funding – ranging from \$10 million to \$3 billion –

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<sup>41</sup> According to the National Conference of State Legislatures, many states have additional restrictions related to abortion, cloning, and sale of fetal tissue that may have an impact on hESC research. See National Conference of State Legislatures, Stem Cell Research (January 2008) at <http://www.ncsl.org/programs/health/Genetics/embfet.htm>.

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<sup>42</sup> *Id.* States that specifically restrict and criminalize hESC research are: Louisiana (§9:121-133; 14:87.2) and South Dakota (§34-14-16, 17, 20; 34-23A-17).

<sup>43</sup> The states whose laws specifically permit hESC research are: California, Connecticut, Illinois, Iowa, Maryland, Missouri, New Jersey, New York, and Wisconsin. *Id.* Some of those laws are little more than statements of support. Missouri voters in 2006, for example, approved a constitutional amendment providing that any stem cell research that is permitted under federal law is also permitted in Missouri. Monica Davey, "Stem Cell Amendment Changes Little in Missouri," *The New York Times* (August 10, 2007). In addition to those states, Washington in 2005 created the Life Sciences Discovery Fund (LSDF) which distributes research grants to scientists in the state. Human embryonic stem cell research projects are eligible to receive LSDF funding. Life Sciences Discovery Fund, FAQ (February 2008) at [http://www.lsdfa.org/about/FAQ\\_gen.pdf](http://www.lsdfa.org/about/FAQ_gen.pdf). In June 2008, the Massachusetts legislature signed a bill to expand and strengthen the Massachusetts Life Sciences Center. Stem cell research projects, though not specifically hESC research projects, will be eligible for funding through the Life Sciences Center. The Massachusetts Life Sciences Center Enabling Statute, M.G.L. ch. 231 (June 24, 2006) at <http://www.masslifesciences.com/statute.html>.



specifically for hESC research within the state.<sup>44</sup> These state initiatives are important efforts to counteract the chilling of research caused by restrictions in federal funding and criminalizing statutes in other states. The funding itself, however, does not cure the problems caused by the federal policy. In the absence of federal guidance incident to federal funding, legislative frameworks, or the transparency of federal granting systems, states needed to create their own regulatory schemes and/or bioethical guidelines. States convened teams of experts to establish parallel processes to fill the gaps created by the federal policy. Such necessary efforts diverted time and resources that otherwise could have been dedicated to research.<sup>45</sup>

State initiatives established in response to President Bush's policy have created an imbalance of intellectual resources with consequences not yet fully known. Some states will become centers for hESC research. Should the taxpayers of those states who funded the research share the benefits of the resulting intellectual property? Should they have first access to participation in protocols to test hESC therapies? These and other issues could have been avoided if the federal government had not impeded hESC research.

Restrictive policies in the United States have had a negative impact on scientific development of

***Responsible hESC research should enjoy the presumption of legality while boundaries that respond to legitimate ethical concerns are debated and reflected in duly adopted laws and regulations. More broadly, the next Administration must start a dialogue that moves this country away from the fear of scientific development and toward a focus on the ethical pursuit of knowledge.***

hESC-based therapies. The current Administration has suppressed research and impeded access to responsible scientific discovery. The President, however, did not act alone. Congress followed suit, choosing to retreat safely within the federally-declared moral high ground rather than confront the challenge of meeting both the values and scientific needs of the country. As a result, the United States

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<sup>44</sup> The states that have appropriated funds specifically for hESC research are: Connecticut, California, Illinois, Maryland, New Jersey, New York, and Wisconsin. See National Conference of State Legislatures, *supra* note 39.

<sup>45</sup> In addition to the money and time spent on creating these administrative processes, states lost significant resources in building other necessary infrastructure. On May 7, 2008, for example, the governing board of California's Institute for Regenerative Medicine (CIRM) voted to distribute \$271 million to 12 institutions to build stem cell research facilities. Press Release, CIRM, "California Stem Cell Agency, Donors and 12 California Institutions Commit \$1.1 Billion to Increase the Capacity for Research in California" (May 7, 2008) at <http://www.cirm.ca.gov/press/pdf/2008/05-07-08.pdf>. Of the total money leveraged in California for the state's stem cell initiative, over \$832 million has been allocated to cover building costs. These new hESC research laboratories will provide segregated spaces for this non-federal hESC research. Andrew Pollak, "\$271 Million for Research on Stem Cells in California," *New York Times* (May 8, 2008).

has lost ground during seven crucial years of research.

Stem cell research undeniably has important bioethical implications. These implications are recognized in the National Academy of Science's guidelines to which responsible hESC researchers voluntarily adhere.<sup>46</sup> Ethical considerations must underlie policies on hESC research. The public, however, has a right to hear and speak about difficult and challenging research matters. Rather than avoid the issue, the next Administration must do the hard work of drawing lines, and must do so with input from the public.

Responsible hESC research should enjoy the presumption of legality while boundaries that respond to legitimate ethical concerns are debated and reflected in duly adopted laws and regulations. More broadly, the next Administration must start a dialogue that moves this country away from the fear of scientific development and toward a focus on the ethical pursuit of knowledge.

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<sup>46</sup> Human Embryonic Stem Cell Research Advisory Committee, "2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research," National Research Council and Institute of Medicine of the National Academies (September 2008) at [http://books.nap.edu/openbook.php?record\\_id=12260&page=R2](http://books.nap.edu/openbook.php?record_id=12260&page=R2).





# THE KNOWLEDGE PROJECT: CENSORSHIP & SCIENCE

The Knowledge Project: Censorship & Science joins principles of scientific inquiry, research, and debate with the First Amendment to protect the free exchange of ideas. The Project documents suppression and censorship of scientific information essential to responsible public policy and individual decision-making. The Project fosters collaboration between the free expression and scientific communities, and develops educational materials and legal theories to advance the free flow of scientific information and the public's right to know.

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## The National Coalition Against Censorship

Founded in 1974, NCAC is an alliance of over fifty national non-profit organizations, including artistic, religious, educational, labor, and civil liberties groups. NCAC works with this coalition and concerned members of the general public to oppose censorship and to promote and defend the First Amendment values of freedom of thought, inquiry and expression.

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