

Journal of the National Association of Administrative Law Judiciary

Volume 22 | Issue 2


Article 5

10-15-2002

Influencing NIH Policy over Embryonic Stem-Cell Research: An Administrative Tug-of-War between Congress and the President

Scott Davison

Follow this and additional works at: <http://digitalcommons.pepperdine.edu/naalj>

 Part of the [Administrative Law Commons](#), [Ethics and Professional Responsibility Commons](#), [Health Law Commons](#), and the [Medical Jurisprudence Commons](#)

Recommended Citation

Scott Davison, *Influencing NIH Policy over Embryonic Stem-Cell Research: An Administrative Tug-of-War between Congress and the President*, 22 J. Nat'l Ass'n Admin. L. Judges. (2002)
available at <http://digitalcommons.pepperdine.edu/naalj/vol22/iss2/5>

This Comment is brought to you for free and open access by the School of Law at Pepperdine Digital Commons. It has been accepted for inclusion in Journal of the National Association of Administrative Law Judiciary by an authorized administrator of Pepperdine Digital Commons. For more information, please contact Kevin.Miller3@pepperdine.edu.

Influencing NIH Policy over Embryonic Stem-Cell Research: An Administrative Tug-of-War between Congress and the President

Scott Davison*

I. INTRODUCTION

“COMMUNITY, IDENTITY, STABILITY.” This is the motto of World State, the global government envisioned by Aldous Huxley in *Brave New World*.¹ These words are imprinted on a shield outside the “Central London Hatchery and Condition Centre,” where the government controls the birth of all new humans by creating scores of clones.² Huxley’s “brave new world” is a well-oiled machine controlled by one omniscient government that maintains the happiness of all its citizens. The same cannot be said of the United States. Instead, we have large government agencies that must react to congressional law and executive policy. In the field of biomedical research, agency decision making can cripple an industry and swamp promising new therapies in red tape. This is the current state of events for embryonic stem-cell research—a controversial new discovery in biomedical science that promises phenomenal results. Scientists hope that research with embryonic stem-cells will produce treatments and cures for debilitating diseases such as diabetes, Parkinson’s, and Alzheimer’s. The medical community continues to pursue this dream with passionate fervor, pressing for every possibility and potential avenue of biological research in an attempt to knock out some of the most deadly and damaging diseases known to man.

* J.D. Candidate, 2003, Pepperdine University School of Law; B.S., Biomedical Science, Texas A&M University.

1. ALDOUS HUXLEY, *BRAVE NEW WORLD* 1 (Harper Collins Publishers 1998) (1946).

2. *Id.* at 3.

Stem-cells were first discovered in 1998 by University of Wisconsin researcher James Thomson.³ An embryonic stem-cell is a cell that is derived from the inner cell mass of a human embryo and has the potential to develop into all or nearly all of the tissues of the body—such as brain cells, muscle cells, nerve cells, or cardiac cells.⁴ With the potential to develop into so many types of cells, scientists call them “pluripotential” embryonic stem-cells.⁵ In the laboratory, these cells divide indefinitely on a petri dish and still maintain their pluripotential characteristics,⁶ thus making them ideal subjects for all types of biomedical research. Embryonic stem-cells in particular are the most attractive to scientists, because adult stem-cells lack the same degree of pluripotentiality and may have limited therapeutic capabilities when compared to embryonic stem-cells.⁷ Scientists believe that stem-cell research, because of the characteristics of stem-cells, could lead to therapies to treat over 128 million diseased Americans.⁸ Treatments for heart disease, diabetes, Parkinson’s, and even regeneration of the nervous system in paralysis patients or brain tissue in stroke victims are all within the breadth of stem-cell research.⁹ Studies have shown stem-cells capable of repairing nerve damage and reversing the symptoms of diabetes.¹⁰ Researchers at Harvard Medical School announced in January 2002 that embryonic stem-cells may alleviate the symptoms of Parkinson’s patients after embryonic stem-cells injected into mice spontaneously converted to the nervous cell responsible for producing dopamine, a crucial chemical missing in patients afflicted with the

3. James A. Thomson, et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 *SCIENCE* 1145, 1145 (1998).

4. See Gabriel S. Gross, *Federally Funding Embryonic Stem Cell Research: An Administrative Analysis*, 2000 *WIS. L. REV.* 855, 855 (2000).

5. Press Release, The White House, Fact Sheet: Embryonic Stem Cell Research, available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html> (August 9, 2001) [hereinafter Fact Sheet].

6. Gross, *supra* note 4, at 856.

7. Press Release, *supra* note 5; see also Christine Kirk, *Research Guidelines: NIH Issues Guidelines for Federally Funded Stem Cell Research*, 28 *J.L. MED. & ETHICS* 411, 412 (2000).

8. Fact Sheet, *supra* note 5.

9. Gross, *supra* note 4, at 856.

10. Rachel K. Sobel, *Miracle Cells? Maybe More Research Dollars, More Ethical Quandries*, *US NEWS & WORLD REP.*, Sept. 4, 2000, at 22.

debilitating brain disease.¹¹ Another recent study at Duke University found that stem-cell transplants in infants with severe combined immunodeficiency are ninety-five percent successful in curing that condition.¹² The potential for embryonic stem-cells to cure a plethora of diseases has brought these cells great significance in the scientific community, but their source has brought them significant attention from the political community as well.

Unfortunately for many researchers, federal funding of embryonic stem-cell research is in the hands of the federal government and is now the subject of an intense public debate. The primary point of contention is the source of the embryonic stem-cells and the process of extracting them. The only method of obtaining an embryonic stem-cell is to destroy a human embryo, which raises paramount ethical and moral concerns for scientists, policymakers, and society as a whole.¹³ The embryo, a medical term for a fertilized egg, is considered by some to be a person, while others contend that the embryo has not achieved personhood yet. Religious organizations, “anti-abortion groups, bio-ethicists, scientists, government officials, members of Congress, and patient advocate groups” all oppose the destruction of the embryo for research purposes.¹⁴ The pro-life movement in particular believes that because an embryo is a human being, destroying the embryo amounts

11. *Rats with Parkinson's Helped by Stem Cells*, THE GLOBE AND MAIL, Jan. 15, 2002, at R8.

12. Thomas H Maugh, II, *Science File IN BRIEF: Stem Cell Treatment for SCID Infants a Success*, L.A. TIMES, Jan. 28, 2002, at A10.

13. Fact Sheet, *supra* note 5. The process of extracting stem-cells from an embryo requires the destruction of that embryo. Gross, *supra* note 4, at 856. Scientifically speaking, the blastocyst, or outer core of the embryo, is separated from the inner mass of cells, where stem-cells are located. *Id.* at 857. It must be noted, however, that embryonic stem-cells are not the only stem-cells available. Several other sources, including adult bone marrow and the umbilical cord of a newborn baby are latent with stem-cells. In fact, scientists have used these stem-cells in biomedical research since the initial discovery in 1998. However, many researchers assert that embryonic stem-cells are more beneficial to research, and that preventing use of embryonic stem-cells will further impede the progress for the great cures to diseases that stem-cell research promises. New research, however, has called some of these claims into doubt. *Infra* note 109.

14. Nelle S. Paegel, *Use of Stem Cells in Biotechnological Research*, 22 WHITTIER L. REV. 1183, 1186 (2001).

to the taking of human life.¹⁵ Proponents of embryonic stem-cell research contend that the embryos are not yet human beings, but “potential” human beings, and thus, deserve a heightened degree of respect, but nothing more.¹⁶ In addition, proponents argue that the embryos used for research purposes are “leftover” embryos from in-vitro fertilization procedures that would otherwise be destroyed or frozen indefinitely.¹⁷ If the embryos are going to be destroyed anyway, they argue, why not use them for noble purposes such as stem-cell research?¹⁸ Of course, if the embryo really is a human life, the destruction of that life is no doubt called into question, no matter how great the reasons for destroying that embryo may be. Thus, with any great ethical debate, the nation’s leaders are quick to weigh in, and any government policy dealing with the controversy, such as federal funding of research involving embryonic stem-cells, is necessarily the subject of immediate concern.

The current debate in the federal government focuses almost entirely on the use of *federal funding* for embryonic stem-cell research. Hence, the *private funding* of embryonic stem-cell research is unaffected (at least not directly) by any decision that has been, or will be made, involving federal funding.¹⁹ Additionally, although a complete ban on embryonic stem-cell research would impact the private sector, it is doubtful that either President Bush or Congress will

15. *Id.* at 1199.

16. Gross, *supra* note 4, at 857.

17. *See id.* During the in-vitro fertilization process, a popular fertility treatment, scientists combine a couple’s sperm and egg to create several different embryos. One embryo is then placed in the female’s uterus until the embryo implants and begins to develop. Once this occurs, the remaining embryos are temporarily frozen for storage, should the couple decide to undergo the process again. However, the in-vitro fertilization clinics eventually destroy the unneeded embryos, a source of controversy in and of itself.

18. *See generally id.*; *see also* Paegel, *supra* note 14, at 1220.

19. Private companies, such as Geron Corporation, are at the forefront of embryonic stem-cell research, and necessarily in competition with any government effort to fund such research. Most corporations, however, support federal funding of embryonic stem-cell research, since they are also applying for federal grant money to conduct the research.

consider taking the matter to that degree.²⁰ Hence, the controversy revolves around whether or not taxpayer dollars should be used to promote embryonic stem-cell research projects. Proponents of embryonic stem-cell research claim that federal funding is essential to jumpstart research in this particular field, and without it, life-saving therapies and drugs might be delayed for years. Opponents of federal funding argue that taxpayers should not have their money spent on something that they consider immoral. The National Institutes of Health (“NIH”), an administrative agency within the Department of Health and Human Services, oversees federal funding for stem-cell research.²¹ The NIH interprets Congressional law, complies with executive orders from the President and creates standards for organizations to obtain federal funding for many types of biomedical research.²²

After a flurry of debate in 2001 over the use of federal funding for embryonic stem-cell research, President Bush engineered a careful compromise that attempted to promote embryonic stem-cell research while respecting the status of the embryo, which he considers to be a human life.²³ The President then charged the NIH with the task of implementing the compromise and developing the rules and guidelines used to allocate federal grant money for embryonic stem-cell research.²⁴ The NIH developed these standards in late 2001, but it

20. The consequences of a complete ban on embryonic stem-cell research create fears of a national “brain drain” that would pull prominent researchers and cutting-edge scientific minds from the United States to countries where more permissive biomedical research is available. David Akin, *Genetics on the Run*, GLOBE & MAIL, reprinted Feb. 6, 2002, at A15. Germany recently struggled with this argument in early 2002 when their Parliament voted to restrict embryonic stem-cell research. *Infra* note 99. In addition, Great Britain recently passed measures guaranteeing the right of scientists to conduct research on embryos, the complete opposite of public policy efforts in the United States. Vanessa Fuhrmans & William Boston, *German Parliament Votes ‘Yes’ on Import of Stem-Cell Lines*, WALL ST. J., Jan. 31, 2002, at B10.

21. Gross, *supra* note 4, at 858-59.

22. *Id.*

23. Press Release, George W. Bush, Remarks by the President on Stem Cell Research, available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html> (August 9, 2001) [hereinafter Bush].

24. *Id.*

remains to be seen whether Congress will exercise its own power and mandate new rules for embryonic stem-cell research; trumping Bush's plan and sending the NIH back to the drawing board once more.

This comment will discuss the administrative history of NIH policy on embryonic stem-cell research and how the President and Congress jointly influence that policy. Part II discusses the history of stem-cell research and government funding, including the most recent developments up to and including the Bush Compromise. In Part III, the impact of the Bush Compromise on NIH policy will be analyzed, along with Congressional reaction and the effect on NIH rulemaking and interpretation. Finally, Part IV will conclude with a discussion of the future of embryonic stem-cell research, NIH policy and the influence of science over this complex administrative issue.

II. HISTORY OF STEM-CELL RESEARCH AND "THE BUSH COMPROMISE"

Before scientists had even discovered stem-cells, let alone their incredible potential, the law had already spoken to the issue of biomedical research on embryos and fetal tissue. President Reagan banned federal funding for any research using fetal tissue at the beginning of his administration, arguing that permitting such controversial experimentation would encourage abortion and indirectly implicate the taxpayers for the increase.²⁵ President George Bush maintained that ban during his four years in office,²⁶ preserving the pro-life view that any experimentation on a fetus or embryo is equivalent to experimentation on a human being. However, the political climate would soon change, bringing significant implications for the biomedical research community. On President Clinton's first day in office in 1993, the ban on fetal tissue research was lifted by a controversial executive order that paved the way for future federal funding for research projects involving embryos and other forms of fetal life and ignited debate over the federal funding of any research that might use fetal tissue.²⁷ Congress reacted in 1995 by attaching a

25. Paegel, *supra* note 14, at 1199.

26. *Id.*

27. *Id.* at 1188.

rider to an appropriations bill that prevented federal funds from being used for any research in which a human embryo is destroyed or subjected to risk of injury.²⁸ Since 1996, similar language prohibiting the use of federal funds for embryo research has appeared within the federal budget.²⁹

Sensing that the conflict required a greater understanding than policymakers were accustomed to, Clinton created the National Bioethics Advisory Commission (“NBAC”) in 1995.³⁰ The President asked the NBAC to research and make recommendations on controversial issues, including embryonic stem-cell research.³¹ The NBAC was made up of researchers, bioethicists, and public policymakers—all with different perspectives on the controversial issues.³² In 1999, the NBAC released a report entitled “Ethical Issues in Human Stem-Cell Research,” which recommended federal funding for embryonic stem-cell research on a broad scale, despite moral and ethical objections.³³ Specifically, the NBAC

28. Consolidated Appropriations Act of 2000, Pub. L. No. 106-113, § 510(a), 113 Stat. 1501, 1501A-275 (1999). The relevant portion states:

None of the funds made available in this Act 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 section 498(b) of the Public Health Service Act (42 USC 289g(b)).

Id.

29. Sharon M. Parker, *Bringing the “Gospel of Life” to American Jurisprudence: A Religious, Ethical, and Philosophical Critique of Federal Funding for Embryonic Stem Cell Research*, 17 CONTEMP. HEALTH L. & POL’Y 771, 776-77 (2001).

30. Nat’l Bioethics Advisory Comm’n, *Ethical Issues in Human Stem Cell Research*, available at <http://www.georgetown.edu/research/nrcbl/nbac/execsumm.pdf> (Sept. 1999).

31. *Id.*

32. *Id.*

33. *Id.* at 70, available at <http://www.georgetown.edu/research/nrcbl/nbac/stemcell.pdf>.

recommended that the NIH permit direct federal funding for the harvesting of stem cells from human embryos.³⁴

Based upon the NBAC recommendation, the NIH then announced in August 2000, that federal funds would be granted for research on embryonic stem-cells.³⁵ Then NIH Director, Harold Varmus, and then Commissioner of the Department of Health and Human Services (“DHHS”), Donna Shalala, requested a legal opinion in 1998 on the applicability of the Congressional research ban to embryonic stem-cell research.³⁶ Two months later, the DHHS concluded that the congressional ban on human embryo research did not apply to embryonic stem-cell research.³⁷ The basis for this interpretation rests on the idea that stem-cells do not comprise a full embryo under the statutory definition³⁸ because they “do not have the capacity to develop into a human being.”³⁹ Stem-cells were therefore not subject to the research ban, as long as federal funds did not pay for the actual physical extraction of the stem-cells from the embryo.⁴⁰ Congress voiced strong opposition to the NIH interpretation and guidelines, alleging that the DHHS interpretation violated the will of Congress. Some members of Congress reasserted the terms of the appropriations rider, emphasizing

34. *Id.*

35. Paegel, *supra* note 14, at 1183.

36. *Id.*, at 1198.

37. *Id.*, at 1184.

38. The definition states:

For purposes of this section, the term “human embryo or embryos” includes any 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 gametes or human diploid cells.

Consolidated Appropriations Act of 2000, Pub. L. No. 106-113, § 510(b), 113 Stat. 1501, 1501A-275 (1999).

39. Elliot Abram et al., *On Human Embryos and Medical Research: An Appeal for Ethically Responsible Science and Public Policy*, 16 ISSUES L. & MED. 261, 266 (2001).

40. *Id.*

that “Congress . . . doesn’t want to have anything to do with the termination of an embryo.”⁴¹

A legal challenge to the NIH interpretation and guidelines to permit research in embryonic stem-cells would be governed by the standard set forth by the Supreme Court in *Chevron v. Natural Resources Defense Council*.⁴² *Chevron* stands for the proposition that when Congress is silent on a particular issue, deference to the appropriate administrative agency is the proper course of action.⁴³ According to at least one legal mind, any challenge to the NIH interpretation would fail under the *Chevron* standard and other Supreme Court precedent.⁴⁴ If *Chevron* is applied, the initial conclusion is to validate the NIH interpretation based on a presumption that Congress is silent as to the particular issue of federal funding for embryonic stem-cell research. However, if the NIH policy to permit research resulting from the destruction of an embryo was interpreted to indirectly cause the destruction of an embryo, the Court could potentially strike down the agency interpretation, a major step back for researchers in favor of embryonic stem-cell research and the potential benefits of federal funding in this arena.

The debate over embryonic stem-cell research heated up with the inauguration of President George W. Bush in January 2001. Paralleling the Clinton style, Bush re-instituted the previous moratorium on federal funding of embryonic research within days of taking office,⁴⁵ thus following in the footsteps of his father and other Republican predecessors. Hence, the new NIH guidelines allowing federal funding were effectively halted before a dime of federal money was handed out.⁴⁶ The moratorium sparked immediate debate, and as results from private research efforts began to highlight the enormous potential of

41. Nicholas Wade, *Government Proposes Regulations for Embryo Cell Research*, N.Y. TIMES, Dec. 2, 1999, at A24 (quoting Congressman Jay Dickey).

42. *Chevron v. Nat’l Res. Def. Council*, 467 U.S. 837 (1984).

43. *Id.*

44. Gross, *supra* note 4, at 881.

45. *Stem Cell Plaintiffs Seek Summary Judgment, Want NIH Guidelines Restored*, 44 THE BLUE SHEET 29, July 18, 2001.

46. *Id.*

stem-cells,⁴⁷ the pressure on Bush to permit federal funding grew.⁴⁸ During the summer of 2001, the stem-cell debate was front-page news, and to-date, the most morally significant issue that President Bush confronted since his inauguration. Many in the press and political circles considered the stem-cell issue the first test of the new President.⁴⁹

After months of careful political maneuvering and discussion, President Bush spoke to the nation in a live television address on August 9, 2001 and announced a bold solution.⁵⁰ Thereafter known as "the Bush Compromise," Bush approved federal funding for embryonic stem-cell research on existing stem-cell lines, but also prohibited funding for any additional stem-cell lines derived after the date of the speech.⁵¹ The Bush Compromise captured the very essence of the word—permitting federal funding for the enormously promising embryonic stem-cell research and respecting the value of human life, even in the embryonic form, that many Americans believe in. Bush stated that over sixty existing stem-cell lines were available for research

47. Paegel, *supra* note 14, at 1188-93. Congress has yet to enact a complete ban on embryonic stem-cell research by any individual or corporation, so efforts by the private sector have continued since the initial discovery of stem cells in 1998. *Id.* The economic potential for stem-cell research is so great that several companies are currently in litigation over the rights to patents on stem-cells and the methods of research. *Id.* at 1196-98. Proponents of embryonic stem-cell research believe that federal funding will provide such an influx of research dollars that the conflicts in the private sector will soon be moot. However, even the NIH has had to negotiate with the patent owners of stem-cells for the rights to distribute those cell lines for federal research dollars. *See infra* note 57.

48. Paegel, *supra* note 14, at 1200-01.

49. The argument that federal funding of embryonic stem-cells was a presidential "test" was asserted both before and immediately after the announcement of the Bush Compromise (*see infra* Section II), but in light of the tragedies of September 11th, it will doubtfully be remembered as such. However, immediately after the Bush Compromise, most believed that the solution hammered out by the President earned him a passing grade. No one could fathom how much Bush's leadership would really be tested in the coming months.

50. Bush, *supra* note 23.

51. *Id.* Specifically, the President permitted research on sixty existing stem-cell lines where the destruction of the embryo had already taken place. *Id.* As Bush put it, "I have concluded that we should allow federal funds to be used for research on these existing stem-cell lines, *where the life and death decision has already been made.*" *Id.* (emphasis added).

at the time of his decision.⁵² In addition, Bush created a President's Council on Bioethics ("Council") "to monitor stem-cell research, to recommend appropriate guidelines and regulations, and to consider all of the medical and ethical ramifications of biomedical innovation."⁵³ Bush appointed prominent biomedical ethicist Leon Kass to lead the Council, and promised to include scientists, doctors, lawyers, and theologians.⁵⁴ In contrast to the NBAC, the Council would no doubt have a somewhat more conservative slant.⁵⁵ However, despite the clever solution penned out by the President, the debate did not end. While the President charged the NIH to implement his new guidelines, Congress continued to devise its own solution, suggesting more lenient regulations of embryonic stem-cell research that allowed the destruction of additional embryos "leftover" from in vitro

52. *Id.* The NIH provided this number to the President after an extensive, worldwide search in the months preceding his announcement. Bush requested the NIH to conduct the search in June, indicating that Bush had most likely already developed the compromise plan that he announced in August, and initiated the NIH search in an effort to legitimize his decision. In fact, the NIH returned to Bush with sixty-four potential embryonic stem-cell lines. *See infra* note 72.

53. *Id.*

54. Fact Sheet, *supra* note 5.

55. *Id.* In a more recent development, the President announced the membership of the eighteen-member Council in January 2002. They include: Elizabeth Blackburn, University of California, San Francisco; Stephen Carter, Yale Law School; Rebecca Dresser, Washington University School of Law; Daniel Foster, University of Texas Southwestern Medical School; Francis Fukuyama, Johns Hopkins University; Michael Gazzaniga, Dartmouth College; Robert George, Princeton University; Alfonso Gomez-Lobo, Georgetown University; Mary Ann Glendon, Harvard University; William Hurlbut, Stanford University; Charles Krauthammer, The Washington Post; William May, Southern Methodist University; Paul McHugh, Johns Hopkins University School of Medicine; Gilbert Meilaender, Valparaiso University; Janet Rowley, University of Chicago; Michael Sandel, Harvard University; and James Wilson, University of California, Los Angeles. *Patients Seek Representation on Bush Bioethics Council*, 34 WASH. DRUG LETTER, Jan. 28, 2002, available at 2002 WL 8399913. Fourteen of the eighteen members are considered conservatives. *Id.* Ironically, the Council announced in late January 2002 that discussion at its first meeting would not involve embryonic stem-cell research, but human cloning. Seth Goldman, *President's Council on Bioethics to Examine Human Cloning Issues*, U-WIRE, January 28, 2002, available at 2002 WL 8295843. The public policy debate on embryonic stem-cell research, in a period of less than six months, has apparently given way to the next scientific push, therapeutic cloning of embryos. *Id.* The cloning debate will be discussed more thoroughly in Section IV, *infra*.

fertilization.⁵⁶ This congressional push reflected an unusual alliance of abortion opponents with proponents, all in support of federal funding for embryonic stem-cell research.⁵⁷ The private sector, somewhat un-phased by the melee in Washington, continued to fund projects with embryonic stem-cells, subject only to public criticism and pressure from embryonic stem-cell research opponents, who claimed that the bottom line is more important to these companies than the embryo itself.⁵⁸

III. THE IMPACT OF THE BUSH COMPROMISE

A. *Effect on the National Institutes of Health*

Weeks after President Bush's announcement, the NIH released a plan for federal funding of research using specified existing human embryonic stem-cells.⁵⁹ The initial guidelines set forth by the NIH provided for federal funding of embryonic stem-cell research as long as: (1) "the derivation process was initiated prior to 9:00p.m. Eastern Daylight Time on August 9, 2001" (the date of President Bush's announcement), (2) the stem-cells are derived from an embryo that was created for reproductive purposes and was no longer needed, (3) donation of the embryo was obtained through informed consent of the biological parents, and (4) that donation must not have involved financial inducements.⁶⁰ These requirements parallel those of the original NIH guidelines for embryonic stem-cell research announced almost one year prior to the Bush Compromise, with the addition of

56. Daniel S. Greenberg, *Bush Stem-Cell Plans Draw Skepticism in Senate*, 358 THE LANCET 849, Sept. 14, 2001, available at 2001 WL 10159575.

57. *Id.*

58. Several companies have recently bowed to this pressure. After announcing in July, 2001 that it would begin cloning human embryos for the sole purpose of harvesting stem-cells (something President Bush sternly criticized), the Jones Institute for Reproductive Medicine at Eastern Virginia Medical School backed off its efforts to pursue human embryonic cloning, announcing that it would stop the practice entirely. *Lab Will End Stem-Cell Policy*, ORLANDO SENTINEL, Jan. 18, 2002, at A15, available at 2002 WL 3025243.

59. Press Release, National Institutes of Health, *National Institutes of Health (NIH) Update on Existing Human Embryonic Stem Cells* (Aug. 27, 2001), at <http://www.nih.gov/news/stemcell/082701list.htm> [hereinafter *NIH Update*].

60. *Id.*

President Bush's restriction that funding take place on a restricted list of previously derived stem-cell lines. In early November 2001, the NIH released a notice of withdrawal of the prior stem-cell regulations originally released a little over one year earlier, thus completing the agency's 180-degree policy turn.⁶¹ Another minor change to the regulations involves the informed consent requirement, which is now a general requirement left to agency interpretation.⁶² Previously, NIH regulations required specific and explicit informed consent.⁶³ The Council is also replacing the NIH Ethics Review Panel, a body similar to an institutional review board that reviewed and approved NIH programs. The Council, therefore, lacks oversight powers over NIH policy which the Ethics Review Panel once held, thereby giving the agency more direct control over rulemaking. This may spark fear of unchecked agency rulemaking, but given the public interest in stem-cell research, it is doubtful that agency officials at the NIH will escape the scrutiny and accountability of the press or the public on such a controversial issue. The NIH also announced the creation of a Human Embryonic Stem-Cell Registry ("Registry") to list the stem-cells that meet the eligibility criteria.⁶⁴ This Registry was finally published in November 2001, and currently lists eleven research entities where embryonic stem-cells may be obtained, with a total of seventy-two separate embryonic stem-cell lines.⁶⁵ Although the events of

61. Press Release, National Institutes of Health, *NIH Guide: Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Embryonic Stem Cells* (Nov. 7, 2001), at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-007.html>.

62. Thomas H. Murray, *Hard Cell: The Ethics and Politics of Stem Cell Research*, 12 AM. PROSPECT, Oct. 1, 2001, at A7, available at 2001 WL 7681221.

63. *Id.*

64. *NIH Update*, *supra* note 59.

65. National Institutes of Health, *National Institutes of Health Human Embryonic Stem Cell Registry*, at <http://escr.nih.gov/> (last visited Feb. 5, 2002). The Registry also published more formal guidelines for embryonic stem-cell lines to qualify for federally-funded research. They state that federal funds may be used for research on existing human embryonic stem-cell lines:

[A]s long as prior to his announcement (1) the derivation process (which commences with the removal of the inner cell mass from the blastocyst) had already been initiated and (2) the embryo from which the stem-cell line was derived no longer had the possibility of development as a human being.

September 11th delayed NIH plans for about a month, agency officials continued to develop drafting proposal sheets and applications for grant proposals in preparation for the publication of the Registry and the announcement of the first available grants for embryonic stem-cell research.⁶⁶ The NIH hopes that effort will hasten the process of processing applications and approving grants. Also, in August 2001, the NIH announced an agreement with the Wisconsin Alumni Research Foundation (“WARF”) for licenses to use the patents on WARF’s embryonic stem-cells.⁶⁷ DHHS Secretary Tommy Thompson testified that the NIH reached a deal with WARF for unrestricted access to five patented cell lines owned by WARF.⁶⁸ However, despite this licensing agreement, the NIH is limited to facilitating the transfer of cells from the owners to the researchers and has no direct control over the embryonic stem-cell lines.⁶⁹ Funding for embryonic stem-cell research is available through a variety of methods devised by the NIH including: grants, contractual agreements, cooperative agreements, and supplements to existing grants.⁷⁰

Id. The additional criteria required that:

[T]he stem-cells must have been derived from an embryo that was created for reproductive purposes[;] the embryo was no longer needed for these purposes[;] informed consent must have been obtained for the donation of the embryo[;] [and] [n]o financial inducements were provided for donation of the embryo.

Id.

66. *Stem Cell Research Guidelines*, 44 THE BLUE SHEET 41, Oct. 10, 2001, at p. 14 [hereinafter *Research Guidelines*].

67. *NIH Update*, *supra* note 59.

68. Greenberg, *supra* note 56. The additional companies with existing embryonic stem-cell lines identified by the NIH include: BresaGen, Inc., Cythera, Inc., Goteburg University (Sweden), Karolinska Institute (Sweden), Monash University (Australia), National Center for Biological Sciences (India), Reliance Life Sciences (India), Technion-Israel Institute of Technology (Israel), University of California at San Francisco, and Wisconsin Alumni Research Foundation. *Embryonic Stem Cells: Health Officials Identify 10 Stem Cell Labs Eligible For U.S. Research Funds*, BLOOD WEEKLY, Sept. 13, 2001, available at 2001 WL 7493882.

69. *NIH Update*, *supra* note 59.

70. *Availability of Stem Cells for Research: Hearing Before the House Judiciary Committee*, 106th Cong. (Oct. 31, 2001) (statement of Wendy Baldwin, Ph.D.).

B. Critics of the Bush Compromise

However, implementation of the Bush Compromise by the NIH has not come without criticism. From the moments immediately after Bush's speech, critics began to question the estimated sixty pre-existing embryonic stem-cell lines purported to be in existence by the President.⁷¹ The NIH, which initially made the claim to President Bush in a private report commissioned by the President over a month before his August 2001 announcement, was forced to defend its' claim that such a significant number of stem-cell lines existed throughout the world, when most biomedical researchers were aware of about two dozen.⁷² After significant criticism, DHHS Secretary Tommy Thompson made several public statements and testified before Congress about the viability of the embryonic stem-cell lines identified by the NIH, finally resolving the issue and verifying that as of the announcement of The Bush Compromise, sixty-four embryonic stem-cell lines existed and were available for use by researchers.⁷³

71. From a scientific standpoint, the number of stem-cell lines is important for several reasons. Cell lines react as differently to biomedical research as human beings do, so having a diverse bank of stem-cell lines with which to test therapies and new drugs, for example, is particularly advantageous. The more diverse the stem-cell lines are, the more tailored a particular therapy will be for the patient, and thus, more effective. In addition, most embryonic stem-cell lines are currently derived from a remarkably similar population base—the average Caucasian male. Thus, without a significant number of cell lines, therapies of the future will be useful to the same population on which the research was done. However, this conclusion may be presumptuous, simply because most scientists advancing these arguments are passionate opponents of government restrictions on embryonic stem-cell research, and may have other motives.

72. Television Interview by Katie Couric with Tommy Thompson, DHHS Secretary, on NBC News: Today (Sept. 7, 2001), *available* at 2001 WL 26427092 [hereinafter *Interview*].

73. *Interview*, *supra* note 72. The NIH Stem Cell Registry currently lists seventy-two cell lines available for research. *Supra* note 51. The difference in numbers is primarily the result of recent scientific developments of ES cell lines that may not have been viable at the time of the Bush Compromise. These additional embryonic stem-cell lines were not extracted from the embryo after the deadline, in violation of Bush's ultimatum, but at the time they were probably in the initial stages of development and not reliable enough to be counted as an official NIH embryonic stem-cell line.

Despite this promise, and the wide availability of embryonic stem-cell lines, researchers were asked by the NIH to halt any research using embryonic stem-cells until new rules were formulated and finalized in accordance with the Bush plan.⁷⁴ The timeline is longer than most imagined, but is typical of government research grant programs.⁷⁵ Nevertheless, researchers awaiting federal funding will face a lengthy application and approval process, meaning federal dollars would not have been available for embryonic stem-cell research until late 2002.⁷⁶ This waiting period is detrimental to The Bush Compromise and the new NIH Guidelines for one main reason—time. The regulatory history of stem-cell research has borne only one consistency throughout its four year existence: the more time required to make a decision, the more often the decision will change. Should NIH policy undergo another overhaul, even more time will be needed to implement the next solution—ultimately delaying any federal funding for several years. Despite the dissatisfaction of many groups with the Bush Compromise, delay may be too great to risk another major policy change.

C. Fate of the Bush Compromise: Will Congress Take Control?

Congressional action is the biggest threat to the Bush Compromise. Even before the Bush Compromise, members of Congress repeatedly made their opinions clear, that the benefits of embryonic stem-cell research would certainly outweigh any moral restraints.⁷⁷ Once Bush established guidelines for the NIH on embryonic stem-cell research, Congress raced to implement its own solution in a classic separation of powers tug-of-war.⁷⁸ With the medical potential to cure many diseases of the growing elderly population, and with the predominantly senior

74. *NIH Update*, *supra* note 59.

75. Of course, this delay pertains solely to those researchers seeking federal funding for their research. The private sector remains unscathed by the recent developments, and has even progressed to the next ethical boundary in their pursuit of the most cost-effective and beneficial therapies—biomedical research using cloned human embryos. George W. Bush, Address, *supra* note 23. See Section IV, *infra*, for a complete discussion of human embryonic cloning.

76. *Interview*, *supra* note 72.

77. *Specter Stem Cell Bill Support Likely Lost to Bush Compromise Contentment*, 44 THE BLUE SHEET 33, Aug. 15, 2001 [hereinafter *Specter Bill*].

78. *Id.* *NIH Embryonic/Adult Stem Cell Comparative Study Requested in DeGette Bill*. 44 THE BLUE SHEET 33, Aug. 15, 2001 [hereinafter *Degette Bill*].

membership of both the House and Senate, it is no wonder that Congress favors embryonic stem-cell research so strongly. Most recently, a Senate subcommittee approved a bill providing for federal funding of embryonic stem-cell research that permits an exception to the restrictions of the Bush Compromise.⁷⁹ Ironically, the proposed legislation gives the President decision-making power to grant further development of embryonic stem-cell lines,⁸⁰ a strategic move most likely intended to put pressure on the President, rather than Congress, should current embryonic stem-cell research opportunities prove inadequate. The legislation specifically permits the President to allow the destruction of more embryos for research than those already specified, but it requires that the new stem-cell lines originate from embryos that would otherwise be destroyed.⁸¹ In the typical Congressional effort to appease wary bioethicists, the law would require stringent informed consent by the donors.⁸² A recent amendment to the bill would permit couples to donate embryos for research purposes if the embryo would otherwise be destroyed.⁸³

All along, the White House has maintained its position that the Bush Compromise will succeed, and in October 2001 supported the House version of that bill, which made no such changes to the original Bush Compromise.⁸⁴ Indeed, DHHS Secretary Tommy Thompson maintained the Bush Administration's decision not to reconsider the August 9, 2001 deadline for embryonic stem-cell lines to be derived, invoking the threat of a presidential veto on any legislation contrary to Bush's new guidelines.⁸⁵ But Senator Arlen Specter, the sponsor of the more expansive Senate bill, claims he has the support of almost seventy-five Senators,⁸⁶ a number that would override a presidential veto should the issue ever arise.⁸⁷ However, in early November 2001

79. *Specter Bill*, *supra* note 77.

80. *Id.*

81. *Id.*

82. *Id.*

83. *Stem Cell Pool May Grow*, THE GRAND RAPIDS PRESS, Nov. 1, 2001, at A2, available at 2001 WL 29517018.

84. *Specter Bill*, *supra* note 74.

85. Greenberg, *supra* note 56.

86. *Id.*

87. *Id.*

the Senate backed off its position to ease the restrictions for embryonic stem-cell research after the insinuation of a Bush veto of the measure.⁸⁸ Another House resolution being pushed would direct the NIH to conduct a study comparing embryonic stem-cell research to adult stem-cell research,⁸⁹ presumably in an attempt to make the issues clearer in determining the need for embryonic stem-cell research over basic stem-cell research as it was originally developed.⁹⁰

Meanwhile, the term of the National Bioethics Advisory Council quietly expired in the Fall of 2001.⁹¹ The final report of the NBAC, released in August 2001, endorsed funding of embryonic stem-cell research with minimal restrictions and a few ethical protections.⁹² Clearly opposed to the President's objectives in this arena, it is little wonder that the NBAC will fold under the newly formed Council on Bioethics.

IV. IMPACT OF THE BUSH COMPROMISE ON THE NIH

A. NIH at a Loss

The NIH has faced a loss of decision-making and interpretive power since the Bush Compromise, mostly as a result of the heightened political climate surrounding embryonic stem-cell research. As long as

88. Alan Fram, *Facing Veto Threat, Senators Drop Effort to Ease Bush Restrictions on Stem Cell Research*, ASSOCIATED PRESS NEWSWIREs, Nov. 2, 2001.

89. *Degette Bill*, *supra* note 75.

90. *See infra* Section IV for more recent developments in the distinction between adult and embryonic stem-cells.

91. *Research Guidelines*, *supra* note 66. While little media attention was given to the expiration of the NBAC, the move was no doubt politically motivated. In its brief tenure, the NBAC released several reports favoring liberal policies, most significantly the 2000 report promoting embryonic stem cell research. Paegel, *supra* note 14, at 1183. This report led to the crucial "reinterpretation" of the Congressional law that prohibited federal funding of any research where an embryo would be harmed or destroyed. It was no doubt assumed that the creation of the President's Council on Bioethics marked the end of the NBAC from a political standpoint. Conveniently for President Bush, the NBAC commission expired before any action was needed.

92. Nat'l Bioethics Advisory Comm'n, *supra* note 30.

government policy pushes the boundaries of the public's morals and ethics, no administrative agency can lie quietly by and engage in rulemaking and interpretation without the careful scrutiny from the President, Congress, and the public. The Bush Compromise effectively closed the loophole in regulation of federal funding for embryonic stem-cell research and prevented the previous NIH interpretation from taking effect. The change in leadership at the DHHS will also ensure that any decision made on the issue of embryonic stem-cell research will align with President Bush's agenda as outlined in the Bush Compromise. Although Secretary Thompson holds personal beliefs in support of federal funding of embryonic stem-cell research without restrictions,⁹³ his loyalty to the President is unwavering⁹⁴ and will doubtfully have any influence on DHHS or NIH rulemaking and interpretation during Bush's tenure in office.

B. NIH Pressed by Current Events

After September 11th, the issue of stem-cell research in general was placed on the back burner,⁹⁵ and the NIH was soon occupied with bio-terrorism rather than federal research grants. In Congress, the issue remained alive, but legislators admitted that support for their measures was weak, especially in the wake of the strong policy statement by Bush in his compromise plan.⁹⁶ In November 2001, Senators dropped language from a spending bill that would have expanded the sources for embryos to use in research beyond the standards set by Bush.⁹⁷ But despite the current lack of political support, Congress has the power to change administrative agency rules by passing new standards for embryonic stem-cell research, and sending the NIH back to the drawing board. However, if the changes in the Bush Compromise follow the path of those currently suggested and expand the availability of embryonic stem-cells for research, the NIH would most likely keep their current standards and merely expand the opportunities available to

93. Greenberg, *supra* note 56.

94. Interview, *supra* note 72.

95. *Senate Subcommittee Approves Federal Funding for Stem-Cell Research*, DOW JONES BUSINESS NEWS, Oct. 10, 2001.

96. *Id.*

97. Alan Fram, *Facing Veto Threat, Senators Drop Effort to Ease Bush Restrictions on Stem Cell Research*, ASSOCIATED PRESS NEWSWIRE, Nov. 2, 2001.

researchers, using the Embryonic Stem-Cell Registry. In this case, the NIH would continue to operate with the new guidelines for embryonic stem-cell research without interruption, and could possibly increase their funding as more opportunities become available. In early 2002, Congress had all but forgotten the embryonic stem-cell issue, taking up human embryonic cloning instead.⁹⁸ However, Congress may have new ammunition to delve back into the issue after a recent vote by the German Parliament on embryonic stem-cell research.⁹⁹ Although the German Parliament approved restrictions more narrow than those in the United States, Congress may see this vote as an example of the proper role for a legislative body.

In addition, Congress must also continue to face the risk of a national "brain drain" of prominent biomedical researchers as a result of more permissive laws in other countries, including Canada and Great Britain.¹⁰⁰ Great Britain, for example, passed a law in 2001 giving scientists permission to clone human embryos, a move deplored by most in the United States.¹⁰¹ In terms of policies on biomedical research, Sweden, Great Britain, and Canada are considered the most liberal.¹⁰² Researchers hoping to make history on the cutting edge of biomedical research simply cannot ignore the lure of these countries, and this fact is likely to influence Congress to act. Perhaps as a hint of things to come, a Senate Judiciary Committee recently took up a bill by California Senator Diane Feinstein that would permit cloning of human embryos for research, but ban cloning to replicate a human.¹⁰³ This

98. Edward Epstein, *Feinstein Offers Measure to OK Curative Cloning/Senate Committee Debates Use of Fetal Stem Cells for Research*, S.F. CHRON., Feb. 6, 2002, at A3.

99. Fuhrmans & Boston, *supra* note 20.

100. Akin, *supra* note 20. The most noteworthy example of a possible trend in scientists leaving the country is the recent decision by Robert Pedersen, one of the world's premiere stem cell researchers, who left California last fall to take a job at the University of Cambridge in England, where he is permitted to clone human embryos in his stem-cell research. *Id.* Of course, the one million pound grant offered to Pedersen probably helped, too. *Id.*

101. Fuhrmans & Boston, *supra* note 20.

102. Akin, *supra* note 20.

103. Epstein, *supra* note 98. Sure to influence this debate is a report from scientists in Massachusetts that used cloned cow embryos to create kidney-like organs that function inside a cow. Rick Weiss, *Scientists Claim an Advance in*

indicates that while the particular debate over stem-cell research may be on hold, the debate over the ethics of embryos is not, and embryonic stem-cell research is sure to come up again.

However, President Bush's Council announced (only weeks after formation) that the topic of their first meeting would be human embryonic cloning, not stem-cell research.¹⁰⁴ Although the meeting did include a discussion of embryonic stem-cell research, the Council met primarily to discuss the cloning issue while Congress is simultaneously debating human cloning.¹⁰⁵

While embryonic stem-cell research has apparently fallen by the wayside for the time being, the issue has not yet been put to rest by the media or the public. Critics of embryonic stem-cell research will cite to the current debate on embryonic human cloning to show that although the public thought it had reached a reasonable compromise with the Bush plan, the approval of embryonic stem-cell research only encouraged the scientific community to push for more egregious, unethical and immoral research.¹⁰⁶

C. *The Bush Compromise: An Exercise in Futility?*

The greatest source of discontent with the Bush Compromise is the belief that Bush did not go far enough—that for adequate research to exist, many more embryonic stem-cell lines must be derived, and the restrictions of the Bush Compromise will prevent this from happening.¹⁰⁷ The challenge to the number of stem-cell lines purported by the NIH demonstrates this concern, but agency officials are quick to point out that federally funded research on embryonic stem-cells will

Therapeutic Cloning, WASH. POST, Jan. 30, 2002, at A4. This marks the first use of cloning technology to grow personalized, genetically matched organs. *Id.*

104. *Across the Nation: Panel Takes on Stem Cell, Cloning Issues*, CHI. TRIB., Jan. 18, 2002, at 12.

105. *Id.*

106. This argument tends to fulfill the old adage, "if you give an inch, they'll take a mile."

107. *Senate Subcommittee Approves Federal Funding for Stem-Cell Research*, *supra* note 95.

not begin until late 2002,¹⁰⁸ so even a valid comparison of the Bush Compromise to alternative plans suggested by critics will not be possible until the research has begun. Only then will the diversity of available stem-cell lines be evaluated properly and compared by scientists and researchers involved in the actual projects.

In late January 2002, a University of Minnesota research group confirmed the discovery of "a new and highly versatile class of adult stem-cell."¹⁰⁹ Although no report has yet been published and the research has yet to be confirmed in other research laboratories, the potential impact of this news is enormous. If this stem-cell possesses the pluripotentiality of an embryonic stem-cell and is easily available and abundant in the body, the need for the embryonic stem-cell will virtually disappear. A final determination of the impact of these new cells may not come until 2003, but in the meantime, it could eliminate the debate over the use of, and need for, embryonic stem-cells at all. In the big picture, however, the fizzling of the embryonic stem-cell issue may only give rise to another issue, such as human embryonic cloning, that will require the same attention and debate. If President Bush applies the same principles to cloning that he did to embryonic stem-cell research, it is likely that he, and the NIH, will come out winners.

V. CONCLUSION

Since the discovery of stem-cells in 1998, few question their potential to provide amazing medical breakthroughs. The unity of the field of medicine wavers only when the distinction between adult stem-cells and embryonic stem-cells is made. With clear support for the research at its most fundamental level, there is little doubt that federal funding for stem-cell research will continue. Even before the debate over embryonic stem-cells began, the NIH was already spending \$250 million annually on adult stem-cell research, which has continued unabated during the current controversy. But a resolution of the debate over federal funding could last years, considering the implications to

108. *Interview, supra* note 72.

109. *Adult Stem Cell Discovery Stirring Up Embryo Debate*, HOUS. CHRON., Jan. 25, 2002, at A12.

the abortion movement and public policy surrounding the legal status of unborn children, a controversy that has yet to be resolved.

Federal funding for embryonic stem-cell research was not scheduled to be approved and distributed until late 2002.¹¹⁰ The policy on federal funding could dramatically change through action by Congress or the President, but is not likely to with the current focus on the war on terrorism and Iraq. The conclusion, for the time being, is that President Bush has exerted significant control over NIH policy and has eliminated the interpretive power of that agency over federal funding for embryonic stem-cell research. Bush has appropriately exerted authority over an administrative agency in interpreting and carrying out federal law, but the question remains as to whether Bush can implement a policy that is not legislative but rather executive in origin.

One thing certain to any observer of biotechnology is that advances in research and technology often require regulatory oversight, legislative limitations, and accountability. Even more certain, however, is that biotechnology has, and always will, outpace regulatory policy, no matter how farsighted the goal. The law is a reactionary institution by nature, and the NIH embodies this nature by only now attempting to fund embryonic stem-cell research that has taken place for over five years. The conflicts between the Bush Compromise and Congressional interests also highlight the difficulties faced by the NIH in attempting to promote medical advances and appropriately limit research under the authority of a conflicted federal government. The Bush Compromise challenged the NIH in a policy area with a torrid history of conflict, but through the development of new guidelines and detailed interpretations, the NIH developed a policy that abides by the Bush Compromise and promotes medical research that will lead America in the Twenty-First Century.

110. *Interview, supra* note 72.

