THE EFFECT OF FEDERAL FUNDING RESTRICTIONS FOR EMBRYONIC STEM CELL RESEARCH ON COLLEGES AND UNIVERSITIES: THE NEED FOR CAUTION WHEN ETHICAL OBJECTIONS TO RESEARCH ARE RAISED

AMY MILLER*

ABSTRACT

This note explores the history of government intervention into embryonic stem cell research. In particular, this paper focuses on how the decisions of the federal government have threatened research being done at colleges

* Candidate for Juris Doctor, Notre Dame Law School, 2015; Bachelor of Arts, Legal Studies, University of Wisconsin-Madison, 2009. I would like to thank Professors O. Carter Snead and John H. Robinson for lending their knowledge and expertise to the writing of this note. I would like to thank the staff of the *Journal of College and University Law* for their efforts through the editing process. Finally, I would like to thank my husband Chris for his hard work and unwavering support; without him none of this would be possible.

and universities, both because educational institutions are the primary source of basic research into the possibilities of embryonic stem cells, and because colleges and universities receive most of their research funding from the federal government. In the end, I argue that, while it is necessary for government officials to take ethical considerations into account when deciding whether to fund scientific research, it is important to also consider the effects such decisions have on educational institutions.

I. INTRODUCTION

In 1998, researchers at the University of Wisconsin devised a method to extract and replicate embryonic stem cells from human embryos, allowing scientists to research the array of possibilities of embryonic stem cells for curing diseases and alleviating other medical conditions.[1] An ethical problem, however, had to be faced in that the harvesting of embryonic stem cells required the destruction of the embryo from which the cells were harvested.[2] The fact that embryos needed to be destroyed in order to harvest stem cells struck some members of the population and government as ethically wrong.[3] Debates among academics, politicians, and religious groups over the ethical implications of embryonic stem cell research and what kinds of governmental intervention, if any, were appropriate revealed that, while many recognized the potential that embryonic stem cell research presented for helping those with serious medical conditions, others worried that destroying embryos for research dehumanized the embryos and that this would have a negative effect on attitudes towards the value of human life.[4]

Prior to the discovery of techniques for the extraction and replication of embryonic stem cells, the science of in vitro fertilization had already stirred political debate and government intervention into scientific research involving embryos.[5] In 1995, in response to ethical questions regarding embryonic research, Congress added the Dickey-Wicker amendment to the National Institutes of Health (NIH) appropriations bill.[6] The amendment

---

1. James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282:5391 SCIENCE 1145 (1998).

2. Sherley v. Sebelius, 644 F.3d 388, 390 (D.C. Cir. 2011).

3. *See* Erin P. George, *The Stem Cell Debate: The Legal, Political and Ethical Issues Surrounding Federal Funding of Scientific Research on Human Embryos*, 12 ALB. L.J. SCI. & TECH. 747, 782, 791 (2002).

4. *See infra* Section IV (discussing the ethical and scientific debate over embryonic stem cell research).

5. Lyria Bennett Moses, *Understanding Legal Responses to Technological Change: The Example of* In Vitro *Fertilization*, 6 MINN. J.L. SCI. & TECH. 505, 509 (2005).

6. Balanced Budget Downpayment Act, Pub. L. No. 104-99, §128, 110 Stat. 26, 34 (1996).

prohibits the NIH from funding research in which human embryos are destroyed.[7] The NIH is the primary source of federal funding for all research projects in the areas of medical and life sciences throughout the United States and, therefore, has a substantial impact on the kinds of scientific research being done throughout the country.[8]

After the discovery of an extraction and replication method for embryonic stem cells, the Clinton administration interpreted the Dickey-Wicker amendment to mean that federal funding would be permitted only in cases where embryonic stem cells had already been extracted before the funded project began.[9] Because the embryo had already been destroyed and the stem cells could be replicated using scientific techniques that posed no risk to any other embryo, this kind of research would not involve the destruction of a human embryo.[10]

In 2001, President Bush directed his administration, along with the NIH, to fund only research on embryonic stem cell lines that had been derived prior to August 9, 2001.[11] This limited the ability of colleges and universities to obtain federal funding for embryonic stem cell research and limited the variety of stem cells that could be researched by these institutions using federal funds. Many of the stem cell lines that had been derived prior to August 9, 2001 were not viable for scientific research, thus compounding the problem of limited resources for colleges and universities seeking to participate in embryonic stem cell research.[12] Because colleges and universities depend largely on the federal government for funding for their research activities,[13] their research was essentially limited to the stem cell lines that President Bush had deemed acceptable. While states and private industry do provide some funding to academic scientific research, this funding is minimal compared to the amount of federal funds provided for such research.[14]

---

7. *Id.*

8. George, *supra* note 3, at 773–74; *see also* NATIONAL SCIENCE FOUNDATION, NSF 14-312, FEDERAL FUNDS FOR RESEARCH AND DEVELOPMENT: FISCAL YEARS 2011-2013 (July 2014), *available at* http://www.nsf.gov/statistics/nsf14312/pdf/nsf14312.pdf.

9. Robert E. McGough, Comment, *A Case for Federal Funding of Human Embryonic Stem Cell Research: The Interplay of Moral Absolutism and Scientific Research*, 18 J. CONTEMP. HEALTH L. & POL'Y 147, 165 (2001).

10. *Id.*

11. *See* President George W. Bush, Stem Cell Address to the Nation (Aug. 9, 2001), *available at* http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html.

12. *See infra* Section VI (discussing the reaction of colleges and universities to President Bush's restrictions on federal funds for embryonic stem cell research).

13. CHRISTINE M. MATTHEWS, CONG. RESEARCH SERV., R41895, FEDERAL SUPPORT FOR ACADEMIC RESEARCH, (Oct. 18, 2012), *available at* https://www.fas.org/sgp/crs/misc/R41895.pdf.

14. *Id.*

In 2009, President Obama relaxed the restrictions on federal funding for embryonic stem cell research, allowing federal funding for a wider variety of embryonic stem cell lines.[15] Part of the President's reasoning behind this decision was his recognition of the substantial scientific potential that embryonic stem cell research offers.[16] President Obama's decision has allowed embryonic stem cell research to move at a faster pace than during the administration of President George W. Bush, with more stem cell lines being added to those available for federal funding.[17] The reaction of the scientific community to this decision was very positive because it opened the door for scientists at academic institutions to work with a much broader set of resources.[18] The period of restrictive funding for new stem cell line research had made scientific research at educational institutions more cumbersome and less diverse than it might otherwise have been, causing that research to become more limited.

The case of stem cell research shows that when facing ethical objections to scientific research, government officials should move cautiously and should carefully consider the effects that restrictions will have on science and medical technology, on those suffering from various, sometimes untreatable, medical ailments, and particularly on colleges and universities as sources of scientific and medical research. Much of the current literature on embryonic stem cell research focuses on the ethical debate regarding that research and on the steps different congresses and presidential administrations have taken in response to new scientific discoveries.[19] There is little literature, however, focusing on the effect these decisions have had on colleges and universities, the main source of this country's basic scientific research.[20] Embryonic stem cell derivation and replication was discovered at a public university and the stem cell bank is located at that public university.[21] Because colleges and universities are a primary source for scientific and medical research and development, and because these institutions rely heavily on federal funds for their research projects,[22] it is important to look at the effects the federal government's decisions regarding embryonic stem

15. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

16. *Id.*

17. *See* Katherine Goodman, Note, *Stem Cell Research Becoming Less Restrictive*, 6 NO. 4 ABA SCITECH LAW 7, 8 (Spring 2010); *see also NIH Human Embryonic Stem Cell Registry*, NATIONAL INSTITUTES OF HEALTH, *available at* http://grants.nih.gov/stem_cells/registry/current.htm (last visited Oct. 2, 2014).

18. Goodman, *supra* note 17, at 9.

19. *See, e.g.*, McGough, *supra* note 9, at 150; George, *supra* note 3; Goodman, *supra* note 17, at 7.

20. Matthews, *supra* note 13, at 14.

21. McGough, *supra* note 9; *WiCell Receives $16 Million NIH Grant to Create National Stem Cell Bank*, UNIV. OF WISCONSIN-MADISON NEWS (Oct. 3, 2005), http://www.news.wisc.edu/11616.

22. Matthews, *supra* note 13, at 7.

cell research have had on these educational institutions. The effect of government intervention into the funding of embryonic stem cell research on colleges and universities will illustrate the need for government officials to move cautiously when deciding whether to fund scientific and medical research based on ethical objections to that research.

II. AN OVERVIEW OF THE SCIENCE BEHIND EMBRYONIC STEM CELL RESEARCH

In 1998, researchers at the University of Wisconsin, headed by Dr. James Thomson, discovered a method to successfully extract, culture, and sustain embryonic stem cells.[23] To derive embryonic stem cells, researchers must extract pluripotent cells from an embryonic blastocyst.[24] The process of formation of an embryonic blastocyst occurs as follows: when a sperm fertilizes an egg, the two create a single totipotent cell.[25] The totipotent cell then divides into two identical totipotent cells, which continue to divide over and over again.[26] After approximately four days, the totipotent cells begin to specialize and form a hollow sphere called a blastocyst.[27] The blastocyst consists of an outer layer of cells that develops into the placenta and other supportive extra-embryonic tissues, and an "inner cell mass" which becomes the embryo.[28] The cells in the inner mass are known as pluripotent cells, which can develop into virtually any type of tissue.[29] The ability to develop into almost any tissue is what makes these kinds of cells so important and promising to scientific and medical researchers.[30] It is from this inner mass of pluripotent cells that embryonic stem cells are extracted and cultured, and future stem cell lines are derived.[31]

While pluripotent cells have the ability to form into most tissue types, these cells cannot, on their own, develop into a human being.[32] Totipotent stem cells are the only stem cells from which a human being can develop.[33] They have the ability to form extra-embryonic membranes and other tissue required to support fetal growth in the womb, in addition to having the ability to form all post-embryonic tissue and organs needed for full develop-

23. Thomson, *supra* note 1.
24. McGough, *supra* note 9, at 154.
25. *Id.*
26. *Id.*
27. *Id.*
28. *Stem Cell Information: Glossary*, NATIONAL INSTITUTES OF HEALTH, http://stemcells.nih.gov/info/pages/glossary.aspx (last visited Oct. 1, 2014).
29. McGough, *supra* note 9, at 154.
30. *Id.* at 155.
31. *Id.* at 154.
32. George, *supra* note 3, at 777.
33. *Id.* at 756.

ment.[34] Any totipotent cell could, in principle, develop into a human being if placed in a woman's uterus.[35] Again, pluripotent stem cells do not have the same ability to form into a human being on their own.[36] Instead, pluripotent stem cells can form into any type of cell in the human body, depending on the kind of cell the pluripotent cells are placed with.[37] The inability of pluripotent cells to form into a human being on their own has been a large part of the reason the NIH has funded the use of embryonic stem cells for research, despite some legislation, like the Dickey-Wicker amendment, that may indicate that Congress intended the contrary.[38] Because pluripotent cells cannot themselves become a human being, they are not considered "organisms" for the purposes of legislation, and therefore funding scientific research on them is usually regarded as allowable.[39]

To date, embryonic stem cells used in research have been exclusively collected from embryos that were created for the purpose of in vitro fertilization by couples who are unable to conceive by natural means.[40] In vitro fertilization involves the creation of an embryo outside of the body.[41] To begin the process of in vitro fertilization, eggs are extracted from a woman during a laparoscopy.[42] The eggs are then placed in a Petri dish and combined with sperm in order to fertilize the eggs and thus create embryos.[43] The embryos remain in the Petri dish until some of them are implanted into a woman's uterus in the hopes that they will attach to the uterine wall and gestate normally and fully into a child.[44] There are often surplus embryos, however, left over from the in vitro procedure, either because there are problems with the embryos, which make them unsuitable for implantation, or because couples have created excess embryos as an insurance policy against the low success rate of in vitro fertilization.[45] When, for whatever reason, there are surplus embryos from an in vitro fertilization procedure, there are a number of things that can happen to them. The leftover embryos can be voluntarily donated by the couple for scientific research, be destroyed, be kept cryogenically frozen with the couple paying the expense,

---

34. *Id*. at 756−57.
35. *Id*. at 757.
36. *Id*.
37. *Id*.
38. *See infra* Section II (discussing the Dickey-Wicker amendment and subsequent interpretation).
39. *See infra* Section II (discussing the NIH's interpretation of the Dickey-Wicker amendment).
40. George, *supra* note 3, at 750, 777 n. 242.
41. *Id*. at 750.
42. *Id*.
43. *Id*.
44. *Id*. at 750−51.
45. *Id*. at 751

or be given by the couple to another couple for use in their attempt at in vitro fertilization.[46] Today, both members of the couple are required to give full and informed consent before their embryos can be used in scientific research projects.[47]

A major source of ethical conflict in embryonic stem cell research is that, in order to derive embryonic stem cells, the embryo must be destroyed.[48] Because isolating the embryonic stem cells requires removing the "inner cell mass" of the blastocyst (the cells that will become the embryo), the embryo is destroyed in the derivation process.[49] Destroying an embryo, however, at this stage is different from destroying a fetus in an abortion process.[50] A blastocyst is a small ball of about 150 cells that is smaller than the size of a pinhead and completely lacks any features that would be recognized as human.[51] Further, blastocysts are sometimes fatally flawed, and therefore the chances of the blastocyst reaching the stage of viability (where the child can live outside of the womb with artificial aid) are far lower than the chances of a healthy growing fetus reaching that stage.[52] And, once embryonic stem cells have been extracted from the blastocyst, the cells are able to replicate in a culture indefinitely, so there is no need to destroy another embryo to derive more cells.[53] Regardless of these facts, many have objected to embryonic stem cell research because they fear that the destruction of embryos for research will devalue human life.[54]

Once the inner pluripotent mass of the blastocyst is extracted, there will be around thirty stem cells that will then be placed in a culture, where the cells will continue to divide differentiating into new cells, thus forming a "stem cell line" of identical cells.[55] An individual embryonic stem cell may then be removed from the line without disrupting either the cells' multiplication process or the ultimate durability of the line.[56] The removed cell may then be used by scientists in a research project.[57]

Embryonic stem cells are important to scientific and medical research

---

46. *Id*.

47. National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,171 (July 7, 2009).

48. Sherley v. Sebelius, 644 F.3d 388, 390−91 (D.C. Cir. 2011).

49. *Id.* at 390.

50. Joshua Whitehill, *Patenting Human Embryonic Stem Cells: What is so Immoral?*, 34 BROOK. J. INT'L. L. 1045, 1045−46 (2009).

51. *Id.* at 1046.

52. *Id*.

53. *Sherley*, 644 F.3d at 390.

54. *See infra* Section IV (discussing the ethical and scientific debate over embryonic stem cell research).

55. *Sherley*, 644 F.3d at 390.

56. *Id*.

57. *Id.*

because they have the ability to develop into virtually any tissue type.[58] "Since many diseases are caused from the death of dysfunctional cells or the death of a single cell type, it is believed that the introduction of healthy stem cells into the body may restore the lost function."[59] Stem cell research has the potential for practical medical application, including the potential for treatments that might ease or entirely eliminate the pain caused by "cardiovascular diseases, autoimmune diseases, diabetes, osteoporosis, cancer, Alzheimer's disease, Parkinson's disease, severe burns, spinal cord injuries and birth defects."[60] Embryonic stem cells also have numerous potential applications outside of disease treatment, including helping to better understand human development, improving gene therapy, expanding testing and development of new drugs, and generating cells and tissue to be used in transplantation.[61] There are currently over 100,000 people waiting for organ transplants in the United States, mostly due to the fact that one or more of their organs are failing.[62] Embryonic stem cells provide the potential to remove some people from this waiting list by repairing their failing organs by providing a renewable source of healthy cells and tissues to repair the organs.[63] In addition, embryonic stem cells could be used to prevent the recipient's negative immune response, a response that can cause a large number of organ transplants to fail.[64]

Aside from embryonic stem cells, all animals — including humans — that have passed the gestational stage have adult stem cells.[65] These stem cells can be extracted from certain tissue of adults with minimal intrusion.[66] Extraction of adult stem cells is much less controversial than extraction of embryonic stem cells, because the extraction does not require the death of any organism.[67] Adult stem cells differ, however, from embryonic stem cells in that adult stem cells are able to replicate into only a limited number of other types of cells, while embryonic stem cells have the virtually unlimited potential to replicate into any kind of cell.[68] "Adult stem cells are said to be 'Multipotent', meaning they are limited in what cells they can turn into."[69] Another reason that adult stem cells do not have the same scientific

58. George, *supra* note 3, at 756.
59. *Id.*
60. McGough, *supra* note 9, at 157.
61. *Id.*; *see also* George, *supra* note 3, at 758.
62. Shannon McGuire, Note, *Embryonic Stem Cells: Marrow of the* Dickey *Matter*, 11 J. HIGH TECH. L. 160, 160 (2010).
63. *Id.* at 161.
64. *Id.*
65. Whitehill, *supra* note 50, at 1051−52.
66. George, *supra* note 3, at 785.
67. *Id.* at 787−88.
68. *Id.* at 757.
69. *Id.*

research potential as embryonic stem cells is that adult stem cells do not have the ability to replicate indefinitely, and will eventually lose their ability to replicate entirely.[70] The vast majority of available data indicates that "[a]dult stem cell therapies will complement, but cannot replace, therapies that may be eventually obtained from [embryonic stem] cells."[71] Many scientists agree that embryonic stem cells, rather than adult stem cells, are the best resource for stem cell research and therapy because they are pluripotent and because they have a much higher capacity to replicate in a culture than adult stem cells.[72]

There has been movement in science to formulate methods of deriving pluripotent cells without having to destroy an embryo, thus avoiding the most common ethical barrier to stem cell research. In addition to embryonic stem cells and adult stem cells, researchers have recently devised a method for reprogramming somatic (body) cells into pluripotent cells.[73] In 2006, scientists in Japan discovered that manipulating four genes in somatic cells caused them to revert to a pluripotent state.[74] This manipulation, however, was done through viruses which would implant their own DNA into the cells, causing an increased risk for genomic abnormalities, most notably cancer.[75] While new methods have been devised to induce pluripotent stem cells, they are not as reliable as the viral method.[76] Further, induced pluripotent stem cells (iPSCs) are not as viable for research as em-

---

70. McGough, *supra* note 9, at 158.

71. *Id.*

72. Anne Clark Pierson, Sherley v. Sebelius*: Circuit Court Allows Federal Funding of Embryonic Stem Cell Research to Continue for Now*, 38 J. L. MED. & ETHICS 875, 875 (2010).

73. *See* Kazutoshi Takahashi & Shinya Yamanaka, *Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors*. 126 CELL 663–76 (Aug. 25, 2006), *available at* http://www.cell.com/cell/fulltext/S0092-8674(06)00976-7.

74. *Id.*

75. *See* Mira C. Puri & Andras Nagy, *Concise Review: Embryonic Stem Cells Versus Induced Pluripotent Stem Cells: The Game Is On*, 30 STEM CELLS 10, 10−14 (Dec 28, 2011), *available at* http://onlinelibrary.wiley.com/doi/10.1002/stem.788/full; *see also* Jiing-Kuan Yee, *Turning Somatic Cells into Pluripotent Stem Cells*, 3 NATURE EDUCATION 25 (2010), *available at* http://www.nature.com/scitable/topicpage/turning-somatic-cells-into-pluripotent-stem-cells-14431451.

76. *See* Yee, *supra* note 75. The scientists note:

> "[m]any alternative gene delivery strategies — including the use of episomal vectors, nonintegrating viral vectors, transient DNA transfection, transposons, and protein transduction — can overcome this problem [of viral DNA transfer]. A general principle common to all these strategies is the transient expression of the four transcription factors at sufficient levels to trigger the initiation of the cell reprogramming event without permanent integration of the four genes into the host genome. Although these strategies work for the most part, the efficiency of generating iPS cell lines is significantly reduced compared with the approach of retroviral and lentiviral vectors."

bryonic stem cells. Because the cells must first go through the process of development into somatic cells, and then go through the process of reprogramming, iPSCs have a greater chance of genomic instability than embryonic stem cells and will oftentimes be inconsistent and variable, and are likely to show premature deterioration when placed with other cells.[77] This makes iPSCs unsuitable for transplantation therapies, and less useful than embryonic stem cells in other research areas.[78]

Another movement in science to avoid ethical issues with stem cell research has been to find a way to derive embryonic stem cells without destroying the embryo. In 2006, scientists at Advanced Cell Technology, located in Worcester, Massachusetts, used a single-cell biopsy procedure, similar to the procedure done for preimplantation genetic diagnosis, which does not harm the embryo.[79] They then attempted to produce embryonic stem cell lines from that single cultured cell.[80] While the scientists were able to create only two viable stem cells lines from numerous procedures, they did prove that the concept of generating embryonic stem cell lines without harming embryos was feasible.[81] In a second set of experiments, the scientists were able to increase the likelihood of generating embryonic stem cell lines with the biopsy procedure using different culturing methods.[82] This second set of experiments also included experiments showing that the embryos biopsied were able to fully develop and that other embryonic stem cells were not necessary to culture new embryonic stem cell lines from the biopsy procedure.[83] This new method of deriving embryonic stem cell lines may help ease many of the ethical concerns over human embryonic stem cell research, since in this process embryos need not be destroyed in order to derive their stem cells.

These new movements in science have been helpful, but have not completely avoided the ethical problems of embryonic stem cell research. For example, the method used by the researchers at Advanced Cell Technology has been patented by their company, making it impossible for other scientists to use the method.[84] Therefore, scientists who wish to use embryonic

77. *See* Puri & Nagy, *supra* note 75, at 12; *see also* Kazim H. Narsinh et al., *Comparison of Human Induced Pluripotent and Embryonic Stem Cells: Fraternal or Identical Twins?*, 19 MOLECULAR THERAPY 635, 635−38 (2011), *available at* http://www.nature.com/mt/journal/v19/n4/full/mt201141a.html.

78. *See* Yee, *supra* note 75.

79. Irina Klimanskaya et al., *Human Embryonic Stem Cell Lines Derived from Single Blastomeres*, 444 NATURE 481, 481−85 (2006), *available at* http://www.nature.com/nature/journal/v444/n7118/full/nature05142.html.

80. *Id.*

81. *Id.*

82. Young Chung et al., *Human Embryonic Stem Cell Lines Generated without Embryo Destruction*, 2 CELL STEM CELL 113, 113−17 (2008).

83. *Id.*

84. *See* Rebecca Taylor, *Embryonic Stem Cell Technique that Doesn't "Harm"*

stem cells for research must still derive the cells from embryos via the method created at the University of Wisconsin, which requires embryo destruction.[85] There is also concern that the process used to remove the single cell from the blastocyst may still cause harm to the embryo.[86] And induced pluripotent stem cells, while having some scientific uses, are still flawed in ways that make them less useful to research than embryonic stem cells.[87] While they are more useful in scientific research, embryonic stem cells are controversial because of ethical and religious concerns that the destruction of embryos for scientific research devalues human life, dehumanizes embryos, and may encourage abortions.[88] These concerns have led to legislative and executive intervention into research involving human embryos.

III. THE HISTORY OF GOVERNMENT INTERVENTION INTO RESEARCH INVOLVING EMBRYOS

It is important to note that the extent to which the federal government has intervened in the realm of scientific research involving human embryos has been either to fund or not to fund such research with federal money.[89] There have never been any serious proposals by the federal government to prohibit research in which embryos are destroyed.[90] At the state level, South Dakota has criminalized embryonic stem cell research,[91] Indiana has made it a crime to use a human embryo created with an ovum provided to a fertility or similar clinic for stem cell research,[92] and other states have criminalized the use of embryos for something other than their authorized use or without consent of the donor.[93] While the federal government has not criminalized human embryonic stem cell research, withholding federal

---

Embryos is Problematic, LIFENEWS.COM (Jan. 16, 2013), http://www.lifenews.com/2013/01/16/embryonic-stem-cell-technique-that-doesnt-harm-embryos-is-problematic.

85. *Id.*

86. *Id.*

87. *See* discussion *supra* Section II (noting that use of viruses in deriving induced pluripotent stem cells leads to genomic abnormalities and the process of reprogramming the cells multiple times leads to genomic instability, making iPSCs less suitable for research than embryonic stem cells).

88. *See* discussion *infra* Section IV (detailing the ethical and scientific debate over embryonic stem cell research).

89. *See* Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007); Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (March 9, 2009).

90. *The Stem Cell Debates*, THE NEW ATLANTIS 9, 16 (Winter 2012), *available at* http://www.thenewatlantis.com/docLib/20120125_TNA34Report.pdf.

91. S.D. CODIFIED LAWS § 34-14-16 (2000).

92. IND. CODE § 35-46-5-3 (2014.

93. *See* LA. REV. STAT. ANN. § 14:101.2 (1999); CAL. PENAL CODE § 367g (West 2011); MICH. COMP. LAWS ANN. § 777.13k (West 2013).

funding from certain kinds of research can have the effect of retarding that research, especially when the research is done in institutions that rely on federal funding for research, such as colleges and universities.[94]

Federal funds for scientific research are distributed by the National Institutes of Health (NIH).[95] The NIH is composed of twenty-seven institutes and centers with a budget of over $20 billion a year.[96] The NIH and seven other agencies make up the Public Health Service, which is controlled by the Department of Health and Human Services.[97] "[T]he goal of the NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability. . . ."[98] While conducting its own research, the NIH also determines how to allocate federal funds for medical and scientific research.[99] Since 1995, Congress has included a provision known as the Dickey-Wicker amendment in the annual appropriations bill for the Department of Health and Human Services.[100] Dickey–Wicker prohibits the NIH from funding: "(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 C.F.R. 46.208(a)(2) and [section 498(b) of the Public Health Service Act] 42 U.S.C. 289g(b)."[101] The risk standard under 45 C.F.R. 46.208(a)(2) referred to by the amendment is that the risk to the fetus from the research must not be greater than minimal,[102] and the risk standard for fetuses in utero under section 498(b) of the Public Health Service Act is that the research must not pose an added risk of suffering, injury, or death to the fetus.[103]

The history surrounding the passing of the Dickey-Wicker amendment suggests the Congress passed it in most part to prevent President Clinton from acting, based on an NIH report recommending federal funding for research using embryos, to fund research on embryos that had been created for in vitro fertilization.[104] In vitro fertilization, first successfully used in

---

94. *See infra* Section VI (discussing the reaction of colleges and universities to the restriction on federal funding of embryonic stem cell research).

95. George, *supra* note 3, at 774.

96. *Id*. at 773.

97. *Id*. at 774.

98. *Id*. at 773−74.

99. *Id*. at 774.

100. Sherley v. Sebelius, 644 F.3d 388, 390 (D.C. Cir. 2011).

101. Balanced Budget Downpayment Act, Pub. L. No. 104-99, §128, 110 Stat. 26, 34 (1996).

102. 45 C.F.R. § 46.204 (2013).

103. 42 U.S.C. § 289g(b) (2012).

104. *Sherley*, 644 F.3d at 388, *referencing* O. Carter Snead, *Science, Public Bioethics, and the Problem of Integration*, 43 U.C. DAVIS L. REV. 1529, 1546 (2010) (describing the history of conflict between the political branches on the issue of human embryo

1978, made possible the fertilization of a human ovum outside of the body.[105] This unique situation brought into question the moral status of the embryo.[106] In response to those questions, the Carter administration created an Ethics Advisory Board for the Department of Health Education and Welfare (now the Department of Health and Human Services).[107] Any federal funding for research on embryos that were fertilized in vitro was required to be approved by the Board.[108] The Board concluded that the moral status of the embryo was entitled to profound respect, but not respect of the same magnitude as persons.[109] Presidents Reagan and George H.W. Bush, who succeeded President Carter in office, refused to fund the Ethics Advisory Board in order to prevent any federal funding of IVF embryo research from being approved.[110] Then, in 1993, at President Clinton's urging, Congress passed the NIH Revitalization Act, which eliminated the Board approval requirement.[111] President Clinton then directed the NIH to make recommendations regarding federal funding of research on human embryos, which the NIH did in a report in 1994.[112] The report recommended allowing broad federal funding for research involving human embryos.[113] In response, Congress added the Dickey-Wicker amendment to the NIH Appropriations Bill in 1995.[114] The amendment has been reauthorized every year since then.[115] As previously stated, the Dickey-Wicker amendment prohibited federal funding of research involving the destruction of human embryos.[116] However, this amendment could not have been passed with human embryonic stem cell research in mind, because, in 1995, researchers at the University of Wisconsin had not yet discovered their method for derivation of embryonic stem cells from human embryos.

Some scholars have questioned the effectiveness and appropriateness of

---

research).

105. Moses, *supra* note 5, at 509.

106. *Id.*

107. *Id.* at 539.

108. *Id.* at 539.

109. Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer, 44 Fed. Reg. 35,033, 35,056 (May 4, 1979).

110. Moses, *supra* note 5, at 539.

111. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 121, 107 Stat. 122, 133 (1993); *see also* O. Carter Snead, *Science, Public Bioethics, and the Problem of Integration*, 43 U.C. DAVIS L. REV. 1529, 1545 (2010).

112. Snead, *supra* note 111, at 1546.

113. NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN EMBRYO RESEARCH PANEL (Sept. 1994).

114. Balanced Budget Downpayment Act, Pub. L. No. 104-99, §128, 110 Stat. 26, 34 (1996); *see also* Snead, *supra* note 111, at 1546.

115. Snead, *supra* note 111, at 1546.

116. Balanced Budget Downpayment Act §128.

the Dickey-Wicker amendment.[117] For instance, certain scholars worry about Dickey-Wicker's status as an appropriations rider.[118] Appropriations riders are used as a means of affecting substantive laws and policies, but such riders are created through a process that does not include committee expertise, which is necessary when the House or Senate creates substantive policy or law.[119] In fact, appropriations acts are not even codified, as they are only temporary and must be renewed each year.[120] Appropriations riders meant to affect substantive policy create problems for the other branches of government, such as the judiciary, who are tasked with interpreting the meaning of the rider, because the riders have no legislative history to look to.[121] Scholars also worry that Dickey-Wicker is regulating an area of research that the amendment predates, namely human embryonic stem cell research.[122] At the time Dickey-Wicker was passed, Congress was concerned only with in vitro fertilization.[123] Because human embryonic stem cell derivation had not yet been discovered at the time Dickey-Wicker was first passed, scholars argue that it was not meant to apply to embryonic stem cell research.[124] They believe that it makes little sense to allow the Dickey-Wicker amendment, a temporary appropriations rider, to determine the issue of federal funding for an area of research which it predates and which it could not have contemplated at the time at which it became law.[125]

The Dickey-Wicker amendment prevented the federal funding of research involving human embryos from the time of its passing in 1995 until January of 1999, when Harriet Rabb, general counsel for the Department of Health and Human Services, issued an opinion about the consequences of the Dickey-Wicker amendment.[126] Rabb determined that pluripotent stem cells do not fall within the definition of "human embryo" under the amendment based on the amendment's characterization of a human embryo

---

117. *See* Nicholas J. Diamond, *The Flaws of Stem Cell Legislation:* Sherley, Brüstle, *and Future Policy Challenges Posed by Induced Pluripotent Stem Cells*, 14 MINN. J.L. SCI. & TECH. 259 (Winter 2013).

118. *Id*. at 277; *see also* Neal E. Devins, *Regulation of Government Agencies through Limitation Riders*, 1987 DUKE L. J. 456 (1987) (arguing that the appropriations process is not the proper vehicle for substantive policymaking).

119. Diamond, *supra* note 117, at 277−78.

120. *See Frequently Asked Questions and Glossary*, OFFICE OF THE LAW REVISION COUNSEL, *available at* http://uscode.house.gov/faq.xhtml (last visited Oct. 2, 2014).

121. Diamond, *supra* note 117, at 278.

122. *Id.*; *see also* McGuire, *supra* note 62, at 177 ("To apply a regulatory law that was enacted before the research protocol was even discovered is not practical nor is it favorable for scientific research and advancement.").

123. *See supra* Section III (noting that Dickey-Wicker was passed in 1995, prior to the discovery of embryonic stem cell derivation).

124. Diamond, *supra* note 117, at 280; McGuire, *supra* note 62, at 177.

125. Diamond, *supra* note 117, at 280; McGuire, *supra* note 62, at 178.

126. Snead, *supra* note 111, at 1546.

as an "organism."[127] Rabb concluded that previously extracted embryonic stem cells are not covered by the amendment because they lack the capacity to develop into an "organism" on their own when implanted in a uterus.[128] This interpretation of the amendment allows for federal funding of stem cell research after the cells have been extracted from an embryo. Because the embryo has already been destroyed to extract the stem cells, the government would not be funding research in which an embryo is destroyed.

However, in 2001, President Bush, in an address to the nation, stated that he had decided to limit federal funding of embryonic stem cell research to the stem cell lines which had been extracted prior to August 9, 2001.[129] President Bush's decision was further explained by subsequent NIH papers, which stated that no research on new stem cells lines derived from human embryos would be allowed to be funded, and that the NIH had identified only sixty-four stem cell lines that were available for federal funding.[130] Furthermore, President Bush's new policy required that federally fundable embryonic stem cell research must have received the fully informed consent of the embryo donors, the research must have used embryos that were created for reproductive purposes in excess of clinical need, the research institution in question must have given no financial incentive to the donors, and that institution was not allowed to use embryos that were created for purely research purposes.[131]

When President Bush made funding available for embryonic stem cell research in 2001, it was the first time federal funding was available for such research.[132] This is not surprising when one considers the timing of the discovery of embryonic stem cell line derivation techniques. University of Wisconsin researchers first announced their discovery of a derivation method in late 1998.[133] Then-President Clinton quickly confronted the issue of funding (particularly the Dickey-Wicker amendment) by instructing general counsel for the Department of Health and Human Services to interpret the amendment with regard to federal funding of research like embry-

127. Memorandum from Harriet S. Rabb, General Counsel of the Department of Health and Human Services, to Harold Varmus, Director of the National Institutes of Health (Jan. 15, 1999).

128. *Id.*

129. Bush, *supra* note 11.

130. *National Institutes of Health (NIH) Update on Existing Human Embryonic Stem Cells*, NATIONAL INSTITUTES OF HEALTH (Aug, 27, 2001) *available at* http://stemcells.nih.gov/policy/statements/pages/082701list.aspx.

131. J. Mark Waxman et al., *The Stem Cell Legislative Process*, 17 HEALTH LAW 23, 24 (2005).

132. *See* The Stem Cell Debates, *supra* note 90, at 12.

133. *See* Terry Devitt, *Wisconsin Scientists Culture Elusive Embryonic Stem Cells*, UNIVERSITY OF WISCONSIN-MADISON NEWS (Nov. 6, 1998), http://www.news.wisc.edu/3327.

onic stem cell research.[134] Counsel came up with an interpretation in January of 1999, laying the framework for federal funding of embryonic stem cell research.[135] However, Clinton's term as president ended just two years later, with President Bush taking office in January 2001.[136] Several months later, President Bush made his announcement regarding his policy choice on federal funding of embryonic stem cell research.[137]

The Bush administration originally identified sixty-four stem cell lines that would be available for federally funded research after August 9, 2001,[138] but, as it turned out, only twenty-one of those lines were viable for scientific research.[139] Therefore, President Bush's decision to limit federal funding to existing stem cell lines ultimately limited the available cells for scientific and medical research to twenty-one lines. It is axiomatic that restricting the raw materials available for research will limit that research. While the stem cell lines that were available for federal funding under President Bush's policy have yielded scientific discoveries,[140] it is impossible to say what other discoveries could have been achieved had federal funding of other stem cell lines not been prohibited. In 2004, scientists at Harvard noted that the stem cell lines approved by President Bush "vary considerably in their usefulness for research and the extent of their characterization."[141] Consequently, the Harvard scientists decided to create new stem cell lines that could more easily be manipulated by scientists for research purposes.[142] In the end, the scientists created 17 new stem cell lines, but noted that their cell lines could not be used in research funded, even in part, by federal funds.[143]

President Bush's decision to limitedly fund embryonic stem cell research brought to the forefront the ethical and scientific debate over the benefits

---

134. McGough, *supra* note 9, at 164.

135. *See supra* Section III.

136. *See The Presidents*, WHITE HOUSE, http://www.whitehouse.gov/about/presidents (last visited Nov. 17, 2014).

137. Bush, s*upra* note 11.

138. Waxman, *supra* note 131, at 24.

139. *See* Janet Kelly, *All NIH Human Embryonic Stem Cell Registry Lines Now Deposited at NSCB*, UNIVERSITY OF WISCONSIN-MADISON NEWS (Jan. 12, 2009), http://www.news.wisc.edu/16120

140. At the University of Wisconsin, the university press indicated that during this time more than a dozen newsworthy discoveries came from embryonic stem cell research being done at that university alone. *See* Terry Devitt, *Research on Human Embryonic Stem Cells Marks 10-Year Milestone*, UNIVERSITY OF WISCONSIN-MADISON NEWS (Nov. 6, 2008), http://www.news.wisc.edu/15920 (detailing the many discoveries of stem cell research conducted at University of Wisconsin-Madison over a decade).

141. Chad A. Cowan et al., *Derivation of Embryonic Stem-Cell Lines from Human Blastocysts*, 350 NEW ENG. J. MED. 1353, 1353−56 (2004), *available at* http://www.nejm.org/doi/full/10.1056/NEJMsr040330.

142. *Id.*

143. *Id.*

and dangers of embryonic stem cell research. It is to that debate that I now turn.

IV. THE ETHICAL AND SCIENTIFIC DEBATE OVER EMBRYONIC STEM CELL RESEARCH

At the heart of the debate over the permissibility of embryonic stem cell research is the conflict between the potential benefits the research could achieve for scores of people suffering from various ailments and the ethical importance of maintaining the human dignity of embryos.

Much of the argument for funding stem cell research involves the promise the research holds for curing disease and relieving pain and suffering.[144] It is easy to understand this side of the argument; while an embryo is a tiny, faceless mass of cells, "[t]he cause for curing disease has a human face, the face of a loved one or neighbor, bent under the suffering of an incompletely understood or treated disease."[145] It is also important to note that the fate of many of the embryos on which research is done is uncertain at the time they are donated.[146] As of March 2014, no one knows exactly how many IVF embryos sit frozen in cryogenic storage, but estimates range from hundreds of thousands to a million.[147] While some of those embryos had the chance of being "adopted" by individuals seeking reproductive assistance, adoption is not common and many will be frozen for an undetermined period of time until they die and are discarded.[148] Thus, most of the frozen embryos have no chance of being born, and it is argued that using those embryos for research such as embryonic stem cell research, which has such potential for good, is a much better fate for them than simply staying frozen until they die.[149]

Many in the academic and political world have recognized the possibilities that embryonic stem cells present for medical research of many diseases and disabilities. Proponents of embryonic stem cell research argue that this research promises the possibility of clinical application in medical fields such as the "autologous repair of tissues and organs that would otherwise require transplantation, restoring vital functions at the cellular level, gene therapy through implantation, and *in vivo* and *in vitro* growth of ge-

144. THE PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH, Recent Developments in the Ethical and Policy Debates 56 (January 2004).

145. *Id* at 58.

146. *Id* at 59.

147. Paul Ford, *Determining the Fate of Frozen Embryos*, CNN (Mar. 24, 2014), http://www.cnn.com/2014/03/24/living/frozen-embryos-elle-relate.

148. THE PRESIDENT'S COUNCIL, *supra* note 144, at 85.

149. *Id.* at 85 n. 114 (pointing to the testimony of Michael West before the Labor, HHS, and Education Subcommittee of the Senate Appropriations Committee in December, 2001).

netically 'corrected' cells."[150] Furthermore, embryonic stem cell research promises to improve "methods of screening new drugs for toxicity and efficacy" without requiring clinical testing on humans.[151]

Lawmakers have also taken note of the benefits that embryonic stem cell research promises for the medical field. In his urge for support of stem cell research in 2005, Representative Castle stated that "[t]his is not the time to allow bad science or ideology to get in the way of doing what is right for the people of this country and of the world. There are 110 million people in the United States of America who potentially could be helped by embryonic stem cell research."[152] Representative Moore also voiced his support for enhancing stem cell research by stating that "[r]ecent scientific research has suggested that embryonic stem cells hold immense potential to successfully treat many serious medical conditions including diabetes, Parkinson's Disease[,] and cancer," and that "the oversight which will come with broad federal support will result in better and more ethically controlled research in the field than if funding was from private sources alone."[153] Both representatives recognized the medical potential that stem cell research promises, and added that federal support of that research would allow for greater oversight by the government to keep the research within ethical limits.[154]

Others fear, however, that allowing embryonic stem cell research to continue uninhibited would morally devalue human life and that such research violates the moral duty to protect human life.[155] The general opposition to embryonic stem cell research is concerned that an increase in embryonic research will lead to an increase in abortions by devaluing human life.[156] "The main argument that is maintained by religious and pro-life groups is the fact that the embryos and fetuses are human beings worthy of respect. Most religious organizations believe that life begins at conception, thus it would be immoral and unethical to destroy embryos for scientific research."[157] Furthermore, some members of the President's Council on Bioethics argued that by allowing embryo destruction for stem cell research, policymakers open the door for scientists to resort to more extreme methods, such as using later-stage embryos or fetuses, if they prove more useful

150. Christopher Ogolla, *Reversing the United States Policy on Human Embryonic Stem Cell Research: A Case of Science, Law and Policy, or Just Plain Politics*, 35 T. MARSHALL L. REV. 91, 92 (2009).

151. *Id.* at 92.

152. 151 CONG. REC. 3775 (2005) (statement of Rep. Castle).

153. 152 CONG. REC. 15852, 15868 (2006) (statement of Rep. Moore).

154. 151 CONG. REC. 3775 (2005); 152 Cong. Rec. 15852, 15868 (2006).

155. Ogolla, *supra* note 150, at 92.

156. George, *supra* note 3, at 782 (noting that religious and pro-life groups feared allowing embryonic stem cell research would morally devalue human life).

157. *Id.*

for research.[158]

In general, government officials have opted for the "special respect" approach to human embryos, arguing that embryos are not afforded the same moral standing as a fully developed human, but are entitled to some degree of respect above being treated as a mere object or means to an end.[159] This view generally leads not to prohibition of research on embryos, but to scrutiny of the reasons for which embryos will be used in scientific research, the circumstances under which the embryos are obtained, and other similar factors.[160] The Ethics Advisory Board to the Department of Health, Education and Welfare in 1979, the NIH Embryo Research Panel in 1994, and the National Bioethics Advisory Commission in 1999 all proffered the "special respect" approach with regard to research involving human embryos.[161]

All of these ideals helped motivate President Bush's decision in 2001 to limit the federal funding of stem cell research.[162] When addressing the nation with regard to this decision, President Bush stated that "I'm a strong supporter of science and technology, and believe they have the potential for incredible good—to improve lives, to save life, to conquer disease. Research offers hope that millions of our loved ones may be cured of a disease and rid of their suffering. . . . [L]ike all Americans, I have great hope for cures."[163] While acknowledging the promise of medical benefits that embryonic stem cell researched contained, President Bush also indicated his concern about protecting the value of human life by stating,

> 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 it has generated.[164]

Later, in 2007, President Bush vetoed legislation to expand federal funding for embryonic stem cell research.[165] He clarified his beliefs and motives in restricting federal funding for embryonic stem cell research through Executive Order 13,435, *Expanding Approved Stem Cell Lines in Ethically*

---

158. THE PRESIDENT'S COUNCIL, *supra* note 144, at 86.

159. *Id.* at 82−83.

160. *Id.* at 83.

161. *Id.*

162. Patrick J. Fleis, Comment, *Stemming the Stem Cell Setback*, 7 MARQ. INTELL. PROP. L. REV. 205, 207 (2003).

163. Press Release, Office of the Press Secretary, *President Discusses Stem Cell Research* (Aug. 9, 2001), *available at* http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html.

164. *Id.*

165. Ogolla, *supra* note 150, at 92.

Responsible Ways.[166] The Order stated that its purpose was to "establish moral and ethical boundaries to allow the Nation to move forward vigorously with medical research, while also maintaining the highest ethical standards and respecting human life and human dignity."[167] The order also made it clear that "no life should be used as a mere means for achieving the medical benefit of another."[168] The order expressed President Bush's belief that "human embryos and fetuses [are]. . .members of the human species" and, therefore, could not be used as mere commodities or as means to an end.[169]

In response to this decision by President Bush, Senator Hillary Clinton said that his Order was "just one example of how the President puts ideology before science, politics before the needs of our families—just one more example of how out of touch with reality he and his party have become."[170] Senator Clinton's response shows how strongly those who support stem cell research feel about the importance of its potential scientific benefits and that they do not believe that ethical objections based on the moral status of the embryo should stymie that research.

Focus by embryonic stem cell research opponents on the moral status of the embryo has caused the debate over stem cell research to be conflated with the debate over abortion.[171] This conflation of issues can be seen in members of the general population's ideas about what an embryo looks like. In 2003, Professor Irving Weissman approached people at random on the street in California and asked them to draw an embryo.[172] Most respondents, he said, drew a fetus with a face, indicating that they believed embryos to be equated with fetuses developed to the point that they had a face.[173] However, scientists generally realize that the issue is embryonic stem cell research, not abortion or reproductive rights. Some react with surprise that something as small and, under a microscope, "dull-looking" as an embryonic stem cell can cause so much debate.[174] The cells themselves seem almost "inconsequential" when viewed through the microscope, and pale in comparison to the faces of the suffering men, women, and children that could be helped by stem cell technology.[175] Therefore, during the time

166. Exec. Order No. 13,435, 72 Fed. Reg. 34,591 (June 20, 2007).
167. *Id.* at 34,592.
168. *Id.*
169. *Id.*
170. Ogolla, *supra* note 150, at 93.
171. Janet L. Dolgin et al., *Attitudes about Human Embryos, Embryonic Stem Cell Research, and Related Matters*, 37 HOFSTRA L. REV. 319, 320 (2008).
172. Steven Kotler, *The Final Frontier*, L.A. WEEKLY (Jan. 30, 2003), http://www.laweekly.com/2003-02-06/news/the-final-frontier/.
173. *Id.*
174. *Id.*
175. *Id.*; *see also* THE PRESIDENT'S COUNCIL, *supra* note 144, at 81.

that federal funding for human embryonic stem cell research was restricted, many scientists hoped for the removal of the funding limitations, so that they could continue their research and work to find cures for diseases.[176]

V. REACTION OF THE SCIENTIFIC COMMUNITY TO THE LIMIT ON FEDERAL FUNDING FOR EMBRYONIC STEM CELL RESEARCH AND ITS EFFECT ON COLLEGES AND UNIVERSITIES

The scientific community reacted with alarm in 2001, when President Bush decided to limit the embryonic stem cells that would be eligible for federal funding. Some scientists, like Roger Pedersen of the University of California at San Francisco, were so concerned about the new restrictions on federal funding for embryonic stem cell research that they decided to move their research out of the United States.[177] Also, because of the relative infancy of the stem cell field at the time of President Bush's restriction on federal funding, uncertainty existed as to what could be expected from the stem cell lines that were in existence at such an early stage in the embryonic stem cell field.[178] Many stem cell researchers wished to continue to study embryonic stem cells using the most scientifically viable lines (which often did not include the 21 approved lines) and, therefore,

> [r]esearch institutions that wished to conduct research using both pre-2001 and post-2001 embryonic stem cell lines had to either set up elaborate accounting systems or else construct completely separate facilities in order to assure that no federal dollars were indirectly used to support research outside of National Institutes of Health (NIH) guidelines.[179]

If a lab used any unapproved lines, they had to go to extreme lengths to separate their research so that federal funds were not used in any way on the unapproved lines.[180] As told by Ali H. Brivanlou, a researcher at Rockefeller University, "You can imagine what it meant not to be able to carry a pipette from one room to another. . .[t]hey even had to repaint the walls to ensure no contamination by federal funds."[181]

The academic world was extremely concerned with President Bush's decision because academic institutions depend on the federal government for funding of their "basic" research. In 1945, Vannevar Bush, who was then

176. Kotler, *supra* note 172.

177. Fleis, *supra* note 162, at 208.

178. Fleis, *supra* note 162, at 212.

179. *Issues and Legislation*, WISCONSIN STEM CELL NOW (2008), *available at* http://www.wistemcellnow.org/issues-and-legislation.

180. Nicholas Wade, *New Stem Cell Lines Open to Research*, N. Y. TIMES, December 3, 2009, http://nytimes.com/2009/12/03/science/03stem.html?_r=0.

181. *Id.*

the Director of the Office of Scientific Research and Development, wrote an influential report to President Franklin Roosevelt in which he argued that government funding for basic research is essential in order to continue enjoying technological progress.[182] Bush defined "basic research" as research "performed without thought of practical ends [that]. . .results in general knowledge and an understanding of nature and its laws" and added that "[b]asic research leads to new knowledge [and]. . .provides scientific capital."[183] Bush argued that "a nation which depends on others for its new basic scientific knowledge will be slow in its industrial progress and weak in its competitive position in world trade."[184] In order to continue to foster basic research, Bush argued, colleges and universities need funding support from the government.[185] He argued that colleges and universities were "uniquely qualified by tradition and by their special characteristics to carry on basic research."[186] The characteristics that made colleges and universities qualified for basic research include the fact that these institutions "are charged with the responsibility of conserving the knowledge accumulated by the past, imparting that knowledge to students, and contributing new knowledge of all kinds" and that scientists in these institutions are free from the adverse pressures of convention, prejudice or commercial necessity and are therefore able to act with security and personal intellectual freedom.[187] Bush noted that industry is inhibited from engaging in basic research because of preconceived goals, by its own standards, and by the constant pressures of commercial necessity.[188] Therefore, Bush argued, colleges and universities need to be supported by public funds so that they could continue to provide basic research for the increasing demands of industry.[189]

Colleges and universities continue to be the primary sources of basic research, which is still widely considered to be essential to creating new industries and promoting technological advancements.[190] In fiscal year 2008, 56% of basic research was being done at colleges and universities.[191] This kind of research is not heavily undertaken by the private sector because it is

182. Vannevar Bush, *Science, The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research*, OFFICE OF SCIENTIFIC RESEARCH AND DEVELOPMENT (July 5, 1945), *available at* http://www.nsf.gov/od/lpa/nsf50/vbush1945.htm.

183. *Id.*

184. *Id.*

185. *Id.*

186. *Id.*

187. Bush, *supra* note 182.

188. *Id.*

189. *Id.*

190. MATTHEWS, *supra* note 13, at 7.

191. *Id.*

often not cost-effective.[192] In the educational setting, however, basic research can meld harmoniously with the educational missions of colleges and universities.[193] Therefore, we must depend on colleges and universities to advance basic research and to continue to create new technologies and areas of industry.

Educational institutions require funding in order to participate in scientific and technological research. While laboratories at academic institutions receive funding for research from their own institutions, from industry, and from the state, most of their research funding comes from the federal government.[194] In fiscal year 2011, federal funding accounted for over 60% of all research and development funding at colleges and universities.[195] By comparison, institutional funding accounted for about 19% of research funding, while industry provided approximately 5% of the total funding for academic research.[196] The rest of the funding for research at colleges and universities comes from the states and other sources.[197] The government-run National Institute of Health (NIH) spends over twenty-three million dollars per year to advance the sciences, most of which otherwise would not have gone to research being done at academic institutions.[198] So, it is clear that the federal government provides a large amount of funding to educational institutions, which tend to be less driven by profit-making motives than private industry. Basic research, done mostly by academic institutions, provides a footing on which private industry can develop, and the federal government's funding allows for a good balance between basic and applied research to be maintained.[199]

An example of the balance between academic and private research, and the effects President Bush's order had on this balance, can be seen in the interaction between the University of Wisconsin's Wisconsin Alumni Research Foundation (WARF) and Geron, a private corporation also engaging in stem cell research. In 1999, WARF negotiated a commercial license with Geron Corporation with regard to several of WARF's patented stem cell lines.[200] In return for the commercial license, Geron funded a large por-

192. *Id.*
193. *Id.* at 2.
194. *Id.* at 7.
195. NATIONAL SCIENCE FOUNDATION, NSF-13-325, HIGHER EDUCATION RESEARCH AND DEVELOPMENT: FISCAL YEAR 2011 (2013).
196. *Id.*
197. *Id.*
198. Fleis, *supra* note 162, at 220.
199. Matthews, *supra* note 13, at 2; *see also* Fleis, *supra* note 162, at 218.
200. Matthew Herder, *In (or out of) the Marketplace of Ideas:* WARF v. Geron *and Lessons for Canada*, 11 DALHOUSIE L.J. 196, 197 (2002); *see also* Fleis, *supra* note 162, at 222.

tion of the University of Wisconsin's research on those lines.[201] In 1999, WARF set up a non-profit corporation called WiCell Research Institute Inc. (WiCell), which offered to distribute embryonic stem cell technology to public researchers.[202] Around the time of President Bush's Order in 2001, and possibly because of the limit of stem cell availability that the order was about to impose, Geron claimed exclusive rights to all the stem cell lines, along with eleven additional cell types.[203] WARF, now realizing that research for new embryonic stem cell lines had been slowed, or possibly even eliminated by President Bush's order, wished to negotiate with other entities, including the NIH, with regard to its stem cell lines.[204] Four days after President Bush's address, WARF filed a complaint against Geron in the U.S. District Court for the Western District of Wisconsin, asserting that Geron did not have exclusive rights to the stem cell lines, and that WARF was free to negotiate with other companies with regard to those lines.[205] On January 9, 2002, WARF and Geron reached a new licensing agreement allowing WARF to grant research rights to public researchers on existing stem cell patents, thus resolving the lawsuit.[206]

Through this example we can see that academia and industry were at one time working together, but later had to reevaluate their position with regard to intellectual property rights of stem cells in the wake of President Bush's order, since new stem cell lines, which could possibly hold new intellectual patent rights, could not be developed as easily with a limit on federal funding.[207] A limitation on the amount of raw materials to work with in embryonic stem cell research made members of both industry and academia more hesitant when negotiating agreements regarding those raw materials.[208] This episode suggests that the restriction placed on federal funding for embryonic stem cell research limited the federal funding available to act as a mediating factor between industry and academia, and also had a profound

201. Fleis, *supra* note 162, at 222.

202. Herder, *supra* note 200, at 199. The history of WiCell itself indicates that it was created in order to preserve stem cell technology in the face of possible limiting regulations. *About WiCell*, WICELL, *available at* http://www.wicell.org/home/about-wicell/about-wicell.cmsx (last visited Oct. 2, 2014) ("[r]ecognizing the potential of these unique cells, and aware that regulations surrounding their use in a university setting were unclear, the Wisconsin Alumni Research Foundation established WiCell in 1999 as a safe haven for the advancement of stem cell research in the politically charged environment of the time.").

203. Herder, *supra* note 200, at 198–99; *see also* Fleis, *supra* note 162, at 222.

204. Fleis, *supra* note 162, at 222; *see also NIH Update on Existing Human Embryonic Stem Cells*, *supra* note 130.

205. Complaint, Wisconsin Alumni Research Fund v. Geron Corp., No 01-C-0459 (W.D. Wis. Aug. 13, 2001); *see also* Herder, *supra* note 200, at 199.

206. Herder, *supra* note 200, at 200.

207. Fleis, *supra* note 162, at 227.

208. *Id.* at 223.

effect on the relationship between the two sectors.

Members of the academic community tend to behave in ways that foster collaboration and community interests.[209] An example of the attitude of community collaboration that exists in the academic world can be seen in the response of the University of Wisconsin to the stem cell limitations imposed by President Bush. In September 2001, shortly after President Bush's executive order, the University of Wisconsin entered into an agreement with NIH to share with NIH the existing, approved stem cell lines held by the University of Wisconsin.[210] This was meant to allow NIH to continue embryonic stem cell research while maintaining the standards for embryonic stem cells set by President Bush.[211] Then, in 2005, the NIH gave the University of Wisconsin $16 million to create a national stem cell bank.[212] Part of the purpose of this bank was to allow academic researchers easier and cheaper access to approved stem cell lines while maintaining their ability to patent their discoveries.[213] At the time of the bank's creation there were twenty-one viable approved stem cell lines.[214] In order to fill the bank with all twenty-one lines, collaboration between universities and private research companies was required.[215] These included stem cells lines given to the University of Wisconsin by the University of California, San Francisco,[216] Cellartis AB, a biotechnology company based in Sweden, Novocell, a U.S. based company, ES Cell International in Singapore, and Technion, a company in Israel.[217] In 2009, this collaboration reached fruition when the National Stem Cell Bank at the University of Wisconsin gathered all twenty-one approved lines of embryonic stem cells.[218] This allowed scientists from nonprofit and academic institutions anywhere in the world to request and receive approximately six million of the human embryonic stem cells in the bank for a fee of only $500.[219] With easy, cheap

209. Fleis, *supra* note 162, at 205; *see also* Bush, *supra* note 182.

210. News Release, National Institutes of Health, *National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement* (Sept. 5, 2001), http://www.nih.gov/news/pr/sep2001/od-05.htm

211. *Id.*

212. *WiCell Receives $16 Million NIH Grant to Create National Stem Cell Bank*, UNIV. OF WISCONSIN-MADISON NEWS (Oct. 3, 2005), http://www.news.wisc.edu/11616.

213. *Id.*

214. *National Stem Cell Bank Announces Addition of New Cell Lines*, UNIV. OF WISCONSIN-MADISON NEWS (Sept. 19, 2006), http://www.news.wisc.edu/14090.

215. *Id.*

216. *Id.*

217. Janet Kelly, *All NIH Human Embryonic Stem Cell Registry Lines Now Deposited at NSCB*, UNIV. OF WISCONSIN-MADISON NEWS (Jan. 12, 2009), http://www.news.wisc.edu/16120.

218. *Id.*

219. *Id.*

access to all approved and viable lines of embryonic stem cells, the academic world provided itself with a great opportunity for continued collaboration and community access to resources and information, in keeping with the norm of community-based behavior that exists in academia.

To further illustrate the fact that academic institutions tend to work in ways that are more collaborative and community-based, consider the following. As mentioned earlier, in 2004, scientists at Harvard, noting the difficulty of scientific manipulation of existing stem cell lines, created seventeen new lines.[220] The scientists created the lines not for profit, but to provide their fellow scientists with more viable raw material for research projects.[221] The desire to share information and raw materials, not the desire to make profit, inspired the scientists to engage in a complex project.

Because federal funding for a great deal of embryonic stem cell research was unavailable after President Bush's funding decision, academic institutions found themselves in need of state and private, philanthropic funding. Luckily for the University of Wisconsin, their prominence in the field of embryonic stem cell research allowed them to get large amounts of funding from both state and private sources. For instance, the State of Wisconsin invested $750 million in biomedical research at the university, much of which went to funding stem cell research.[222] The University of Wisconsin's stem cell research team was also able to obtain a $1.25 million grant from the W.M. Keck Foundation of Los Angeles to further their research into stem cells.[223] However, for other, smaller, and less well known colleges and universities attempting research on embryonic stem cells, generating funding from sources other than the federal government may have been much more difficult, especially considering the fact that the federal government provides a majority of the funds for scientific research at these institutions.

VI. PRESIDENT OBAMA'S DECISION TO LIFT THE RESTRICTIONS ON FEDERAL FUNDING FOR EMBRYONIC STEM CELL RESEARCH

In 2009, President Obama issued an executive order lifting the restrictions on federal funding for embryonic stem cell research.[224] In lifting these restrictions, President Obama did not use moral rhetoric, but instead

220. Cowen et al., *supra* note 141.

221. *Id.*

222. Terry Devitt, *Wisconsin Poised to Invest $750 Million in Biomedical Research*, UNIV. OF WISCONSIN-MADISON NEWS (Nov. 20, 2004), http://www.news.wisc.edu/10446.

223. *Team Receives $1.25 Million Grant for Stem Cell Research*, UNIV. OF WISCONSIN-MADISON NEWS (Feb. 3, 2005), http://www.news.wisc.edu/10654.

224. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

pointed to the potential of stem cells in medical applications.[225] The reason given by President Obama in issuing the order to lift the restrictions imposed by President Bush was that "[r]esearch involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions."[226] Obama noted that medical and scientific advances in the field of embryonic stem cell research over the previous several years had been encouraging, and that these advancements had led to widespread agreement in the scientific community that embryonic stem cell research should be supported by federal funds.[227] The purpose of President Obama's order was to remove prior limitations placed on scientific inquiry into the potential of embryonic stem cells by the Bush administration, to expand NIH financial support for the exploration of human stem cell research, and, by so doing, "to enhance the contribution by America's scientists to important new discoveries and new therapies for the benefit of humankind."[228] The president placed three general restrictions on embryonic stem cell research that the NIH could fund: the research had to be done responsibly, the research had to be scientifically worthy, and the research had to be permitted by law.[229] When signing his executive order, President Obama noted that:

> This Order is an important step in advancing the cause of science in America. But let's be clear: promoting science isn't just about providing resources - it is also about protecting free and open inquiry. It is about letting scientists like those here today do their jobs, free from manipulation or coercion, and listening to what they tell us, even when it's inconvenient - especially when it's inconvenient. It is about ensuring that scientific data is never distorted or concealed to serve a political agenda - and that we make scientific decisions based on facts, not ideology.[230]

In other words, President Obama found it important not only for the federal government to support scientific research through the provision of funds, but also to allow the scientific community an opportunity to inquire into previously unexplored areas without the fear of backlash from the government based on an ideologically driven policy. Obama wished to curtail the

225. Diamond, *supra* note 117, at 282.
226. Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).
227. *Id.*
228. *Id.*
229. *Id.*
230. Remarks of President Barack Obama – As Prepared for Delivery Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum, OFFICE OF THE PRESS SECRETARY (Mar. 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/.

impact of the ethical concerns that had previously inspired prior federal policy with regard to new scientific research.[231]

Even after President Obama's order lifting the restrictions on funding for embryonic stem cell research, the funding permitted by law was still limited by the Dickey-Wicker amendment.[232]The NIH guidelines promulgated in response to President Obama's order specifically state that, in accordance with Dickey-Wicker, no NIH funding may be used to support the *derivation* of stem cells from human embryos.[233] However, the NIH's interpretation of the Dickey-Wicker amendment does allow for federal funding of *research* done on embryonic stem cells that have already been derived.[234]

Specifically, the NIH's guidelines provided that, for the purpose of the guidelines, "'human embryonic stem cells (hESCs)' are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers."[235] Although hESCs are derived from embryos, such stem cells are not themselves human embryos.[236] Institutions applying for NIH funds for research on human embryonic stem cells "may use hESCs that. . .were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose, were donated by individuals who sought reproductive treatment. . .and who gave voluntary written consent for the human embryos to be used for research purposes. . .and where certain requirements can be assured through documentation."[237] These "certain requirements" are: (1) that all options pertaining to the embryos no longer needed for IVF which are available in the health care facility where IVF treatment was sought were explained to the individual(s) who sought reproductive treatment, (2) that no payments of any kind were offered for the donated embryos, (3) that policies or procedures, or both, were in place at the health care facility where the embryos were donated such that neither consenting nor refusing to donate embryos for research would affect the quality of care provided to potential donor(s), and (4) that there was a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes.[238] Finally, it was required that, during the consent process, the donor(s) were informed of certain information re-

231. *See* Diamond, *supra* note 117, at 283.
232. *See* Ogolla, *supra* note 150, at 98.
233. Pierson, *supra* note 72, at 876.
234. *Id.*
235. National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170 (July 7, 2009).
236. *Id.* at 32,171.
237. *Id.* at 32,174.
238. *Id.*

garding the use of embryos in embryonic stem cell research.[239] While the new guidelines allowed federal funding for research on more embryonic stem cell lines than were available previously, the guidelines still placed many restrictions on which embryonic stem cells may receive federal funding for research.

The NIH's guidelines were upheld by the D.C. Circuit in *Sherley v. Sebelius*, a case in which researchers on adult stem cells brought a claim that embryonic stem cell research violated the Dickey-Wicker amendment.[240] The court concluded that it did not, and included in its reasoning the NIH's guidelines' statement that

> "(s)ince 1999, the Department of Health and Human Services (HHS) has consistently interpreted [Dickey–Wicker] as not applicable to research using hESCs, because hESCs are not embryos as defined by Section 509. This longstanding interpretation has been left unchanged by Congress, which has annually reenacted the Dickey Amendment with full knowledge that HHS has been funding hESC research since 2001. These guidelines therefore recognize the distinction, accepted by Congress, between the derivation of stem cells from an embryo that results in the embryo's destruction, for which Federal funding is prohibited, and research involving hESCs that does not involve an embryo nor result in an embryo's destruction, for which Federal funding is permitted."[241]

The court and the NIH realized that Congress must have impliedly agreed with the guidelines set by the NIH in 1999, as Congress never took steps to override those guidelines with legislation.[242]

The decision of President Obama to lift the restrictions on available embryonic stem cell lines, and the NIH's subsequent guidelines, has made it much easier for colleges and universities to do research on embryonic stem cells and to obtain funding for such research.[243] As early as December 2009, the NIH had approved thirteen new stem cell lines to be added to the

239. *Id.* The potential donors were required to be informed that the embryos would be used to derive hESCs for research, what would happen to the embryos in the derivation of hESCs for research, that hESCs derived from the embryos might be kept for many years, that the donation was made without any restriction or direction regarding the individual(s) who may receive medical benefit from the use of the hESCs, that the research was not intended to provide direct medical benefit to the donor(s), that the results of research using the hESCs may have commercial potential, and that the donor(s) would not receive financial or any other benefits from any such commercial development. *Id.* at 32,174−75.

240. 644 F.3d 388 (D.C. Cir. 2011).

241. National Institutes of Health Guidelines for Human Stem Cell Research, *supra* note 235, at 32,173.

242. *Sherley*, 644 F.3d at 388, 391.

243. Goodman, *supra* note 17.

NIH guidelines, with another ninety-six lines awaiting approval.[244] Although most of the embryonic stem cell research in the United States was still being done using the Bush-approved lines in late 2009, in 2010 at least 8% of embryonic stem cell research was being done on stem cell lines made available only by lifting the Bush restrictions.[245] The NIH has now approved two-hundred and ninety-two new stem cell lines since President Obama's decision to lift the restrictions in 2009.[246] While President Obama has opened the door for embryonic stem cell research to move forward by removing ethically based policy objections to funding that research, many researchers are still trying to find a way to obtain embryonic stem cells without having to destroy an embryo, thus avoiding the moral debate altogether.[247]

VII. CONCLUSION

The decision of President Bush to limit the availability of federal funding for embryonic stem cell research — a decision which was motivated by moral and religious considerations — had the foreseeable effect of limiting the research that could be done by colleges and universities into embryonic stem cells. The decision also had the effect of limiting the variety of embryonic stem cells available as materials for research that was federally funded in any way, thereby limiting the research that could be done. Embryonic stem cell research promises the possibility of great medical benefits to millions of people suffering from various diseases and disabilities, and colleges and universities are the primary source for basic research into this new frontier of scientific development. Stifling academic research into embryonic stem cells for ethical reasons may have had the effect of preventing many people from obtaining possible cures for their diseases or therapies to reduce their pain.

This is not to say that ethical considerations should not be taken into account when shaping public policy regarding scientific inquiry. While ethical considerations are necessary for preventing questionable, and even at times immoral, use of scientific inquiry, these considerations must be factored in with consideration of not only potential benefits of scientific inquiry, but also the effect of policy on one of the key sources of scientific inquiry, namely colleges and universities. As the primary source of basic

244. *Id.*

245. The Stem Cell Debates, *supra* note 90, at 35.

246. *NIH Human Embryonic Stem Cell Registry*, NATIONAL INSTITUTES OF HEALTH, *available at* http://grants.nih.gov/stem_cells/registry/current.htm (last visited Oct. 2, 2014).

247. *See supra* Section II (discussing the science behind embryonic stem cell research). Two new areas of research are discussed: attempting to induce adult somatic cells to a pluripotent state, and attempting to derive embryonic stem cell lines without having to destroy the embryos from which they are derived. *Id.*

research and with a significant percentage of their research budgets coming from the federal government, colleges and universities deserve consideration in the policy debate over scientific inquiry. As research continues, scientists will undoubtedly continue to pursue issues that are laden with ethical problems. While it is important to address ethical questions and maintain standards of ethics in scientific inquiry, the important place of colleges and universities in the process of scientific progress suggests that these institutions be given a seat at the table at which those ethical questions will be addressed.