ON PRESIDENTS, AGENCIES, AND THE STEM CELLS BETWEEN THEM: A LEGAL ANALYSIS OF PRESIDENT BUSH'S AND THE FEDERAL GOVERNMENT'S POLICY ON THE FUNDING OF RESEARCH INVOLVING HUMAN EMBRYONIC STEM CELLS

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ABSTRACT

On August 9, 2001, President George W. Bush announced his policy on research involving human embryonic stem cells and proclaimed that federal funding would be allocated only to research involving human embryonic stem cell lines produced prior to his announcement (the Directive). Immediately thereafter, the National Institutes of Health (NIH) announced that it would act in accordance and full compliance with the Directive and took action to implement it. Since then, the Directive has dictated the nature and extent of scientific research involving human embryonic stem cells. Yet, astonishingly, despite being the subject of a boisterous debate, the Directive's legality as well as the legality of the NIH's actions have never been questioned nor ascertained. This Article seeks to fill this gap.

After analyzing the Directive and the NIH's ensuing actions in light of the NIH Revitalization Act of 1993 and the Administrative Procedure Act, this Article argues that the Directive and the NIH's actions taken to

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implement it were illegal. Based on this conclusion, the Article discusses the possible legal challenges that may be raised with respect to the Directive and the NIH's actions.

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INTRODUCTION

On August 9, 2001 at about 8:00 p.m., surrounded by families of children conceived from embryo donations and by members of Congress, President George W. Bush addressed the nation from his ranch in Crawford, Texas and announced his new policy on federal funding for research involving human embryonic stem cells (hESCs).[1] President Bush started by describing the deep religious and ethical sentiments that brought him to make this policy decision[2] and ultimately proclaimed that federal funding would be allocated only to research involving hESC lines produced prior to his Address.[3] Immediately following President Bush's Address, the Acting Director of the National Institutes of Health (NIH), Dr. Ruth Kirschstein, and the Secretary of Health and Human Services (HHS), Tommy G. Thompson, both released statements announcing that they would act in accordance and in full compliance with the Directive.[4] And so, President Bush's Directive became "the law of the land" and stands unwavering at the crux of the Federal Government's policy regarding the funding for research involving hESCs.

The Directive and subsequent policies adopted by the Bush Administration have been the topic of a multitude of articles dealing with their ramifications. The Directive has inspired an abundance of state legislation either embracing the decision or rejecting and undermining it.[5] The Bush Administration's policies even became one of the focal points of Senator John Kerry's presidential election campaign in 2004 and of the

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1. President George W. Bush, Address to the Nation on Stem Cell Research, 2 PUB. PAPERS 953 (Aug. 9, 2001) [hereinafter President Bush's Address]. I will subsequently refer to this speech as President Bush's Address, President Bush's Stem Cell Decision, or President Bush's Directive.

2. *Id.* at 955 ("My position on these issues is shaped by deeply held beliefs. I'm a strong supporter of science and technology . . . . I also believe human life is a sacred gift from our Creator.").

3. *See id.* ("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.").

4. *See* Press Release, Ruth Kirschstein, Acting Director of the National Institutes of Health, NIH Statement on the President's Stem Cell Address (Aug. 9, 2001), *available at* http://www.nih.gov/news/pr/aug2001/od-09.htm [hereinafter Kirschstein Statement] (describing President Bush's Decision as "sound" and expressing "understand[ing of] the President's clear desire to move forward with care"); Press Release, Tommy G. Thompson, Secretary, Dep't of Health and Human Servs., Regarding the President's Decision on Human Embryonic Stem Cell Research (Aug. 9, 2001), *available at* http://www.hhs.gov/news/press/2001pres/20010809.html [hereinafter Thompson Statement] (praising the President's decision as a courageous one that shows leadership and stating that he would be proud to carry it out).

5. *See generally* Lauren Thuy Nguyen, *The Fate of Stem Cell Research and a Proposal for Future Legislative Regulation*, 46 SANTA CLARA L. REV. 419, 433-37 (2006) (detailing efforts in some states such as California and New Jersey to protect and endorse stem cell research funding).

Democratic Party's platform in the recent congressional elections.[6] Yet, with all that has been written and said about President Bush's Directive and the policies implementing it, the focus was always on the economical, ethical, scientific, and social implications and justifications; quite astonishingly, their legality seems to have never been questioned or analyzed.[7] This Article seeks to fill this void by answering the question whether President Bush's Directive and the Administration's policy on funding for research involving hESCs is legal.

Part I of this Article provides the scientific background necessary for understanding President Bush's Directive and surveys the regulatory history of research involving embryos and hESCs in the United States. Part II then examines and evaluates the validity of President Bush's Directive and of the ensuing actions taken by the NIH, arguing that they were illegal and not legally sustainable. Part III then discusses the possible legal challenges that may be raised with respect to the Directive and the NIH's actions. This Article concludes with predictions about the future of the regulation of research involving hESCs.

I. HUMAN EMBRYONIC STEM CELLS–SCIENTIFIC AND REGULATORY BACKGROUND

A. Human Embryonic Stem Cells and Their Uses in Medicine and Science

Prior to delving into the legal discussion, it may be helpful to review what embryonic stem cells are, their scientific purpose and medical potential, and why they incite such a bitter ethical debate.

Stem cells in general (rather than embryonic stem cells) are living cells that are unspecialized; namely, they have not (yet) undergone a process called "differentiation," which turns them into cells that fulfill a specific

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6. *See, e.g.*, Charlie Savage, *Stem Cell Issue Opens Campaign Divide*, BOSTON GLOBE, Aug. 8, 2004, at A1; Dan Vergano, *Stem-Cell Debate Another Division Between Bush, Kerry*, USA TODAY, Oct. 26, 2004, *available at* http://www.usatoday.com/news/politicselections/nation/issues/2004-10-26-stem-cell-research_x.htm.

7. A number of articles have dealt with the issue of the legality of President Bush's Directive indirectly by analyzing it alongside similar administrative and presidential actions. *See, e.g.*, Tara L. Branum, *President or King? The Use and Abuse of Executive Orders in Modern-Day America*, 28 J. LEGIS. 1, 45-47 (2002) (classifying President Bush's Directive as improper because it did not leave the issue for Congress to decide); Christopher S. Yoo, Steven G. Calabresi & Anthony J. Colangelo, *The Unitary Executive in the Modern Era, 1945-2004*, 90 IOWA L. REV. 601, 725-26 (2005) (praising President Bush's Directive for what the authors view as being exemplary of his leadership and strong principled pro-life stance). However, President Bush's Directive itself was never the focus of an in-depth legal analysis as it is in this Article.

function within the body (e.g., red blood cells, heart-muscle cells).[8] Under certain conditions, they may undergo differentiation into specialized cell types that are able to fulfill specific bodily functions.[9] Finally, unlike most of the other cells in our body, stem cells may continue to divide (proliferate) over extended periods of time without "committing" themselves to a certain specialized cell type or function—they may remain in a "stem cell state."[10]

Because of these characteristics, stem cells are a potentially unlimited source of specialized cells for research and for transplantation therapies meant to "replenish" injured tissues that need specific kinds of cells. Some of these therapies, like bone marrow transplantation,[11] already exist, while others are currently being researched.[12] Furthermore, because of their special qualities, stem cells may also have other beneficial uses—in research meant to develop methods of prevention and treatment of birth defects; in creation of models, which would make drug development processes faster and cheaper;[13] and in gene therapy.[14]

Stem cells may be subdivided into three classes. The first type of stem cells, with the most differentiation potential, is "totipotent stem cells," which make up an early embryo, and which are a potential source of any

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8. National Institutes of Health (NIH), Stem Cell Basics, I.A., What are stem cells and why are they important?, http://stemcells.nih.gov/info/basics/basics1.asp (last visited Oct. 21, 2007) [hereinafter Stem Cell Basics]; NIH, Stem Cell Basics, II., What are the unique properties of all stem cells?, http://stemcells.nih.gov/info/basics/basics2.asp (last visited Oct. 21, 2007) [hereinafter Unique Properties of Stem Cells].

9. Stem Cell Basics, *supra* note 8; Unique Properties of Stem Cells, *supra* note 8.

10. Stem Cell Basics, *supra* note 8; Unique Properties of Stem Cells, *supra* note 8.

11. Bone marrow transplantations are essentially stem cell transplantations where patients lacking the capability of replenishing their own blood cells receive hematopoietic stem cells (blood stem cells), which are meant to proliferate and differentiate to replenish the blood cells they need. For further discussion of bone marrow transplantation and other, more modern techniques for acquiring hematopoietic stem cells, see Jos Domen, Amy Wagers & Irving L. Weissman, *Bone Marrow (Hematopoietic) Stem Cells*, *in* NIH REGENERATIVE MEDICINE REPORT 13, 14, 22 (2006), *available at* http://stemcells.nih.gov/info/scireport/2006report.htm [hereinafter REGENERATIVE MEDICINE].

12. Some of the uses for stem cells, which are currently in the research and development stage, include using stem cells as a source of pancreatic cells for treatment of diabetes, using dopamine-secreting cells for the treatment of Parkinson's disease, and so forth. *See generally id.* at 13-34; David M. Panchision, *Repairing the Nervous System with Stem Cells*, *in* REGENERATIVE MEDICINE, *supra* note 11, at 35-44 (discussing how stem cells could be used to treat nervous system disorders); Thomas P. Zwaka, *Use of Genetically Modified Stem Cells in Experimental Gene Therapies*, *in* REGENERATIVE MEDICINE, *supra* note 11, at 45-52 (illustrating how stem cells can be used in gene therapies for persons with cystic fibrosis and severe combined immunodeficiency).

13. Junying Yu & James A. Thomson, *Embryonic Stem Cells*, *in* REGENERATIVE MEDICINE, *supra* note 11, at 3 (illustrating how stem cells can help to identify drug targets as well as prevent and treat birth defects). For further information on the uses of human embryonic stem cells (hESCs), see *id.* at 4, 8.

14. *See, e.g.*, NIH, *Use of Genetically Modified Stem Cells in Experimental Gene Therapies*, *in* STEM CELLS: SCIENTIFIC PROGRESS AND FUTURE RESEARCH DIRECTIONS 99-105 (2001), *available at* http://stemcells.nih.gov/staticresources/info/scireport/PDFs/chapter11.pdf (discussing the benefits of embryonic stem cells in gene therapy).

cell type in an organism's body.[15] The second type of stem cells, with slightly less differentiation potential, is "pluripotent stem cells," also known as embryonic stem cells (ESCs).[16] These cells may be a source of all of the different kinds of cells that make up an organism's body, save early totipotent embryonic cells.[17] Lastly, there are "multipotent stem cells," which have differentiated further than pluripotent stem cells.[18] Within this group of multipotent stem cells are "adult stem cells," which serve as a source of replenishment of cells in the bodies of adult organisms.[19]

A general agreement has emerged among leading scientists in the area of stem cell research that research involving pluripotent stem cells holds numerous advantages over research involving adult stem cells.[20] Among the reasons for this agreement is the fact that pluripotent stem cells are more readily available[21] than adult stem cells (which are rare), difficult to extract from the tissues in which they reside, and extremely hard to proliferate while keeping undifferentiated.[22] Another reason is that ESCs' low level of commitment makes them potentially more versatile than other, more "committed" stem cells—they may differentiate into more types of specialized cells.[23]

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15. *See* NIH, Stem Cell Information, Frequently Asked Questions, http://stemcells.nih.gov/info/faqs.asp (last visited Oct. 21, 2007) [hereinafter NIH FAQs] (categorizing stem cells into three classes).

16. *Id.* It is noteworthy that according to recent scientific publications, a group of scientists managed to create hESC lines from totipotent cells rather than from pluripotent cells. *See* Irina Klimanskaya et al., *Human Embryonic Stem Cell Lines Derived from Single Blastomeres*, NATURE, Nov. 23, 2006, at 481.

17. NIH FAQs, *supra* note 15.

18. *Id.*

19. *See* NIH, Stem Cell Basics, IV., What are adult stem cells?, http://stemcells.nih.gov/info/basics/basics4.asp (last visited Oct. 21, 2007) (describing the differences between adult stem cells and embryonic stem cells).

20. *See* NIH Statement Before the Senate Appropriations Subcomm. on Labor, Health and Human Services, Education and Related Agencies (Apr. 26, 2000), *available at* http://stemcells.nih.gov/policy/statements/state.asp [hereinafter NIH Statement] (noting that human pluripotent stem cells hold promise for advances in the prevention, treatment, and diagnosis of many diseases).

21. Currently, in the United States there are about 400,000 unused frozen embryos from which embryonic stem cells may be extracted, which, if remain unused for a prolonged period of time, will be disposed of. *See* Junying Yu & James Thomson, *Embryonic Stem Cells*, *in* REGENERATIVE MEDICINE, *supra* note 11, at 1, 3.

22. *See* NIH Statement, *supra* note 20; NIH FAQs, *supra* note 15; NIH, Stem Cell Basics, V., What are the similarities and differences between embryonic and adult stem cells?, http://stemcells.nih.gov/info/basics/basics5.asp (last visited Oct. 21, 2007) [hereinafter Embryonic and Adult Stem Cells].

23. NIH Statement, *supra* note 20; NIH FAQs, *supra* note 15; Embryonic and Adult Stem Cells, *supra* note 22.

To be able to utilize ESCs, researchers have to extract these cells from very early embryos and turn them into cell lines[24]—a process that destroys the embryos.[25] This practice, when applied in human embryos, encounters strong opposition on two main grounds. The first is an ethical ground according to which human embryos have a "special moral status" as "early humans," and thus the practice of destroying such embryos for research purposes constitutes a denial of the respect they are entitled to as an early form of human life. The second ground for opposition is established upon the religious premise that embryos are endowed with God-given life, and that destroying them in the research process constitutes killing. Despite this opposition, since the derivation of the first hESCs in 1998,[26] over 120 hESC lines have been created worldwide.[27]

B. The Regulation of Embryo Research Prior to 1998

Though hESCs were first derived only in 1998, in order to fully understand the regulation of research involving hESCs,[28] it is necessary to revisit some constituting events in the regulation of human embryo research, which directly led to and shaped the regulation of research involving hESCs.

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24. A cell line is essentially a culture of identical cells that have been transformed in a way that allows them to proliferate in culture indefinitely and that have been kept in that state (of continuous proliferation) for a prolonged period of time. In other words, it is an "immortal" cell culture that will keep on proliferating for as long as it is provided with proper nourishment. This is as opposed to "normal" cells, which proliferate only a limited number of times. For further information on the method of creating ESC lines, see the National Institutes of Health, Stem Cell Basics, III., What are embryonic stem cells?, http://stemcells.nih.gov/info/basics/basics3.asp (last visited Oct. 21, 2007). Another method of obtaining pluripotent stem cells is by creating embryos solely for research purposes from egg and sperm donations. *Id.*

25. It is worth noting that some scientists have recently published claims that they have developed methods for creating hESC lines without destroying embryos. *See* Klimanskaya et al., *supra* note 16, at 481; Xin Zhang et al., *Derivation of Human Embryonic Stem Cells from Developing and Arrested Embryos*, STEM CELLS, Sept. 21, 2006, *available at* http://www.StemCells.com/cgi/content/full/24/12/2669; Constance Holden, *Stem Cells Without the Fuss?*, SCIENCENOW, June 6, 2007; Elizabeth Finkel, *Researchers Derive Stem Cells from Monkeys*, SCIENCENOW, June 19, 2007; Rick Weiss, *Lab Cites Stem Cell Advance: Method of Harvest Could Leave Embryos Undamaged*, WASH. POST, Jan. 11, 2008, at A4. Yet, these publications have encountered skepticism by both proponents and opponents of research involving hESCs. *See, e.g.*, Alison Abbott, *"Ethical" Stem Cell Paper Under Attack*, NATURE, Sept. 7, 2006, at 12; Nicholas Wade, *In New Method for Stem Cells, Viable Embryos*, N.Y. TIMES, Aug. 24, 2006, at A2; Constance Holden, *Life From Arrested Development?*, SCIENCENOW, Sept. 22, 2006; *Scientists Create Stem Cell Line from Already Dead Embryo*, ASSOCIATED PRESS, Sept. 22, 2006.

26. *See infra* note 68.

27. Yu & Thomson, *supra* note 21, at 6.

28. I distinguish between hESC research, which is the research *of* hESCs, and research involving hESCs, which is any research that makes use of hESCs even for purposes that do not include learning about the hESCs themselves. Since President Bush's Directive affects both kinds, I will use the latter more inclusive term—research involving hESCs—throughout this Article.

Throughout the 1980s, HHS did not allocate federal funding for research involving human embryos.[29] This was because under HHS regulations, funding of such research required the pre-approval of an Ethics Advisory Board (EAB).[30] But since the mandate of the last EAB lapsed in 1980[31] and no new EAB was appointed in its stead, the HHS practically imposed a de facto moratorium on federal embryo research,[32] which lasted until Congress passed the NIH Revitalization Act (NIHRA) in 1993.[33]

The change in the federal research policy regarding human embryos brought about by the NIHRA can be traced back to a set of events, seemingly unrelated to the aforementioned de facto moratorium, about six years prior to the passing of the NIHRA. In October 1987, the NIH received a request by some of its own investigators to approve a research protocol involving an experimental implantation of human fetal cells taken from aborted human embryos into the brain of a Parkinson's patient.[34] Because of the "broad scientific and ethical implications surrounding this area of research,"[35] although there was no existing regulatory barrier posed before such research at that time, the Director of the NIH voluntarily decided to request the approval of the Assistant Secretary for Health (ASH) to support this study.[36] On March 22, 1988, the Assistant Secretary announced that he was withholding approval of the project and placed a temporary moratorium on the federal support of research involving fetal tissue transplantation pending further consideration "of the relevant ethical, legal, and scientific issues by an outside group of experts"[37] that "would

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29. *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 23 (2004), *available at* http://www.bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf [hereinafter PRESIDENT'S COUNCIL REPORT] (explaining that members of Congress became concerned about the potential use of aborted fetuses following *Roe v. Wade*).

30. 40 Fed. Reg. 33,526, 33,529 (Aug. 8, 1975); *see also* 1 NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH 34 (1999), *available at* http://bioethics.georgetown.edu/nbac/stemcell.pdf [hereinafter NBAC REPORT] (describing the Ethics Advisory Board's recommendations with respect to research involving human embryos).

31. NBAC REPORT, *id.* at 34.

32. *Id.*

33. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122 (1993).

34. NAT'L INSTS. OF HEALTH, REPORT OF THE ADVISORY COMMITTEE TO THE DIRECTOR: HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH 1 (1988) [hereinafter HUMAN FETAL TISSUE REPORT].

35. *Id.*

36. *Id.*; *see also* NAT'L INSTS. OF HEALTH, THERAPEUTIC HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH ACTIVITIES FUNDED BY THE NATIONAL INSTITUTES OF HEALTH IN FY 1998: REPORT TO CONGRESS PART III (1999), *available at* http://ospp.od.nih.gov/policy/fetal.asp [hereinafter REPORT TO CONGRESS] (stating that the ASH advised the NIH that it was withholding approval of the project pending consideration of the issues from the Human Fetal Tissue Transplantation Research Panel (HFTTRP)).

37. REPORT TO CONGRESS, *supra* note 36.

examine comprehensively the use of human fetal tissue from induced abortions for transplantation" and advise "whether this kind of research should be performed, and if so, under what circumstances."[38] Pursuant to these instructions, the NIH formed the Human Fetal Tissue Transplantation Research Panel (HFTTRP) to the Advisory Committee to the Director (ACD).[39] The HFTTRP held numerous meetings and, in December 1988, submitted its report to the ACD.[40] The HFTTRP found the use of tissue from induced abortions in therapeutic transplantation research to be "acceptable public policy" and proposed guidelines to assure that such research would be conducted in an ethical manner.[41] The ACD unanimously accepted the recommendations[42] and passed them on to the Director of the NIH, who also accepted them and recommended to the Secretary to lift the moratorium.[43] Interestingly, in November 1989, Secretary Louis Sullivan decided to reject these recommendations and continue the moratorium on federal funding for transplantation research involving human fetal tissue indefinitely.[44]

However, Secretary Sullivan's moratorium did not go unchecked by Congress. Outraged by the Secretary's actions,[45] in a clear and rare expression of discontent with the administrative handling of legislatively delegated powers and of legislative intent to promote human embryo research, Congress passed the NIHRA in 1993.[46] The NIHRA explicitly abolished Secretary Sullivan's moratorium,[47] rescinded the requirement for an EAB's approval of research applications involving embryo research,[48]

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38. Human Fetal Tissue Transplantation Research Panel; Advisory Committee to the Director; Meeting, 53 Fed. Reg. 24,500 (June 29, 1988).

39. *Id.* The Advisory Committee to the Director of the NIH was formed in 1966 to "assist the Office of the Director, NIH, in the making of major plans and policies, especially those related to the allocation of NIH funds and resources." Advisory Committee to the Director, Charter of the ACD, http://www.nih.gov/about/director/acd/index.htm (last visited Dec. 2, 2007).

40. HUMAN FETAL TISSUE REPORT, *supra* note 34, at 2.

41. *Id.* at 4-5; *see also* S. REP. NO. 103-2, at 13 (1993) (describing the HFTTRP and its recommendations).

42. HUMAN FETAL TISSUE REPORT, *supra* note 34, at 4-5.

43. S. REP. NO 103-2, at 13.

44. *Id.* Congress lifted this moratorium in 1993 in the National Institutes of Health Revitalization Act (NIHRA). *See* Michael Specter, *Fetal-Tissue Research Ban Formally Extended; Moral and Ethical Problems Said To Outweigh Possible Benefits*, WASH. POST, Nov. 3, 1989, at A5.

45. S. REP. NO 103-2, at 13.

46. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122 (1993).

47. *Id.* § 113, 107 Stat. at 132.

48. *See* S. REP. NO 103-2, at 12-15. Congress actually turned the HHS's de facto moratorium on research involving embryos "upside down" so that the default would no longer be that grant applications for research involving embryos could not be accepted unless ethically approved, but rather that such research proposals were eligible for funding unless an independent Ethics Advisory Board explicitly recommended otherwise. For further discussion, see *infra* Part II.B.1.

and imposed restrictions on the HHS's ability to withhold funds for research on ethical grounds so that such a withholding could not take place without the recommendation of an independent EAB.[49]

Following the enactment of the NIHRA, the NIH began to receive applications for funding of research involving human embryos.[50] The Secretary of HHS at that time, Donna Shalala, aware of the bioethical issues stemming from such research, decided to establish an EAB in accordance with the NIHRA, and instructed the NIH to proceed accordingly.[51] The NIH, acting under these instructions and in accordance with the requirements of the NIHRA,[52] formed the Human Embryo Research Panel. The Panel's mandate was to "consider various areas of research involving the ex-utero preimplantation human embryo[53] and to provide advice as to those areas that (1) [were] acceptable for Federal funding, (2) warrant additional review, and (3) [were] unacceptable for Federal support."[54] In September 1994, after seven months of work, the Human Embryo Research Panel published its final report and recommendations regarding research involving human embryos.[55] First, the Panel concluded that in principle, and pending the fulfillment of some preliminary requirements, there were numerous types of research involving preimplanted human embryos that were ethically permissible.[56] Most importantly, the Panel determined that creation of human embryos solely for research purposes was permissible if such research could not otherwise be conducted and when "a compelling case can be made that [the research] is necessary for the validity of a study that is potentially of outstanding scientific and therapeutic value."[57] The report also specifically held that research aimed at the development of human embryonic stem cells should

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49. National Institutes of Health Revitalization Act of 1993 § 101, 107 Stat. at 126. For further discussion of the NIHRA and its requirements, see *infra* Part II.B.1.

50. *See* Doe v. Shalala, 862 F. Supp. 1421, 1424-25 (D. Md. 1994) ("With the passage of the Revitalization Act, NIH in fact received a number of applications seeking financial support of research. . . .").

51. *Id*.

52. 42 U.S.C. § 289a-1(b)(5) (2000).

53. The Human Embryo Research Panel used the term "ex-utero preimplantted embryo" to describe human embryos that were the result of IVF treatments, which yielded more embryos than the women treated actually cared to have implanted in them and which were therefore kept frozen. *See* 1 THE NATIONAL INSTITUTES OF HEALTH, REPORT OF THE HUMAN EMBRYO RESEARCH PANEL, at ix (1994).

54. *Id.*

55. *Id.* at x-xx.

56. *Id.* at x-xi, xvii. These preliminary requirements included conditions such as: that the research on the human embryo could not be otherwise accomplished by using alternative means (e.g., experimentation with animals), that strict informed consent requirements had been met, that only the minimum number of embryos possible for the purposes of the research would be used, that the embryos used would not be older than fourteen days, and so forth.

57. *Id.* at xii.

be permitted, subject to the conditions that the source of the embryos used for the creation of the hESCs would be surplus embryos produced for infertility treatments or clinical research and that the progenitors consented.[58] On December 1, 1994, the NIH's ACD unanimously accepted the Panel's Report,[59] but on the very next day, President Clinton released a terse statement (President Clinton's Embryo Decision) instructing the NIH not to allocate funds for supporting the creation of embryos for research purposes.[60] Thus, President Clinton's Embryo Decision negated one of the Panel's most controversial recommendations, namely the creation of embryos exclusively for research purposes. Nevertheless, his Decision did not prohibit research involving surplus embryos left from in-vitro fertilization (IVF) treatments, and so the NIH proceeded to develop guidelines for funding research using embryos not created solely for research purposes.[61] However, on January 26, 1996, before the NIH was

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58. *Id.* at xvii. In addition, the Panel recommended *not* to support numerous kinds of research that were deemed to pose "serious ethical concerns," including research involving human cloning, research of embryos beyond the stage of the closure of the neural tube, pre-implantation diagnosis for the purpose of sex selection, development of human-nonhuman chimeras, cross species fertilization, and more. *See id.* at xix-xx.

59. NBAC REPORT *supra* note 30, at 34.

60. *See* William J. Clinton, Statement on Federal Funding of Research on Human Embryos, 30 WEEKLY COMP. PRES. DOC. 2459, 2459-60 (Dec. 2, 1994) [hereinafter President Clinton's Embryo Decision]. President Clinton's Embryo Decision only noted the following:

> The Director of the National Institutes of Health has received a report regarding federal funding of research on human embryos. The subject raises profound ethical and moral questions as well as issues concerning the appropriate allocation of Federal funds. I appreciate the work of the committees that have considered this complex issue, and I understand that advances in vitro fertilization research and other areas could derive from such work. However, I do not believe that Federal funds should be used to support the creation of human embryos for research purposes, and I have directed that NIH not allocate any resources for such research. In order to ensure that advice on complex bioethical issues that affect our society can continue to be developed, we are planning to move forward with the establishment of a National Bioethics Advisory Commission over the next year.

Id. President Clinton's Embryo Decision was not backed or followed by any officiating action such as issuing an executive order and was never published in the Federal Register, but rather only in the Weekly Compilation of Presidential Documents. *See id.* at 2459-60. For further discussion of President Clinton's Embryo Decision and its legal status, see *infra* Part III.A. Interestingly, President Clinton repeated the practice of instructing executive agencies not to fund certain kinds of research that he perceived as bioethically problematic at least once more in a statement released to the media and titled "memorandum," where he explicitly directed "that no Federal funds will be used for human cloning." *See* President William J. Clinton, Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, 33 WEEKLY COMP. PRES. DOC. 281 (Mar. 4, 1997) [hereinafter President Clinton's Cloning Decision].

Ironically, as I will later show, President Bush's Directive seems to have been the spitting image of President Clinton's Embryo Decision.

61. *See* IRENE STITH-COLEMAN, CRS REPORT FOR CONGRESS: HUMAN EMBRYO RESEARCH 2 (1998), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/95-910_STM.pdf (stating that after the President's December 1994 Order, the agency proceeded with plans to develop guidelines to support research using spare embryos); *see also* NBAC REPORT, *supra* note 30, at 34.

able to approve any application for funding embryo research,[62] Congress passed the Dickey Amendment, which amended the 1996 Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act,[63] cutting the NIH's efforts short.

The Dickey Amendment prohibited federal funding for research involving "the creation of a human embryo or embryos for research purposes"[64] and any research in which "a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death" greater than a measure allowed by the regulations governing research on fetuses in utero.[65] Congress has passed similar clauses in the respective appropriations bill every year since,[66] thus rendering research involving the creation, harming, or destruction of human embryos ineligible for federal funding. And since the creation of hESC lines inevitably involves the

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62. *See* PRESIDENT'S COUNCIL REPORT, *supra* note 29, at 25 (noting mildly that Congress "did not endorse this course of action").

63. The Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, § 128(2), 110 Stat. 26, 34 (1996).

64. *Id.* The Dickey Amendment, which was named after former Representative Jay Dickey who originally sponsored it, reiterated President Clinton's Embryo Decision from 1994 and provided it with legislative backing. For further discussion of this point, see *infra* Part III.A.

65. The Balanced Budget Downpayment Act, I, § 128(2), 110 Stat. at 34. The full language of the Amendment includes:

> 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 42 U.S.C. 289g(b) [of the Public Health Service Act].
>
> For purposes of this section, the phrase "human embryo or embryos" shall include 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.

Id.

66. *See, e.g.*, Omnibus Consolidated Appropriations Act, Pub. L. No. 104-208, § 512, 110 Stat. 3009-270 (1996); Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, Pub. L. No. 105-78, § 513, 111 Stat. 1467, 1517 (1997); Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, § 511, 112 Stat. 2681-386 (1998); Consolidated Appropriations Act, Pub. L. No. 106-113, § 510, 113 Stat. 1501A-275 (1999); Consolidated Appropriations Act–FY 2001, Pub. L. No. 106-554, § 510, 114 Stat. 2763A-71 (2000); Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, Pub. L. No. 107-116, § 510, 115 Stat. 2177, 2219 (2002); Consolidated Appropriations Resolution, Pub. L. No. 108-7, § 510, 117 Stat. 11 (2003); Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, § 510, 118 Stat. 3277 (2004); Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, § 509, 118 Stat. 2809-3163 (2004); Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, Pub. L. No. 109-149, § 509, 119 Stat. 2833-80 (2005).

destruction of a human blastocyst,[67] the Dickey Amendment has rendered research involving the creation of such hESC lines similarly ineligible for federal funding.[68]

C. Federal Regulation of Stem Cell Research Between Two Presidents—1998 to the Present

The news about the creation of the first hESC line in late 1998 brought about an abundance of regulatory activity aimed at evaluating the moral and legal status of such cells. In November 1998, President Clinton asked his National Bioethics Advisory Commission (NBAC) to "undertake a thorough review of the issues associated with human stem cell research, balancing all ethical and medical considerations."[69] In the meantime, it was unclear whether the Dickey Amendment, which excluded the *creation* of hESC lines with federal funding—because such creation inevitably involves the destruction of embryos—also meant that the federal government could not partake in research involving such hESC lines that already existed, and which were created without federal funding.[70] To answer this question, the Director of the NIH, Dr. Harold Varmus, approached the General Counsel of HHS, Harriet Rabb, and asked for her opinion regarding the legality of federal funding for research involving hESC lines that were created without federal support.[71] On January 15, 1999, in a legal opinion sent to Dr. Varmus, Harriet Rabb opined that the wording of the Dickey Amendment did not prevent the NIH from funding research involving already-created hESC lines because such hESCs—once extracted from an embryo—did not meet the definition of a human embryo, and hence did not fall under the Amendment's prohibition on the funding

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67. *See infra* Part I.A and text accompanying note 25.

68. Congress, however, did not prohibit such research from taking place altogether; it was (and still is) possible for private entities to conduct such research. Hence, when a group of scientists led by Dr. James Thomson from the University of Wisconsin finally managed to create hESC lines from embryos donated by couples undergoing IVF treatments, they did so without federal funding. *See* James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, SCIENCE, Nov. 6, 1998, at 1145-47; *see also* Statement of Harold Varmus, M.D., Director, NIH, Department of Health and Human Services, Before the Senate Appropriations Subcomm. on Labor, Health and Human Services, Education and Related Agencies (Dec. 2, 1998), *available at* http://stemcells.nih.gov/policy/statements/120298.asp [hereinafter Statement of Harold Varmus] ("Federal funds were not used in either of the experiments that you will hear about today.").

69. Letter from President William J. Clinton to Dr. Harold Shapiro, Chair of the National Bioethics Advisory Commission (Nov. 14, 1998), *reprinted in* NBAC REPORT, *supra* note 30, at 88.

70. *See* PRESIDENT'S COUNCIL REPORT, *supra* note 29, at 27 (describing this confusion).

71. Statement of Harold Varmus, *supra* note 68.

of the destruction of human embryos.[72] In other words, the Rabb Opinion held that federal funding could be granted for research involving hESCs, so long as the destruction of the embryos that led to the creation of the hESC lines had not been federally funded.[73] Pursuant to the Rabb Opinion, the NIH assigned a Working Group to develop guidelines and oversight mechanisms for research involving human stem cells, and announced a withholding of funds for such research[74] until the Working Group developed such guidelines.[75]

In September 1999, the NBAC at last published the report requested by President Clinton almost one year earlier.[76] The underlying premise of the NBAC Report was that "although the human embryo and fetus deserve respect as forms of human life, the scientific and clinical benefits of stem cell research should not be foregone."[77] In its report, the NBAC recommended, first and foremost, that federal legislation and regulation be changed so as to allow funding for the use and derivation of hESCs from embryos remaining unused after infertility treatments (namely, not embryos created solely for research purposes).[78] The NBAC further recommended that any donation of such embryos must fulfill numerous requirements, including obtaining informed consent from the embryos' donors, approaching potential donors only once they had already decided to discard their excess frozen embryos, informing the donors that their embryos would be destroyed, and regulating the entire area of research through "appropriate regulations that include public oversight and review."[79]

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72. *See* Memorandum from Harriet S. Rabb, General Counsel of the Department of Health and Human Services, to Harold Varmus, M.D., Director, NIH, on Federal Funding for Research Involving Human Pluripotent Stem Cells (Jan. 15, 1999), http://www.georgetown.edu/research/nrcbl/documents/rabbmemo.pdf [hereinafter Rabb Opinion]. According to the Rabb Opinion, hESCs are not subject to the definition of an "embryo" under the Dickey Amendment because an embryo is defined under the Amendment as an "organism" whereas scientific and medically accepted definitions of "organism," namely an individual constituted to carry out all life functions, do not cover hESCs.

73. *Id.* It is noteworthy that even though the Rabb Opinion was accepted as legally valid and as "stay[ing] within the letter of the law," it was nonetheless criticized for "contradict[ing] both the spirit of the law and the principle that underlies it." *See* PRESIDENT'S COUNCIL REPORT, *supra* note 29, at 27; O. Carter Snead, *The Pedagogical Significance of the Bush Stem Cell Policy: A Window into Bioethical Regulation in the United States*, 5 YALE J. HEALTH POL'Y L. & ETHICS 491, 494 (2005).

74. The source of the NIH Director's authority to announce this (yet another) moratorium on human embryonic research is not clear, especially in light of the provisions of the NIHRA, which explicitly require a prior EAB recommendation to impose such a moratorium. *See* 42 U.S.C. §§ 289a-1(b)(1), (3) (2000).

75. Statement of Harold Varmus, *supra* note 68.

76. NBAC REPORT, *supra* note 30.

77. *Id*. at xi.

78. *Id*. at iii-iv.

79. *Id*. at iv-ix.

Pursuant to the publication of the NBAC Report, and having considered its recommendations,[80] the NIH Working Group that was appointed in early 1999[81] finished developing its guidelines for ensuring that NIH-funded hESC research "is conducted in an ethical and legal manner."[82] In December 1999, the NIH published these proposed guidelines, calling for comments from the public (Proposed Guidelines).[83] The Proposed Guidelines followed the recommendations of the NBAC Report and allowed federal funding for research utilizing hESCs if: (1) the hESCs were derived from surplus embryos that were originally created for infertility treatments; (2) the decision to donate excess embryos was clearly separate from the decision to create the embryos; and (3) the decision to donate was made at the time the donors decided to dispose of the embryos.[84] The Proposed Guidelines also outlined areas of research involving hESCs that were ineligible for NIH funding, including the derivation of hESCs from human embryos and research on hESCs that were derived from embryos created for research purposes (thus explicitly applying the Dickey

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80. Press Release, National Institutes of Health, NIH Publishes Draft Guidelines for Stem Cell Research (Dec. 1, 1999), http://www.nih.gov/news/pr/dec99/od-01.htm (last visited Dec. 2, 2007).

81. *See* NIH, NIH Fact Sheet on Human Pluripotent Stem Cell Research Guidelines (Jan. 2001), http://stemcells.nih.gov/news/newsarchives/stemfactsheet.asp (last visited Dec. 2, 2007) [hereinafter NIH Fact Sheet] ("In April 1999, the NIH convened a working group of the Advisory Committee to the Director.").

82. National Institutes of Health, Draft National Institutes of Health Guidelines for Research Involving Human Pluripotent Stem Cells (December 1999), 64 Fed. Reg. 67,576, 67,576 (Dec. 2, 1999) [hereinafter Proposed Guidelines].

83. *Id.* It is worth noting that since the Proposed Guidelines involved "a matter relating to . . . public property, loans, grants, benefits, or contracts," the NIH was presumably exempt from following the notice and comment requirements of the Administrative Procedure Act in promulgating them. *See* Administrative Procedure Act (APA), 5 U.S.C. § 553(a)(2) (2000). However, the NIH, like all other HHS agencies, has been subject since 1971 to a direction by the Secretary of the Department of Health, Education, and Welfare (HEW) to "utilize the public participation procedures of the APA, 5 U.S.C. § 553" regardless of the exemption. *See* Statement of Policy: Public Participation in Rule Making, 36 Fed. Reg. 2,532, 2,532 (Feb. 5, 1971). As a result of this voluntary election to abide by the notice and comment requirements of § 553, courts have held the HHS to strict compliance with these requirements. *See, e.g.*, Mt. Diablo Hosp. Dist. v. Bowen, 860 F.2d 951, 956-57 n.6 (9th Cir. 1988) ("In 1971 . . . the Secretary waived the public benefits exception . . . . Rules promulgated by the Secretary after 1971 are therefore subject to the normal section 553 requirements."); Cubanski v. Heckler, 781 F.2d 1421, 1428 (9th Cir. 1986) ("The Secretary voluntarily waived the APA 'benefits' exception in 1971 . . . . The [HHS] thereby imposed upon itself procedural requirements 'not required by law'. . . . The Secretary's waiver has a binding effect independent of the APA."); Buschmann v. Schweiker, 676 F.2d 352, 356 n.4 (9th Cir. 1982); Humana of S.C., Inc. v. Califano, 590 F.2d 1070, 1084 (D.C. Cir. 1978) ("[T]he Secretary in 1971 elected to waive the exemption and to submit to the normal requirements of the [APA], and regulations promulgated since that time are subject to mandatory rulemaking procedures.") (citation omitted). For discussion of the NIH's compliance with the APA's requirements in repealing the Guidelines, see *infra* Part II.C.

84. Proposed Guidelines, 64 Fed. Reg. at 67,577. Other requirements set by the Draft Guidelines include strict and detailed informed consent requirements, privacy requirements and more. *Id.* at 67,577-78.

Amendment to the context of research involving hESCs), human-nonhuman research, and various kinds of cloning research.[85] In addition, as the NBAC recommended, the Proposed Guidelines suggested the creation of mechanisms to oversee research involving hESCs, including a Human Pluripotent Stem Cell Review Group (HPSCRG), which would review applications for research involving hESCs submitted to the NIH.[86]

On August 25, 2000, almost nine months after the publication of the Proposed Guidelines and extensive review of comments received on them,[87] the NIH published the Guidelines for Research Using Human Pluripotent Stem Cells (Final Guidelines) in the Federal Register.[88] The Final Guidelines included all the main components of the Proposed Guidelines as mentioned above (including the areas of research ineligible for funding and the establishment of the HPSCRG)[89] and lifted the moratorium on research using human pluripotent stem cells derived from human embryos that was announced by the Director of the NIH in January 1999.[90] Yet, it took the NIH almost another seven months to appoint the HPSCRG and start receiving requests for funding for research in accordance with the Final Guidelines.[91] In fact, the process of the regulation of funding for research involving hESCs was so slow, and lingered for so long, that even after more than two years following the initiation of the process by President Clinton and his Director of NIH, it was still not possible to receive federal funding for such research.

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85. *Id.* at 67,579.

86. *Id.*

87. During the comment period, "[t]he NIH received approximately 50,000 comments from members of Congress, patient advocacy groups, scientific societies, religious organizations, and private citizens." *See* National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,976-79 (Aug. 25, 2000) [hereinafter Final Guidelines].

88. *Id.*; *see also* Press Release, National Institutes of Health, NIH Publishes Final Guidelines for Stem Cell Research (Aug. 23, 2000), http://www.nih.gov/news/pr/aug2000/od-23.htm (last visited Dec. 2, 2007) (announcing the publication of the Final Guidelines).

89. Final Guidelines, 65 Fed. Reg. at 51,976-81.

90. *Id.* at 51,976. *See supra* notes 74-75 and accompanying text.

91. *See* NIH, Approval Process for the Documentation of Compliance with NIH Guidelines on the Use of Human Pluripotent Stem Cells in NIH Research Proposed for Support Under Grants and Cooperative Agreements, Notice OD-02-007 (Nov. 7, 2001), *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-003.html [hereinafter Notice OD-02-007] (stating that the first meeting of the Human Pluripotent Stem Cell Review Group (HPSCRG) would take place on March 15, 2001); NIH, Approval Process for the Documentation of Compliance with NIH Guidelines on the Use of Human Pluripotent Stem Cells in NIH Intramural Research (Jan. 16, 2001), *available at* http://stemcells.nih.gov/news/newsarchives/irpnotice_011601.asp; NIH Fact Sheet, *supra* note 81 ("The NIH is in the process of finalizing the members of the HPSCRG in preparation for a March deadline for the receipt of requests for NIH funding for human pluripotent stem cell research.").

In January 2001, close to the beginning of President Bush's presidency, the NIH was still dragging its feet regarding the appointment of the HPSCRG in preparation for the submission of research applications involving hESCs, which were due by March 15, 2001.[92] It soon became clear that the change in office was going to have a radical influence on the administration's policy regarding stem cell research. Almost as soon as President Bush took office, he charged his Secretary of HHS, Tommy Thompson, with conducting a review of the Final Guidelines and with putting the Guidelines "on hold" pending the results of that review.[93] In addition, in April 2001, HHS officials ordered the Acting Director of the NIH, Ruth Kirschstein, to indefinitely postpone a scheduled meeting of the newly appointed HPSCRG, which was supposed to review the first applications for research grants under the Final Guidelines,[94] thus de facto revoking the Final Guidelines.

Although the legality of this de facto revocation was highly questionable,[95] a district court order upheld and even bolstered the Bush Administration's actions.[96] On March 8, 2001, a group of plaintiffs consisting of religious groups and pro-life activists filed an action against the Government seeking an order and declaratory relief, which would determine that the Final Guidelines were unlawful and would enjoin the Government from applying them and from funding research involving

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92. *See* Notice OD-02-007, *supra* note 91 (illustrating the schedule for receipt and review by the HPSCRG).

93. PRESIDENT'S COUNCIL REPORT, *supra* note 29, at 28; Gretchen Vogel, *Stem Cell Review Setback*, SCIENCENOW, Apr. 16, 2001.

94. Though such an order or instruction was never officially published, and though it was not known whether Secretary Thompson or President Bush gave this order, the HHS Spokesman, Bill Hall, admitted that such instruction was in fact given and explained that "the department felt that it makes the most sense to hold off until the guideline review that the department is doing is complete." *See* Rick Weiss, *Bush Administration Order Halts Stem Cell Meeting; NIH Planned Session to Review Fund Requests*, WASH. POST, Apr. 21, 2001, at A2; Nicholas Wade, *Grants for Stem Cell Work Are Delayed*, N.Y. TIMES, Apr. 24, 2001, at F6.

95. According to federal case law "an agency decision which effectively suspends the implementation of important and duly promulgated standards . . . constitutes rulemaking subject to notice and comment requirements of 5 U.S.C. § 553." *See* Envtl. Def. Fund, Inc. v. Gorsuch, 713 F.2d 802, 816-17 (D.C. Cir. 1983); Envtl. Def. Fund, Inc. v. EPA, 716 F.2d 915, 920 (D.C. Cir. 1983) ("The suspension or delayed implementation of a final regulation normally constitutes substantive rulemaking under APA § 553. Thus . . . [it is] subject to APA notice and comment provisions.") (citations omitted); Natural Res. Def. Council, Inc. v. EPA, 683 F.2d 752, 761-63 (3d Cir. 1982) ("[The] EPA's action in indefinitely postponing the effective date of the amendments . . . was subject to the APA's rulemaking requirements."). The Bush Administration's suspension of the Final Guidelines did not meet the notice and comment requirements of the APA. Thus, the suspension of the Final Guidelines was illegal. For further discussion of why the APA's notice and comment requirements apply to the Final Guidelines despite the exemption of matters involving grants or benefits from these requirements, see *supra* note 83.

96. Nightlight Christian Adoptions v. Thompson, No. 1.01 CV 00502-RCL (D.D.C. May 4, 2001) (order staying lawsuit).

hESCs.[97] Ironically, the Bush Administration was apparently only too happy to comply with the Plaintiffs' demands. The Administration quickly yielded to them and entered into a stipulation in which the Administration took it upon itself to avoid: (1) any funding of hESC research; (2) the approval of any application thereof; and (3) the convening of the HPSCRG, at least until the completion of its own review of the Final Guidelines, which was not subject to any timetable.[98] On May 4, 2001, Judge Lamberth of the District Court cemented the agreement between the parties by entering an order to stay the proceedings subject to the terms of the parties' stipulation.[99] Thus, the Judge gave his stamp of approval to the Bush Administration's illegal suspension of the Final Guidelines[100] and effectively sealed their indefinite suspension,[101] which continues until today.

During the following months, President Bush was engaged in the reexamination of the issue of research involving hESCs. He consulted with clergymen (including the late Pope John Paul II), religious groups, ethicists (including the bioethicists Daniel Callahan and Leon Kass, whom President Bush would later appoint to be the head of his Council on Bioethics), members of Congress, patient groups, and scientists (including a group of NIH scientists who told President Bush that more than sixty-five hESC lines existed at that time).[102]

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97. Complaint for Declaratory and Injunctive Relief at 2, Nightlight Christian Adoptions v. Thompson, No. 1.01 CV 00502-RCL (D.D.C. Mar. 8, 2001).

98. Nightlight Christian Adoptions v. Thompson, No. 1.01 CV 00502-RCL (D.D.C. May 4, 2001) (order staying lawsuit).

99. *Id.*

100. *See supra* note 95.

101. *Id.*; *see also* Joseph Curl, *Judge Halts Stem Cell Research Pending HHS Review*, WASH. TIMES, May 11, 2001, at A3 (summarizing recent political and judicial efforts to curtail stem cell research). It is worth noting that shortly after the *Nightlight* decision, a group of scientists led by the creator of the first hESC lines, Dr. James Thomson, and three patients, including the late actor Christopher Reeve, filed another lawsuit in the same court asking the court to declare the Final Guidelines legal and instruct the government to apply them. *See* Complaint for Declaratory and Injunctive Relief, Thomson v. Thompson, No. 1:01-CV-00973-RCL (D.D.C. May 8, 2001)*; see also* Gretchen Vogel, *Researchers Sue to Study Stem Cells*, SCIENCENOW, May 22, 2001. On August 8, 2001, a day before President Bush's Statement, Judge Lamberth landed a final blow to the application of the Final Guidelines by staying this lawsuit "pending the decision by [the Government] whether to provide federal funding for human embryonic stem cell research." Thomson v. Thompson, No. 1:01-CV-00973-RCL (D.D.C. Aug. 8, 2001) (order staying lawsuit). Thus, Judge Lamberth's decision practically afforded the government unlimited time to review the Final Guidelines.

102. Richard Lacayo, *How Bush Got There*, TIME, Aug. 12, 2001, at 17; Allessandra Stanley, *Bush Hears Pope Condemn Research in Human Embryos*, N.Y. TIMES, July 24, 2001, at A1. Apparently, the number of hESC lines, which scientists claimed already existed at that time made a crucial impact on the formulation of President Bush's Directive. *See* Lacayo, *supra*.

At this point, with respect to the issue of federal funding for research involving hESCs, President Bush no longer made a distinction between his opinions and those of his Administration. Rather, he viewed the issue as *his own personal matter*, which was to be decided *solely and exclusively by him*. This position was well-reflected in some of President Bush's descriptions of the way he approached the issue of research involving hESCs and in the way he addressed it.[103] For example, President Bush repeatedly stressed that *he* personally, was the one considering the issue of research involving hESCs, that *he* was the one who encountered the dilemmas involved in this issue, and that *he* was taking *his* time making *his* decision.[104] President Bush's posture in this respect was well-reflected in the language he used in his Address:

> *I've* asked those questions and others of scientists, scholars, bioethicists, religious leaders, doctors, researchers, Members of Congress, my Cabinet, and my friends. *I* have read heartfelt letters from many Americans. *I* have given this issue a great deal of thought, prayer, and considerable reflection. And *I* have found widespread disagreement.
>
> . . . .
>
> *My* position on these issues is shaped by deeply held beliefs. *I'm* a strong supporter of science and technology . . . .
>
> *I* also believe human life is a sacred gift from our Creator.
>
> . . . .
>
> *I* have concluded that we should allow Federal funds to be used for research on these existing stem cell lines . . . .
>
> . . . *I* have made this decision with great care, and I pray it is the right one.[105]

And so, when President Bush finally made *his* decision with respect to the funding of research involving hESCs, he chose to deliver it directly to *his* constituents in the first televised address he made since taking office.[106]

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103. *See* Lacayo, *supra* note 102 ("For a while this year it seemed that George W. Bush buttonholed everybody he met to get his or her view on stem-cell research.").

104. President Bush said: "I take this issue very seriously . . . . It's also an issue that has got serious moral implications, and our nation must think carefully before we proceed . . . . And, therefore, my process has been, frankly, unusually deliberative for my administration. I'm taking my time." Stanley, *supra* note 102. In another place, President Bush explained his Decision by saying that "[u]nder *my* policy, existing stem cell lines, to be used in publicly supported research, must be derived (1) with the informed consent of donors, (2) from excess embryos creates solely for reproductive purposes and (3) without any financial inducements to the donors." *See* George W. Bush, *Stem Cell Science and the Preservation of Life*, N.Y. TIMES, Aug. 12, 2001, at WK13 [hereinafter *President Bush's Op-Ed Piece*] (emphasis added).

105. President Bush's Address, *supra* note 1, at 954-56 (emphasis added).

106. *Id.*

On August 9, 2001, President Bush delivered his Stem Cell Decision, which allowed only for funding of research involving hESC lines that were: (1) created prior to his Address;[107] (2) made of excess embryos created strictly for reproductive purposes; (3) where the embryos were obtained with the informed consent of the donors; and (4) without any financial inducement to the donors.[108] In addition, President Bush's Directive forbade any funding of research involving the creation of human embryos solely for research purposes and the cloning of human embryos for any purpose.[109]

A curious fact about President Bush's Directive is that, unlike most presidential executive orders and directives, it was never published in the Federal Register and was only delivered as a televised Address (along with a Fact Sheet). Failing to publish the Directive seems even stranger in light of the fact that President Bush *did* sign an executive order establishing his new Council on Bioethics, which he also announced in his Address,[110] but refrained from doing the same with respect to the crux of his Address, namely the prohibition on funding for research involving hESCs created thereafter.[111]

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107. According to the NIH, "prior to his Address" means that the hESC derivation process should have been initiated prior to 9:00 p.m. EDT on August 9, 2001. *See* NIH Update on Existing Human Embryonic Stem Cells (Aug. 27, 2001), http://stemcells.nih.gov/policy/statements/082701list.asp (last visited Dec. 2, 2007) [hereinafter NIH Update].

108. President Bush's Address, *supra* note 1.

109. The White House Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), http://whitehouse.gov/news/releases/2001/08/20010809-1.html (last visited Dec. 2, 2007) [hereinafter Fact Sheet]. It is interesting to note that in delivering his decision, President Bush refrained from directly referring to the kinds of research that may not receive federal funding, and used a rhetoric which only addressed the types of research he *would* allow his Administration to fund. The "forbidden" types of research were thus enumerated only in a "fact sheet," which was released concurrent with the Address and which strictly held that "[f]ederal funds will *only* be used for research on existing stem cell lines" and that "[n]o federal funds will be used for . . . the derivation or use of stem cell lines derived from newly destroyed embryos." *Id.* (emphasis added). The use of this language allowed President Bush's Administration and supporters to portray his Decision as actually *allowing funding* for stem cell research rather than withholding such funding. *See, e.g.*, Rick Weiss, *Promising More–and Less; Scientists See Growth in Field, Lament Limits*, WASH. POST, Aug. 10, 2001, at A1; President Council's Report, *supra* note 29, at 28; Testimony of Tommy G. Thompson, Secretary of Health and Human Services Before the Senate Health, Education, Labor and Pensions Comm. (Sept. 5, 2001), *available at* http://www.hhs.gov/news/speech/2001/010905.html ("President Bush has opened the laboratory door. Now, let's get our best and brightest scientists into the lab so they can go to work."). However, it is important to note that it was in fact the Administration's actions prior to President Bush's Address that hindered the implementation of the Final Guidelines, which would have probably allowed for such funding much sooner.

110. Exec. Order No. 13,237, 66 Fed. Reg. 59,851 (Nov. 28, 2001). The established Council, which was headed by Dr. Leon Kass and which was mostly manned by members holding a conservative viewpoint, later published its report on stem cell research, which retroactively, ethically endorsed President Bush's Directive. *See generally* PRESIDENT'S COUNCIL REPORT, *supra* note 29.

111. For further discussion of this omission and its possible reasons, see *infra* Part II.A and note 283.

Despite the fact that President Bush did not "formalize" his Directive and did not specifically instruct HHS and the NIH to follow his Stem Cell Decision, within hours of his Address, both Secretary Thompson and the Acting Director of the NIH, Ruth Kirschstein published their endorsement of President Bush's Directive,[112] and thus sealed the fate of the portion of the Final Guidelines that dealt with hESCs.[113] Two weeks after President Bush's Address, the NIH announced that it was initializing a new process to enable funding of research involving hESCs in accordance with President Bush's Directive and a prohibition on its intramural investigators (in what was apparently yet another moratorium) to conduct research on any hESCs until the new procedures were in place.[114]

On November 7, 2001, the NIH officially announced that it was accepting grant applications for research involving hESC lines that complied with President Bush's Directive[115] and the creation of hESC registry, which included all of the hESC lines that met those requirements.[116] Notably, around the time of President Bush's Address, there was some confusion and disagreement regarding the actual number of viable and available hESC lines that complied with President Bush's Directive.[117] To date, the NIH hESC registry includes sixty-seven lines, and only twenty-one are actually available for researchers who wish to apply for federal funding.[118]

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112. Kirschstein Statement, *supra* note 4; Thompson Statement, *supra* note 4.

113. Ironically, it was Ruth Kirschstein who only a year earlier, signed the publication of the Final Guidelines. For further discussion of Ruth Kischstein's actions, see *infra* Part II.C.

114. NIH Funding of Research Using Specified Existing Human Embryonic Stem Cells, NOT-OD-01-058 (Aug. 23, 2001), *available at* http://grants.nih.gov/grants/guide/notice-files/not-od-01-058.html, *superseded by* NOT-OD-01-059 (Aug. 27, 2001).

115. Notice of Extended Receipt Date and Supplemental Information Guidance for Applications Requesting Funding that Proposes Research with Human Embryonic Stem Cells, NOT-OD-02-006 (Nov. 7, 2001), *available at* http://grants.nih.gov/grants/guide/notice-files/not-od-02-006.html; Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry, *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html.

116. *See* NIH, NIH Human Embryonic Stem Cell Registry, http://stemcells.nih.gov/research/registry (last visited Dec. 2, 2007) (listing the derivations of stem cells that are eligible for federal funding).

117. While one NIH publication stated that there were sixty-four hESC lines, another mentioned seventy-eight, a third mentioned seventy-one, and so forth. *See* NIH Update, *supra* note 107 (sixty-four); Department of Health and Human Services, Fact Sheet–Embryonic Stem Cell Research (July 14, 2004), http://www.hhs.gov/news/press/2004pres/20040714b.html (seventy-eight); NIH, NIH's Role in Federal Policy–Stem Cell Research (Aug. 12, 2005), http://stemcells.nih.gov/policy/NIHFedPolicy.asp (seventy-one).

118. Yu & Thomson, *supra* note 21, at 6. The discrepancy between the number of hESC lines in the registry and the number of such lines actually available results from various reasons. According to the NIH hESC registry, some of the hESCs never became cell lines due to halted growth or failure to remain undifferentiated. One line was withdrawn by its donor, others are "unavailable for shipping," and so forth. The number of hESC lines available for research is significantly smaller than the number of such lines President Bush was led to believe were available prior to reaching his Stem Cell Decision, which was

On November 14, 2001, the NIH announced the demise of the parts of the Final Guidelines dealing with funding for research involving hESCs.[119] The only reason mentioned by the NIH for the withdrawal of the Final Guidelines was that "[t]he President has determined the criteria that allow Federal funding for research using existing embryonic stem cell lines . . . . Thus, the NIH Guidelines as they relate to human pluripotent stem cells . . . are no longer needed."[120] This last notice essentially gave the regulatory framework for research involving hESCs its final form as it exists today.

Since August 2001, Congress has tried to change the regulatory scheme of funding for research involving hESCs numerous times[121] without much success.[122] Most notably, on July 18, 2006, the Senate passed the Stem Cell Research Enhancement Act of 2005.[123] This Act was supposed to add § 498D to the Public Health Service Act (PHSA),[124] which would have instructed the Secretary of HHS to start conducting and supporting research involving hESCs so long as the hESC lines involved in the research complied with the following "ethical requirements":

> (1) The stem cells were derived from human embryos that have been donated from in vitro fertilization clinics, were created for the purposes of fertility treatment, and were in excess of the clinical need of the individuals seeking such treatment.
>
> (2) Prior to the consideration of embryo donation and through consultation with the individuals seeking fertility treatment, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded.

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actually even smaller at the time he gave his Address—only one or two in the spring of 2002! *See President Bush's Op-Ed Piece*, *supra* note 104; NIH FAQs, *supra* note 15.

119. National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 66 Fed. Reg. 57,107 (Nov. 14, 2001).

120. Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells, NOT-OD-02-007 (Nov. 7, 2001), *available at* http://grants.nih.gov/grants/guide/notice-files/not-od-02-007.html.

121. *E.g.*, Stem Cell Replenishment Act of 2005, H.R. 162, 109th Cong. (2005); Human Cloning Ban and Stem Cell Research Protection Act of 2003, S. 303, 108th Cong. (2003); Science of Stem Cell Research Act, H.R. 4011, 107th Cong. (2002); Stem Cell Research Act of 2001, H.R. 2059, 107th Cong. (2001); Stem Cell Research for Patient Benefit Act of 2001, H.R. 2747, 107th Cong. (2001) (sought to codify the Final Guidelines); New Century Health Advantage Act, H.R. 2838, 107th Cong. (2001) (sought to require the NIH to conduct human embryonic stem cell research and repeal the Dickey Amendment).

122. None of Congress's bills or acts, save two, were ever voted into law, and the only bills that were actually voted for by both Houses were vetoed by President Bush. *See infra* notes 126-31.

123. Stem Cell Research Enhancement Act of 2005, H.R. 810, 109th Cong (2006).

124. Public Health Service Act, ch. 373, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 201-300ii-4 (2000)).

> (3) The individuals seeking fertility treatment donated the embryos with written informed consent and without receiving any financial or other inducements to make the donation.[125]

The passing of the Stem Cell Research Enhancement Act by a Republican Congress[126] expressed an unequivocal congressional discontent with the current regulatory scheme for funding research involving hESCs, which is based on the policy set by President Bush's Directive. Yet eventually, on July 19, 2006, President Bush vetoed the Stem Cell Research Enhancement Act.[127] Attempts to raise the two-thirds majority in the House failed and the Act was abandoned.[128] In 2007, the newly formed Democratic majority in Congress again passed the Stem Cell Research Enhancement Act.[129] Once more, President Bush vetoed the Act[130] and there was no two-thirds majority in Congress to override the veto.[131] And so, since President Bush's Address in August 2001, and until today, the only federal funding available for research involving hESCs is for research that uses the twenty-one hESC lines that meet President Bush's Directive's criteria.

II. LEGAL ANALYSIS OF PRESIDENT BUSH'S DIRECTIVE AND HIS ADMINISTRATION'S ENSUING POLICY

Having described the regulatory framework of research involving hESCs, it is now possible to begin its legal examination. The first step in analyzing President Bush's Directive and the NIH's ensuing actions is to identify the type of presidential directive it is and the ramifications of the Directive's form, if any, on its enforceability. Once the question of form is addressed, this Article will discuss the main substantive question of whether President Bush had the legal authority to give his Directive and

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125. These requirements are almost identical to those set in President Bush's Directive except for the fact that they do not restrict federal funding to hESC lines created prior to August 9, 2001, at 9:00 p.m. In this respect, the Human Stem Cell Research Enhancement Act of 2005 would have essentially enacted the Final Guidelines into law.

126. Despite the fact that the first session of the 109th Congress was clearly Republican, the Stem Cell Research Enhancement Act of 2005 passed by a majority of 238-194 in the House of Representatives, and 63-37 in the Senate.

127. Press Release, White House, Message to the House of Representatives, 2006 WL 2007324 (July 19, 2006).

128. In a vote in the House of Representatives that same day, the supporters of the Act managed to raise a majority of 235 yeas against 193 nays.

129. On January 11, 2007, the House of Representatives passed a bill identical to the Stem Cell Research Enhancement Act of 2005. *See* Stem Cell Research Enhancement Act of 2007, H.R. 3, 110th Cong. (2007). Three months later, on April 11, 2007, the bill passed in the Senate. *See* S. 5, 110th Cong. (2007).

130. Press Release, White House, President Bush Discusses Stem Cell Veto and Executive Order, 2007 WLNR 11640195 (June 20, 2007).

131. *See* Sheryl Gay Stolberg, *Bush Vetoes Bill Removing Stem Cell Limits, Saying 'All Human Life is Sacred'*, N.Y. TIMES, June 21, 2007, at A21 ("Democrats concede they do not have enough votes for a veto override.").

require the NIH to comply, and—assuming he had such authority—whether he used it appropriately. Finally, if the answer to the previous question is in the affirmative, in order to evaluate the legality of the current regulatory scheme of funding for research involving hESCs, it is necessary to determine whether the NIH's actions implementing President Bush's Directive were in accord with the NIH's own authorities, duties, and responsibilities under the law.

A. Classification of President Bush's Directive's Form and Evaluation of Its Validity from a Procedural Standpoint

It is said that presidential directives are the "most elusive in [their] capacity to be legally analyzed and constrained."[132] There are over twenty types of such ill-defined presidential directive instruments including, but not limited to: executive orders, proclamations, presidential memoranda, and signing statements.[133] In addition, neither the Constitution nor any statute or case law defines exactly what presidential directives are, how to distinguish among their different kinds,[134] how the President may use them and to what end, what procedural requirements must be fulfilled in using them in general and each of them in particular, and what is the permissible scope of their substance.[135] The only exceptions are those presidential directives categorized as executive orders and proclamations, which are subject to the Federal Register Act[136] and to Executive Order No. 11,030.[137] Therefore, so long as their directives bear forms other than "executive

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132. PETER L. STRAUSS, TODD D. RAKOFF & CYNTHIA R. FARINA, ADMINISTRATIVE LAW: CASES AND COMMENTS 193 (10th ed. 2003).

133. *See* Harold C. Relyea, *Congressional Research Service Report for Congress: Presidential Directives: Background and Overview* (2005), *available at* http://www.fas.org/irp/crs/98-611.pdf (providing an overview of the different kinds of directives used by presidents in the twentieth century).

134. *See* Todd F. Gaziano, *The Use and Abuse of Executive Orders and Other Presidential Directives*, 5 TEX. REV. L. & POL. 267, 282, 290-91 (2001) (discussing the difficulties in discerning between different presidential directives); *see also* COMMITTEE ON GOVERNMENT OPERATIONS, 85TH CONG., EXECUTIVE ORDERS AND PROCLAMATIONS: A STUDY OF A USE OF PRESIDENTIAL POWERS 1 (1957) [hereinafter CONGRESSIONAL STUDY OF EXECUTIVE POWER] ("There is no law or even Executive order which attempts to define the terms 'Executive order' or 'proclamation.'").

135. *See* Gaziano, *supra* note 134, at 282 (emphasizing the broad discretion presidents have in using directives).

136. The Federal Register Act, ch. 417, 49 Stat. 500 (1935) (codified as amended at 44 U.S.C. §§ 1501-1511) (1964), requires that executive orders and proclamations generally be published in the Federal Register. *See* 44 U.S.C. § 1505(a).

137. Exec. Order. No. 11,030, 27 Fed. Reg. 5847 (June 21, 1962). The Order requires, among other things, that executive orders and proclamations "contain a citation of the authority under which [they are] issued" and that they be submitted to the Attorney General who must approve their substance, form, and legality. *Id.*; *see also* Gaziano, *supra* note 134, at 292-93 (discussing procedures for issuing proclamations and executive orders).

orders" or "proclamations," presidents may tailor their directives in any way they want, giving them any title they want, and using them for any means they see fit, without having consequences on the enforceability of the directives from a formal standpoint.[138]

President Bush and his Administration, probably well aware of this situation, seem to have taken advantage of it in designing President Bush's Directive so as to ensure that its form would be impervious to judicial review.[139] First, the President delivered his Address orally, on television, and it was never published in the Federal Register.[140] The accompanying Fact Sheet was never published in any formal government publication.[141] Second, neither the Address nor the Fact Sheet bears the signature of the President, and the Address does not include any specific operational instructions directed at executive officers, but is merely a vague pronouncement of moral preferences.[142] Finally, the Address and Fact Sheet carry none of the conventional titles, which could have helped to classify them under one of the known forms of presidential directives (e.g., "executive order" or "memorandum").[143] Thus, President Bush's Directive does not seem to fall squarely under any of the known types of

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138. According to Gaziano, "a new President and a creative bureaucracy could come up with twenty-four new 'types' [of presidential directives] if they wished to do so." *See* Gaziano, *supra* note 134, at 291.

139. Had the Administration chosen to issue the Directive in the more conventional form of an executive order, it would have been obliged to state its source of authority as well as to have its content approved by the Attorney General. *See supra* notes 136-37. As I will later show, the Bush Administration would have been hard pressed to do either of these things. *See infra* Part II.B. And so, it is prudent to assume that the Administration's omission to cement the Stem Cell Decision—which is one of President Bush's Administration's landmark policies—in such a duly issued executive order since August 2001 has not been the result of neglect, but rather of a deliberate effort by the Administration to avoid having to state the Directive's source of authority, which might cast its legal legitimacy in a questionable light.

140. President Bush's Address was only published in the Weekly Compilation of Presidential Documents, and in the Public Papers of the Presidents of the United States. *See* President Bush's Address, *supra* note 1; President George W. Bush, Address to the Nation on Stem Cell Research, 37 WEEKLY COMP. PRES. DOC. 1151 (Aug. 9, 2001).

141. The Fact Sheet seems to be available only through the White House Office of the Press Secretary. *See* Fact Sheet, *supra* note 109.

142. *Id.* The "operative" part of President Bush's Directive only surfaces in the accompanying Fact Sheet.

143. The title of the written version of the Address is "President Discusses Stem Cell Research," and the title of the Fact Sheet is "Fact Sheet: Embryonic Stem Cell Research." According to Gaziano, the primary method of classification of presidential directives relies almost exclusively on the title they are given. *See* Gaziano, *supra* note 134, at 288-89; *see also* CONGRESSIONAL STUDY OF EXECUTIVE POWER, *supra* note 134, at 1; Branum, *supra* note 7, at 7.

presidential directives.[144] As a result, there are no formal or procedural requirements applicable to it, so it cannot suffer from any formal or procedural flaw, which might have affected its validity or enforceability.

B. Analysis and Evaluation of President Bush's Authority to Issue His Directive and Enforce It on the NIH

Similar to the lack of regulation characterizing the formal and procedural aspects of presidential directives, there is very little law regulating the President's authority to issue such directives[145] and how one can evaluate the legality of such directives. Except for the axiomatic premise that presidential acts must be based on a legal source of authority (or else the President would actually be acting as an autocrat),[146] the most important source of guidance on these issues is found in Justice Jackson's famous and highly influential opinion in the matter of *Youngstown Sheet & Tube Co. v. Sawyer*.[147] According to Justice Jackson, when evaluating the legitimacy of presidential actions, a court should weigh the actions' sources of statutory and constitutional authority, and assess their compatibility with congressional powers and legislation.[148] Justice Jackson describes three "tiers" of authority for presidential actions.[149] In the "first tier" are presidential actions taken "pursuant to an express or implied authorization

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144. President Bush's Address does bear some resemblance to a loosely defined, somewhat obscure, class of presidential directives mentioned by Relyea, called "Presidential Announcements" and defined as "oral presidential directives . . . captured in an announcement which records what the President has prescribed or instructed." *See* Relyea, *supra* note 133, at 12. Yet, Relyea adds that Presidential Announcements "often are recorded in the *Weekly Compilation of Presidential Documents* . . . . However, they do not appear in the *Federal Register* or in the *Public Papers of the Presidents of the United States*." *Id.* President Bush's Address, while not published in the Federal Register, *was* published in the Public Papers of the Presidents of the United States, and thus falls outside the definition of this type of presidential directive.

It is interesting to note that a similar conclusion could also be drawn with respect to President Clinton's 1993 Embryo Decision, which was titled "Statement on Federal Funding of Research on Human Embryos" and was never published in the Federal Register but rather only in the *Weekly Compilation of Presidential Documents* and in the *Public Papers of the Presidents of the United States*. *See supra* note 60; *see also* President William J. Clinton, Statement on Federal Funding of Research on Human Embryos, 2 PUB. PAPERS 2142 (Dec. 2, 1994). Hence, President Clinton's Embryo Decision may also be viewed as falling outside of any of the known types of presidential directives.

145. Such authority is sometimes mentioned in particular statutes or may be construed as implied from powers constitutionally or statutorily granted to the President. *See* Gaziano, *supra* note 134, at 271-72, 276.

146. Some analogize such a president, who makes unrestricted use of executive power, to a "regulatory policy czar" or even to a king. *See* Cynthia R. Farina, *The "Chief Executive" and the Quiet Constitutional Revolution*, 49 ADMIN. L. REV. 179, 181 (1997); Branum, *supra* note 7, at 1, 33.

147. 343 U.S. 579 (1952).

148. *Id.* at 635-38 ("Presidential powers are not fixed but fluctuate, depending upon their disjunction or conjunction with those of Congress.").

149. *Id.*

of Congress," in which the President's authority "is at its maximum."[150] The "second tier" includes presidential actions taken "in absence of either a congressional grant or denial of authority."[151] Finally, the "third tier" includes presidential actions that are "incompatible with the expressed or implied will of Congress," in which the President's power "is at its lowest ebb."[152] This Article begins its examination of the validity of President Bush's Directive with a survey of the law governing the area of funding for scientific research in general and research involving hESCs in particular. Then, this Article classifies President Bush's Directive and analyzes its validity under the appropriate "tier" offered in Justice Jackson's *Youngstown* opinion (*Youngstown* Analysis).

1. The Legal Framework of Federal Funding for Scientific Research

Generally, the authority to fund biomedical research is granted to the Secretary of HHS, who acts through officers within NIH. The Public Health Service Act (PHSA) provides that "the Secretary is authorized to . . . make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for . . . research projects."[153] Section 405 of the PHSA authorizes the Secretary, acting through the Directors of the NIH's Research Institutes[154] to "encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences."[155] All funding decisions are subject to policies set by the Director of NIH, who is authorized to make such policies for the entire NIH.[156]

Several statutes expressly affect the funding of human embryo research.[157] The most important is the Dickey Amendment. According to the Amendment:

> None of the funds made available in [HHS Appropriations Acts] may be used for . . . the creation of a human embryo or embryos for research purposes . . . or . . . 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.[158]

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150. *Id.* at 635.
151. *Id.* at 637.
152. *Id.*
153. 42 U.S.C. § 241(a)(3) (2000).
154. The NIH itself is an assemblage of individual research institutes, each of which charged with a particular area of research. *See id.* § 281.
155. *Id.* § 284(b)(1)(A).
156. *Id.* § 282(b)(1).
157. For instance, the NIHRA determines that "[t]he Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes." *See id.* § 289g-1(a)(1).
158. The Balanced Budget Downpayment Act, I, Pub. L. No. 104-99, § 128(2), 110 Stat. 26 (1996).

In light of the Rabb Opinion, which found that the NIH could fund research involving already-created hESC lines because such research would not qualify as the destruction of human embryos under the Dickey Amendment, it is widely accepted that the Dickey Amendment does not prohibit the funding of research that indirectly involves the destruction of human embryos (e.g., research involving stem cell lines created from destroyed embryos).[159] When read alongside each other, the Dickey Amendment and the PHSA authorize the Directors of the NIH's Research Institutes to support and conduct research involving hESCs so long as the research does not involve the creation of hESC lines or pose substantial risk to human embryos.

Most importantly, all funding for research conducted and supported by the NIH, including research involving embryos and hESCs, is also subject to the general instruction of § 101 of the NIHRA:

> (b) Ethical review of research
>
> (1) Procedures regarding withholding of funds
>
> If research has been recommended for approval . . . the Secretary [of HHS] may not withhold funds for the research because of ethical considerations unless—
>
> (A) the Secretary convenes an advisory board in accordance with paragraph (5) to study such considerations; and
>
> (B)(i) the majority of the advisory board recommends that, because of such considerations, the Secretary withhold funds for the research; or
>
> (ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds . . . that the recommendation is arbitrary and capricious.
>
> . . .
>
> (3) Applicability
>
> The limitation established in paragraph (1) . . . shall apply without regard to whether the withholding of funds on such basis is characterized as a disapproval, a moratorium, a prohibition, or other characterization.
>
> . . .

159. *See supra* note 72 and accompanying text. Interestingly, by allowing for funding for research involving hESC lines (even if very few) President Bush's Directive seems to have accepted this premise. This position is also reflected in President Bush's op-ed piece, in which he explicitly stated that "[f]ederal funding for research on existing stem cell lines will move forward." *See President Bush's Op-Ed Piece*, *supra* note 104.

> (5) Ethics advisory boards
>
> (A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board . . .
>
> (B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of biomedical or behavioral research with respect to which the board has been convened.
>
> (ii) . . . [T]he board shall submit to the Secretary . . . a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. . .
>
> (C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The Secretary shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—
>
> (i) no fewer than 1 shall be an attorney;
>
> (ii) no fewer than 1 shall be an ethicist;
>
> (iii) no fewer than 1 shall be a practicing physician;
>
> (iv) no fewer than 1 shall be a theologian; and
>
> (v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.[160]

The basis of this section was Congress's belief that "[c]ontinued progress in health research is seriously threatened by . . . administrative actions that undermine the peer review process at NIH and block research that holds promise for millions of Americans suffering from disease."[161] Accordingly, § 101 was "intended to prohibit unilateral actions that block research approved by the merit review system"[162] by forbidding "unreasonable prohibitions . . . imposed in an arbitrary manner on exceptional and promising research that have received approval by NIH's rigorous scientific, technical, and ethical review system"[163] and to "restore the freedom of inquiry essential to the continued success of the country's biomedical research."[164]

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160. 42 U.S.C. § 289a-1(b)(1)-(5).
161. S. REP. NO. 103-2, at 13 (1993).
162. *Id.* at 15.
163. *Id.* at 13.
164. *Id.* at 15.

To achieve these goals, § 101 establishes a "default" under which such funding for scientifically meritorious research should be granted unless it is duly withheld.[165] Furthermore, while the Secretary, acting through his subordinates, has authority to support and conduct research involving hESCs that meets the restrictions of the Dickey Amendment, § 101 takes away the Secretary's authority to withhold funding from scientifically meritorious research involving hESCs because of ethical considerations without first receiving a recommendation to do so from an independent, duly-appointed Ethics Advisory Board. With this conclusion in mind, it is now possible to turn to the *Youngstown* Analysis of President Bush's Directive.

2. Classification of President Bush's Directive Under Justice Jackson's Taxonomy

The question is now: under which of the "tiers" described by Justice Jackson does President Bush's Directive fall? In order to fall under the "first tier," a presidential action should rely on express or implied statutory authority.[166] If this had been the case, we could have expected that President Bush's Address or the Fact Sheet would state the source of authority which they may have relied on,[167] yet neither of them does.[168] Therefore, we must determine whether President Bush's Directive could have relied on such an express or implied authorization in legislation.

A survey of congressional legislation reveals that no statute explicitly grants the President the authority to decide the permissible object or means of scientific research in general or for purposes of funding in particular.

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165. *Id.* at 20 ("It is the committee's intent that . . . all research proposals that are approved by the merit review system and are awarded funding, and for which there is no justifiable reason for withholding or withdrawing funding, should be funded."); *see also supra* note 48.

166. *See* Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 635 (1952) (Jackson, J., concurring) (noting that in such cases, the President's power is at its maximum).

167. According to Branum, presidential directives normally state the source of their authority (whether legal or constitutional). In the rare case that a presidential directive totally disregards the issue of its authority, courts tend to question the validity of the presidential directive. *See* Branum, *supra* note 7, at 67-68.

168. Puzzlingly, no one has ever explicitly stated the source of President Bush's authority to give his Directive and enforce it upon the NIH. The only reference I was able to find to the possible source of President Bush's authority to give his Directive was by O. Carter Snead, the General Counsel of President Bush's own Council on Bioethics. In an article dedicated entirely to President Bush's Stem Cell Decision, Snead briefly mentioned that "the Bush policy demonstrates . . . a robust exercise of the *President's authority as head of the executive branch* to allocate the appropriated funding according to the Administration's priorities" (emphasis added). *See* Snead, *supra* note 73, at 498. Hence, according to Snead, the President's source of authority to give his Directive was simply his being the "head of the Executive Branch." As will be explained later in this section, this laconic explanation insinuates an "inherent" or "aggregate" constitutional presidential authority based on Article II of the Constitution. *See infra* Part II.B.3.

Hence, the question becomes whether President Bush's Directive relied on implied statutory authority.

Examining the statutes that regulate HHS and NIH funding of scientific research[169] reaffirms that the legislative language, on its face, does not lend itself to a construction implying that the President has the authority to intervene in the regulation of the funding for any type of scientific research, either inside or outside the context of research involving hESCs. Nevertheless, some scholars argue that there is more to the concept of implied presidential statutory authority.

The issue of implied presidential statutory authority is part of a lively debate regarding the measure of the President's control over the way executive officers carry out their statutorily-granted discretionary authorities and the President's power to affect the policies and decisions they make. This dispute is part of the longstanding and hotly debated controversy over the "unitary executive."[170] In this particular context, the debate revolves around the existence of a presidential takeover power—whether the President has the power to set policies and make decisions for executive agencies by "taking over" the duties bestowed upon them in legislation.[171] One of the most prominent proponents of this "presidential takeover power" stemming from an implied presidential statutory authority is Dean Elana Kagan. According to Dean Kagan, the President has (and should have) the power to direct executive agencies by setting their policies and making decisions for them.[172] Yet, unlike most proponents of the "unitary executive" theory, Dean Kagan does not find the source of the President's authority to take over the powers granted to agencies in the Constitution; rather, she reads legislation in a way that includes an implied presidential authority to take control of almost all of the legislative powers granted by Congress to particular agencies and executive officers.[173] Dean Kagan asserts that where a statute does not *explicitly exclude* the President

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169. *See generally* 42 U.S.C. §§ 201-300ii-4 (2000).

170. For opposing views on the issue of the "unitary executive" and presidential powers to exert control over administrative agencies, see generally Yoo et al., *supra* note 7; Martin S. Flaherty, *The Most Dangerous Branch*, 105 YALE L.J. 1725 (1996). *See also* Elana Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2272-81 (2001). This dispute will be further discussed later in this section. *See infra* Part II.B.3.

171. For further discussion of this issue, see *infra* Part II.B.3.a.

172. *See* Kagan, *supra* note 170, at 2320, 2326-28 (noting that the President does not have authority to direct officials from independent agencies without the express grant of Congress).

173. *Id.* Kagan bases this construction of legislation on public policy reasons rather than on an historical reading of the Constitution. *See id.* at 2331-46.

from having the power to *possess* the discretionary authorities it grants to executive agencies, the statute should be construed to imply that the President has the power to use such authorities as his own.[174]

Under Kagan's Doctrine, President Bush had the power to take over all of the authorities granted to the HHS and the NIH with respect to the funding of scientific research, including hESC research. Thus, to the extent that the HHS and the NIH had the authority to make a policy decision prohibiting the allocation of funding to research involving hESCs created after August 9, 2001, Kagan's Doctrine would assert that President Bush had the same authority and could have relied on this power in issuing his Directive.

However, even if we accept Dean Kagan's argument—which some scholars vehemently do not[175]—President Bush's Directive could not have relied on this supposed implied statutory authority because NIHRA § 101 explicitly prevents HHS and the NIH from withholding funding for scientific research on ethical grounds without the prior recommendation of a duly appointed EAB.[176] Even if we espouse Kagan's Doctrine and presume that President Bush had all of the powers Congress granted to HHS and the NIH, he could still not have had a power that Congress did not grant to these agencies. In other words, since HHS and the NIH lack the authority to make decisions regarding the funding of scientific research based on ethical grounds without the prior approval of an EAB, so does President Bush.

We can surmise that President Bush's Directive could not have relied on an express or implied statutory authority, and thus does not fall within the boundaries of the "first tier" described in *Youngstown*. In addition, in light of the legislation regulating the funding of biomedical research[177]—which indicates that Congress did not leave this area "an open field" for presidential action—we can determine that President Bush's Directive does

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174. *Id.* at 2251. It is important to note that to date there seems to be no court decision implementing or even mentioning Dean Kagan's unitary executive theory (Kagan's Doctrine) or anything similar in analyzing presidential powers.

175. Some of the most convincing arguments against Kagan's Doctrine's basis and rationales are made by Kevin Stack. *See* Kevin M. Stack, *The President's Statutory Powers to Administer the Laws*, 106 COLUM. L. REV. 263 (2006). One of Stack's main arguments is that, contrary to Dean Kagan's assertions, Congress's practice of granting, in a handful of cases, legislative authorities to the President in name indicates that when Congress intends to grant the President legislative powers it does so explicitly and hence that her inference that wherever Congress did not do so indicates the existence of presidential powers goes not only against interpretation principles but also against common sense. *See id.* at 268, 276-99. Stack makes a compelling case against Kagan's Doctrine. His arguments and examples put the thesis promoted by Dean Kagan in a new light and substantially undermine the statutory construction that lies at the base of Kagan's Doctrine.

176. *See* 42 U.S.C. § 289a-1(b) (2000); *see also supra* Part II.B.1.

177. *See supra* Part II.B.1.

not fall under Justice Jackson's "second tier," which applies to presidential acts in the absence of a congressional grant or denial of authority.[178]

Subsequently, and taking into consideration the language of NIHRA § 101—a language which explicitly seeks to *remove* from executive officers the power to make bioethical decisions with respect to the funding of research and requires them to have the bioethical issues properly deliberated in a highly visible public forum beforehand—President Bush's Directive seems to fall neatly under the definition of the "third tier" described in *Youngstown*. In giving his Directive, President Bush did exactly what Congress expressly sought to prohibit: in his capacity as the highest executive officer in the federal government, he made a decision to withhold funding for biomedical research involving hESCs. He did so based on his own moral and ethical beliefs, and without first receiving a recommendation to do so from an independent EAB, thus rendering his actions incompatible with § 101. Having reached this conclusion, this Article will now proceed to analyze the validity of President Bush's Directive under the premises of the "third tier."

3. Analysis of the Validity of President Bush's Directive as Presidential Action Incompatible with the Expressed Will of Congress

According to Justice Jackson:

> When the President takes measures incompatible with the expressed or implied will of Congress, his power is at its lowest ebb, for then he can rely only upon his own constitutional powers minus any constitutional powers of Congress over the matter. Courts can sustain exclusive Presidential control in such a case only by disabling the Congress from acting upon the subject. Presidential claim to a power at once so conclusive and preclusive must be scrutinized with caution, for what is at stake is the equilibrium established by our constitutional system.[179]

Following this "roadmap" for judicial review of presidential actions, we will assess the validity of President Bush's Directive by weighing the possible constitutional powers, which may have granted him the authority to give his Directive despite NIHRA § 101.

Lacking express constitutional language granting the President the authority to decide on matters involving scientific research and its funding, President Bush's Directive's only other possible source of authority is

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178. *See* Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 637, 639 (1952) (Jackson, J., concurring) (explaining that "in absence of either a congressional grant or denial of [presidential] authority," Congress and the President have concurrent authority, which requires a more flexible examination than under either the "first tier" or the "third tier").

179. *Id.* at 637-38.

inherent presidential authority under the "Vesting Clause."[180] In order to determine whether such inherent authority could have empowered President Bush to give his Directive, we need to answer the following two questions: (1) what is the measure of direction Presidents may exert over executive agencies and does the presidential power to direct executive agencies, which presumably stems from the President's inherent authority, include the authority to set policies for agencies as President Bush did in his Directive; and (2) could inherent authority have empowered President Bush to "override" and act in variance with NIHRA § 101.

a. Inherent Presidential Authority and Its Applicability to President Bush's Directive

"Inherent" or "aggregate" authority, as it has been referred to, is a somewhat controversial source of presidential constitutional power. The central proposition of the claim of inherent presidential constitutional authority is that under the auspices of the Vesting Clause,[181] the President, as Chief Executive, is endowed with the power to direct the actions of executive agencies.

The controversy surrounding the existence of an inherent authority derives not only from its origin and undefined scope,[182] but mostly from the fact that the Supreme Court has never explicitly acknowledged the existence of such authority.[183] This may be attributed, at least in part, to the

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180. U.S. CONST. art. II, § 1, cl. 1 ("The executive Power shall be vested in a President of the United States of America.").

181. *Id.*

182. *See* PHILLIP J. COOPER, BY ORDER OF THE PRESIDENT: THE USE AND ABUSE OF EXECUTIVE DIRECT ACTION, 4-5 (2002) (discussing the origins of "inherent authority"). Similar and even stricter words may be found in Justice Jackson's concurring opinion in *Youngstown*:

> Loose and irresponsible use of adjectives colors all non-legal and much legal discussion of presidential powers. "Inherent" powers, "implied" powers, "incidental" powers, "plenary" powers, "war" powers and "emergency" powers are used, often interchangeably and without fixed or ascertainable meanings.
>
> The vagueness and generality of the clauses that set forth presidential powers afford a plausible basis for pressures within and without an administration for presidential action beyond that supported by those whose responsibility it is to defend his actions in court. . . . While it is not surprising that counsel should grasp support from such unadjudicated claims of power, a judge cannot accept self-serving press statements of the attorney for one of the interested parties as authority in answering a constitutional question . . . . But prudence has counseled that actual reliance on such nebulous claims stop short of provoking a judicial test.

See Youngstown, 343 U.S. at 646-47 (Jackson, J., concurring).

183. The Supreme Court has referred to the concept of inherent presidential authority on numerous occasions, but the author is unaware of any case in which the Supreme Court has ever actually acknowledged the existence of an inherent authority in the President as a source of presidential power in a matter before the court. *See, e.g.*, Hamdi v. Rumsfeld, 542 U.S. 507, 516-17 (2004); *id.* at 552 (Souter J., concurring in part, dissenting in part, and concurring in the judgment); Loving v. United States, 517 U.S. 748, 773 (1996); *see also* Branum, *supra* note 7, at 68; George v. Ishimaru, 849 F. Supp. 68, 71-73 (D.D.C. 1994)

fact that the language of inherent authority only surfaces when it is clear that the President does not have any other identifiable source of authority from which his acts may draw legitimacy.[184]

Nonetheless, in light of the frequent invocation of inherent authority arguments by the Government—especially by the Clinton and Bush Administrations[185]—and for the sake of completeness of the analysis of President Bush's Directive, this Article assumes that inherent authority is as valid a source of presidential power as these Administrations have held it out to be. Thus, this part of the analysis assumes that, hypothetically, President Bush could have established his Directive on his Article II power to direct administrative agencies' actions and policies.[186]

("This court rejects the argument that the President has 'inherent' appointment authority under the Take Care Clause of Article II of the Constitution to appoint persons to positions like this one. . . . No court has ever recognized that the President has such inherent authority. . . . The important work of the Commission on Civil Rights should not be impeded by continuing to argue about "inherent" Presidential power which no court in the nation's history has ever recognized.").

184. Henry Monaghan captured the essence of this phenomenon:

> [W]hen . . . no readily identifiable legislative warrant exists, and arguably the President is implementing presidential policy alone, a different constitutional vocabulary surfaces. The Vesting Clause, the Take Care Clause, the Presidential Oath to 'preserve, protect and defend the constitution of the United States,' and the Presidents 'inherent,' . . . or 'aggregate' powers are all invoked in defense of the President's conduct . . . . Each of these terms is simply a different formulation of the fundamental claim that the President's conduct is valid even though no statutory authority exists.

See Henry P. Monaghan, *The Protective Power of the Presidency*, 93 COLUM. L. REV. 1, 14 (1993).

185. *See, e.g.*, Doolin Sec. Sav. Bank, F.S.B. v. Office of Thrift Supervision, 139 F.3d 203, 211 n.6 (D.C. Cir. 1998) (rejecting an inherent power argument made by the Clinton Administration); *Ishimaru*, 849 F. Supp. at 71-72 (rejecting the argument that the President has "inherent" appointment authority under Article II of the Constitution); *Hamdi*, 542 U.S. at 516-17 (avoiding the issue of inherent presidential authority by finding that Congress authorized the President to order the plaintiff's detention); ACLU v. NSA, 438 F. Supp. 2d 754, 780-81 (E.D. Mich. 2006) (holding that the President, as Commander in Chief, did not have inherent power to authorize the NSA to intercept international telephone and internet communications without a warrant)*; see also* Yoo et al., *supra* note 7, at 729-30 ("Support for the unitariness of the executive branch does not necessarily require supporting the broad claims of inherent executive authority advanced by the Bush Administration."); Kagan, *supra* note 170, at 2320-21 (addressing "President Clinton's repeated invocation of a vaguely defined 'executive authority' to direct administrative officials to adopt certain presidential policies"); Gaziano, *supra* note 134, at 281 ("Some of President Clinton's claims of implied and inherent authority were outrageous.").

186. Despite my approach to the concept of "inherent authority" in this part of the Article, it is my opinion that "inherent authority" is a superfluous and sometimes even dangerous concept that the courts must not allow to exist as a valid source of presidential authority. In most cases in which the government raises "inherent authority" arguments, the use of this concept is misleading and mistaken and the government actually means to argue that the authority for the presidential action was implied from one of the President's express constitutional powers. (This type of mistake often occurs with relation to the President's powers under the "Commander in Chief" Clause.) Yet, in other cases, as described by Monaghan, the government has been invoking "inherent authority" to bolster arguments that the President had the power to take certain actions unsanctioned by any other express or implied constitutional or statutory authority. *See* Monaghan, *supra* note 184, at 24-32

However, President Bush's Directive did much more than merely provide direction to the NIH with respect to the funding of research involving hESCs: it set its policies for it. Can the President do that? Does the scope of the President's inherent authority include the ability to set policies for executive agencies? As mentioned above, a lively dispute persists with respect to the extent of control the President may exert over administrative agencies' actions and the measure of his ability to direct their policies.

i. The Unitary Executive Debate over the Presidential Power to Direct Executive Agencies

Three schools of thought predominate the debate surrounding the President's power to control discretionary authorities granted to executive officers. The first school, which I will refer to as Constitutional Unitarianism, envisions the President as somewhat of a "super-executive" who may, under the Constitution, "take over" almost any responsibility assigned to any inferior officer,[187] including policymaking authorities, and act in their stead in his own capacity as President or, alternatively, nullify the actions of which he does not approve.[188] According to this school of thought, the "presidential takeover power" exists even when the authorizing statute explicitly grants a discretionary executive power to a particular officer.[189]

The main rationale of Constitutional Unitarianism is that the Vesting Clause grants "executive power" solely and exclusively to the President, who is the source of the executive power in the Government and who merely delegates it to entities and officers that Congress has charged with tasks, whereas these entities and officers are otherwise powerless to act

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(critiquing this approach). I believe that accepting the government's inherent authority arguments in such cases may be dangerous since it would ratify the existence of presidential powers beyond those granted to the President by the Constitution or in legislation and thus beyond the checks and balances set forth in our constitutional scheme and the framework of the Separation of Powers Doctrine. This type of authority resembles the kind of power that an autocrat would have, not a President of a democracy. *See* Branum, *supra* note 7, at 33.

187. The exception to this is quasi-judicial administrative functions, namely when an agency is required to make decisions which affect specific individuals in specific cases. *See* Myers v. United States, 272 U.S. 52, 135 (1926) (explaining that the President has no power to influence or control executive officers when they are acting in a quasi-judicial manner); Portland Audubon Soc'y v. Endangered Species Comm., 984 F.2d 1534, 1546-48 (9th Cir. 1993) (acknowledging that "when an agency performs a quasi-judicial . . . function its independence must be protected" and that "[t]here is no presidential prerogative to influence quasi-judicial administrative agency proceeding").

188. *See* Yoo et al., *supra* note 7, at 607.

189. *See* Steven G. Calabresi & Saikrishna B. Prakash, *The President's Power to Execute the Laws*, 104 YALE L.J. 541, 595 (1994) ("Because the President alone has the constitutional power to execute federal law, it would seem to follow that, notwithstanding the text of any given statute, the President must be able to execute that statute.").

unless and until such presidential delegation takes place.[190] Therefore, according to Constitutional Unitarians, Congress simply cannot grant executive power to any entity that is beyond the reach of the President,[191] who is vested with the residual power to do, essentially, "whatever remains to be done after the formal Article I lawmaking process is concluded."[192] Accordingly, under Constitutional Unitarianism, executive agencies are merely a means to "assist" the President in carrying out the duties of the Chief Executive.[193] Thus, under the Constitutional Unitarian theory, because President Bush himself was the source of the NIH's authorities, he had the authority to make funding decisions and set funding policies for the NIH, as he did in his Directive, as well as to nullify the NIH's previously promulgated Final Guidelines, which he did not approve of and which did not align with his Stem Cell Decision.

The second school of thought, which I will refer to as Non-Constitutional Unitarianism, believes, like Constitutional Unitarians, that the President has takeover powers as well as the power to nullify executive policies and actions. However, unlike Constitutional Unitarians who rely on originalist-historical arguments, Non-Constitutional Unitarians argue that the President ought to have such Powers as a matter of public policy and desirable constitutional interpretation.[194] For the purposes of the analysis of President Bush's Directive, the Non-Constitutional Unitarian view is identical to that of the Constitutional Unitarian theory in the sense that it too would perceive President Bush's Directive as properly relying on a presidential authority to set and nullify policies for executive agencies.

Finally, the third school of thought, which I will call Moderate Unitarianism, consists of those who believe that the President's authorities to direct executive agencies do not and must not entail the power to set policies and make decisions for agencies and in their stead but merely allow the President to "stir them in the right direction" through various means.[195] Unlike the two previous schools of thought, Moderate Unitarians

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190. *See id.* at 593 ("[T]he Executive Power Clause grants 'the executive Power' solely and exclusively to the President. . . . Until and unless the President delegates 'the executive Power' to . . . entities or officers, they are constitutionally disempowered from acting.").

191. *Id.*

192. Farina, *supra* note 146, at 181 (emphasis omitted) (criticizing the Constitutional Unitarian approach).

193. Constitutional Unitarians believe that although the President is the one who has the executive power, the President obviously cannot fulfill all the tasks imposed by Congress upon executive agencies alone and thus enlists the assistance of executive officers. *See* Calabresi & Prakash, *supra* note 189, at 593-94, 597-98.

194. *See* Kagan, *supra* note 170; *see also* Lawrence Lessig & Cass R. Sunstein, *The President and the Administration*, 94 COLUM. L. REV. 1 (1994) (basing their support of a unitary executive on constitutional interpretation).

195. *See* Farina, *supra* note 146 (condemning what she referred to as "the cult of the Chief Executive"); Peter L. Strauss, *Presidential Rulemaking*, 72 CHI.-KENT L. REV. 965, 968 (1997) [hereinafter Strauss, *Presidential Rulemaking*] (arguing that President Clinton's

perceive the President as more of a "manager" and view presidential power over executive agencies as stopping short of the ability to dictate policies for and instruct such agencies on how they should use their discretionary powers.[196] Under the Moderate Unitarian approach, agencies "have relationships with the President in which he is neither dominant nor powerless."[197] Moderate Unitarians therefore contend that in matters involving substantive decisions, executive officers are required to resist attempts by the President to impose his opinions upon them.[198] In a nutshell: supervision and direction are acceptable and even welcome, but substitution is not.

The Moderate Unitarian contention most relevant to this Article is that in setting policies for agencies, the President undermines the Separation of Powers Doctrine by partaking in the agencies' rulemaking function, thereby overstepping into the "quasi-legislative" dimension of agencies.[199]

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practice of "owning" administrative actions "insufficiently respects the tension inherent in the Constitution between Congress's power . . . and the fact of a single chief executive"); Peter L. Strauss, *The Place of Agencies in Government: Separation of Powers and the Fourth Branch*, 84 COLUM. L. REV. 573 (1984) [hereinafter Strauss, *Separation of Powers and the Fourth Branch*] (proposing a framework for analysis of the relationship between the President and agencies that balances the need for presidential oversight of the agencies with congressional authority and role in government); *see also* Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 25 (1995) (claiming that the President cannot make decisions for executive agencies if Congress previously allocated authority to the agencies). Moderate Unitarianism acknowledges that the President has (and should have) various means of influencing agencies, like the constitutional power to remove executive officers and appoint others in their stead (with the limited exception of independent commissions created by Congress) as well as numerous 'procedural' authorities over agencies including the authority to provide information to agencies so as to promote coordination in matters touching upon national policies, the authority to require agencies' response on policy concerns relevant to them, or even the authority to direct agencies to further consider certain perspectives on a certain policy issue. *See* Strauss, *Separation of Powers and the Fourth Branch*, *supra*, at 649-50. *See generally* Peter L. Strauss & Cass R. Sunstein, *The Role of the President and OMB in Informal Rulemaking*, 38 ADMIN. L. REV. 181 (1986).

196. For a discussion of policy issues as they relate to Constitutional and Non-Constitutional Unitarianism as opposed to Moderate Unitarianism, see generally Thomas O. McGarity, *Presidential Control of Regulatory Agency Decisionmaking*, 36 AM. U. L. REV. 443, 445-63 (1987).

197. Strauss, *Separation of Powers and the Fourth Branch*, *supra* note 195, at 583; *see also* Strauss, *Presidential Rulemaking*, *supra* note 195, at 981-84 (arguing that the President may inquire into the duties delegated to agencies as long as he understands that the final decisions regarding the duties belong to the agency).

198. *See* Strauss, *Presidential Rulemaking*, *supra* note 195, at 973 ("That means that it is [an executive officer's] right, and in some cases it may be his obligation, to refuse the President's direction, even if he realizes that his disappointed boss may immediately send him out of office.").

199. *See id.* at 967-68 (finding that the President's practice insufficiently respects the tension between Congress's power and his own office, namely "between the legal and the political"); *see also* Kagan, *supra* note 170, at 2320 ("Congress indeed has delegated discretionary power, but only to specified executive branch officials; by assuming responsibility for this power, the President thus exceeds the appropriate bounds of his office.").

In addition, Moderate Unitarians contend that the Executive Office of the President lacks the resources necessary for making decisions, which require expertise and are therefore better left to executive agencies and officers.[200] Thus, under the Moderate Unitarian theory, President Bush was prohibited from setting policies regarding the funding of research involving hESCs for the NIH, could not have simply nullified the Final Guidelines' part regulating such research, and did not have the power to give a presidential directive to that effect.

ii. The Unitary Executive Debate in Court—Which School of Thought Prevails?

Courts seem to have never directly endorsed any of the above schools of thought.[201] Yet, in numerous cases involving issues pertaining to the "unitary executive" debate, the Supreme Court rejected the Constitutional Unitarian positions and leaned more toward the theory of Moderate Unitarianism. The most obvious example of this judicial inclination is the pair of presidential removal-power cases, *Myers v. United States*[202] and *Humphrey's Executor v. United States.*[203] In both cases, the issue was the extent of the President's authority to remove executive officers, and in both cases, the Government, taking the Constitutional Unitarian stance, argued that the President had constitutional authority to remove any executive officer at will. In *Myers,* the Supreme Court found that the President has an almost unlimited removal power stemming from the Article II vested executive powers.[204] But only nine years later, the Supreme Court in *Humphrey's Executor* ruled that Congress may restrict the President's

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200. *See* Farina, *supra* note 146, at 185 ("[I]t is unrealistic to think that the President can supervise the entire regulatory enterprise in any comprehensive and meaningful way."). Allowing presidential involvement in such decisions would obviously increase the political component in these decisions at the expense of the expertise component. The Moderate Unitarian stance is that in this politics/expertise tradeoff, we must not allow "politics" to completely take over "expertise," which plays a vital role in many executive decisions.

201. *See* Kagan, *supra* note 170, at 2250, 2271, 2322 (asserting that "the courts never have recognized the legal power of the President to direct even removable officials as to the exercise of their delegated authority"); *see also* Stack, *supra* note 175, at 270 (mentioning that although the question of whether the President has directive authority when a statute grants power to an executive officer was already prevalent during the nineteenth century, it "has never been squarely addressed by the Supreme Court").

202. 272 U.S. 52 (1926).

203. 295 U.S. 602 (1935).

204. *Myers,* 272 U.S. at 134-35. In *Myers*, the Supreme Court decided the constitutionality of a statute providing that certain postmasters could only be removed with the approval of the Senate. The Court ruled that the statute was unconstitutional due to its infringement upon the principle of separation of powers and thus upheld the President's removal of a postmaster without the approval of the Senate. However, it is important to note that the *Myers* Court acknowledged, though in dictum, that Congress may be able to limit the President's ability to direct executive officials. *Id.* at 135.

removal power, thus practically rejecting the Constitutional Unitarian contention that Article II, § 1 grants the President an almost unlimited power to run the executive branch as the President sees fit.[205]

Another example of the Supreme Court's rejection of the Constitutional Unitarian position is the seminal case of *Morrison v. Olson.*[206] In *Morrison,* the Supreme Court was once again called on to decide the constitutionality of a statute, namely the Ethics in Government Act, which insulated the position of Special Prosecutor from the influence and control of the President. The Supreme Court held that the Act was constitutional and that the Attorney General, as the President's representative, lacked the power to remove the Special Prosecutor at will (i.e. without "good cause") or control the way in which the Special Prosecutor carried out those duties. By doing so, the Supreme Court once again acknowledged Congress's ability to insulate certain executive officers and functions from the control of the President, and basically declined to accept the Constitutional Unitarian argument regarding the exclusivity and scope of the President's reign over all that is executive.[207]

These cases may suggest the existence of a "judicial trend" in the Supreme Court towards Moderate Unitarianism in general.[208] Notably, these cases lie at the base of the conventional scholarly view, which also seems to follow the Moderate Unitarian approach: that the President lacks the authority to set policies and make decisions for executive agencies and in their stead.[209] However, it appears that a "judicial trend" and a scholarly

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205. *Humphrey's Ex'r*, 295 U.S. at 629-32. The issue in *Humphrey's Executor* was similar to that in *Myers*. Once again the President sought to remove an executive officer, only this time the officer was a Federal Trade Commissioner and the Supreme Court had to decide whether Congress could limit the President's powers of removal as it did with respect to FTC Commissioners. The Supreme Court ruled that Congress's law "insulating" the FTC Commissioners from the removal powers of the President was constitutional. However, the Court distinguished this case from *Myers* by holding again that actual participation of Congress in the removal process would be unconstitutional.

206. 487 U.S. 654 (1988).

207. *See id.* at 693-96 ("It is undeniable that the Act reduces the amount of control or supervision that the Attorney General and, through him, the President exercises over . . . investigation and prosecution . . . . The Attorney General . . . does not determine the counsel's jurisdiction; and his power to remove a counsel is limited.").

208. A much earlier indication of this "trend" (and possibly one of its precursors) is dictum in the Supreme Court's decision in *Kendall v. United States*, which seems to advocate the Moderate Unitarian approach with respect to presidential takeover powers. 37 U.S. 524, 610 (1838).

209. *See* Kagan, *supra* note 170, at 2320, 2324. As Dean Kagan observed:

> The conventional view in administrative law, in apparent accord with [*Myers* and *Humphrey's Executor*], holds that the President lacks the power to direct an agency official to take designated actions within the sphere of that official's delegated discretion. The President has no authority to act as the decisionmaker, either by resolving disputes in the OMB process or by issuing substantive directives. This is because Congress, under the removal precedents, can insulate administrative policymaking from the President, and Congress has exercised this power by

convention are not authoritative enough to provide us with an unequivocal determination regarding the President's power to set policies for executive agencies. Furthermore, any attempt to predict whether this Moderate Unitarian inclination of the Supreme Court—which appears to have existed when *Morrison* was decided about twenty years ago[210]—will persist (especially in the realigned Roberts Court), should be taken with a grain of salt. Therefore, it appears that we remain without any conclusive answer regarding the existence of presidential takeover powers in general and their applicability to President Bush's Directive in particular.

Nonetheless, as before, for the sake of completeness of the analysis, this Article will make the assumption that setting a policy for the NIH was within the boundaries of President Bush's constitutional inherent authority. This is not to say that in the particular case of President Bush's Directive, he properly used this inherent authority or that he may set funding policies for the NIH as he did, but merely that in principle, it is assumed that he could have found the power to do so with the inherent authority arguably vested in him. Thus, it is now necessary to determine whether President Bush's presumable inherent authority (to set policies for the NIH) gave him the power to override NIHRA § 101.

b. Inherent Authority as a Power to Override NIHRA § 101

This Article will now return to the "third tier" framework laid out in *Youngstown* and use it to evaluate the validity of President Bush's actions. At the heart of this part of the discussion lies the question of whether President Bush's supposed inherent authority to set policies for the NIH enabled him to give his Directive in spite of the NIHRA's instruction that a recommendation from a duly-established EAB precede an administrative decision to withhold federal funding from scientific research on ethical grounds.

A longstanding Supreme Court rule prohibits the President from acting in variance with a clear and valid statutory instruction,[211] even in a state of

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delegating the relevant discretion to a specified agency official, rather than to the President.

Id. at 2323, 2325; *see also* Pildes & Sunstein, *supra* note 195, at 24 ("What we might call the conventional view relies on the following three points[:] . . . (c) the President has no authority to make the decision himself, at least if Congress has conferred the relevant authority on an agency head.").

210. *See supra* notes 206-07 and accompanying text.

211. *See* Little v. Barreme, 6 U.S. (2 Cranch) 170, 177-78 (1804) (holding that the congressional statute was clear and that the President had no power to expand its scope); *see also* CONGRESSIONAL STUDY OF EXECUTIVE POWER, *supra* note 134, at 10; Pildes & Sunstein, *supra* note 195, at 24-25 ("[N]either the President nor the agency head may violate the law, and to that extent both must follow the substantive statutory standard, whatever their policy views may be.").

emergency.[212] Yet, in light of the fact that the presidential act in the matter before us claims reliance on an inherent constitutional power, the issue at hand is somewhat more intricate than that which came before the Court in *Little v. Barreme*, which set this precedent.

Using "third tier" terminology, we can say that in his Directive, President Bush "took a measure" that was clearly "incompatible with the expressed will of Congress," as manifested in NIHRA § 101. Hence, President Bush's power was "at its lowest ebb," and he could only have relied on his Constitutional powers, which presumably consisted of the President's inherent authority to direct executive agencies. Following Justice Jackson's scheme, we should determine whether this presidential power supersedes Congress's constitutional legislative power under Article I, §§ 1 and 18 to legislate the NIHRA. According to *Youngstown*, presidential measures incompatible with the will of Congress would only be upheld by the courts where the President can claim an *exclusive* power to act and where such claim has been "scrutinized with caution" by the court. In other words, courts would only uphold presidential acts that go against clear statutory instructions in cases where it is clear that the Constitution empowers the President to act exclusively and Congress has no business interfering.[213] But is funding for scientific research in general, or for research involving hESCs in particular, an area that the Constitution designates as exclusively within the realm of the President's powers? The answer appears to be in the negative and so the conclusion of this *Youngstown* Analysis is that President Bush's Directive could not have overridden the NIHRA, even if it did rely on an inherent presidential authority to set funding policies for the NIH.

Still, as convincing and widely quoted as Justice Jackson's *Youngstown* opinion may be, it is only dicta, and is therefore not instructive, but rather suggestive, and so are the conclusions it yields. Nevertheless, several court decisions dealing with presidential acts that violated congressional statutes bolster our conclusion that President Bush's Directive could not have overridden the NIHRA. These decisions indicate that Justice Jackson's opinion in *Youngstown* is a true reflection of the law, of the way courts perceive presidential acts that transgress congressional legislation, and of the very narrow latitude they are willing to afford to such acts.

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212. *See* Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579 (1952) (rejecting the argument that the President's "inherent power" to take action in a state of emergency legitimized the seizure of the steel mills); *see also* Monaghan, *supra* note 184, at 24-32 ("Whether or not any president can live with it, the literary theory of 'The executive Power' recognizes no presidential license to disregard otherwise concededly applicable legislation, even in an emergency.").

213. Examples of such cases may include the President's powers to set foreign policies (not including the signing of treaties) and to act as Commander in Chief.

The first example is, appropriately, the *Youngstown* Court's own majority opinion, which examined the validity of an executive order that facilitated the governmental seizure of privately owned steel mills.[214] Indeed, the presidential directive in *Youngstown*, which, according to the Government, relied on the President's inherent authority,[215] did not directly violate any particular congressional statute. However, as the Court acknowledged, the executive order not only failed to comply with statutory requirements for governmental seizures,[216] but also strove to settle a labor dispute by using seizure—a method Congress had previously refused to adopt.[217] Hence, the presidential directive in *Youngstown*, which the court refused to uphold, was really an attempt by the President to circumvent Congress's will by ignoring the law in much the same way President Bush's Directive simply ignored NIHRA § 101 requirements and the congressional will behind it.

Furthermore, in analyzing the Government's claim of inherent constitutional authority to issue the executive order, the *Youngstown* Court ruled that:

> In the framework of our Constitution, the President's power to see that the laws are faithfully executed refutes the idea that he is to be a lawmaker . . . . The President's order does not direct that a congressional policy be executed in a manner prescribed by Congress—it directs that a presidential policy be executed in a manner prescribed by the President.[218]

Accordingly, the *Youngstown* Court upheld the District Court's injunction against the President's executive order.

This case demonstrates the Supreme Court's reluctance to uphold an executive order, which implemented a presidential policy that both contravened and was at the expense of congressional policy properly set in legislation.[219] Although the majority's opinion in *Youngstown* apparently

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214. *See Youngstown,* 343 U.S. at 582-83.

215. *See id.* at 582-84 (noting that the Government asserted that "a strike disrupting steel production for even a brief period would so endanger the well-being and safety of the Nation that the President had 'inherent power' to do what he had done").

216. *See id.* at 585-86 ("There are two statutes which do authorize the President to take both personal and real property under certain conditions. However, the Government admits that these conditions were not met and that the President's order was not rooted in either of the statutes.").

217. *See id.* at 586 ("Moreover, the use of the seizure technique to solve labor disputes in order to prevent work stoppages was not only unauthorized by any congressional enactment; prior to this controversy, Congress had refused to adopt that method of settling labor disputes.").

218. *Id.* at 587-88.

219. *See id.* at 588 ("The power of Congress to adopt such public policies as those proclaimed by the order is beyond question."). As explained above, the congressional policy took shape in two forms: one, in two statutes regulating governmental taking of property, and two, in refusal to allow for taking as means of settling labor disputes.

would have perceived the presidential action there as falling within the boundaries of the "second tier," it nonetheless reflects the general sentiment expressed in Justice Jackson's opinion with respect to presidential actions that circumvent legislation.

Another testament to the validity of the insights encapsulated in Justice Jackson's opinion and to their applicability to President Bush's Directive may be found in two cases—*State Highway Commission of Missouri v. Volpe*[220] and *Train v. City of New York*[221]—both of which deal with the President's power to set money spending policies where such policies go against positive statutory instruction to spend certain sums. Though these cases did not involve direct judicial review of presidential instruction of executive officers, in both cases, the courts acknowledged that the administrative act under review was the result of a presidential instruction to act in spite of federal legislation.[222] Subsequently, in both cases, the courts overruled the administrative acts that implemented the presidential instruction not to spend,[223] thus once again indicating the courts' aversion to presidential policies and acts that are in clear conflict with legislation. These cases are also a testament to the courts' unwillingness to defer to presidential instruction of executive agencies to implement presidential policies in a manner blatantly inconsistent with the law. Applying *State Highway* and *Train v. City of New York* to President Bush's Directive not only indicates that courts would not accept the Directive, but also that the courts would frown upon the NIH's implementation of President Bush's Stem Cell Decision.[224]

The D.C. Circuit's decision in *Chamber of Commerce v. Reich*[225]—the second case ever in which a presidential executive order was overruled in its entirety[226]—is another example of the courts' unwillingness to tolerate

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220. 479 F.2d 1099 (8th Cir. 1973).

221. 420 U.S. 35 (1975).

222. In *State Highway*, the Eighth Circuit reviewed a decision by the Secretary of Transportation to defer his authority to allocate funds apportioned by Congress to highway development in Missouri due to a presidential policy to limit government expenditures to control the inflation. 479 F.2d at 1103, 1108. In *Train v. City of New York*, the Supreme Court reviewed a decision by the Environmental Protection Agency (EPA) not to allot the City of New York funds appropriated by Congress for development of water and sewage infrastructure, whereas the EPA's decision was the result of a direct instruction by the President to limit the sums which were originally appropriated for this purpose. 420 U.S. at 40.

223. *See State Highway*, 479 F.2d at 1118 (enjoining the defendants from withholding authority to appropriate funds under the Federal Aid Highway Act in Missouri); *City of New York*, 420 U.S. at 44, 47 (finding that the letter from the President and the Administrator's withholding of the funds could not "be squared with the statute").

224. For a discussion of the NIH's policy implementing President Bush's Directive, see *infra* Part II.C.

225. 74 F.3d 1322 (D.C. Cir. 1996).

226. *See* Branum, *supra* note 7, at 38 (explaining that President Clinton was "only the second President to have an executive order struck down by the courts in its entirety").

presidential actions intended to circumvent statutes. In *Reich*, the Government attempted to defend an executive order issued by President Clinton, which clearly contradicted a congressional act, by arguing that another later, though more general statute granted the President the authority to issue his order in abrogation of the former statute.[227] The D.C. Circuit did not accept the Government's arguments and held that the earlier, more specific statute preempted President Clinton's executive order.[228] Although the Court's reasoning in this matter seemed to involve mere statutory construction, its decision indicated the Court's reluctance to uphold a presidential action that stands in clear conflict with a valid statute.[229]

Lastly, the D.C. Circuit's decision in *Building & Construction v. Allbaugh*[230] addressed the validity of an executive order issued by President George W. Bush that prohibited executive agencies entering into agreements with contractors from requiring or prohibiting the implementation of certain pro-union labor practices,[231] and which was presumably in conflict with the National Labor Relations Act (NLRA).[232] In its arguments during the trial, the Government contended that the President's authority to issue the executive order stemmed from his inherent constitutional power to direct executive agencies.[233] The District Court did not accept the Government's arguments regarding the President's authority to issue the order, but rather found it to be "presidential lawmaking" a lá *Youngstown*, and overruled the relevant part in the executive order as preempted by the NLRA.[234] On appeal, the D.C. Circuit accepted the Government's argument that the President's authority to issue the executive order stemmed from his "supervisory authority over the Executive Branch"[235] in an area of regulation that is not preempted by the

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227. *See Reich*, 74 F.3d at 1332-33 (rejecting the argument that the Procurement Act of 1949 granted broad power to the President over the more specific National Labor Relations Act).

228. *Id.* at 1332-39.

229. *See id.* at 1338-39 (concluding that "the Executive Order is regulatory in nature and is pre-empted by the NLRA which guarantees the right to hire permanent replacements"); *see also* Gaziano, *supra* note 134, at 287 ("*Reich* stands for the seemingly obvious proposition that the President may not use his statutory discretion in one area to override a right or duty established in another law.").

230. 295 F.3d 28 (D.C. Cir. 2002).

231. Exec. Order No. 13,202, 66 Fed. Reg. 11,225 (Feb. 17, 2001).

232. National Labor Relations Act (NLRA), ch. 372, 49 Stat. 449 (1935) (codified at 29 U.S.C. §§ 151-169 (2000)); *see* Bldg. & Constr. Trades Dep't v. Allbaugh, 172 F. Supp. 2d 138, 162 (D.D.C. 2001) (making two sections of President Bush's executive order invalid because they were preempted by the NLRA).

233. *See Allbaugh*, 172 F. Supp. 2d at 159 ("Defendants' constitutional argument rests on the 'well-established' power . . . to supervise and guide subordinate executive officials to ensure the consistent execution of the laws.").

234. *Id.* at 172.

235. *Allbaugh*, 295 F.3d at 32-33.

NLRA,[236] and thus overturned the District Court's decision and upheld the executive order.[237] Yet, the important part of the D.C. Circuit's decision for our purposes is its reasoning. The D.C. Circuit did not base its decision on the premise that the President's inherent authority empowered him to act in variance with congressional statutes, but rather on the fact that the disputed segment in the executive order was preceded by the words "[t]o the extent permitted by law."[238] In the eyes of the D.C. Circuit, the prefix "to the extent permitted by law" was assurance enough that "if [an agency implementing the executive order] is prohibited, by statute or other law, from implementing the Executive Order, then the Executive Order itself instructs the agency to follow the law."[239] In fact, the D.C. Circuit found the redeeming qualities of this prefix so great that had the presidential directive in *Youngstown* been supplemented with this qualification, the court opined that it would have made most of the discussion regarding its validity moot.[240] *Building & Construction* therefore demonstrates once more the courts' view that presidential actions are permissible and will be tolerated only to the extent they do not contravene valid congressional legislation.

The aforementioned cases indicate that Justice Jackson's opinion is a true crystallization of how courts perceive and rule in matters involving presidential actions that run against valid statutory instruction. Evidently, courts tend to be suspicious of presidential directives that do not comport with legislation, and they tend not to uphold such directives or their progeny.[241] The conclusion to be drawn from the above is that Justice

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236. *Id.* at 34.
237. *Id.* at 36.
238. *Id.* at 33.
239. *Id.*
240. *Id.* Thus, it appears that according to the D.C. Circuit, if all presidential directives had the prefix "to the extent permitted by law" there would never be questions regarding their legality or validity. As a side note, I find it worth adding that I believe the D.C. Circuit was wrong in its decision that practically allows the President to leave the legal inquiry about the legality of his executive orders' instructions to agencies and expect them to find what is "permitted by law" and what is not. Turning the phrase "to the extent permitted by law" into a "kosher stamp" for just any presidential directive—outrageous and outright illegal as it may be—might encourage the President to issue directives of dubious legality which might eventually be enforced by executive officers who wish to avoid direct confrontations with the President. This clearly undesirable situation cannot simply be cured via semantic maneuvers.
241. Notably, an even broader possible implication of these cases is that courts would not hastily acknowledge and enforce a presidential claim of authority that has no, or hardly any checks on it, especially as Justice Jackson says, when such a right is in direct contradiction of the legitimate use of constitutional authority by another branch of the government (e.g., Congress's Article I authority to legislate the NIHRA). *See* Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 637-38 (1952). The *Youngstown* decision and the majority opinion in *Morrison* both support this proposition. According to the *Morrison* Court, the President's powers may not be construed to be entirely separate or detached from the powers granted to the other branches of government. Morrison v. Olson, 487 U.S. 654,

Jackson's opinion may well be viewed as the judicial standard—or blueprint for such a standard—that courts would apply in cases of presidential claims of inherent authority to instruct executive agencies to take action in contravention of legislation. Application of this standard would mean that inherent authority may not serve the President as a power to override federal statutes in general, and that to the extent that President Bush relied on such an authority in giving his Directive, it could not have enabled him to give his Directive in contradiction to the NIHRA.

Having found that inherent authority—despite the permissive assumptions made here regarding its existence and expansive scope—could not have empowered President Bush to give his Directive in contravention to the NIHRA, and with the lack of any other source of authority that President Bush's Directive could have relied on, we must determine that the Directive is illegal, and thus invalid.

C. The NIH's Actions Examined

The immediate implication of President Bush's Directive's invalidity is that it did not, and does not carry any authority over executive agencies. However, prior to discussing the implications of its illegality in more detail, there is merit in an examination of the measures taken by the NIH following President Bush's Address and their legality.

Professor Peter Strauss once wrote that "[i]t is far easier [for an executive officer] to act as a servant, than as an independent authority under instructions from one's principal."[242] This epigram seems to concisely capture the NIH's response to President Bush's Directive. On the day President Bush gave his Address, Dr. Ruth Kirschstein, the Acting Director of the NIH at that time, subordinated her discretion[243] and the

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693-94 (1988). In other words, the *Morrison* Court opined that the President's actions do not occur in a "vacuum," but rather are in constant interaction with other powers that exist within the Government—powers which the President's actions must reckon with. *See also* William J. Olson & Alan Woll, *Executive Orders and National Emergencies: How Presidents Have Come to "Run the Country" by Usurping Legislative Power*, 358 CATO INST. POLICY ANALYSIS 8-10 (1999) ("The Court's preference for constitutionally enacted laws over presidential directives not clearly based on constitutional or statutory authority is evident from its treatment of the implementation of regulations promulgated under such directives.").

242. Strauss, *Presidential Rulemaking*, *supra* note 195, at 974.

243. Under 42 U.S.C. § 282(b)(1), the Director of NIH has the authority to set policies for the entire NIH. For further discussion of this policymaking authority, see *supra* Part II.B.1.

discretion of the Directors of the NIH's Research Institutes[244] to that of the President by immediately and unreservedly endorsing President Bush's Stem Cell Decision.[245]

A Moderate Unitarian scrutiny of the NIH's actions following President Bush's Directive implicates that the NIH's actions amounted to unjustified obsequiousness towards the President, which is not only repugnant to principles of proper administration, but is also illegal. According to Moderate Unitarianism, regardless of NIHRA § 101, the NIH's Acting Director had an obligation to not simply accept President Bush's imposition of his own personal policy upon the NIH, even if that would have meant that she might risk her office.[246] Rather, Dr. Kirschstein, as an acting head of an agency, was duty bound to use her autonomous discretion. She ought to have seriously considered the President's stance on the issue of research involving hESCs[247] (and was indeed under a constitutional obligation to do so), but nonetheless eventually make the decision by herself and with the best interests of the public in mind rather than the personal sentiments of the President. Thus, under a Moderate Unitarian approach, the submissiveness of the NIH and its Acting Director constituted an illegal substitution of their own discretion with that of the President. Moreover, under Moderate Unitarian theory, the NIH's actions amounted to abandonment of its public stewardship and statutory charge, which are meant to serve as an important check on the President's executive authority from becoming all-inclusive and all-reaching.[248] In simpler terms, the Moderate Unitarian approach would hold that the NIH forsook its duties and acted as the President's lackey, thus allowing the President's beliefs to become the law of the land. Hence, under the Moderate Unitarian approach, the NIH's actions pursuant to President Bush's Directive constituted a capricious executive decision and an abuse of the NIH's discretion to make its own research funding decisions, such that a court should set them aside.[249]

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244. Under 42 U.S.C. § 284(b)(1), the Secretary, acting through the Directors of the NIH's research institutes, may grant funding for scientific research.

245. *See* Kirschstein Statement, *supra* note 4. For a detailed discussion of the actions taken by the NIH to implement President Bush's Directive, see *supra* Part I.C.

246. *See supra* text accompanying note 198.

247. *See* Stack, *supra* note 175, at 314 (stating that executive officials are subject to "an obligation to carefully consider the President's position[s]").

248. *See id.* at 316 ("[T]he mere possibility of resistance [by executive officials to the President's preferred construction or use of a statute] creates a legal check on presidential abuse internal to the executive branch. . . .").

249. *See* 5 U.S.C. § 706(2)(A) (2000) (directing reviewing courts to hold unlawful and set aside actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"). For further discussion of this possible cause of action, see *infra* Part III.D.

However, it appears that Dr. Kirschstein's NIH did not share the Moderate Unitarian viewpoint. In what seems to be the NIH's only explanation for its unqualified acceptance of President Bush's Directive, the NIH proclaims on its website:

> As the head of the executive branch of the federal government, which includes the National Institutes of Health, the President of the United States has the final responsibility and authority to set federal government policy for funding human embryonic stem cell research. But Congress has appropriations authority and can possibly override the President's decision.[250]

Indeed, this is a true statement of the Constitutional Unitarian view. And yet, even under a Constitutional Unitarian approach, the NIH's actions were clearly illegal.

First and foremost, regardless of President Bush's authority to give his Directive, the Directors of the NIH Research Institutes and its Acting Director (NIH Officers) were still bound to follow the numerous requirements of NIHRA § 101,[251] including the requirement that, before they impose a moratorium on certain kinds of scientific research (e.g., involving hESCs produced after August 9, 2001 at 9:00 p.m.), they must receive a recommendation to do so from a duly-established Ethics Advisory Board.[252] Having not fulfilled this requirement, the NIH Officers' actions pursuant to President Bush's Directive were in excess of the Officers' statutory authority, and thus illegal.[253]

Moreover, the NIH's announcement of its withdrawal of the Final Guidelines' part relating to research involving hESCs (the Repeal) constitutes in and of itself an illegal action under the Administrative Procedure Act. Since the Final Guidelines came under the definition of a

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250. NIH FAQs, *supra* note 15.

251. *See supra* Part II.B.1. It is worth noting that both the NIH's Research Institutes Directors' authority to fund scientific research under 42 U.S.C. § 284(b)(1) and the NIH Director's authority to make general policies for the entire NIH under 42 U.S.C. § 282(b)(1) stem from the power of the Secretary. Specifically, both sections state that the duties and authorities they grant are actually the Secretary's, who is acting *through* his subordinates, the NIH Officers. Hence, to the extent that the funding granting authority in 42 U.S.C. § 284 and the policymaking authority in 42 U.S.C. § 282(b)(1) are being used by the NIH Officers, these Officers are duty-bound by limitations imposed on the source of their own authority, namely the Secretary, such as those enumerated in the NIHRA § 101. This proposition is also supported by the principle that a principal may not delegate powers greater than the powers she possesses herself. Thus, a delegate cannot possibly have more power than the principal could have delegated to her and the NIH Officers could not have ignored the NIHRA § 101 simply because it is addressed to the Secretary.

252. 42 U.S.C. § 289a-1(b) (2000).

253. It is also worth mentioning in the context of the grants' allocation proceedings, which the NIH Officers failed to follow, that although there is no question that the NIH Officers had ample discretion in making funding decisions with respect to particular kinds of research or a particular research project, they did not have such discretion with respect whether or not *to consider* the allocation of such funding to begin with.

"rule"[254] in the APA and were not exempt from its notice and comment requirements,[255] their promulgation and repeal were subject to these requirements.[256] These requirements dictate that prior to repealing the Final Guidelines or a part thereof, the NIH was under an obligation to publish a general notice in the Federal Register about its intention to repeal the Guidelines, provide interested parties an opportunity to comment on the planned repeal, consider the comments and the relevant matters presented, and only then use its discretion to make an informed decision about repealing the Guidelines.[257] The NIH indeed published a notice in the Federal Register announcing the Repeal.[258] Yet, it did not provide interested parties the opportunity to comment on the planned Repeal and subsequently, did not weigh any opposition prior to the Repeal. Rather, the announcement unilaterally imposed the restrictions in violation of the APA's notice and comment requirements[259] (which, as mentioned earlier, HHS undertook to follow[260]). It appears that the NIH attempted to justify these omissions by arguing that President Bush's Directive made compliance with these requirements unnecessary, thus invoking the "good cause" exception to the notice and comment requirements.[261] Specifically, in its withdrawal notice, the NIH stated that "[t]he President has determined the criteria that allow Federal funding for research using existing embryonic stem cell lines . . . . Thus, the [Final] Guidelines as they relate to [hESC] derived from human embryos are no longer needed."[262] Nonetheless, although HHS's undertaking to follow the notice and comment requirements does not apply to cases where the "good cause" exception is applicable,[263] it is doubtful whether courts would accept this explanation as justification for the NIH's noncompliance with the APA's notice and comment requirements. According to several Courts of Appeals' decisions, the "good cause" exception would not only be narrowly construed, but would also apply only in a limited set of

254. The Final Guidelines fell under the definition of a "rule" under 5 U.S.C. § 551(4), and therefore, their repeal was considered "rulemaking" under 5 U.S.C. § 551(5).

255. *See supra* note 83.

256. 5 U.S.C. § 553 (2000); *see also* Consumer Energy Council of Am. v. FERC, 673 F.2d 425, 446 (D.C. Cir. 1982); Envtl. Def. Fund, Inc. v. Gorsuch, 713 F.2d 802, 816 (D.C. Cir. 1983); Natural Res. Def. Council, Inc. v. EPA, 683 F.2d 752, 761-65 (3d Cir. 1982).

257. 5 U.S.C. § 553(c).

258. National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 66 Fed. Reg. 57,107 (Nov. 14, 2001).

259. *Id.*

260. *See supra* note 83.

261. 5 U.S.C. § 553(b)(B).

262. Guidelines for Research Using Stem Cells, 66 Fed. Reg. at 57,107.

263. Because the HHS's undertaking involves only matters of grants and benefits, it does not necessarily apply to matters coming under the premise of 5 U.S.C. § 553(b), i.e., "when the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B).

circumstances that do not exist in this case.[264] Hence, it seems that the NIH's explanation of its noncompliance with the APA's notice and comment requirements was not sufficient to exempt it from these requirements, and the Repeal was illegal under the APA.

An interesting question that arises in this context is whether President Bush's Directive was authoritative enough to enable the NIH to simply disregard the APA's instructions. In other words, could the President have lawfully given the NIH instructions and empowered it to act in violation of the APA? Following the Supreme Court's reasoning in *Franklin v. Massachusetts*,[265] it may be argued that, just like presidential actions are not reviewable under the APA out of "respect for the separation of powers and the unique constitutional position of the President,"[266] agency actions that follow and implement such presidential actions may be exempt from the APA.[267] Applying this proposition to the matter at hand would result in the conclusion that since President Bush's Directive's disregard of the APA's notice and comment requirements is not reviewable under the APA, so too are the pursuant actions taken by the NIH to implement the Directive. However, even if we assume that President Bush's Directive's violation of the APA would be deemed non-reviewable under the APA,[268]

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264. According to 5 U.S.C. § 553(b)(B), there are three grounds for finding "good cause," namely when "notice and comment" would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). "Impracticability" is interpreted as applicable in cases of emergency. Am. Fed'n Gov't Emp. v. Block, 655 F.2d 1153, 1156 (D.C. Cir. 1981) (limiting use of the good cause exceptions to "emergency situations"). However, no such emergency existed in the matter of President Bush's Directive, and so it is unlikely that courts would accept a "good cause" for emergency argument. *See* Consumer Energy Council of Am. v. FERC, 673 F.2d 425, 447-48 (D.C. Cir. 1982) (holding that an emergency does not exist when an agency finds regulations to be defective); *see also* Envtl. Def. Fund, Inc. v. EPA, 716 F.2d 915, 920 (D.C. Cir. 1983); Natural Res. Def. Council, Inc. v. EPA, 683 F.2d 752, 764 (3d Cir. 1982). As for non-necessity, according to the D.C. Circuit, this ground would have applied only had the Repeal been a "routine determination, insignificant in nature and impact and inconsequential to the industry and to the public." *See* Util. Solid Waste Activities Group v. EPA, 236 F.3d 749, 755 (D.C. Cir. 2000) (quoting South Carolina v. Block, 558 F. Supp. 1004, 1016 (D.S.C. 1983)). Since the Repeal is anything but "routine," "insignificant in nature and impact," and is consequential to the industry and the public, this ground too, would not be available to the NIH in attempting to rely on the "good cause" exception. And as for the "public interest" ground for the "good cause" exception, according to the D.C. Circuit it would only apply when "the interest of the public would be defeated by any requirement of advance notice." *Id.* at 755 (quoting United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 31 (1947)). As before, it is hard to see how following the notice and comment requirements in this case would defeat the public's interest, and so we should surmise that none of the grounds enumerated in 5 U.S.C. § 553(b)(B) are applicable to the Repeal and thus that the NIH could not have relied on them.

265. 505 U.S. 788 (1992).

266. *Id.* at 800-01.

267. In so doing, courts following *Franklin* would actually accept a narrow set of circumstances in which the President may act in violation of the APA.

268. Opposing this proposition is the aforementioned courts' intolerance of presidential actions that may contradict valid law. *See supra* Part II.B.3.

this conclusion seems to be far-fetched with respect to the NIH. The APA is unequivocal about its applicability to agency actions.[269] Despite the *Franklin* Court's holding that applying the APA to the President would require an express statement by Congress to this effect,[270] Congress has made it clear that the APA applies to executive agencies. Therefore, it is highly unlikely that courts would require a further "statement of applicability" of the APA to executive actions, including actions that are the direct result of presidential directives. In other words, even if we accept the proposition that presidential actions may legitimately run in the face of the APA, it does not follow that agencies may wield *Franklin* as a shield against judicial review when they are acting under such Presidential instructions.[271] Hence, the NIH could not have used President Bush's Directive as a justification for its disregard of the APA's notice and comment requirements.

III. THE IMPLICATIONS OF THE ILLEGALITY OF PRESIDENT BUSH'S DIRECTIVE AND OF THE ENSUING ACTIONS TAKEN BY THE NIH

The severity of the findings reached in the previous Part—that President Bush's Directive lacked authority and that the NIH's implementation of his Directive was blatantly illegal (the Contestable Actions)—is undeniable and invites a judicial challenge. This Part will discuss some possible challenges that the Contestable Actions may face and enumerate some legal remedies called for by such challenges. But, prior to discussing such challenges, it is important to address the preliminary issue of standing.

One would assume that scientists seeking to secure federal funding for scientifically meritorious research proposals[272] involving hESC lines created after August 9, 2001, or otherwise not in compliance with President Bush's Stem Cell Decision would have standing. Such scientists would

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269. *See* 5 U.S.C. § 551(1) (2000) ("'[A]gency' means each authority of the Government of the United States, whether or not it is within or subject to review by another agency. . . .").

270. *Franklin*, 505 U.S. at 801.

271. Such a situation not only runs against the basic principle that agency action must be based on legal mandate, but also goes directly against the Separation of Powers Doctrine and the important principle of checks and balances since it proposes a sphere in which a President may be allowed to act and authorize actions that go against the law without such actions being subject to judicial review. It is most improbable that courts would seriously consider such a proposition.

272. It may be argued that scientific merit and allocation of funding thereof is a matter "committed to agency discretion by law" under 5 U.S.C. § 701(a)(2), and therefore, not subject to judicial review. *See* Lincoln v. Vigil, 508 U.S. 182, 192-94 (1993). However, the arguments possibly raised by scientist-plaintiffs with respect to the Contestable Actions would not involve the non-allocation of research funds by the NIH for hESC research, but rather the actions taken by the NIH with respect to the repeal of the mechanism that would have allowed for the allocation of such funding. Hence, 5 U.S.C. § 702(a)(2) should not be a justiciability barrier in the matter at hand.

probably not have a particular hardship establishing that their claims fall within the "zone of interests"[273] under the APA[274] as well as under the NIHRA.[275] However, a question may arise with respect to such scientists' ability to show that the Contestable Actions have caused them an injury-in-fact[276] and that they have a personal stake in the lawsuit's outcome.[277] Presumably, since there is no certainty that such scientists would have been able to secure discretional funds from the NIH to support their hESC research had the Final Guidelines been in place, it is unclear whether they may be able to convince a court that they have been injured by the Contestable Actions and therefore, have a personal stake in overturning them.

Nevertheless, it is unlikely that the issue of injury-in-fact and stake in the outcome of the proceedings would bar scientists whose research involves hESCs from establishing that they would have standing. First, the Supreme Court has held in cases involving a hardship posed by the government to obtain a benefit, that it is not necessary for the plaintiff to prove that she would have obtained the benefit "but for the hardship" in order to establish standing. Rather she must show only that the she is able and ready to apply for the benefit and that the governmental policy is preventing her from doing so.[278] Second, the Supreme Court has held on more than one occasion that the injury-in-fact requirement may be satisfied not only by demonstrating an economic injury, but that an injury may be of other kinds.[279] For example, a group of hESC researchers could claim that their

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273. *See* Ass'n of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 153, 156 (1970); *see also* Clarke v. Sec. Indus. Ass'n, 479 U.S. 388, 399-400 (1987) (discussing the "zone of interests" test).

274. 5 U.S.C. § 702 (2000); *see also Data Processing*, 397 U.S. at 154 ("Where statutes are concerned, the trend is toward enlargement of the class of people who may protest administrative action.").

275. 42 U.S.C. § 289a-1 (2000).

276. *See Data Processing*, 397 U.S. at 152 ("The first question is whether the plaintiff alleges that the challenged action has caused him injury in fact, economic or otherwise.").

277. *See* JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW, § 2.12(f)(2), 91 (7th ed. 2004) ("Whether a party has 'alleged such a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues' is, we are told, 'the gist' of the question of standing.").

278. *Id.*; *see, e.g.*, N.E. Fla. Chapter of the Associated Gen. Contractors of Am. v. Jacksonville, 508 U.S. 656, 666 (1993). Notably, this case involved an equal protection matter and the injury-in-fact element therein was "the [plaintiffs'] inability to compete on an equal footing in the bidding process, not the loss of a contract." *Id.* Similarly, it may be argued that in the matter at hand the scientist-plaintiffs' injury-in-fact has been their inability to apply for federal funding for research involving hESCs not in accordance with President Bush's Directive rather than the loss of the funds themselves.

279. *See, e.g.*, *Data Processing*, 397 U.S. at 154 ("That interest, at times, may reflect 'aesthetic, conservational, and recreational' as well as economic values." (quoting Scenic Hudson Preservation Conf. v. FPC, 354 F.2d 608, 616 (2d Cir. 1965))); United States v. Students Challenging Regulatory Agency Procedures (SCRAP), 412 U.S. 669, 686-89 (1973) (granting standing where aggrieved party claimed injury due to diminished use and enjoyment of local natural resources).

injury relates to their interest in the advancement of science as it pertains to hESC research, which is hindered by the impediments to scientific progress put in place by the Contestable Actions. Similarly, they may argue that their injury relates to an interest they have as biomedical researchers in the harm caused to the public's health by the impediments on advancement of stem cell based therapies placed by the Contestable Actions. It therefore appears that researchers partaking in research involving hESCs may arguably have standing to challenge the Contestable Actions.

A. Challenging President Bush's Directive

A challenge to President Bush's Directive is likely to be based on the argument that it essentially constitutes forbidden presidential lawmaking. President Bush's and the NIH's emphasis that the Directive is "*the President's policy*"[280] bolsters this argument. Furthermore, the fact that the Directive runs against the explicit instructions of the NIHRA makes it all the more clear that President Bush's Directive "does not direct that a congressional policy be executed in a manner prescribed by Congress—it directs that a presidential policy be executed in a manner prescribed by the President."[281]

The basic premise of this challenge is that allowing President Bush's Directive to persist despite its clear undermining of a constitutionally valid congressional statute would legitimize the usurpation of legislative authority by presidents.[282] Furthermore, in issuing his Directive, despite his likely awareness of his lack of authority to promote *his* policy (i.e., his Stem Cell Decision),[283] President Bush's actions run against one of most basic understandings about the nature of the Government of the United States, namely that it is "a government of laws, and not of men."[284] Thus, courts would likely find that President Bush's Directive is in clear violation of the Doctrine of Separation of Powers and strike it down in its entirety, despite their basic reluctance to revoke presidential directives.[285]

"But He [the Democratic President] Started It"

A popular defense argument among Presidents whose actions are challenged is that their actions did not go beyond prior unchallenged

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280. *See supra* Part I.C, notes 102-05 and accompanying text.
281. Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579*,* 588 (1952).
282. *See* Olson & Woll, *supra* note 241, at 8 ("Although some directives are proper exercises of executive power, others are clearly usurpations of legislative authority.").
283. It is highly improbable that President Bush and his advisors were unaware of the potential conflict between his Stem Cell Decision and the NIHRA.
284. Marbury v. Madison, 5 U.S. (1 Cranch) 137, 163 (1803).
285. *See* Branum, *supra* note 7, at 59-60, 78-79 (emphasizing how few presidential directives have been modified, revoked or struck down).

Presidential acts.[286] Thus, the Government might try to defend President Bush's Directive by arguing that similar directives issued by President Clinton went unchallenged and that President Bush's Directive "operates" in an area that has already been influenced by the actions of President Clinton and should be left to work its effect without court interference.[287]

Indeed, President Clinton's use of presidential directives to impose his policies on executive agencies[288]—like in the cases of his Embryo Decision and Cloning Decision mentioned earlier[289]—sometimes amounted to presidential lawmaking.[290] And indeed, it appears that President Clinton's Embryo Decision,[291] which was never challenged although it too prohibited funding for certain kinds of embryo research in abrogation of NIHRA § 101, is almost identical in its legal circumstances to President Bush's Directive.[292] However, President Clinton's earlier illegal directives cannot immunize or cure the similar illegality of President Bush's Directive. The contention that one defective presidential action may draw legitimacy from

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286. *See Youngstown*, 343 U.S. at 646 ("The Solicitor General lastly grounds support of the seizure upon nebulous, inherent powers never expressly granted but said to have accrued to the office from the customs and claims of preceding administrations.").

287. Branum alludes to this argument contending that President Bush was forced to give his Directive because of the Clinton Administration's allegedly illegal prying into this area, which required President Bush "to negate actions of President Clinton that had effectively taken the policy decision away from the legislature and placed it in the realm of the executive." *See* Branum, *supra* note 7, at 45.

288. *See Executive Orders and Presidential Directives: Hearing Before the House Subcomm. on Commercial and Administrative Law of the Comm. on the Judiciary*, 107th Cong. 2 (2001) [hereinafter *Hearing on Presidential Directives*] (criticizing this "attitude" and quoting President Clinton's Senior Domestic Policy Advisor, Paul Begalla, who said "Stroke of a pen, law of the land, kind of cool."); Gaziano, *supra* note 134, at 272-73; Kagan, *supra* note 170, at 2249, 2290; Strauss, *Presidential Rulemaking*, *supra* note 195, at 967.

289. *See supra* note 60.

290. *See* Branum, *supra* note 7, at 36-37 ("Clinton may have misused executive orders more blatantly than his predecessors . . . ."); Kagan, *supra* note 170, at 2320-21 (contrasting President Clinton's invocation of "executive authority" with Justice Black's opinion in *Youngstown*); *see also Hearing on Presidential Directives*, *supra* note 288, at 2 (discussing the threat posed to legislative authority from the Executive branch's prevalent use of executive orders and citing President Clinton's administration as an example).

291. *See supra* note 60.

292. Neither directive mentions its source of authority nor was published in the Federal Register. *See supra* note 144. Also, both directives have an undefined form, and both run in clear violation of the NIHRA. President Clinton's Embryo Decision even blatantly disregarded the recommendations of a duly appointed EAB, the Human Embryo Research Panel. *See supra* Part I.B, notes 51-60 and accompanying text. It is worth noting that President Clinton's Cloning Decision also violates the NIHRA in much the same way as President Clinton's Embryo Decision and President Bush's Directive. *See supra* note 60. Yet, unlike President Bush's Directive that has been subject to ongoing challenges by Congress (*see supra* notes 121-31 and accompanying text), President Clinton's Embryo Decision was ratified by Congress's subsequent passing of the Dickey Amendment. *See supra* notes 63-68 and accompanying text. Interestingly, it appears that should Congress henceforth refrain from reenacting the Dickey Amendment as it has been doing every year, President Clinton's Embryo Decision would lose its "blanket of legitimacy" making it as illegal as President Bush's Directive.

the defectiveness of an earlier similar presidential action seems too feeble to hold water in court. Hence, although the aforementioned directives issued by President Clinton also appear to constitute a usurpation of legislative authority, they do not in any way justify such usurpation by President Bush's Directive. Rather, they too are challengeable as presidential lawmaking.

B. Challenging the NIH's Withholding of Funding for Research Involving hESCs

Probably the most significant challenge to the NIH's actions pursuant to President Bush's Directive would rely on the fact that these actions were taken in spite of, and contrary to, the instructions of the NIHRA. As explained above, the NIHRA prevents NIH officers from withholding funding for scientific research due to ethical reasons.[293] Hence, a challenge to the NIH's withholding of funding for research involving hESCs would contend that taking these actions without relying on the recommendation of a duly-established EAB constituted an imposition of a moratorium on research involving hESCs and an ongoing violation of the NIHRA.[294]

In other words, a challenge to the NIH's denial of funds for research involving hESC lines that do not comply with President Bush's Stem Cell Decision would argue that unless and until the NIH abides by the requirements of the NIHRA, it may not withhold funding from research involving any kind of hESCs and must allocate funding for such research projects subject only to their scientific merit.[295] It therefore follows that the NIH is currently acting outside of its statutory authority and in violation of statutory limitations imposed on it,[296] and thus its withholding of funding is unlawful and courts should set it aside.

C. Challenging the NIH's Unilateral Repeal of the Final Guidelines

As explained above, the Repeal violated the APA's notice and comment requirements.[297] A possible challenge posed to the Repeal would argue that it should have complied with the notice and comment requirements of 5 U.S.C. § 553, namely, that it should have taken place after giving interested parties an opportunity to comment on the planned withdrawal, weighing of the objections, and only then making an informed and properly reasoned decision on the withdrawal of the Final Guidelines. This kind of

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293. *See supra* Part II.C, notes 251-52 and accompanying text.
294. 42 U.S.C. § 289a-1(b)(1), (3)-(5) (2000).
295. *Id.*
296. 5 U.S.C. § 706(2)(C) (2000).
297. *See supra* Part II.C, notes 254-71 and accompanying text.

challenge would stress that the NIH's failure to take these measures constituted a substantive flaw in the Repeal that conflicts with the APA's requirements.[298] As a result, courts should set aside the Repeal, thereby reinstating the part of the Final Guidelines that regulates the funding of research involving hESCs. The practical implication of such a ruling would be that parties seeking federal funding for research involving hESC lines that do not comply with President Bush's Stem Cell Decision, would be able to do so subject to the more lenient standards of the reinstated Final Guidelines.[299]

D. Challenging the NIH's Decision to Abide by President Bush's Stem Cell Decision

One may pose several challenges to the NIH's adoption and implementation of President Bush's Stem Cell Decision. First, one can argue that Acting Director Kirchstein's surrender of statutory authority to President Bush to make policy decisions for the NIH by adopting his Stem Cell Decision without actually using her own discretion was an abuse of her discretion to set policies for the NIH,[300] which amounted to an unlawful abuse of discretion under the APA.[301] One could further contend that the Acting Director's adoption of President Bush's Stem Cell Decision as the NIH's own policy in its entirety—without any qualms or reservations, without paying respect to its underlying rationale and considering its alternatives,[302] without considering whether it promotes good public policy, and without weighing such considerations—may also tag her actions, and thus the actions of the NIH, as arbitrary and capricious.[303]

Furthermore, Moderate Unitarians would probably add that the Acting Director's omission of her own discretion in this matter was not in accordance with *her* statutory duty[304] to make such a discretionary decision by herself under the authority granted to her in the Public Health Service Act.[305] Should a court accept this argument, it may serve to justify an

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298. 5 U.S.C. § 706(2)(D).
299. *See supra* Part I.C, notes 84-86 and accompanying text.
300. 42 U.S.C. § 282(b).
301. 5 U.S.C. § 706(2)(A).
302. It may be argued that the NIH's policy, which is in fact President Bush's Stem Cell Decision, did not properly weigh different aspects of the issues related to research involving hESCs. One could argue, for example, that the NIH's policy gives excessive weight to ethical and religious considerations while giving very little if any weight to important scientific and public policy considerations. *See, e.g.*, Ryan Fujikawa, Note, *Federal Funding of Human Embryonic Stem Cell Research: An Institutional Examination*, 78 S. CAL. L. REV. 1075 (2005).
303. 5 U.S.C. § 706(2)(A); *see also supra* Part II.C.
304. *Id.* § 706(2)(C).
305. 42 U.S.C. § 282(b). This argument would be based on the Moderate Unitarian reading of statutory duties as applying exclusively to the specific executive officers named

injunction against the NIH, enjoining it from enforcing President Bush's Directive and instructing the Director of the NIH to use her own discretion in making a decision regarding the NIH's funding policy of research involving hESCs (to the extent the NIHRA leaves this issue to the discretion of the Director of the NIH).

It is worth adding a few words in this context on the standard of review courts would probably apply to such challenges. Courts generally grant agencies' discretionary decisions and actions a great measure of deference and are not easily persuaded to set them aside.[306] However, in order to merit this measure of deference, agency decisions must be based on the agency's expertise in the area of regulation it is charged with implementing.[307] Without demonstration of reliance on such expertise by the agency, courts would not defer to the agency's decision.[308] Accordingly, since the NIH's policy on the funding of research involving hESCs does not reflect its expertise on this issue, but merely its reliance on the President's opinions,[309] courts would probably not grant it the deference they normally would have under the *Chevron* Doctrine.[310] Furthermore, courts only defer to and uphold agency decisions that are properly reasoned.[311] According to the Supreme Court, this is especially true where,

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in the authorizing statute. However, it is important to note that to date there is no court decision accepting such Moderate Unitarian contentions, so it is hard to assess how willing courts would be to entertain this argument.

306. *See* Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-44 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme. . . . .").

307. *See* Pub. Citizen Health Research Group v. Tyson, 796 F.2d 1479, 1505 (D.C. Cir. 1986) ("While we acknowledge our deference to the agency's expertise in most cases, we cannot defer when the agency simply has not exercised its expertise.").

308. *Id.*

309. Despite his outspoken efforts to inform himself prior to making his Stem Cell Decision, President Bush may not be considered an expert in the area of research involving hESCs.

310. In addition, in the NIHRA, Congress directly spoke on the precise question of withholding of federal funding for scientific research on ethical grounds and its instruction on this matter constitutes an explicit congressional prohibition on actions such as those taken by the NIH with respect to the funding of research involving hESC. Therefore, courts should not grant *Chevron* deference to the NIH's policy on funding for research involving hESCs. *See Chevron*, 467 U.S. at 842-43. It is also worth mentioning that, according to Stack, courts should only grant *Chevron* deference to agency actions and decisions that follow presidential directives where a statute expressly grants authority to make such a decision specifically to the President. *See* Stack, *supra* note 175, at 263, 268-69, 307, 310-11.

311. *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) ("[T]the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'") (citation omitted); *see also* BellSouth Corp. v. FCC, 162 F.3d 1215, 1222 (D.C. Cir. 1999) ("Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, we must undo its action." (quoting Petroleum Communications, Inc. v. FCC, 22 F.3d 1164, 1172 (D.C. Cir.1994))).

as here, the agency is repealing a previous policy.[312] The NIH failed to provide a reasoned explanation for its actions and only justified the Repeal and its adoption of President Bush's Stem Cell Decision as its policy by stating that these measures were compatible with President Bush's Stem Cell Decision.[313] Arguably, even under the assumption that agency action may be greatly influenced by presidential policy preferences, this hardly seems like the kind of reasoning that courts would accept in order to uphold an agency's decision. Hence, it is likely that in a challenge to the NIH's policy—like the ones mentioned above—a court would not grant it *Chevron* deference, but would find the policy lacking in reasoning and would thus set it aside as arbitrary and capricious.

In conclusion, an interesting question arises: if there are so many ways and reasons to challenge President Bush's Directive and its implementation by the NIH, how can we explain the fact that no one has ever raised such challenges in court? One plausible explanation may lie in Dean Kagan's description of a shift in what Strauss called the "psychology of government"[314]—namely, that executive officers have become so "desensitized" to the accelerating use of presidential directives that impose policies on them and have become so used to the Constitutional Unitarian rhetoric accompanying such directives that they no longer doubt the applicability or validity of such directives. A second parallel phenomenon apparently has accompanied this phenomenon and intensified its effects. The media, and as a result the general public, have grown "numb" to the ever increasing intrusions of presidential directives—especially during the Clinton and Bush Administrations[315]—into what used to be perceived as the sole domain of executive agencies' discretion.[316] By the time President Bush gave his Directive, the public, the media, and the agencies themselves had grown so accustomed to such presidential assertions of authority that evidently no one proceeded to challenge what seemed to be yet another assertion of the rising presidential power, no more or less outrageous than many others before it. Add to these factors what Gaziano describes as a low level of public understanding of the legal foundation and proper uses

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312. *See State Farm*, 463 U.S. at 41-42 ("[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance.").

313. *See supra* text accompanying note 120.

314. Kagan, *supra* note 170, at 2299; Strauss, *Presidential Rulemaking*, *supra* note 195, at 986.

315. *See generally* Strauss, *Presidential Rulemaking*, *supra* note 195; Branum, *supra* note 7; Olson & Woll, *supra* note 241 (discussing President Clinton's presidential directives).

316. For a similar argument related to the regulation of funding of research involving hESCs, see Branum, *supra* note 7, at 46-47.

of presidential directives[317] and the legal community's preoccupation with the debate over the "unitary executive,"[318] and the result is that President Bush's Directive and its progeny were allowed to pass unchallenged.

Another, less dramatic explanation as to why President Bush's Directive and the ensuing NIH policy remain uncontested may be that no party partaking in research involving hESCs in the United States has been ready and willing to spend the time, money, and effort necessary to challenge them in court. Despite these hurdles, I hope that this Article would serve to encourage interested parties to challenge President Bush's Directive and its implementation by the NIH.

CONCLUSION

For over six and a half years, President Bush's Stem Cell Decision has been dictating the nature and extent of scientific research involving human embryonic stem cells. Yet, astonishingly, despite being the subject of a boisterous debate, its legality, as well as that of the actions taken by the NIH to carry it out, have never been questioned nor ascertained. This Article sought to fill this vacuum.

This Article has shown that even under the most permissive assumptions President Bush's Directive cannot be reconciled with NIHRA § 101. This Article further demonstrated that the actions taken by the NIH to implement President Bush's Directive constituted clear violations of the NIHRA and the APA—the extent of which depends on one's viewpoint in the "unitary executive" debate. Finally, this Article argued that these flaws render both President Bush's Directive and the ensuing actions taken by the NIH illegal and thus challengeable in court. I anticipate that such challenges would result in striking down President Bush's Directive and in setting aside the NIH's adoption of his Stem Cell Decision as its policy. Furthermore, such a challenge may also prompt a court to overrule the NIH's withdrawal of the Final Guidelines' language dealing with research involving hESCs and to reinstate language allowing federal funding for types of research involving hESCs disallowed by President Bush's Directive.

An interesting issue that remains, which may justify a separate, more elaborate inquiry, is what President Bush and the NIH could do in order to *legally* enforce President Bush's Stem Cell Decision. Arguably, the NIH may entrust the entire issue of the ethical soundness of research involving hESCs to an Ethics Advisory Board, which it could establish pursuant to the NIHRA. Alternatively or additionally, President Bush might use his

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317. Gaziano, *supra* note 134, at 269-70.
318. *See supra* Part II.B.3.a.i.

authority to direct executive agencies in a less controversial manner to pile up procedural requirements or obstacles for any attempt to actually fund such research involving hESCs, so as to render such funding practically impossible or prohibitively burdensome.

Though it is hard to anticipate whether the current Administration would elect to take any of these measures or whether President Bush's Directive and the NIH's ensuing actions will eventually face a challenge in court, it is prudent to assume that President Bush's Stem Cell Decision will eventually be discarded. With the newly formed Democratic majority in Congress, we should probably expect more bills akin to the Stem Cell Research Act of 2005, which would seek to impose federal funding for research involving hESCs, though potential presidential vetoes await. Furthermore, rapid encroachments on the efficacy of the current federal government's policy by state funding and international research, increasing public pressure to fund research involving hESCs, development of new techniques to produce hESCs without destroying embryos, and the United States' incentive to stay in the forefront of scientific research will all, sooner or later, bring the demise of the current policy in favor of one that is more permissive. President Bush's Stem Cell Decision swims against the current and—as other cases of ethically controversial though useful scientific technologies teach us—will eventually yield to progress; it is only a matter of time. Yet, the way this chapter in our regulatory history will end may have bearing on crucial issues regarding the nature of the Chief Executive and the extent of its "unitariness." Will it finally be limited by courts or by Congress, or will it remain uninhibited as is reflected in President Bush's Directive? In addition, hopefully Congress will take heed of the regulatory knot described in this Article as a cue that the time has finally come to create a federal mechanism for the formulation of government-wide bioethical policies, as other countries have done.