NOTE

FEDERAL FUNDING OF HUMAN EMBRYONIC STEM CELL RESEARCH: AN INSTITUTIONAL EXAMINATION

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I. INTRODUCTION

Stem cells present an intriguing dilemma. They tantalize with their boundless medical potential, but challenge with equally limitless questions about their ethical consequences. If not for this ethical challenge, the question of federal funding for stem cells would be simple: How much funding and to whom? Instead, ethical objections, closely related to other highly controversial political issues, sweep stem cell policy into a political vortex. In recent years, this storm has reduced science's role in the equation—transforming the issue from a tangible question of science and technology into an abstract debate setting ethical catastrophes against as yet undiscovered miracle cures. Given the political firestorm, government actors have treaded carefully, implementing halfway measures and justifying them by obscuring portions of the real debate from the public. The resultant policy, culminating in President George W. Bush's August 2001 limitation on federal funding to existing stem cell lines, is driven by a blend of outdated legislation and imperfect institutional arrangements—a

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combination that, admittedly, handicaps the nation's ability to explore the potential benefits of human embryonic stem cells ("hES"). More importantly, the policy fails to address the fundamental problem that purportedly justifies its existence: the ability to control the issue's controversial ethical dilemmas.

The events that followed Bush's policy decision—events that illustrate the beginnings of a policy entrenchment—were the impetus for this Note. Examples include the government response to the September 11 attacks, South Korea's successful cloning of a human embryo, private funding initiatives, and extensive state legislation designed to act where the federal government has not. Each of these events, the latter two of which were reactions to a policy that had officially set the rules for the game, exacerbates the current problems with stem cell policymaking and makes reform of the current institutional framework less likely. While the Bush Administration sold this policy as a "stop-gap" solution subject to reexamination upon further discovery, this Note stresses that the current setup belies such hopes. As currently situated, policy change will require a shift in political institutions, not scientific discovery.

This Note delves into the institutional structures and processes that govern stem cell policy and explores substantive critiques of the current policy without judging the policy on its merits.[1] It does not seek to evaluate the policy outcome, but instead uses the existence of genuine negative effects, both present and future, to press the need for reform in the policymaking process. The current process increasingly alienates the federal government from the front lines of the critically important stem cell debate; each passing day makes any eventual change more difficult and costly.

This Note continues in five parts. Part II lays out the background of the hES debate, including the technological and legal aspects of the issue. Part III summarizes some of the more common social, economic, and ethical concerns. Taken together, these parts demonstrate the overall significance of hES research, illustrate the complexities that make this issue a particularly unique policy challenge, and describe the historical development of the current regulatory scheme. Part IV then presents the primary argument: the evolution of stem cell policy and its related institutions has resulted in an institutional setup that is ill suited to govern hES research. This part takes a historical-comparative approach to the

1. General normative questions of government's proper role in various policy areas are outside the scope of this Note.

relevant institutions and actors in stem cell policy, from the early stages of fetal tissue research, to the dueling administrative agendas of President Bill Clinton and President George W. Bush. It examines not only how these actors influenced policy over time, but also how policies fed back into institutional development. The analysis in Part IV illustrates how a mixture of congressional passivity, institutional developments within the Office of the President, and judicial silence not only gave Bush the opportunity and authority to implement his policy decision, but also strongly influenced the substantive outcome. The policy, based largely on the President's personal agenda, may have placated the public's desire for a response, but the policy's inconsistency left the great majority of affected interest groups distressed. Part V lays out several possible remedies to the current problem, and Part VI offers some final conclusions.

II. TECHNICAL, LEGAL, AND ETHICAL BACKGROUND TO THE STEM CELL DEBATE

A. TECHNICAL BACKGROUND

1. The Facts on Stem Cells in General and Embryonic Stem Cells in Particular

Stem cells are the building blocks of the human body.[2] Found in embryos and specific tissues of both children and adults,[3] these cells have three basic properties that account for their potential benefits. First, they are unspecialized blank slates—they have no "tissue-specific structures that allow [them] to perform specialized functions."[4] Second, unlike muscle, blood, or nerve cells, stem cells are capable of dividing and renewing themselves through a process known as proliferation.[5] Third, these cells may develop from unspecialized cells into specialized cell types through a process called differentiation.[6]

Stem cells that are located in different parts of the body are understood to have disparate potentials. For example, adult stem cells, located in adult tissues such as the blood, bone marrow, and brain, have

2. *See* Nat'l Insts. of Health Stem Cell Information Online, *Stem Cell Basics*, *at* http://stemcells.nih.gov/info/basics/basics1.asp (last visited May 25, 2005) [hereinafter *Stem Cell Basics*].

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

limited differentiation capabilities and can develop only into the cell types of the tissues in which they reside.[7] While recent scholarship has suggested that these adult stem cells may be coaxed into giving rise to different cell types,[8] the current consensus is that hES, found in the embryonic layer of week-old embryos, possess significantly more differentiation potential and thus greater scientific promise.[9]

Within the broader category of hES, there are three basic types of cells (totipotent, pluripotent, and multipotent) that each have different developmental capabilities. Totipotent stem cells have the potential to become any type of cell, tissue, or organ, and each individual cell has the theoretical potential to develop into a "fully functional organism."[10] Pluripotent stem cells have similar developmental potential, but lack the capacity to independently develop into fully functioning organisms.[11] Multipotent stem cells are more limited in their developmental capacity, restricted to generating only certain types of simple tissues such as bone, cartilage, muscle, and fat.[12] Based on these characteristics, pluripotent stem cells are the subject of the most attention because they do not have the ability to become persons, but *do* have the ability to differentiate into any type of cell, tissue, or organ. Therefore, these cells present significant research potential, and the research involving them does not itself invoke any ethical debate.[13] The controversy arises, however, from the source of these pluripotent cells. That is, in order to obtain them, one must either "destroy" a donated embryo, or an embryo that has been created or cloned

7. *Id.*

8. *Id.* This process, known as "plasticity," remains in the theoretical and developmental levels with regard to adult stem cells. Recent research has shown adult stem cells to have limited plasticity, the potential of which is currently under investigation by the National Institutes of Health ("NIH"). *See id.* Increased plasticity in adult stem cells naturally leads to an increased potential for adult stem cells in cell-based regenerative therapies. *Id.*

9. *See* Amy Ligler, *Egregious Error or Admirable Advance: The Memorandum of Understanding That Enables Federally Funded Basic Human Embryonic Stem Cell Research*, 2001 DUKE L. & TECH. REV. 37, ¶ 2 (2001), *at* http://www.law.duke.edu/journals/dltr/articles/2001dltr0037.html.

10. *See* AUDREY R. CHAPMAN, MARK S. FRANKEL & MICHELE S. GARFINKEL, AM. ASS'N FOR THE ADVANCEMENT OF SCI. & INST. FOR CIVIL SOC'Y, STEM CELL RESEARCH AND APPLICATIONS: MONITORING THE FRONTIERS OF BIOMEDICAL RESEARCH 1 (1999), http://www.aaas.org/spp/dspp/sfrl/projects/stem/report.pdf. This potential raises immediate ethical concerns about cloning humans, as will be discussed *infra* Part III.B.3.

11. *Id.*

12. *Id.*

13. Totipotent cells, because of their vast development potential, engender ethical issues independent of their source. That is, totipotent cells are controversial even without considering the fact that they must be extracted from human embryos.

through a process known as somatic cell nuclear transfer ("SCNT"). These methods of extraction invoke ethical debate, taken up in Part III.

2. The Promise of Stem Cell Research

Stem cells command attention in the national debate because of their immense potential for advancing medical treatment. A growing number of scientists, interest groups, and celebrities has elevated the noise level surrounding hES by publicly advocating their potential benefits. Views on the probability of realizing such potential vary. Research proponents praise the current applicability of research and believe further study will yield useable results in the near future. Skeptics believe that such benefits are far from certain. These skeptics advocate patience and demand tangible results before using the dreaded word "potential" to inform future policy decisions. Thomas Okarma, President of Geron Corporation, exemplifies some of the (understandably) boundless optimism of private industry in his statements regarding stem cell research: "The potential for these cells is to allow permanent repair of failing organs by injecting healthy functional cells developed from them, an approach called regenerative medicine . . . . Regenerative medicine would be a *totally new value paradigm* for clinical therapeutics."[14] Okarma is one of many who believe that hES research could transform the medical field as we know it.

Whether or not science taps into the vast potential for hES research, its political significance is undeniable. The promise of hES research has already changed the *political* value paradigm, striking down partisan lines and defying traditional ideological compartmentalization. Endless possibilities erode principled boundaries that once seemed impenetrable. Stem cell research touches a wide range of maladies that strike individuals of any race, class, or political party, and the legion of influential supporters reflects this unbiased benefit.[15]

14. Janet L. Dolgin, *Embryonic Discourse: Abortion, Stem Cells, and Cloning*, 31 FLA. ST. U. L. REV. 101, 111 (2003) (emphasis added).

15. Nancy Reagan, wife of the late Republican President, has been an outspoken advocate of stem cell research. Likewise, her son Ron spoke at the 2004 Democratic National Convention in support of the issue. Republican Governor Arnold Schwarzenegger was one of the leaders of California's 2004 proposition to provide over $3 billion in state funds to hES research. The elephant in the room of Republican stem cell supporters is abortion—an issue that has been a core element of the Republican platform. Because anti-abortion arguments typically evolve from the first principle that life begins at conception, the destruction of embryos for hES research purposes remains anathema to the anti-abortion contingent of the Republican Party.

B. THE CURRENT LEGAL AND REGULATORY SCHEME

Dr. James Thompson first isolated hES in 1998.[16] Thus, while research on hES may be a relatively modern development, policymakers have dealt with the issue of human subject research, particularly research on fetuses and embryos, for quite some time. This section narrates the historical development of hES policy, organized around several significant scientific and political events that dictated the course of the policy.

1. Fetal Tissue Research: *Roe v. Wade* and *In Vitro* Fertilization

In 1973, following the Supreme Court's decision in *Roe v. Wade*,[17] growing concern on the subject of fetal tissue research led some members of Congress to act.[18] Later that year, the Department of Health, Education, and Welfare ("DHEW," existing today as the Department of Health and Human Services, "DHHS") initiated a moratorium on any potential DHEW sponsorship or funding of research using human fetuses. In 1974, Congress subsequently passed the National Research Act,[19] establishing The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("Commission"). Congress charged the Commission with investigating the research of living fetuses and enacted a four-month moratorium that would end after the Commission had made its findings and recommendations.[20]

16. Nat'l Insts. of Health Stem Cell Information Online, *Frequently Asked Questions*, *at* http://stemcells.nih.gov/info/faqs.asp (last visited May. 25, 2005).

17. Roe v. Wade, 410 U.S. 113 (1973). *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 23 (2004), http://www.bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf [hereinafter COUNCIL]. President George W. Bush established The President's Council on Bioethics, which published this report in January 2004. Notably, the report applies an interpretive gloss on the moratorium and subsequent investigation order by Congress—stating that the order applied to "living embryos" despite the fact that the actual public law applied to "living fetuses," made no mention of embryos, and did not provide a satisfactory definition of a fetus. *Compare id.* at 23, *with* Nat'l Research Act, Pub. L. No. 93-348, 88 Stat. 342 (passed by the 93rd Congress as H.R. 7724, July 12, 1974).

18. *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 23 (2004) http://www.bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf [hereinafter COUNCIL]. President George W. Bush established The President's Council on Bioethics, which published this report in January 2004. Notably, the report applies an interpretive gloss on the moratorium and subsequent investigation order by Congress—stating that the order applied to "living embryos" despite the fact that the actual public law applied to "living fetuses," made no mention of embryos, and did not provide a satisfactory definition of a fetus. *Compare id.* at 23, *with* Nat'l Research Act, Pub. L. No. 93-348, 88 Stat. 342 (passed by the 93rd Congress as H.R. 7724, July 12, 1974).

19. National Research Act, Pub. L. No. 93-348, §§ 201, 202, 213, 88 Stat. 342 (introduced as H.R. 7724 and passed by the 93rd Congress on July 12, 1974).

20. The exact congressional order was as follows:

Already aware of the potential for embryos being created outside the womb—with the first successful *in vitro* fertilization ("IVF") in 1969 and the eventual birth of an *in vitro* baby—the Commission nevertheless limited the definition of fetus to the "product of conception from the time of *implantation* onward."[21] In response to the Commission's 1975 recommendations, DHEW established an Ethics Advisory Board ("EAB") to propose standards and research protocols for federal funding of research using human fetuses and to consider particular applications for funding.[22] The EAB, in reporting on the ethical acceptability of IVF research, concluded that federal support was acceptable provided that certain conditions were met. The requirements included informed consent for the use of gametes, an articulated important scientific goal that was "'not reasonably attainable by other means,'" and no maintenance of an embryo outside the womb "'beyond the stage normally associated with the completion of implantation (fourteen days after fertilization).'"[23] The DHEW failed to implement the EAB recommendations, however, and the board was eventually dissolved in 1980.[24] Because the National Research Act required the EAB to review funding proposals, the dissolution of the board without replacement led to a de facto ban on funding for IVF and fetal tissue research through the 1980s.[25]

In 1988, towards the end of his second term, President Ronald Reagan ended the institutional silence and took a formal stance against fetal tissue implantation. The administrative agency charged with distributing federal research funds, the National Institutes of Health ("NIH"), subsequently began a voluntary moratorium, pending discussion of the legal and ethical

> The Commission shall conduct an investigation and study of the nature and extent of research involving living fetuses, the purposes for which such research has been undertaken, and alternative means for achieving such purposes. The Commission shall, not later than the expiration of the 4-month period beginning on the first day of the first month that follows the date on which all the members of the commission have taken office, recommend to the secretary policies defining the circumstances (if any) under which such research may be conducted or supported.

Id. § 202(3)(B) (emphasis added).

21. *See* COUNCIL, *supra* note 18, at 23 (emphasis added).

22. *Id.*

23. NAT'L BIOETHICS ADVISORY COMM'N, 1 ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH 34 (1999) [hereinafter NBAC, ETHICAL ISSUES] (quoting DEP'T HEALTH, EDUC., AND WELFARE, ETHICS ADVISORY BD., REPORT AND CONCLUSIONS: HEW SUPPORT OF RESEARCH INVOLVING HUMAN *IN VITRO* FERTILIZATION AND EMBRYO TRANSFER 106–07 (1979)), http://www.georgetown.edu/research/nrcbl/nbac/stemcell.pdf.

24. *Id.*

25. COUNCIL, *supra* note 18, at 24.

issues involved.[26] In September 1988, shortly before the election of President George H. W. Bush, an NIH advisory committee unanimously voted to lift the moratorium, but neither Reagan nor Bush acted on its recommendation.[27]

2. A Change in Outlook: The Clinton Administration

a. Congress Passes the National Institutes of Health Revitalization Act

On just his second day in office in 1993, Clinton lifted the moratorium on federally funded fetal tissue research and soon after, Congress began conducting hearings on the matter.[28] In March 1993, Congress passed the NIH Revitalization Act, eliminating the prior requirement that research protocols were to be reviewed by the EAB.[29] Accordingly, the NIH convened the Human Embryo Research Panel ("Panel") and instructed it to "set forth standards for determining which *projects* could be funded ethically, and which should be considered 'unacceptable for federal funding.'"[30] The Panel subsequently "identified several areas of potential research activity that it considered ethically appropriate for federal support." Research involving human embryos was among these areas, but only if the research satisfied certain ethical standards, such as obtaining progenitors' consent.[31] Additionally, in a highly controversial conclusion, the Panel suggested that the creation of human embryos for certain research purposes might be ethically acceptable.[32] In December 1993, Clinton did not object to these proposals, thereby allowing the NIH to begin accepting grant applications for funding of research using embryos left over from IVF procedures.[33] Clinton did, however, reject the notion that federal funds should be used to create human embryos expressly for research purposes.[34]

26. Heather J. Meeker, *Issues of Property, Ethics and Consent in the Transplantation of Fetal Reproductive Tissue*, 9 HIGH TECH L.J. 185, 192 (1994).

27. *Id.*

28. *Id.* That Congress waited to act further buttresses the argument that the executive controlled the agenda regarding fetal research.

29. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 121(c), 107 Stat. 122 (repealing 45 C.F.R. § 46.204(d) (1992)); COUNCIL, *supra* note 18, at 24.

30. *See* NBAC, ETHICAL ISSUES, *supra* note 23, at 34 (quoting Meeting Notice, Request for Public Comment, 59 Fed. Reg. 28,874–75 (June 3, 1994) (notice of meeting; the NBAC publication slightly misquotes the Federal Register)).

31. *See* NBAC, ETHICAL ISSUES, *supra* note 23, at 34.

32. *Id.*

33. *Id.*; COUNCIL, *supra* note 18, at 25.

34. COUNCIL, *supra* note 18, at 25; NBAC, ETHICAL ISSUES, *supra* note 23, at 34.

b. The Dickey Amendment

In accordance with the President's declarations, NIH director Harold Varmus began taking steps toward establishing a process to receive grant applications for fetal research. Before any funding decisions could be finalized at the administrative level, however, Congress attached a rider to the 1996 DHHS appropriations bill prohibiting the use of any federal funds for activities involving the following:

> (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 C.F.R. 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).[35]

This rider, known as the Dickey Amendment, is the first piece of legislation specifically targeting embryo research without mentioning *in vitro* techniques. The Amendment's text references DHHS Regulations first passed in 1974 that deal with the boundaries of fetal tissue generally, and IVF research in particular.[36] Subpart A of these regulations, also referred to as the Common Rule,[37] requires the establishment of Institutional Review

35. Pub. L. No. 104-99 § 128, 110 Stat. 26, 34 (1996). The Dickey Amendment has been attached to every subsequent Labor/HHS appropriations bill since 1996. The most recent version is codified in Pub. L. No. 108-447 § 509, as follows:

> SEC. 509. (a) 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 C.F.R. § 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289(g)(b)).
> (b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 C.F.R. 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Consolidated Appropriations Act of 2005, Pub. L. No. 108-447, § 509, 118 Stat. 2809 (2004). The amendment thus remains good law, though it neglects to consider that Subpart B of the DHHS regulations has been revised, and 45 C.F.R. § 46.208(a)(2) has been repealed since November 2001. 66 Fed. Reg. 56,775 (Nov. 13, 2001) (codified at 45 C.F.R. pt. 46 (2005)). The comments to the amendment declare that "the current definition of fetus contained in the regulations appropriately includes embryos *in utero*, and that research involving embryos is otherwise adequately addressed by existing statutory requirements." *Id.*

36. 45 C.F.R. §§ 46.101–46.124 (2005) (these sections are collectively known as the "Common Rule"); 45 C.F.R. §§ 46.201–46.208 (2005) (these sections are from Part 46, Subpart B, entitled "Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research"). As mentioned *infra*, Subpart B was amended in 2001, repealing section 46.208, which had specifically mentioned embryos created by *in vitro* procedures. The new Subpart B now includes *in vitro* embryos within the definition of fetus: "the product of conception from implantation until delivery." 45 C.F.R. § 46.202.

37. The regulation is called the Common Rule because it has "been adopted by most federal agencies that sponsor human research." Gabriel S. Gross, *Federally Funding Human Embryonic Stem*

Boards ("IRBs") to approve any testing on human subjects.[38] The Common Rule also describes membership requirements for these IRBs, as well as the criteria for the approval of research.[39] Application of the Common Rule, and thus IRB review, to the stem cell debate is undisputed.

By contrast, there has been some confusion as to the applicability of the DHHS regulations' Subpart B, which imposes additional regulatory requirements on federal grants that deal with the fetus, pregnant women, and IVF.[40] This confusion was cleared up in November 2001 when Subpart B was amended to eliminate any specific reference to IVF or embryos. The amended Subpart B only references fetuses, but legislative commentary declared that embryos *in vitro* were appropriately protected within the definition of a fetus and that existing regulations already provided sufficient protection for embryo research in general. In other words, in 2001, the NIH was required to protect all embryos with the same procedural devices and minimal risk standards afforded fetuses. The Dickey Amendment also referenced the National Research Act, which requires that any fetuses, and thus embryos, researched with federal funds must be exposed to minimal risk levels irrespective of any intent to abort or carry to full term.[41]

3. The Dolly Controversy

In March 1997, shortly after the Roslin Institute released news of its successful cloning of Dolly the sheep, the Clinton Administration released a Memorandum for the Heads of Executive Departments and Agencies, in which the President declared that "no Federal funds shall be allocated for cloning of human beings."[42] Nevertheless, in the very same statement, Clinton used the increased attention levels to respond to Congress's

Cell Research: An Administrative Analysis, 2000 WIS. L. REV. 855, 861. The Common Rule is comprised of Subpart A of the DHHS regulations. 45 C.F.R. §§ 46.102, 46.107–46.109.

38. 45 C.F.R. §§ 46.102, 46.107–46.109.

39. 45 C.F.R. §§ 46.107, 46.109. *See, e.g.*, Gross, *supra* note 37, at 861.

40. *See, e.g.*, NBAC, ETHICAL ISSUES, *supra* note 23, at 35 (noting the additional duties that would fall upon IRBs if Subpart B applied to *all* embryo research). *See also* Gross, *supra* note 37, at 861–62.

41. 42 U.S.C. § 289(g)(b) (2000). The statute also refers back to Subpart A of the DHHS regulations (the Common Rule), which defines the allowable level of risk as follows: "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 45 C.F.R. § 46.102(i).

42. NBAC, ETHICAL ISSUES, *supra* note 23, at 37 (quoting Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, Office of the White House Press Secretary (Mar. 4, 1997), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1997_public_papers&docid=pap_text-144).

attempts to limit his funding policies, particularly through the Dickey Amendment. The President acknowledged that the Amendment prohibited certain types of federal funding for embryo research, but reiterated that it did "not explicitly cover human embryos created for implantation and [did] not cover all Federal agencies."[43] With a single statement, Clinton responded to the cloning controversy, while reserving the right to fund research on embryos that were the by-product of IVF.

In June 1997, the President received and accepted the conclusions of a report, *Cloning Human Beings*, prepared by the National Bioethics Advisory Commission ("NBAC").[44] These conclusions included a moratorium on public or private research to create a child through SCNT, but not on laboratory research using the technique.[45] Moreover, as Congress moved to introduce legislation to ban human cloning practices later that year, the Clinton Administration issued a Statement of Administration Policy, providing in part that "the Administration supports amendments to S. 1601 that would . . . permit somatic cell nuclear transfer using human cells *for the purpose of developing stem cell . . . technology to prevent and treat serious and life-threatening diseases*."[46] This statement, however, carried no weight of law, and Congress was unable to pass any legislation on the matter.

4. Isolating Stem Cells: The NBAC Report and NIH Guidelines

Following Thompson's breakthrough isolation of hES from a human embryo in 1998, Clinton requested that the NBAC "conduct a thorough review of the issues associated with . . . human stem cell research, balancing all medical and ethical issues."[47] Concurrent to the NBAC investigation, then chair of the NIH, Harold Varmus, sought out DHHS General Counsel Harriet Rabb, in order to secure her legal opinion on

43. *Id.*

44. In the letter of transmittal discussing the scope of this report, NBAC Chair Harold Shapiro noted that the Dolly controversy was indeed the impetus for the report. *See* Harold T. Shapiro, *Letter of Transmittal to the President* for NAT'L BIOETHICS ADVISORY COMM'N, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS (1997). Furthermore, the letter noted that both the "legal and moral issues raised can only be resolved, even temporarily, by a great deal more widespread deliberation and education." *Id.* Noting the pluralistic nature of society and the decided lack of moral consensus, Shapiro claimed that the only thing government could do to quell some of the widespread public concern was to raise understanding of the issues and to distinguish between "science and science fiction." *Id.*

45. NBAC, ETHICAL ISSUES, *supra* note 23, at 37.

46. *Id.* (quoting Statement of Administration Policy, S. 1601, Human Cloning Prohibition Act, Executive Office of the President of the United States (Feb. 9, 1998)).

47. Harold T. Shapiro, *Letter of Transmittal to the President* for NBAC, ETHICAL ISSUES, *supra* note 23 (quoting Letter from President Clinton, to NBAC (Nov. 14, 1998)).

compliance with the Dickey Amendment. Ms. Rabb opined that the Dickey Amendment did "not prevent NIH from supporting research that uses ES cells derived from this source because the cells themselves do not meet the statutory, medical, or biological definition of a human embryo."[48] In other words, while federal funds could not be used to extract hES cells from an embryo, such funds could be used to support the subsequent research of those hES cells. Later, in September 1999, NBAC produced its report entitled *Ethical Issues in Human Stem Cell Research*.[49] In that report, the NBAC recommended that Congress amend the ban to permit federal funding of research involving excess embryos. The recommendation was justified "largely in terms of loyalty to medicine's goals of healing, prevention, and *research* . . . 'rightly characterized by the principles of beneficence and nonmaleficence.'"[50]

In December 1999, considering the above NBAC recommendations, as well as those of a specially commissioned Working Group of the Advisory Committee to the Director,[51] NIH published an initial set of embryo research guidelines in the *Federal Register* and opened them up to comment.[52] In November 1999, at the conclusion of the comment process, the NIH released its final version of the guidelines ("Guidelines") in the *Federal Register* and on their Web site. The NIH Guidelines marked out appropriate areas for federal funding and, in following Rabb's opinion, explicitly permitted federal funding for research on stem cells that had been derived from human embryos using private funds.[53] The NIH Guidelines also reiterated the difference between embryos created for research

48. NBAC, ETHICAL ISSUES, *supra* note 23, at 35 (describing Memorandum from Harriet Rabb, to Harold Varmus (Jan. 15, 1999)).

49. NBAC, ETHICAL ISSUES, *supra* note 23.

50. John C. Fletcher, *NBAC's Arguments on Embryo Research: Strengths and Weaknesses*, *in* THE HUMAN EMBRYONIC STEM CELL DEBATE: SCIENCE, ETHICS AND PUBLIC POLICY 61, 62 (Suzanne Holland et al. eds., 2001) [hereinafter STEM CELL DEBATE] (quoting NBAC, ETHICAL ISSUES, *supra* note 23, at 69).

51. The Working Group, composed of scientists, patients and patient advocates, ethicists, clinicians, and lawyers, met on April 8, 1999. During these meetings, the Working Group heard from the public, members of professional associations, and Congress. *See* National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,977 (Aug. 25, 2000).

52. *Id*. Due to the volume of public comment, the original sixty-day comment period was extended an additional twenty-eight days. Over 50,000 comments were received. *Id*.

53. The Guidelines state, in part, that "[s]tudies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment." 65 Fed. Reg. at 51,976. The Guidelines go on to address issues of consent in the donation of the embryo and further note which areas are ineligible for funds. 65 Fed. Reg. at 51,976, 51,981.

purposes and those created for reproductive purposes. Any research on hES derived from the former was ineligible for funding. Research on hES derived from the latter method was eligible. This distinction, coupled with stringent documentation requirements on the informed consent of the donors, underscored the Administration's ethical concern over improper incentives that may lead to a "black market" for human embryos.[54] The purpose of the NIH Guidelines, in some respects, was to strengthen the legitimacy of federally funded hES research by ensuring that it would be conducted in an "ethical and legal manner."[55]

5. Another Change in Outlook: The Bush Compromise

Immediately upon taking office in January 2001—and before the NIH could make any funding decisions pursuant to their newly released Guidelines—President George W. Bush addressed hES research by putting the NIH on hold, and ordering "another look at the options regarding human embryonic stem cell research policy."[56] In August 2001, Bush articulated his own policy, forcing the NIH to repeal its Guidelines.[57] Citing his moral and religious beliefs, and consultation with experts in both the scientific and ethical fields, Bush announced his decision to restrict federal funding to existing stem cell lines.[58]

Following the public pronouncement, Bush proclaimed that the establishment of a Council on Bioethics ("Council") would serve to continue the investigation into the legal and ethical issues involved and advise the executive on any necessary adjustments to the policy. The Council subsequently published several reports stating that the impetus for the Bush decision was a mixture of legal and ethical considerations including the Dickey Amendment, the principles underlying the Dickey Amendment, and the significance of offering federal funding to hES research.[59]

54. 65 Fed. Reg. at 51,976–77.

55. 65 Fed. Reg. at 51,976.

56. COUNCIL, *supra* note 18, at 28.

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

58. Press Release, President George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001), *at* http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html.

59. COUNCIL, *supra* note 18, at 28–41.

III. DEBATE OVER THE CURRENT SOLUTION

The debate over the current regulatory regime is significant for three reasons. First, it demonstrates the legal, ethical, and economic difficulties of the issue—and thereby provides some insight about why the issue is politically challenging. Second, the debate sheds light on some of the negative consequences resulting from the current Bush compromise and, in so doing, provides a justification for further investigation of the decisionmaking process. Third, once investigation is undertaken, the debate offers a means for measuring whether process reform improves the current situation. The following section presents the primary objections to the current policy regime, as well as the current Administration's answer to each side. Generally speaking, critics of the Bush policy claim that the policy is arbitrary, unsustainable, and inconsistent,[60] while the Bush Administration claims that such faults are the necessary result of delicately balancing the compelling interests presented below.

A. SOCIOECONOMIC ISSUES

The pharmaceutical industry takes in annual revenues in the billions,[61] and the relatively nubile biotech industry is growing at an incredible rate. The promise of stem cell research, if fulfilled, will thus have significant economic consequences and spawn a legion of new policy issues. The following discussion illustrates some of the socioeconomic effects of the Bush compromise.

1. Availability and Unjust Enrichment

Access to health care has always been a politically charged issue.[62] Should workable stem cell therapies ever develop without federal funding, the "fairness of access" issue will intensify.[63] Private companies, already at the cutting edge of the biotech explosion, have assumed an even greater role following Bush's decision to limit federal funding to a small population of existing lines. Some of the implications of this trend are that private companies limit their research to profit-maximizing therapies, and

60. *Id.* at 63–74.

61. *See, e.g.*, Tom Ramstack, *Rockville Biotech Firm Taps New Chief*, WASH. TIMES, Nov. 23, 2004, at C10, 2004 WLNR 12146027; Stephen S. Hall, *The Drug Lords*, N.Y. TIMES, Nov. 14, 2004, § 7, 2004 WLNR 8234576.

62. Witness the most recent controversy surrounding Medicare reform that affected the availability of prescription drugs to seniors.

63. *See* Margaret R. McLean, *Stem Cells: Shaping the Future in Public Policy*, *in* STEM CELL DEBATE, *supra* note 50, at 197, 202–04.

that new therapies may not receive proper insurance coverage at the initial stages.[64] Indeed, given the risky nature of stem cell therapies,[65] unsubsidized private companies may justifiably make claims to significant price premiums for their therapies, should their research yield fruitful results.

Yet another issue involves the windfall that the Bush decision granted to the holders of existing stem cell lines in August 2001.[66] The companies who hold patents in these lines, the two largest being Geron Corporation and the Wisconsin Alumni Research Fund ("WARF"), were essentially granted legal monopolies by the federal government in the form of an exclusive dealing contract between the NIH and existing patent holders. The exclusive grants, combined with the President's limitation on federal funding outside existing lines, allow private companies to conduct research without the ordinary governmental regulation that would come from periodic congressional appropriation.

2. Global Competitive Disadvantage

Regardless of how one feels about the probability that stem cell research may yield fruitful results, recent events have made clear that the United States will fall behind in the race to uncover the potential of stem cells. Margaret McLean refers to this as the "Dolly Effect," whereby the nation's policy changes only after "the sheep has left the barn."[67] Put another way, current stem cell policy is reactive—driven more by exogenous events that compel change than any endogenous self-evaluation.[68] This passive approach to stem cell research has arguably produced two negative effects: (1) a "brain drain" of some of the best scientists leaving our borders and our academic institutions in order to

64. *See id.*

65. *See, e.g.*, Debora Vrana, *Investors Divided on Stem Cells Biotech: Venture Capitalists Besiege One Research Firm, but Long Payoff, Risk Deter Most*, L.A. TIMES, Sept. 1, 2001, at C1, 2001 WL 2514779.

66. *See* Ligler, *supra* note 9, at 1.

67. McLean, *supra* note 63, at 198.

68. As the previous sections demonstrated, the development of human subject research in general has been marked by a series of significant external events that force policymakers to adjust. These events range from the decision in *Roe v. Wade*, 410 U.S. 113 (1973), to the cloning of a sheep in Great Britain. As this Note will describe, the current stem cell policy takes the stem cell debate largely outside the federal government's hands, preventing it from conducting the necessary research to make endogenous change through self-evaluation. Instead, change will be compelled by future events, most likely in other countries.

pursue goals abroad,[69] and (2) a competitive disadvantage imposed by the policy of limiting substantial federal funds to certain stem cell lines.[70]

Admittedly, these disadvantages are difficult to quantify and may be overstated. Some commentators believe that the existing stem cell lines, because they can be perpetuated, provide enough raw materials to push the United States through the early stages of stem cell research—though recent events have undercut such arguments, most notably, the confirmation that many of the existing stem cell lines have been irreversibly contaminated.[71] And furthermore, the brain drain has not been as prevalent as the initial exodus of Professor Roger Pederson first suggested.[72] In fact, several states and private entities have stepped into the void and provided the necessary funding.[73]

3. The State Race to Compete

States have had mixed reactions to Bush's compromise solution. A number of them have passed legislation regulating research on embryos and fetuses; at least nine have categorically banned human embryo experimentation—meaning that even the potential commercial and therapeutic products resulting from those stem cell lines could be barred from being sold within those states.[74] On the other hand, states such as California and New Jersey have passed funding propositions in an attempt to become leading forums for stem cell research.[75] As will be explained in Part III.E.2, the state reaction to the federal government's stem cell decision is the first round of gaming the existing system, opportunistically filling the gaps that the current scheme has laid out. As states become

69. *See, e.g.*, David Firn, *Professor Warns US Will Miss out over Stem Cells: Researcher Moving to UK*, FIN. TIMES, Aug. 15, 2001, at Front Page, 2001 WL 25577487.

70. *See id.* There is a plethora of articles decrying the state of stem cell research without federal funding on additional lines. Of course, most of these articles are authored by those academics generally in favor of stem cell research and in need of federal funding.

71. *See* Carl T. Hall, *California Stem Cell Advocates Seek Research Freedom; Existing Lines Found to Be Contaminated; Pelosi, Others Want Loosening of Rules*, S.F. CHRON., Jan. 25, 2005, at B1, 2005 WLNR 1021680.

72. *See* Firn, *supra* note 69.

73. *E.g.*, Laura Johannes & Antonio Regalado, *Privately Funded Research Yields New Stem-Cell Lines*, WALL ST. J., Mar. 4, 2004, at B1, 2004 WL-WSJ 56921943 (noting that Harvard researchers have circumvented the policy by extracting stem cells from IVF embryos with their own funds).

74. Ligler, *supra* note 9, at 7.

75. *See* Laura Mansnerus, *New Jersey Faces Tough Competition for Stem Cell Scientists*, N.Y. TIMES, Jan. 17, 2005, at B1, 2005 WLNR 620801. The $380 million proposal by Acting Governor Richard J. Codey signaled a race for second place behind California (but ahead of Wisconsin and Illinois). It is not only a race for a cure, but also, more importantly, a race to keep researchers and money within state borders. *Id.*

increasingly invested in the process, it may become more difficult for the federal government to reenter the equation.

B. MORAL, ETHICAL, AND LEGAL ISSUES

In his August announcement, Bush stated that his decision was shaped in part by ethical concerns and his own moral and religious beliefs.[76] Likewise, opponents of hES research believe that any discussion of funding stem cell research cannot proceed without first addressing these sizeable ethical and moral concerns.

1. The "Special Protection" of Embryos and the Abortion Debate

The legal, moral, and ethical status of the embryo is at the core of this entire debate. If pluripotent stem cells—cells that have been accepted as distinct from embryos because they cannot develop into human beings—could be obtained from a source other than embryos, this debate would have significantly less "noise." Unfortunately, because pluripotent stem cells are extracted from embryos through a process that renders the embryo nonviable, a host of questions arise regarding the level of protection that embryos should receive. Clinton believed that embryos deserved a heightened level of protection, but not the near-absolute right that viable fetuses received.[77] By contrast, Bush ascribed a higher level of protection to the embryo. Under his valuation, the destruction of future embryos was not worth an incremental increase in the probability that workable therapies may be developed.[78] Bush's Council on Bioethics, in analyzing the ethical landscape, discussed the moral status of the human embryo in great detail, finding that many of the arguments advanced by advocates of stem cell research involve scientific matters of continuity, but that without attaching ethical or moral significance to their positions, such arguments could not reduce the higher protection that Congress has accorded to embryos through the Dickey Amendment.[79]

76. *See* Bush, *supra* note 58.

77. *See* COUNCIL, *supra* note 18, at 30–31.

78. In limiting federal funds to those stem cell lines where the "life and death decision ha[d] already been made," President Bush was fully aware of the widely held belief in the scientific community that workable treatments were most likely achieved through embryonic stem cells and that federal dollars would be necessary for rapid progress in this area. Bush, *supra* note 58.

79. *See* COUNCIL, *supra* note 18, at 31–32. Continuity deals with several physical or developmental areas that may signal whether an embryo rises to the level of a "person." The Council's argument suggests that simple science, because it does not operate in the same sphere as moral boundaries, cannot prove that the potential for human life should be granted any less dignity. *See id.* at 48.

In determining the proper level of protection, there are two primary ethical issues at stake involving two sources of pluripotent stem cells. The first and most significant issue centers around hES derived from leftover embryos created for use in IVF procedures. These leftover embryos raise questions of intent. That is, does the special respect accorded to embryos depend on the intentions of their owners to use them or discard them? Advocates of the use of leftover embryos contend that the donor's intent not to use the embryos (but instead to discard them) means they are not viable by statutory definition and that extraction of stem cells from these embryos should not trigger the Dickey Amendment's prohibition on harming human embryos for research purposes. In other words, because these embryos are set to be discarded, no further harm to the embryos is caused by using them for research purposes. Opponents believe, on the other hand, that the ultimate intention of embryo implantation is irrelevant (and thus viability is irrelevant) to the special respect that is to be accorded to such embryos, especially because it is the owners who have placed the leftover embryos in the position in the first place.[80]

The second issue addresses another source of hES, embryos created through SCNT. Should the product of SCNT deserve the same protection as embryos derived through the union of male sperm and female ova? Whatever the answer, such an embryo carries with it the additional ethical burden imposed by the cloning debate, as discussed *infra* in Part III.B.3.

Discussion regarding the appropriate protection for embryos ultimately involves abortion. Aside from the obvious contention by anti-abortion activists that embryos deserve absolute protection from conception onward, recall that in the early days of fetal tissue research, one of Congress's primary concerns was whether such research would be conducted on aborted fetuses and whether such research could create incentives for abortions. To prevent any possibility that there may be some "abortion lure," strict guidelines were in place to ensure that the abortion was not financially motivated. Similar issues abound in the current hES

80. *See, e.g.*, COUNCIL, *supra* note 18, at 84–86; Karen Lebacqz, *On the Elusive Nature of Respect*, *in* STEM CELL DEBATE, *supra* note 50, at 149, 158–59. (stating that there are two requirements for the proper respect that is to be accorded to embryos: (1) the embryo must be valued in and of itself—it cannot be treated "cavalierly"; and (2) embryos *can* be killed, but moral duties still apply—that is, if there is an alternative, it should be explored). Moreover, early legislation showed that the amount of respect to be accorded an embryo was independent of whether that embryo was going to be implanted or aborted. *See supra* text accompanying note 41.

debate.[81] This Note concedes that both sides agree on policies to prevent embryo creation for research purposes and to ensure donor consent. The political debate instead revolves around the issue of whether the federal government should fund research that uses the product of properly motivated and consented donation.

2. Funding the Product of Unethical Behavior

A continuing criticism of Bush's compromise is the inconsistency associated with funding a harm already done. In other words, funding the research of destroyed embryos is tantamount to the federal government endorsing their initial destruction.[82] The Administration's response is that given that Congress has not banned the practice of extracting stem cells from embryos altogether, the executive branch does not need to send so strong a message.[83] While acknowledging that funding the products of past embryo destruction may be inconsistent with a desire to accord embryos special protection, the Council emphasized the avoidance of *future* embryo destruction.[84] In reality, these hair-splitting rationales illuminate what was essentially a political compromise, a silent nod from both sides of the partisan aisle to the growing credibility of the scientific potential of stem cell research.[85]

3. The Cloning Debate

As discussed above, the process of creating an embryo through SCNT has been commonly referred to as cloning, which raises difficult issues of "creating" human beings by circumventing the traditional fertilization

81. *See generally* Valerie J. Janosky, *Stem Cells: Potential Cures or Abortion Lures?*, 6 DEPAUL J. HEALTH CARE L. 111 (exploring the scientific and moral debate involved in the use of fetal stem cells in medical research).

82. COUNCIL, *supra* note 18, at 37–38.

83. *Id.* at 40–41. The Council notes the possibility of Congressional action, but finds that the current funding-focused policy more accurately maps the countours of the public stem cell debate—both for opponents and proponents of stem cell research.

84. COUNCIL, *supra* note 18, at 35 ("[T]he policy's central feature—the announcement date separating eligible from ineligible stem cell lines—holds firm to the principle that *public funds* should not be used to encourage or support the destruction of *future embryos*.").

85. As previously mentioned, one of the most vocal advocates from the Republican Party is Nancy Reagan, wife of former President Reagan. In a revealing statement, an observer noted that Reagan would never have backed stem cell research, to which a Reagan confidant replied, "Ronald Reagan didn't have to take care of Ronald Reagan for the last 10 years." *See* Alessandra Stanley, *Nancy Reagan Opposes Bush in Backing Stem Cell Research*, PITTSBURGH POST GAZETTE, Sept. 29, 2002, at A19, 2002 WL 21906975.

process.[86] With this in mind, cloning opponents point to the risk of inuring, a variant of the slippery slope argument. By making slow inroads toward a practice widely considered unethical, that practice may grow more acceptable as the public grows accustomed to each gradual step. In particular, this concept encapsulates the definitional debate of therapeutic cloning (using SCNT to treat diseases) versus reproductive cloning (using SCNT to create human beings). Many have argued that research proponents have simply attempted to render cloning ethically palatable by calling it therapeutic rather than reproductive, when in fact it involves the same exact process.[87] Resolving this debate will require more scientific discovery into whether there can be a defensible separation between therapeutic and reproductive cloning. But even if the public accepts the concept of therapeutic cloning, such a method carries the added stigma that the embryos were specifically created for research purposes—something that seems to have little support outside of small segments of the scientific community.

4. Deficiency of Private Industry Controls

Preventing federal funding without banning stem cell research outside the existing stem cell lines rightly or wrongly signals to private industry that it, and not the government, controls the ethical forum. Both proponents and opponents of stem cell research find fault with the ability of private industry to control the shape of future stem cell research. Research advocates fear that the potential benefits of stem cells will be limited to the wealthy as research becomes a profit maximizing activity and government fails to use its power of the purse to direct research for the public good.[88]

Moreover, opponents fear that private industry may not heed the various ethical checks and balances that government imposes, either in the area of informed consent of embryos or in treading the tenuous line

86. Of course, similar debates took place when *in vitro* fertilization yielded its first fully grown child. Other related areas of ethical concern include the possibility of developing an embryo into a child outside the womb. These debates fall outside the scope of this Note, but warrant similar comparison in the context of how government makes funding decisions when moral or ethical issues play significant roles.

87. For a discussion of how the distinction between therapeutic and reproductive cloning is being clouded, see Gregory E. Kaebnick, *All Clones Are Not the Same*, N.Y. TIMES, Jan. 2, 2003, at A17, 2003 WLNR 5183793. For a discussion of how the two processes differ, see Kirk Semple, *U.N. to Consider Whether to Ban Some, or All, Forms of Cloning of Human Embryos*, N.Y. TIMES, Nov. 11, 2003, at A11, 2003 WLNR 5632254.

88. It is worth noting that Clinton's NBAC, when tasked with researching stem cell issues, concluded that funding was appropriate and outlined several ethical oversight procedures for private industry actors who were to receive funding. *See* NBAC, ETHICAL ISSUES, *supra* note 23, at vii–ix.

between reproductive and therapeutic cloning.[89] Private entities, such as Geron Corporation, have made attempts to increase meaningful *public* dialogue through the formation of advisory boards, like the Geron Corporation Ethics Advisory Board.[90] Without indulging the skepticism that public relations may be the sole motivator behind such action, commentators have noted that "research protocol review and ethics review within a private company such as Geron are necessarily private" and cannot ensure that the issues are being considered from a public good standpoint.[91]

C. CONCLUSION

This brief survey of the relevant ethical issues and economic concerns of the stem cell debate defines the basis for a justifiable argument for reviewing the current policy. The economic effects and ethical dilemmas require further study, but the current policy obscures the debate from the federal level, and instead limits the forum for exploration to the states and the private sector. The bottom line is that Bush's stem cell policy involves both economic consequences and heated ethical questions that require informed debate. The question, then, is whether the current process for shaping stem cell policy, which has thus far provided an unsatisfactory outcome (economically, socially, and ethically), requires change. The following part adopts a framework for analyzing the policy-shaping process and evaluates it according to basic normative goals.

III. THE ANALYSIS: CRITIQUE OF THE CURRENT PROCESS

The background information presented in Parts I and II illustrated the problems unique to the stem cell debate. Stem cell research implicates technological, ethical, social, and economic issues that are particularly difficult to weigh because the benefits of stem cell research are speculative at best. Many political issues involve such complexity to a certain degree, but rarely does one issue involve so many areas of heated controversy.[92]

89. NBAC, ETHICAL ISSUES, *supra* note 23, at 61.

90. McLean, *supra* note 63, at 200.

91. *Id.* When McLean refers to a "private" company, she is not referring to its corporate status. Geron is a publicly traded corporation and, in fact, claims that completely private reviews lack credibility due to a concern for maximizing shareholder value. *Id.*

92. Compare, for example, the recent political debate over prescription healthcare for seniors that required consideration of equitable distribution issues of taxation, social and ethical issues of elderly care, and economic issues of drug manufacturing, import, and export. Even a cursory inspection finds that such a heated debate nevertheless lacks the complex technological and ethical issues inherent in the stem cell debate, such as therapeutic versus reproductive cloning, or protecting current life versus protecting future life. When it comes to stem cells, there is life and death on *both* sides of the issue.

Part II illustrated how the stem cell debate balances questions of life and death on both sides: interest groups on either side make legitimate arguments about their desire to protect life.[93] Part II also demonstrated some of the shortcomings of the current policy outcomes.

Part III now uses an institutional analysis to explain how policy has reached its current state of stable dissatisfaction, critique the current decisionmaking process and policy of stem cell research, and posit several reasons why failure to alter the current institutional arrangement may have negative long term consequences. This part proceeds in three sections. Section A lays out an institutional framework for analyzing stem cell policy and sets forth a few normative goals for the decisionmaking process. Section B applies the institutional lens to the historical development of stem cell policy through the Clinton and Bush Administrations, evaluates the decisionmaking process based on the normative goals set forth in Section A, and concludes that the current equilibrium reached by Bush's refusal to use federal funds on new stem cell lines is the inevitable result of a history of conflicting agendas. Section C offers an impetus for change by pointing to several theories that suggest that the longer this current equilibrium exists, the more difficult change will be in the long run.

A. THE FRAMEWORK FOR ANALYSIS

Perhaps the most difficult hurdle in such an analysis is identifying whether or not there is a problem that requires fixing. Judging policy is always tricky, especially in an area as polarizing as stem cell research. What the prior sections have tried to establish, however, is that the current policy is unacceptable. With this assumption in hand, the institutional analysis seeks to root out the policy's main problems and identify a prescriptive solution.

1. The New Institutionalism

This Note approaches stem cell policy from an institutionalist perspective. "New institutional" thinking incorporates a bevy of scholarship in modern political science that focuses on political institutions, approaching them from a variety of viewpoints that range from the highly contextual historical-comparative approach to the more abstract rational

93. In a perverse sense, the abortion debate may eventually present an easier solution because it is about protecting life versus protecting choice. At present levels of technical understanding, stem cells do not offer even this minimal distinction.

choice approach.[94] Early American institutionalism ("formalism") focused attention on the formal arrangements and institutions created by the Constitution[95] and suffered from the genuine criticism that it was a methodology for "stasis, not dynamics."[96] In other words, "old" institutionalism was about short-term stability, but failed to comprehensively explore or explain long run institutional evolution.[97] Similarly, analyses that focused primarily on individual behavior failed to produce a theory for "political equilibrium and . . . political change."[98] The modern institutional approach, quite logically (if not inevitably), attempted to blend elements of the two. It provided behavioral models with the requisite theoretical underpinnings to satisfy political scientists' desire for informed prediction. Generally speaking, the "unifying creed" of the new institutionalism "is that the architecture of institutions counts, the rules by which they do business matter, and the meanings vested in procedures are consequential."[99] For purposes of this Note, institutional analysis also provides a means of examining the tension between political leaders, who are agents of change, and institutions, which are by definition resistant to change.[100]

The new institutionalism proceeds in diverse modes, each offering insights into the explanations and predictions about current stem cell policy. Incorporating elements of rational choice theory,[101] Kenneth Shepsle explains that the new institutionalism "seek[s] to explain characteristics of social outcomes on the basis not only of agent preferences and optimizing behavior, but also on the basis of institutional features."[102]

94. *See, e.g.*, Bert A. Rockman, *The New Institutionalism and the Old Institutions*, *in* NEW PERSPECTIVES ON AMERICAN POLITICS 143, 146–54 (Lawrence C. Dodd & Calvin Jillson eds., 1994) (setting forth a summary of each of three institutional approaches to policymaking: historical comparative, bounded rationality, and rational choice).

95. *See* Karen Orren & Stephen Skowronek, *Beyond the Iconography of Order: Notes for a "New Institutionalism"*, *in* THE DYNAMICS OF AMERICAN POLITICS 311, 313 (Lawrence C. Dodd & Calvin Jillson eds., 1994).

96. Rockman, *supra* note 94, at 143. Karen Orren and Stephen Skowronek note, however, that formalism advanced political thought in at least two ways: (1) use of a historical document that reflected the "concrete expression of the political culture's most basic value commitments" as a standard for critical inquiry; and (2) use of the divergence of political reality from these formal institutions as a driver for reform. *See* Orren & Skowronek, *supra* note 95, at 313.

97. *See* Rockman, *supra* note 94, at 143–46.

98. *Id.* at 145.

99. *Id.* at 146.

100. *See id.* at 144.

101. Rational choice theory is also associated with social choice, game theory, or decision theory approaches to political life. *See* Kenneth A. Shepsle, *Studying Institutions: Some Lessons from the Rational Choice Approach*, 1 J. THEORETICAL POL. 131, 134 (1989).

102. *See id.* at 135.

Shepsle posits that this interaction of individual preferences and institutional process rules could be graphed as an extensive form game,[103] providing a temporal context to the time-bound minutiae of rational choice by emphasizing the importance of sequence: the order in which actors form and alter the rules of institutions matters because it sets the rules for future actors.[104] Additional context is provided through incorporating specific actor identities and their accompanying preferences and capabilities. Shepsle's analysis culminates in a "structure-induced equilibrium . . . that is *invulnerable* in the sense that no other alternative, allowed by the rules of procedure, is preferred by all the individuals, structural units, and coalitions that possess distinctive veto or voting power."[105] This equilibrium is resistant to endogenous change and, barring an exogenous "shock to the system," offers the predictive power of generalized theory.[106] The unfortunate consequence of such an equilibrium, however, is that an institutional arrangement that is ill suited to a particular issue will nevertheless prevail unless the prospective gains from change outweigh the transaction costs of effecting them.[107]

Karen Orren and Stephen Skowronek elaborate on the timing issue and give further context to the analysis, declaring that time is the central consideration in the new institutionalism: the historical development of institutions illustrates the overlapping political logics of past and present regimes.[108] In that sense, the analysis is dynamic: there are no bounded political periods, such as the Bush era or the Clinton era, but rather each subsequent regime's effect on institutions generates a system of "patterned disorder,"[109] whereby some groups are simultaneously given access to one institution and frustrated by another.[110] In other words, a given point in

103. *See id.* at 137.

104. *See id.*

105. *Id.* at 137.

106. *Id.* at 141.

107. *Id.* at 144. It may help to give some context to this theory by providing a simplistic preview of the analysis that follows *infra*. Suppose Congress, because of its complex legislative procedures and committee system, was ill suited to make decisions in a technologically and ethically complex (not to mention rapidly changing) issue such as the future of federal funding of human stem cell research. The costs of changing congressional structure to suit such an issue would be prohibitive. Therefore, absent some significant exogenous event, Congress would abstain from the issue altogether, leaving it either to the executive or to administrative agencies.

108. *See* Orren & Skowronek, *supra* note 95, at 320–23.

109. *Id.* at 330.

110. *See id.* As an example, Skowronek and Orren point to the New Deal, during which the divergent capacities granted to two administrative agencies within the same electoral regime helped to explain the success of the Agricultural Adjustment Act and the failure of the National Recovery Administration. *See id.* at 322.

time typically reflects dissonance, not fit, as institutional remnants of past regimes coexist and shape the effectiveness of new ones.[111] Obviously, this does not insinuate that policymaking is impossible; it merely suggests a rationale for policy that may at times appear inconsistent or incongruous.

In addition to the importance of historical development, Skowronek and Orren point to three other fundamental aspects of institutional study. First, "political institutions control (or attempt to control) the behavior of persons or institutions other than themselves."[112] Second, "institutions are purposive or intentional."[113] Third, "institutions are typically created by other institutions."[114] The first two points raise issues of legitimacy or authority. Because political institutions inherently attempt to control third parties (that is, the relevant mass public), institutions must have some legitimacy. Moreover, because institutions are purposive, that purpose may have to be articulated to the public to further establish institutional legitimacy. A loss of legitimacy either by political leaders or institutions may thus present one potential driver for a policy shift from a political equilibrium. Unfortunately, such an upheaval may be itself inefficient, as the third point suggests; because institutions are born with incongruities, any adaptive change through political learning may just as easily exacerbate a problem as alleviate it.

In sum, the institutional approach used here focuses on the development of rules within the policymaking game, the leaders who set the rules, the access granted to various interest groups or players, and the effect of such policy on third parties. Leaders seeking to further their political agendas will attempt to avoid institutional constraints while simultaneously binding other actors by setting the institutional rules. This constant conflict, over time, leads to conflicting overlapping institutional arrangements that then create an organized chaos, frustrating interested parties and leading to often contradictory and inefficient policy outcomes. While this Note borrows from the scholarship for illustrative purposes, it does not purport to advance the scholarship in a theoretical way. It merely seeks to use this framework to evaluate both the processes that shape stem cell policy and the substantive policy itself, and ultimately provide a basis for suggesting both the need for and the means to change.[115]

111. *See id.*
112. *Id.* at 325.
113. *Id.* at 326.
114. *Id.* at 328.
115. *See* Rockman, *supra* note 94, at 143–61.

2. Standards for Evaluating the Current Process

Evaluating stem cell policy inevitably requires making normative judgments. There are several common standards used to determine the effectiveness of government institutions in managing policy, including democratic rule, stability, and access for diverse groups.[116] Indeed, there are innumerable ways to measure the effectiveness of an institutional arrangement, and each standard is itself subject to argument about whether it is a proper goal. For example, in the rapidly progressing stem cell debate, we may *want* our most visible leader (the President) to make a unilateral decision in order to improve accountability and demonstrate the necessary responsiveness.

Because it is often difficult to determine what is the "best" process, this Note hesitates to answer such normative questions. In other words, this Note does not seek to argue whether stem cell research should be a political or purely scientific issue, or whether it should consider absolutism of morals or the "science" of ethics, but rather attempts only to assess whether the current policy meets two relatively uncontroversial normative goals, given the unique ethical and technological dimensions of stem cell research:[117] one, allowance of an honest and informed debate;[118] and two, development of a policy that has the proper degree of responsiveness to a rapidly changing area. As the following will show, despite prior mention of the importance of institutional legitimacy,[119] legitimacy is *not* a proper goal

116. *See* R. Kent Weaver & Bert A. Rockman, *Assessing the Effects of Institutions*, *in* DO INSTITUTIONS MATTER? 1, 6 (R. Kent Weaver & Bert A. Rockman eds., 1993). Kent Weaver and Bert Rockman explain that ten specific capabilities may be useful in measuring institutional effectiveness: (1) setting and maintaining priorities, (2) targeting resources, (3) innovating, (4) coordinating conflicting objectives, (5) ability to impose losses on powerful groups, (6) representing diffuse, unorganized interests, (7) ensuring effective implementation, (8) ensuring policy stability, (9) making and maintaining international commitments, and (10) managing political cleavages. *Id.* These are some of the measures by which the current stem cell policy falls short from a normative effectiveness perspective. Weaver and Rockman acknowledge that such objective measures may be unsatisfactory simply because the nation may not value such goals. *Id.* at 7. To that end, this Note acknowledges these criteria, but focuses on several alternative standards that *should* be valued based on the unique nature of stem cell research.

117. *See infra* Part III.C.

118. The goal of informed debate derives in part from the somewhat utopian vision of deliberative democracy, or each member of the public reaching a genuine conclusion after informed debate. *See, e.g.*, AMY GUTMANN & DENNIS THOMPSON, DEMOCRACY AND DISAGREEMENT 12 (1996). While some scholars believe such an ideal is unattainable in today's political environment of a disinterested mass public, the goal is nevertheless worth pursuing. However politicized the debate may be, it manages to secure a degree of legitimacy that even deliberate democracy should acknowledge is the best we can expect in a partial interest society. *See* Christopher H. Schroeder, *Deliberative Democracy's Attempt to Turn Politics into Law*, 65 LAW & CONTEMP. PROBS., Summer 2002, at 95.

119. *See supra* text accompanying note 114.

of stem cell research. In fact, the Clinton and Bush Administrations' abilities to achieve legitimacy for their stem cell funding policies is one of the primary symptoms of a faulty institutional arrangement. Even inefficient processes and policies can gain legitimacy so long as the parties controlling the agenda successfully sell them to the mass public. The goal of legitimacy thus cast aside, the remaining question is the extent to which the current policy meets the above normative goals of informed debate and optimal responsiveness, goals that are often at odds with leaders seeking to use institutions to legitimize and entrench their own preferred policies.

B. THE CURRENT SYSTEM PREVENTS HONEST AND INFORMED DEBATE: A HISTORICAL LOOK

1. The Reagan Administration Takes the Reins in 1988

Reagan's decision to take a formal stance against fetal tissue implantation represented an institutional shift in the form of the executive branch seizing power. In taking a formal stance and ending the de facto deadlock, Reagan altered the rules of the game and took control of the agenda. Executive control of stem cell policy continued throughout subsequent administrations, which was clearly evident when Clinton lifted the moratorium in his first few days of office. Since Reagan, each President has capitalized on executive authority, using its growing powers to direct the path of stem cell research policy.

2. The Development of Stem Cell Specific Policy: Clinton Versus Bush

Public policy debates are often exercises in rhetoric.[120] The rhetoric of the current stem cell debate exists in two exclusive dimensions, the scientific and the ethical. Paul Wolpe and Glenn McGee describe these as the "definitional valence" and the "ethical valence," respectively.[121]

120. Paul Root Wolpe & Glenn McGee, *"Expert Bioethics" as Professional Discourse: The Case of Stem Cells*, *in* STEM CELL DEBATE, *supra* note 50, at 185, 185.

121. *Id.* at 186–87. There are many other ways to phrase this scientific and ethical divide. The Council's report does not speak of different paradigms, but rather approaches the issues from different "perspectives," positing that the divide between stem cell advocates and opponents is the result of each side asking different questions. The Clinton Administration, approaching the issue as though an embryo was accorded special, but not absolute, respect, phrased their question as: "How can embryonic stem cell research, conducted in accordance with standards of informed consent and free donation, be maximally aided within the limits of the law?" The Bush Administration, approaching the issue as though "life, including early life, is biologically human . . . and valuable" phrased its question as: "How can embryonic stem cell research, conducted in accordance with basic research ethics, be maximally aided within the bounds of the principle that nascent human life should not be destroyed for research?"

Clinton's deliberations were restricted to the definitional valence: his Administration sought to define the acceptable limits of stem cell research in both legislative and technological forums. Bush, conversely, restricted his deliberations to the ethical valence; his Administration sought to phrase the stem cell debate in terms of balancing the ending of life with the potential for preserving life. If the line that divides these two valences is defined as the principle of protecting a human embryo, then that line represented an upper bound for Clinton and a lower bound for Bush. Clinton sought to do whatever possible to further research without violating restrictions imposed by the legislature or the scientific community, whereas Bush sought to further research without violating restrictions imposed by ethical boundaries.

Both the Clinton and Bush Administrations sought to implement their own views on the subject by using their authority to limit the debate to the valence that best suited their preferences. The following examines exactly how each administration controlled stem cell debate through its institutional authority to set the agenda, reduced the debate to a single valence, and used a "rubber stamp" organization to institutionalize its policies and legitimize the discourse for the public. Without identifying the *proper* paradigm to discuss stem cell issues, this section describes how each President used his capabilities to choose and shape the discussion forum.[122]

a. The Clinton Administration Neglected Moral Concerns

The Clinton Administration's view on stem cell research was clear. In the first few days of his Administration, Clinton lifted the moratorium on fetal tissue research, signaling his willingness to at least entertain the possibilities that such research might present. Moreover, while Congress was considering a cloning ban, Clinton released a Statement of Administration Policy, providing in part that "the Administration supports amendments to S. 1601 that would . . . permit somatic cell nuclear transfer

See COUNCIL, *supra* note 18, at 31–32. For further demonstration of this divide, see James F. Blumstein, *Regulatory Review by the Executive Office of the President: An Overview and Policy Analysis of Current Issues*, 51 DUKE L.J. 851, 880–84 (2001) (discussing how a cost-benefit paradigm may actually offend some people, such as environmentalists, who do not believe that such an analysis is appropriate when discussing the environment). Similarly, stem cell opponents, operating in the ethical valence, have little or no tolerance for "cost-benefit" analyses regarding human life.

122. *See, e.g.*, Andrew W. Siegel, *Locating Convergence: Ethics, Public Policy, and Human Stem Cell Research*, *in* NAT'L BIOETHICS ADVISORY COMM'N, 2 ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH J1, J9–J10 (commissioned paper) (referencing R. Alta Charo, *The Hunting of the Snark: The Moral Status of Embryos, Right-to-Lifers, and Third World Women*, 6 STAN. L. & POL'Y REV. 11 (1995)) (describing Charo's approach to avoiding moral issues by focusing on politics).

using human cells for the purpose of developing stem cell . . . technology to prevent and treat serious and life-threatening diseases."[123] While Clinton did make it clear that he opposed cloning for reproductive purposes, or cloning that threatened to cross the line between man and beast,[124] he did want to make sure a line was drawn that would maximize research potential. Perhaps most telling was Clinton's explicit desire to avoid the restrictions set on his Administration by the Dickey Amendment. Not only did Clinton expressly limit the Dickey Amendment's application, but he also approved the NIH Guidelines—guidelines that were formulated after NIH chief Harold Varmus consulted legal counsel as to the possibility of funding stem cell research despite the presence of the Dickey Amendment. Given this evident preference for promoting stem cell research,[125] Clinton set the agenda for debate by challenging the definitional boundaries of existing legislation.

b. Controlling the Debate: Reducing the Effect of Ethical Concerns by Emphasizing Definition

The Clinton Administration focused the majority of the stem cell debate on definitional issues, such as the difference between reproductive and therapeutic cloning, and the physical differences among embryos at varying stages of development. By emphasizing definitional issues, Clinton was able to distance the stem cell debate from the more controversial issues of cloning and abortion, and reduce the ethical noise generated by opponents. Critics contend that stem cell advocates (particularly in *Science* and *Nature* magazines) improperly separated the ethics of the cloning debate from the stem cell debate.[126] These critics believe that the ethical issues in both fields are sufficiently similar that each will benefit the other's discussion.[127]

123. *See* NBAC, ETHICAL ISSUES, *supra* note 23, at 37.

124. For example, when informed of scientists' ability to cross human cells with bovine cells to produce a workable embryo, Clinton quickly condemned the practice. Thus, even Clinton was guilty of dismissing offhand a research possibility because it seemed offensive from 900 feet. *See* Phillip B.C. Jones, *Funding of Human Stem Cell Research by the United States*, 3 ELECTRONIC J. BIOTECH. 30, 30 (2000), http://www.ejbiotechnology.info/content/vol3/issue1/full/3/3.pdf.

125. *See, e.g.*, Fletcher, *supra* note 50, at 62. John Fletcher believes Clinton improperly elevated the importance of research. *See id.*

126. Wolpe & McGee, *supra* note 120, at 186–89 ("[T]hese journals were overt and covert participants in the attempt of researchers to wield scientific expertise as a weapon to control definitions.").

127. The recent achievements in South Korea involving SCNT strengthen the connection between the ethical implications of SCNT and stem cells. SCNT presents a promising source of stem cells because it can be genetically tailored. Such promise is tempered, however, in light of the cloning issue that has been repeatedly stalled and ultimately tabled without a binding resolution in the United Nations' General Assembly. *See infra* text accompanying notes 169–71.

Clinton's emphasis on definitional aspects is evident in two respects. First, his NBAC claimed that the stem cell debate was separate from the prior issues that Congress and past administrations had dealt with, including IVF and fetal tissue research. The NBAC report proclaimed that "[w]ith the exception of a few state statutes, no viable regulatory system exists to guide or control the practice of human embryo research in the United States."[128] The NBAC thus refuted opponents of stem cell research who had argued that prior legislation addressing federal funding of research on fetal tissue had already specifically covered cells and tissues obtained from embryos. The NBAC pointed out that the NIH Revitalization Act covered the "conventional understanding of aborted fetal tissue," and that hES research dealt with live embryos, rather than tissue removed from "dead human embryo[s]."[129]

Second, the definition of "killing" an embryo was changed in light of new discoveries that an original donor embryo may be recreated using "nuclear transfer of recovered, recultivated, donated cells into an enucleated egg."[130] While this discovery did not change the fact that an embryo is "harmed" following removal of its stem cells, it did lighten the implication that the process "killed" the embryo, perhaps making the process easier for the mass public to accept.

c. The NBAC Rubber Stamp

Wolpe and McGee contend that the Clinton Administration silenced opponents who "could not overcome the considerable authority of the supporters—the prestige of those framing the debate, their institutional legitimacy, and, perhaps most important, their greater access to professional journals whose commentaries and interpretations of the issue informed the lay media."[131] The "institutional legitimacy" refers to Clinton's handpicked NBAC, an institution that carried with it legitimacy as the "de facto ethical deliberative body for controversial scientific research."[132] While the debate initially commenced through professional

128. *See* NBAC, ETHICAL ISSUES, *supra* note 23, at 33.

129. *Id.* at 41 n.49. *See* NIH Revitalization Act, 42 U.S.C. §§ 289g-1, 289g-2 (2000). *See also* Gross, *supra* note 37, at 876–78 (arguing that judging the propriety of NIH Guidelines under the test articulated in *Chevron v. NRDC*, 467 U.S. 837 (1984), does not necessitate considering the authority of the NIH Revitalization Act).

130. Wolpe & McGee, *supra* note 120, at 191–92.

131. *Id.* at 187. Wolpe and McGee point out the key offenders were the journals *Science* and *Nature*, publications that were "overt and covert participants" as supporters of stem cell research in the rhetoric battle. *Id.*

132. *Id.* at 193. Wolpe and McGee illustrate the NBAC's status as the de facto ethical deliberative body based on the perception of outside interest groups. *Id.*

journals such as *Science* magazine, the news of Dolly's cloning caused enough of a public stir that Clinton empowered NBAC to make policy recommendations. The NBAC opened the debate to "[p]oliticians, major scientific associations and journals, special interest groups, scientists, and bioethicists,"[133] but framed the debate along definitional lines in accordance with the Administration's wishes. When the NBAC was again empowered by the President to investigate the issues that arose following James Thompson's isolation of hES, the debate was again "opened" as commissioned papers presented viewpoints from both advocates and supporters of stem cell research. Nevertheless, the final NBAC Report on stem cells ultimately reached conclusions similar to the NIH Guidelines, and not coincidentally, recommended a policy largely in accordance with Clinton's own articulated preferences.[134]

3. The Bush Policy Prevents Proper Scientific Cost-Benefit Analysis

a. The Bush Administration Neglected Scientific Concerns

One of the more telling pieces of evidence in Bush's drive to neglect scientific concerns was his immediate mandate that the NIH revisit the Guidelines it had just recently researched and authored. The administrative agency best suited to researching such issues was now being told to reexamine their findings through a different lens. This new lens was Bush's own and reflected his attempt at controlling the debate.

b. Controlling the Debate: Reducing the Definitional Issues in Favor of a Moral Bright Line

When Bush took office, both the newly released NIH Guidelines and his own personal desire to match Clinton's immediate lifting of the moratorium on fetal research spurred him to confront the issue in the first few months of his term.[135] Bush's decision in August 2001 addressed the potential benefits of stem cell research, but constantly referred back to his personal religious, moral, and ethical concerns—concerns that essentially

133. *Id.* at 187.

134. Of note is that the NBAC report separates the legal framework for stem cell research into different areas depending upon the three different sources of stem cells: (1) aborted fetuses, (2) embryos created through IVF, and (3) SCNT. *See* NBAC, ETHICAL ISSUES, *supra* note 23, at 29–36. The NBAC investigated the particular ethical problems of each source to emphasize the importance of defining scientific terms when making decisions regarding the suitable funding decision.

135. In fact, several commentators have pointed out that opportunities for entrepreneurial advocates to push their policies are especially evident in the first few days of an administration. *See, e.g.*, John W. Kingdon, *Agendas, Ideas, and Policy Change*, *in* NEW PERSPECTIVES ON AMERICAN POLITICS, *supra* note 94, at 215, 228.

built an impenetrable wall against proper consideration of the scientific merits. In essence, the speech reflected a marked shift in the debate from the definitional valence to the ethical valence.[136]

In an attempt to entrench his policy, Bush allowed the NBAC charter to expire and subsequently formed his own Council to investigate the issue. The Council was headed by Leon Kass, a key advisor in the initial stages of Bush's deliberation and a well-documented adherent to strict ethical principles. Moreover, the ideological slant of the Council's membership was brought more in line with Bush's own beliefs, as many of the scientific voices on the Council reflected Kass's strict principles. Newly formed and empowered to justify the President's compromise, the Council pointed to the spirit of the Dickey Amendment in constructing a moral bright line that prohibited embryo destruction. Unlike the Clinton era deliberations, the protection of an embryo was absolute, and could not now be measured against any possible gain.

Bush reportedly took his time with the decision, making sure to meet the proper deliberative requirements. Circumstantial evidence, however, suggests that the investigation was heavily focused on ethical issues, to the detriment of proper scientific considerations. First, scientists have pointed out that Bush's reliance on the existence of over sixty stem cell lines was based on cursory investigation and quickly proved overly optimistic.[137] Second, while giving credence to the scientific potential, Bush repeatedly emphasized the moral and religious beliefs that motivated his decision—beliefs that are unlikely to adapt to any new concepts of scientific discovery.[138] Third, Kass noted that the Bush Compromise was a decision made to comply with the *spirit* of the Dickey Amendment.[139] As do Bush's

136. *See* Wolpe & McGee, *supra* note 120, at 186.

137. The viability of the listed stem cell lines was questioned the same month that Bush announced his decision. *See* Ceci Connolly & Rick Weiss, *Stem Cell Colonies' Viability Unproven; Some in NIH List of 64 Termed Young, Fragile*, WASH. POST, Aug. 28, 2001, at A1, 2001 WL 23189987. Recent data has confirmed this fragility. *See* Hall, *supra* note 71.

138. Excerpts from the speech include: "My position on these issues is shaped by deeply held beliefs"; and "I also believe human life is a sacred gift from our Creator." Bush, *supra* note 58. Additionally, the speech begins with references to ongoing debate in churches and amongst people of different faiths. *Id.* Christopher Schroeder points out that any religious beliefs that may have motivated Bush's decision would necessarily suggest a failure to consider the proper ideal of deliberative democracy, though Schroeder continues to argue that such a failure does not ruin the decision's legitimacy. *See* Schroeder, *supra* note 118, at 127 (arguing that the deliberative ideal may be unreachable because today's politics require satisfying the paretal interests of a public that is too busy to deliberate over the full issue). *See generally* Blumstein, *supra* note 121, at 880–84 (noting the inability of certain considerations, such as the utility of a clean environment, to be calculated into cost-benefit analyses).

139. *See* COUNCIL, *supra* note 18, at 28.

ethics, the spirit of the amendment draws a bright line that makes it difficult to give proper consideration to any potential advances in the scientific community.

Perhaps the best illustration that the stem cell framework was being shifted to foreclose any meaningful scientific debate comes from the mouth of Bush appointee and DHHS Secretary, Tommy Thompson. In 2001, Bush policy supporters were asserting that changes in the scientific field would not change Bush's decision, because the decision was grounded in "a principle that would not change in light of scientific advances or delays."[140] At the same time, Thomson told reporters that "neither unexpected scientific breakthroughs nor unanticipated research problems would cause Bush to reconsider" the approach drawn by the policy, because it was based on "a high moral line that this President is not going to cross."[141]

To this point, the Council's report added:

> [I]f the policy is founded primarily in a determination to prevent government funds from encouraging the destruction of human embryos, and only secondarily in a judgment about the value of embryonic stem cell research, then advances in research alone (or the absence of advances alone) would not be sufficient to overturn it. If it is sound before such advances, some argue, it would still be valid after —though again, of course, whether it is right to begin with is itself a point of great contention.[142]

c. The Council on Bioethics Rubber Stamp

Similar to Clinton's NBAC, the Council served as the legitimizing rubber stamp for the Bush decision.[143] The Commission was formed *after* the President had already made his decision. Not surprisingly, given the President's choice of Leon Kass to chair the Council, the resultant report

140. *See* COUNCIL, *supra* note 18, at 67.

141. *Id.*

142. *See id.* (internal citations omitted) (discussing the unsustainability of the current policy). Bush's appointment of Tommy Thompson, a pro-life advocate who, as the former governor of Wisconsin, also supported the stem cell research that originated at the University of Wisconsin, created an interesting scenario. Pro-life supporters were grateful to have the ear of the Administration, but expressed reservations about whether that ear would extend to the stem cell debate. That Thompson supported the Bush policy reflects the degree of control that Presidents exert over their appointees and executive agencies, as will be discussed *infra* in further detail. Of course, the cynical alternative, that Thompson may simply be supporting his old constituency (who, incidentally, hold the rights to many of the patents currently open to federal funding), is a matter of inference.

143. In a symbolic move, following the expiration of the NBAC charter, the government's bioethics Web site, which had originally linked to the NBAC's homepage, now redirects to the Council's Web site.

supported and justified the President's policy.[144] The Council's clear allegiance to the President was further emphasized, following the recent replacement of two Council members who were known to disagree with the Bush policy.[145] This partisan organization, structurally located within the Office of the President, offers little hope that the executive will be provided with the necessary unbiased information to adjust to the changing realities of the stem cell debate. The Council, as the NBAC before it, was simply a means to institutionalize the executive's policies. Thus, policy change will be difficult without the "assistance" of some extraordinary external events.

Defenders of the Bush policy, seeking to soften the moral bright line, point to the fact that the policy's inconsistencies are derived from the President's own confusion as to the definition of when life begins, or whether an embryo created specifically for research purposes (and as such, was never intended to become a human being) is a life. Supporters of the policy go on to argue that scientific advancement may in fact change the ground on which the President's moral line is drawn, and alter the decision to fund only existing stem cell lines. The body responsible for pointing out the possibility of a policy change, however, is the very Council formed to justify the President's decision. Based on the language in the Council's report, which discusses and quickly discounts scientific arguments regarding the moral status of the embryo, changing the ground for debate is only a distant possibility.

144. In particular, the Council's Report justifying Bush's policy downplays the various sources from which embryos may be obtained and instead emphasizes that the development of IVF techniques caused a fundamental conceptual separation between fetal and embryonic research. In 1979, when the EAB issued its first report in support of IVF, "human embryo research . . . raised unique prospects and concerns that were distinct from some of those involved in human fetal research." *See* COUNCIL, *supra* note 18, at 24. In other words, the Council believes that embryo research, applicable to the present debate, was being formulated as early as 1979, when IVF was first becoming a major issue. Given this logic, the early protections for embryos, implemented before stem cells were first isolated, would apply today. Thus, DHHS regulations and congressional bans that did not directly address stem cells could be applicable in these cases simply by highlighting that they had contemplated research on embryos *in vitro*. There is merit to this argument, in that the DHHS regulations explicitly noted that embryos *in vitro* should be protected, regardless of their intended use (that is, whether they were to be aborted or not).

More importantly, the organization of the Council's Report is instructive, in that the justification of the Bush decision does not highlight any of the current scientific data behind stem cell research, but instead rests exclusively on moral and legal grounds. Subsequent chapters identify areas that could change the President's mind (such as continuity arguments), but they are quickly discounted. Instead, the Council emphasizes alternate avenues such as the potential for the far less controversial adult stem cells. *Id.* at 46.

145. *See, e.g.*, Gareth Cook, *President's Panel Skewed Facts, Two Scientists Say*, BOSTON GLOBE, Mar. 6, 2004, at A1, 2004 WL 59775486. There were also complaints as to the initial makeup of the Council. *See* Sandra Sobieraj, *Bioethics Appointment Bothers* In Vitro *Fertilization Advocates*, MILWAUKEE J. SENTINEL, Nov. 29, 2001, at 3A, 2001 WL 27438522.

C. EVALUATING THE PROCESS: THE INSTITUTIONAL SETUP THAT PREVENTS HONEST AND INFORMED DEBATE

There are three primary institutional characteristics that permitted the failure of honest debate in the stem cell context. First, Congress has not specifically addressed or acted on hES, leaving the matter to the executive office. Second, the "quasi-legislative" function, traditionally performed by executive agencies and independent administrative agencies, has been weakened by the growth of centralized regulatory review and the advent of rubber stamp advisory boards. This development has largely negated the ameliorative power agencies provide to the democratic process, and, in fact, has falsely legitimized the hES federal funding issue for the mass public. Third, the judiciary has adopted a deferential standard of review for administrative agency decisions.

1. Congressional Silence

Complex legislation typically "runs great risks in a system containing [as] many hurdles and veto points" as the dueling houses of Congress, where the House is often sympathetic to majority preferences, while the Senate responds to strong minorities.[146] Considering the highly complex nature of the stem cell issue, its treatment in Congress is a recipe for deadlock.

While Congress offers both authority and legitimacy in democratic policymaking, it has been either unable or unwilling to pass definitive legislation on the issue of stem cell research.[147] Commentators have argued that Congress's institutional limitations have rendered it unable to adapt to today's complex and volatile issues effectively.[148] For example, Congress responded to Clinton's burgeoning fetal research agenda with the Dickey

146. Rockman, *supra* note 94, at 158.

147. The current argument questions whether the Dickey Amendment—passed before Dr. Thompson first isolated stem cells and thus void of language that explicitly mentions hES—is applicable to the current controversy. Opponents of federal funding for hES research argue that the Dickey Amendment and Common Rule (referring to Subpart A of the DHHS regulation) prevents federal funding of such research. While certain members of Congress are among the opponents for federal funding of hES research, the legislature has thus far been unable to pass a clarifying bill.

148. *See, e.g.*, Hugh Heclo, *Issue Networks and the Executive Establishment*, *in* THE NEW AMERICAN POLITICAL SYSTEM 87, 102–05 (Anthony King ed., 1990) (arguing that the growing complexity of political issues has led to the creation of issue networks of interested political actors, a policy technocracy that circumvents some of the notions of policymaking in traditional democracy); Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1712 (1975) (finding acceptance of agency control "inevitable . . . [given] the inability of Congress . . . to fashion precise directives).

Amendment, but this appropriations rider has not been updated to reflect Dr. Thompson's isolation of hES in 1998.[149] In the stem cell debate, the ambiguities of congressional legislation and the inability of Congress to adapt to the frequent discoveries in the hES arena allowed both the President and the NIH to circumvent their wishes. For instance, the NIH Guidelines, adopted through notice and comment rulemaking, adroitly sidestepped critical aspects of the Dickey Amendment. Though certain members of Congress immediately condemned this maneuver, the outrage had little practical effect. The issue was addressed only after Bush took office and ordered the NIH to reexamine the Dickey Amendment.

Congress's silence is striking given the growing number of hES supporters on both sides of the aisle. Given the level of bipartisan support, Congress is the logical forum for debating stem cell research policy. Unfortunately, Congress has been unable to accommodate such a debate, primarily because the transaction costs of building a bipartisan coalition to combat the President's institutionalized polices are too high and the internal pressure for change is insufficient. In the absence of congressional action, the President has resisted bipartisan political pressures and maintained his moral separation from any scientific or political arguments. This institutional framework that places stem cell policy primarily in the hands of the executive thus raises the cost of political coalition building in Congress, further handicapping the goal of an informed process to formulate hES policy. Congress's silence on human cloning is likewise revealing, in that it essentially defers to the executive and administrative agencies, even on seemingly clear-cut issues.[150] Congress's silence has given the executive the necessary latitude to exercise its own institutional capabilities and frame the debate.

2. Centralized Regulatory Review

Congressional silence on stem cell policy, on its own, is not an insurmountable problem. In fact, many argue that this is preferable, given

149. Legislative attempts to amend the Public Health Services Act, 42 U.S.C. § 289, one of the statutes referenced by the Dickey Amendment, have yielded no fruitful results. *See, e.g.*, S. 245, 108th Cong. (2004) (introduced by Sen. Sam Brownback (R-KS) in Jan. 2004); H.R. 3594, 108th Cong. (2003) (introduced by Rep. Diana DeGette (D-CO) in Nov. 2003). Even a recent bipartisan proposal by Senators Orrin Hatch (R-UT), Dianne Feinstein (D-CA), and Arlen Specter (R-PA), among others, never made it out of committee. Human Cloning Ban and Stem Cell Research Protection Act of 2003, S. 303, 108th Cong. (2003).

150. *See* Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship?*, 15 HARV. J.L. & TECH. 85, 88–89 (2001) (positing that the FDA's claims of jurisdiction are possible only because Congress and the President have failed to speak on the issue).

the growing complexity of issues and the development of issue networks, whose intimacy with the details of a particular issue allows for more informed decisionmaking in highly technical areas.[151] The simultaneous development of centralized regulatory review, and reduction of the administrative agencies' quasi-legislative function, however, minimizes the technical knowledge of administrative agencies and fails to adequately fill the void left by congressional silence.

"[P]residential oversight of the regulatory process, though relatively new, has become a permanent part of the institutional design of American government."[152] The development of centralized regulatory review was a response to the growing view that agencies were an "uncontrolled, hydra-headed array . . . afflicted with tunnel vision and spurred by 'public interest' advocates."[153] To rein in the increasing costs that agencies were imposing on society, Reagan promulgated Executive Order No. 12,291, which required executive agencies to fill out Regulatory Impact Analyses, to be approved by the Office of Management and Budget ("OMB," an executive administrative agency).[154] Reagan also issued Executive Order No. 12,498, which established a regulatory planning process by which the OMB could influence the plans of executive agencies.[155] Clinton later reaffirmed this order and eventually promulgated his own, Executive Order No. 12,866, which included independent agencies in the process.[156] Elena Kagan, a former senior member of Clinton's domestic policy staff, noted that "presidential control of administration, in critical respects, expanded dramatically during the Clinton years, making the regulatory activity of the executive branch agencies more and more an extension of the President's own policy and political agenda."[157] Regardless of the positive or negative aspects of the development itself, centralized regulatory review limits agency discretion and reduces its technocratic function, which is protected only by the judicial "hard look" doctrine.[158]

151. *See* Heclo, *supra* note 148.

152. Blumstein, *supra* note 121, at 854 (quoting Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 15 (1995)).

153. Richard B. Stewart, *Administrative Law in the Twenty-First Century*, 78 N.Y.U. L. Rev. 437, 443 (2003).

154. Exec. Order No. 12,291, 3 C.F.R. 127 (1981), *reprinted in* 5 U.S.C. § 601 (2000).

155. Exec. Order No. 12,498, 3 C.F.R. 323 (1985) (repealed 1993).

156. Exec. Order No. 12,866, 3 C.F.R. 638 (1993), *reprinted in* 5 U.S.C. § 601 (2000).

157. Blumstein, *supra* note 121, at 854 (quoting Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2246–47 (2001)).

158. This doctrine requires courts to ensure that agencies are not responding to political pressures by "requiring a process of reasoned judgment in which an agency explains what it does and why." *Id.* at 894.

In the case of stem cells, Bush's reversal of the NIH Guidelines reveals some of the political pressure the executive can place on an agency. James Blumstein posits that the apparent lack of conflicts in Clinton's Administration was largely due to the fact that Clinton's ideology aligned with NIH's contemporaneous administrators. The harmony between Clinton and the NIH indicated nothing about the failure of the executive to exert his will.[159] In general, centralized regulatory review allows the executive to affect both the retrospective and prospective aspects of rulemaking, and thus allows it to successfully implement and entrench its policies through administrative agencies. Bush exhibited such control despite the fact that his ideology may not align with the general desires of the institution.[160]

3. Judicial Silence

The next logical question presented is whether the judiciary has protected the administrative agency's technocratic function through "hard look" review. The answer, for now, appears to be no. The Supreme Court has examined issues on the periphery, but has not spoken on the particular issue of interpreting congressional intent regarding stem cell research. Some argue that this silence is the result of a pronounced deferential standard of review for administrative agency action and a narrow focus on administrative procedure, rather than on the substance of administrative decisions.[161] Whatever the case, the judiciary has found it inappropriate to discipline the policy moves of either the executive or administrative agencies in this area. Thus, the judiciary has removed itself from the stem cell policy debate by exercising its ability to defer to existing policy decisions.

4. Initial Conclusions

In sum, the answer to whether the current institutional arrangement offers the potential for honest and informed debate is a resounding no. The

159. *See id.* at 869 & n.92.

160. To the extent that institutions seek to retain control, the NIH would be hesitant to give up its control over funding decisions in the hES area to comport with the Bush Compromise. Reluctance to relinquish control would be independent of any ideological bent that the majority of the agency exhibits. Despite this reluctance and the remnants of Clinton's influence, Bush has shown the ability to alter the institutional agenda and entrench his own. This reinforces the centralized regulatory review theory and illustrates Orren and Skowronek's theory that institutions existing in a state of patterned anarchy may lead to contradictory policies. *See* Orren & Skowronek, *supra* note 95, at 329–30.

161. *See, e.g.*, Gross, *supra* note 37, at 876–78 (discussing the deferential standard the Supreme Court set out in *Chevron v. NRDC*, 467 U.S. 837 (1984)).

need for honest debate was hinted at in the beginning of this Note, which summarized the most significant controversies in stem cell research, both to demonstrate the debate's complexity, and to identify the unique difficulties that arise when ethical issues are involved. In essence, cost-benefit analyses are difficult because both the costs and benefits (simply put, death and life) are impossible to quantify and appear on both sides of the equation. Only honest debate that encompasses the widest possible range of considerations can hope to inform this difficult analysis. Unfortunately, the policy controller, in this case the President, has concealed one side of the debate from the public discourse, in an attempt to further his own policies. This concealment, by both the Clinton and Bush Administrations, reduces stem cells to a battle of rhetoric rather than substance. Stem cell research, due to its close proximity to two lightning rods for controversy, health care and abortion, is especially fraught with ethical landmines, and thus is particularly vulnerable to this kind of battle of rhetoric.

The competition to frame the debate in one valence or another is evident in the primary criticisms of both the Clinton and Bush policies. Clinton's critics believe that his policy was an "exercise in sophistry, not ethics,"[162] whereas Bush's policy has been criticized as poorly informed from a scientific perspective. In fact, each shortcoming was intentional, the necessary result of shaping the debate in order to implement their preferences and appease the mass public. While shielding the issues may be a necessary part of dealing with a public with a short attention span, this obfuscation in process presents troubling policy outcomes. First, assuming, as this Note does, that a technically complex area such as stem cell policy must have more of a balance between science and ethics, then maximizing the pool of available information is integral to finding the optimal policy compromise. Second, the shielding and subsequent approval of an issue by a rubber stamp agency is falsely portraying a political decision as an expertly informed one. Third, because the debate is so closely tied to politically charged issues, claims of electoral accountability cannot justify the President's growing domination over stem cell policy. For example, the President is not elected based on his views on stem cell research, but may be elected on the basis of abortion views; when Bush fuses the two issues through intentional forum manipulation, he shuts off potential discourse that may actually prove useful in separating the two, thereby solidifying this link, to the detriment of an informed stem cell policy.

162. Wolpe & McGee, *supra* note 120, at 191 (internal citation omitted).

The current policy is unsatisfactory to most of the highly interested groups, but reflects exactly the type of inefficient outcome that results from institutional anarchy. The Clinton Administration's attempts to take the first steps in stem cell research allowed Bush to adopt a compromise agreement that seized upon the work already done, while minimally violating his own political base. Ironically, Bush's decision to permit limited federal funding actually strengthens his political position by giving him the legitimacy to explain his policy outcome as a winning arrangement for both sides, while allowing him to continue adherence to his moral bright line. Without the general outrage that may have resulted from a blanket ban on federal funding, Bush entrenched his position by raising the costs of building a coalition necessary to overcome his preference. It appears that only an external event on a level with producing a marketable hES treatment would force the President to lower his moral boundary.[163] Unfortunately, as the succeeding sections show, that event may come too late.

D. THE CURRENT INSTITUTIONAL ARRANGEMENT IS POORLY SUITED TO PARTICULAR STEM CELL CONCERNS WITH FLEXIBILITY

The second normative question this Note asks is whether the current institutional setup allows for the proper flexibility in a rapidly changing arena. At first glance, this is an oxymoron, given that institutions are notoriously resistant to change. The real inquiry then, is whether the setup provides enough access points to develop an awareness of the need for change. In that sense, some argue that centralized regulatory review is a positive development, especially in highly politicized issues, because it increases political accountability and reduces response time.[164] Others have pointed out that because regulatory agencies may suffer from regulatory fatigue and are often slow to respond to changing circumstances,[165] reducing the amount of discretion within agencies not only effectively reduces the costs of downstream or ex post executive oversight,[166] but also

163. As noted above, the recent revelation that the stem cell lines that qualified for federal funding were contaminated has not produced a sufficient stir to sway Bush from his moral bright line. This is most likely because many citizens feel that the promise of stem cell research will be attained by states willing to pay billions of dollars for a chance to become the preeminent locale for such treatments. *See* Hall, *supra* note 71; Mansnerus, *supra* note 75.

164. *See, e.g.*, Nina A. Mendelson, *Agency Burrowing: Entrenching Policies and Personnel Before a New President Arrives*, 78 N.Y.U. L. REV. 557 (2003).

165. *See* Stewart, *supra* note 153, at 446–48.

166. Of course, oversight costs may also be reduced through regulatory alternatives such as government-stakeholder network structures or economic incentive systems that lessen the need for formal rulemaking. *See id.* This, in turn, would lead to the kind of administrative discretion and lack of

serves to remove bureaucracy from the reform process and place that responsibility squarely in the executive's hands. Because stem cell policy is such a highly politicized and technically complex issue, however, the benefits of added efficiency from executive control are outweighed by the executive's likelihood of making electorally motivated decisions. Electoral pressure compels the executive to oversimplify issues by sealing off aspects of informed debate, particularly when those issues are highly politicized. By obscuring the debate and centralizing regulatory review, Bush has eliminated any means of self-evaluation through additional research. He has closed off any access points to drive reform in the very institutions through which reform is most likely.

The moral bright-line rule Bush applied and institutionalized will eventually cause the federal government to lose control of, and familiarity with, the scientific issues associated with hES. The NIH, the single largest source of scientific research funds in our nation, will not be able to apply its expertise to the critical area of stem cell policymaking, especially funding decisions. Instead, the Agency remains on the periphery of the debate, tasked with funding research on adult stem cells, multipotent stem cells, and other areas with admittedly little chance of yielding the kind of results possible through pluripotent hES. Without gradually building experience in hES research, the Agency will be hard-pressed and ill equipped to respond if and when future events force the dilemma onto their doorstep. For example, assume hES treatments become reality and future administrations are compelled by public opinion to alter the current equilibrium and cross the moral bright line. At that point, NIH will be in the nascent stages of making funding decisions and conducting ethical reviews of grant applications. To the extent that experience leads to institutional learning and lowers institutional setup costs, the government will be at a significant disadvantage.

Moreover, the history of stem cell policy demonstrates the power of watershed events in shaping stem cell policy, from the advent of IVF, to Dolly the Sheep, to Dr. Thompson's isolation of hES. The current institutional arrangement obscures the scientific or definitional valence and virtually ensures that future stem cell policy will continue to be effected not

communication (and electoral accountability) that Richard Pildes and Cass Sunstein find especially "troubling" in highly political decisions. *See* Blumstein, *supra* note 121, at 893 & n.217. The point is that while there is no single correct position to take on improving the efficiency of bureaucratic decisionmaking, we can hope to avoid being completely attached to time-bound descriptive minutiae by abstracting from the specific issue of stem cells to the more general issue of highly political debates that require moral judgments.

by endogenous development within the federal government, but instead by exogenous events. The longer the current institutional arrangement keeps the federal government on the boundary of stem cell development, the more likely any future incorporation will result in chaotic and inefficient outcomes. The next section delves even further into the potential consequences of inaction.

E. THE RISING COSTS OF REFORM

By institutionalizing his policies, Bush has raised the transaction costs of reform and captured third parties. Even as these losing parties in the current institutional arrangement press for reform, their chances of success decrease with each passing week, as the following political developments demonstrate.

1. Increased Centralized Regulatory Review

The problem of centralized regulatory review giving the President too much control over the information flow in the stem cell debate will only increase over time. The events of September 11 solidified a feeling that quick political action is necessary to deal with crisis situations. In this respect, the growth of informal power that began with the creation of the Department of Homeland Security will only serve to further entrench the executive's role in stem cell policy.[167] Additionally, it is generally unlikely that executive power, once taken, will subside. Reagan's strengthening of presidential control over executive agencies, and in particular, human research, has only been increased, even as administrations of different political parties have taken control of the White House.[168]

The United Nations ("U.N.") debate over a ban on human cloning presents a prime example of the increased power of the executive agenda. While all 191 members of the U.N. General Assembly have long agreed on a ban on reproductive cloning, the Assembly has been unable to pass a treaty banning cloning of any kind due to a three-year fight over whether to extend that ban to therapeutic cloning.[169] The United States, through the Bush Administration, has been the most outspoken opponent of a ban limited to reproductive cloning, refusing to debate the definitional issues,

167. *See* Dana Milbank & Bradley Graham, *With Crisis, More Fluid Style at White House; Faster Decision-Making Has Flip Side: Confusion*, WASH. POST, Oct. 10, 2001, at A4.

168. *See supra* Part III.B.

169. Warren Hoge, *U.S. Drops Effort for Treaty Banning Cloning*, N.Y. TIMES, Nov. 20, 2004, at A3, 2004 WLNR 11732848.

and instead proposing a complete prohibition on cloning of any kind. Ironically, this vehement opposition comes despite the fact that the U.S. Congress has been unable to pass such a categorical ban.[170] A recent development in the contentious debate in the U.N. left no doubt as to who controlled the agenda: "in a symbolic victory for the Bush Administration, a divided General Assembly passed a nonbinding declaration banning all human cloning, including that for medical research."[171]

2. Policy Entrenchment: Revisiting the Policy May Not Be Effective

Now that Bush has finally set the policy regarding federal funding of stem cells, the so-called rules of the game have been established. Supporters of the Bush policy believe that the current setup, which allows federal funding for research on lines that existed in August 2001, provides the necessary research materials for the beginning stages of stem cell research.[172] But doubts remain as to whether this assurance is sufficient. Theories of policy entrenchment suggest that structure-induced equilibrium is robust—that relevant actors will begin to respond to the rules of the game and begin to invest both economic capital and time. These parties will then have a vested interest in the current setup and resist changes. This path-dependent theory[173] suggests that revisiting the policy may not be as easy as its supporters believe, especially if the governing party seeks to maintain a cognitive consistency with past policies.[174]

A second entrenching effect is the notion of feedback loops, or the idea that "policies make politics" and affect existing institutions.[175] Harvard government professor Paul Pierson suggests that feedback loops

170. Warren Hoge, *U.S. Stem Cell Policy Delays U.N. Action on Human Cloning*, N.Y. TIMES, Oct. 24, 2004, at 1(8), 2004 WLNR 4786305. The Bush Administration's efforts pit us against Britain, Belgium, and other traditional allies, though they did have the strong backing of Costa Rica. *Id.*

171. Warren Hoge, *World Briefing United Nations: Cloning Ban Victory for U.S.*, N.Y. TIMES, Mar. 9, 2005, at A6, 2005 WLNR 3586653.

172. For example, Elias Zerhouni, current head of the NIH, claimed that the White House restrictions were not impeding stem cell research because the field was still in its early stages. If the restrictions were to present a problem, Zerhouni claimed, he would ask the President to reopen the issue. *National Roundup*, THE STAR-LEDGER (NJ), Nov. 27, 2003, at 10.

173. The nature of path dependence is such that starting positions are vital. In this case, the Bush policy is the first "formal" action to set the policy rules of the game. For examples of path dependent theories in action, see the work of Paul Pierson and Douglas North among others. *See, e.g.*, Paul Pierson, *When Effect Becomes Cause: Policy Feedback and Political Change*, 45 WORLD POL. 595, 606–11 (1993).

174. *See id.* at 606–16. Because the present policy is justified by a desire to prevent future embryo destruction, and thus comply with the "spirit" of the Dickey Amendment, maintaining cognitive consistency with this rationale makes it difficult to adjust polices to new discoveries.

175. *Id.* at 595.

are readily evident in empirical case studies of past government policies.[176] He points out, for example, that Theda Skocpol, in her study of welfare policies, observed that policies affect interest groups by providing incentives.[177] Policies may also strengthen the access these policy beneficiaries have to decisionmakers.[178]

Such entrenchment effects may already be in motion. For example, several states have already rushed to fill the void left by the lack of federal funding in an attempt to become leaders in the field. The obvious incentive is the amount of business that stem cell research could bring to a state with stem cell treatment programs.[179] California's recent passage of Proposition 71, supported by a Republican governor, will provide *billions* of dollars to stem cell research over the next ten years.[180] Unfortunately, anecdotal evidence already suggests that because California started fresh with a "miniature version of the National Institutes of Health,"[181] called the California Institute of Regenerative Medicine ("CIRM"), there have been significant growing pains, headaches, and high set up costs.[182] For example, the first meeting of the twenty-nine member Independent Oversight Committee that the proposition created to direct the CIRM was considered a "near disaster." Several critical items had to be canceled at the last minute due to complaints that the meeting "essentially shut out public input, provided no background on complex questions and gave inadequate advance notice."[183] Currently flailing in its infancy, the CIRM thus not only fails the normative standards of informed debate and flexibility set forth throughout this Note, but also threatens to do further damage to the goal of informed debate by giving access points to interested groups

176. *Id.* at 609.

177. *Id.* at 598–600 (discussing THEDA SKOPCOL, PROTECTING SOLDIERS AND MOTHERS: THE POLITICAL ORIGINS OF SOCIAL POLICY IN THE UNITED STATES (1992)).

178. *Id.* at 601.

179. *See supra* text accompanying note 75.

180. Media coverage following the passage of Proposition 71 characterized the issue as "[d]efying Bush." Dean E. Murphy, *The 2004 Elections: Issues—Initiatives; Defying Bush Administration, Voters in California Back $3 Billion for Stem Cell Research*, N.Y. TIMES, Nov. 4, 2004, at P10, 2004 WLNR 6562338. Others noted that California had become the "epicenter" of stem cell research. Andrew Pollack, *The 2004 Elections: Technology; Measure Passed, California Weighs Its Future as a Stem Cell Epicenter*, N.Y. TIMES, Nov. 4, 2004, at C10, 2004 WLNR 6562386.

181. Andrew Pollack, *California Stem Cell Program on Fast Track*, N.Y. TIMES, Jan. 11, 2005, at A16, 2005 WLNR 352333.

182. *See* Carl T. Hall, *Bumpy Start for Stem Cell Program; Critics Say Board Isn't as Public as It Ought to Be*, S.F. CHRON., Jan. 4, 2005, at B1, 2005 WLNR 102265 (noting that the twenty-nine member Independent Citizens Oversight Committee appointed to direct the new institute "isn't trying hard enough to conduct its affairs in public").

183. *Id.*

seeking to gain influence while the institution remains relatively unformed and vulnerable.[184]

Even assuming the fledgling CIRM eventually manages to thrive, the redundant costs of creating a brand new state agency could have been easily avoided had the federal government provided the expertise of its own experienced agency, the NIH. Most importantly, the large scale of the hES research program California seeks to build, in order to become the epicenter of state sponsored stem cell research, will force critical ethical issues to be determined within the confines of an untested institution. This development only further demonstrates the degree to which the federal government will remain shut out of the important developments in the future stem cell debate.

On a smaller scale, private institutions, such as Harvard, the University of California at San Francisco, and Stanford, have sidestepped federal restrictions and raised significant sums of money to freely isolate, research, and distribute stem cells.[185] With the incentive to evade federal regulations in place, both private and public actors will adjust accordingly, altering the institutional structure as time passes. All parties—states, private universities, and the aforementioned private institutions granted virtual monopolies on the existing stem cell lines—will each have a vested interest in maintaining the current policy, and will seek to claim any premium from workable therapies developed using their stem cell lines. The NIH, again, will be left out of the loop, in a "stagnant research environment [using] . . . old biology."[186] While the strength of such effects is speculative at this point in time, the entrenchment is already underway.

Most important, however, is the fact that Bush has publicly, and perhaps irreversibly, assumed the policymaking mantle for the federal government. His address was televised nationwide and the buildup to the

184. Such complaints start at the top, where Robert N. Klein, a Palo Alto housing developer and coauthor of the initiative, was picked to lead the new institute, despite concerns that he may have authored the job description to fit his qualifications, and that he donated to the campaigns of three of the four individuals who nominated him. Carolyn Marshall, *Financier to Lead Institute on Stem Cells*, N.Y. TIMES, Dec. 18, 2004, at A13, 2004 WLNR 14293213. Moreover, other appointed board members include representatives of California universities and research institutes that stand to receive significant research grants, as well as employees of biotechnology companies. Pollack, *supra* note 181. It would be unwise to fully trust that these interested members of the academic community will exercise the necessary ethical self-restraint when such restraint could negatively affect their bottom lines.

185. Carl T. Hall, *Stem-Cell Research's Creative Financing; Federal Strictures Prompt Push for Private, State Funds*, S.F. CHRON., Mar. 15, 2004, at A1, 2004 WLNR 7633936.

186. *Id.*

decision was covered in mainstream magazines and newspapers.[187] Because of this public act, the future of *federal* hES policy will likely remain in the hands of the executive office. Consequently, recommendations on changing the process must focus on the President.

IV. A PRESCRIPTIVE SOLUTION: REVITALIZING THE NIH

The above discussion demonstrates two normative failures that result from the current institutional arrangement for shaping stem cell policy. At the outset of this Note, the question was framed not as "who should decide" the stem cell issue, but rather, as "how should that decision be made." This framing reflects an understanding that the President has publicly, and perhaps irreversibly, assumed the policymaking authority in this area, and that while institutions may be robust over time, insofar as policy changes may feed back into existing institutions, slight policy changes may ameliorate some of the negative effects of current procedural defects. Consequently, the executive retains the ability to use slight policy changes to cure some of the current problems detailed throughout this Note.

The key to such change is eliminating the rule of exogenous events or policy by upheaval. Because the hES issue is highly political and fraught with complexity, policymakers are pressured into obscuring certain subtleties in order to appease the public when a decision is made. And once that decision has been set, policymakers and institutions are slow to react to outside stimuli that do not rise to the level of crises. In order to reduce current procedural defects in policymaking that lead to policy shaped without adequate public debate, the political pressure exerted by exogenous events must be reduced. This can be achieved through *consistency* or keeping a constant stream of information flowing to the public, which will dampen the effects of highly publicized events on politicians.

The difficulty with such a solution is the mass public's inability to properly grasp complicated concepts in a pluralistic society, even when they are willing to spend the time to do so.[188] While due to the moral issues involved, "significant segments of the community" will likely remain doubtful regardless of the information available, public policy should nevertheless strive to reach an outcome that is "the least offensive to the

187. Notably, throughout the buildup, there was never any talk of whether the President had the proper authority and thus the legitimacy to make stem cell policy decisions. In fact, the general public is "blissfully unaware" of how the President implements such decisions. *See* PHILIP J. COOPER, BY ORDER OF THE PRESIDENT: THE USE AND ABUSE OF EXECUTIVE DIRECT ACTION 15 (2002).

188. *See, e.g.*, Schroeder, *supra* note 118, at 125–26 (noting that citizens did a poor job deliberating about stem cells despite paying "fair attention to it").

most persons."[189] The obstacles to pursuit of a deliberative ideal do not diminish the propriety of striving for that goal. In other words, while the discourse may not be perfect, policy should aim to improve the debate as much as possible, in order to ensure the maximum amount of legitimacy. This is especially important in an area so dominated by policymakers who are not elected on the basis of stem cell policy views.

The key to achieving this discourse is to empower the administrative agency closest to the issue—the NIH—and to limit the power of the highly partisan, rubber-stamp Council on Bioethics. Just as Clinton passed the NIH Revitalization Act, Bush should likewise task the Agency with the responsibility of conducting continuous investigation as to both the scientific and ethical advancements in hES research. The growth of centralized regulatory review may give the President confidence in his ability to control the Agency. Furthermore, moving the debate from the Council to the NIH may mitigate the perceived rubber stamp effect and give stem cell research some properly earned legitimacy.

By empowering the NIH and limiting the strength of the Council, the President can retain a degree of control *and* legitimacy. At the same time, reintroducing the NIH to the stem cell debate would allow the Agency to better inform the public, using its expertise in educating with consistent information disclosures. Not only would this reduce the President's need to obscure debate for political reasons, but it would also give the public more access to the policymaking process through notice and comment rulemaking, and allow NIH to remain a relevant player on the frontlines of stem cell research. To a certain extent, keeping the federal government involved may mitigate the eventual costs involved in scrambling to adjust to external events down the road.

There are several obstacles to this suggestion, beginning with the vast scholarship on regulatory pathologies and the nondemocratic nature of agencies.[190] Nevertheless, subject to the growing constraint of centralized regulatory review, the quasi-legislative deliberative and technocratic functioning of the administrative agency makes it the most legitimate

189. McLean, *supra* note 63, at 201.

190. *See, e.g.*, William N. Eskridge, Jr. & John Ferejohn, *Structuring Lawmaking to Reduce Cognitive Bias: A Critical View*, 87 CORNELL L. REV. 616 (2002) (recently summarizing regulatory pathologies). *Cf.* Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 978–79 (1992) (explaining that an underlying justification of the *Chevron* decision was that "agency decisionmaking is always more democratic than judicial decisionmaking because all agencies are accountable (to some degree) to the President").

institution to decide policy.[191] An additional obstacle is that the President may not easily relinquish control of a politically charged issue. The continued power of regulatory review, however, may make the President more willing to open stem cell policy to informed debate within a relatively nonpartisan institution such as the NIH. If the NIH is then allowed to conduct an ongoing informed investigation, it slightly depoliticizes the issue and increases the likelihood that the eventual responses and recommendations will be based on a wider breadth of knowledge. As a final control, the President will continue to set the agenda, and should the NIH fail to produce an adequately deliberative result, he will still be equipped with the ability to cast aside their results (if he offers a satisfactory and legitimate explanation to the public).

Congress plays little, if any, role in this discussion of prescriptive solutions. Congress is less well equipped to set the agenda for an area as rapidly developing as stem cell research. Such volatile policy issues do not lend themselves to legislative solutions, simply because while Congress takes the time to deliberate, unchecked and unbalanced institutions, such as the executive, rush in and exert their authority.[192] Moreover, Congress's agenda is too heavily influenced by unpredictable external factors that sway public opinion, to be able to properly implement a responsive stem cell policy. Stem cell debate stalled in Congress in the wake of September 11, and despite recent attempts to revive the issue, there has been no significant action on stem cell policy.[193] That is not to say that Congress should have *no* role in stem cell policy, but it would be unrealistic to call on Congress for a solution to stem cell policy's shortcomings, when the past has revealed no indication that such action is forthcoming.

191. *See* Stewart, *supra* note 153, at 437–46 (noting that various models of administrative functioning coexist, and in these models, both the OMB and the judiciary provide oversight). Such administrative discretion must be handed out cautiously, however, as giving an agency power will increase access incentives for interested groups and could lead to severe problems of factional abuse of power, tyranny of expertise, and public-regarding outcomes (including distributional equity). To that extent, centralized regulatory review will help to reduce the potential for agency capture theory.

192. *See* COOPER, *supra* note 187, at 12 (stating that when the President acts in emergency situations, such action is rarely remedied by either Congress or the courts).

193. *See supra* note 149. Congress has acted on the periphery, namely a recent bill passed by the Senate to expand the rights of fetuses during an assault on pregnant women. *See* Amy Fagan, *Senate Approves Fetal-Homicide Bill*, WASH. TIMES, Mar. 26, 2004, http://www.washtimes.com/national/20040326-124033-4729r.htm. To further illustrate the current nature of congressional agenda setting, one of the primary drivers behind this bill was the clamor generated by the highly publicized Laci Peterson murder case.

The judiciary similarly has little role to play, largely because of its ex post role and general deferential standard of review.[194] The hard look review mentioned in Part III.C.2, protecting the technocratic functioning of the Agency from presidential control, may give the President pause in his ability to control the NIH. But this prescriptive solution only deals with the agency's ability to disseminate information to the public, not with its rulemaking capacity. To that end, the judicial review aspect is minimized.

The question remains, however, whether such a change in process will ultimately have a positive impact on policy outcomes. Will a change in the institutional rules feed back into existing policies to further empower the NIH? Will it have a positive effect on the public discourse? To the extent that the NIH will be operating in a state of patterned anarchy and flux, its ability to support a constant public debate may also have the added bonus of mitigating entrenchment effects, simply by keeping the issue in a perceived state of flux. To the extent possible, the federal government will put interested actors on notice that the debate is ongoing and prevent them from investing heavily in the rules of the game.

V. CONCLUSION

The ethical and scientific complexity of stem cell research requires open discourse and informed decisionmaking in order to reach an optimal policy outcome. Unfortunately, the current institutional arrangement results in obscured debate and abbreviated decisionmaking. Some may argue that stem cell research should be governed by a politically driven policy because it involves so many controversial issues.[195] This Note has attempted to explain, however, why political pressures are harmful to stem cell policy, and why it is consequently necessary to have an open and informed policy debate. The political pressure on policymakers encourages them to obscure and oversimplify the complexities of stem cell policy for the sake of reaching voters, and takes a toll on the integrity of stem cell policy. Increasing the availability and diversity of information in the public debate can help alleviate political pressure and allow for more informed decisionmaking. Shifting the forum from the rubber-stamping advisor of a

194. For example, the deferential scrutiny standard articulated in *Chevron*. Chevron v. NRDC, 467 U.S. 837 (1984). *See, e.g.*, Gross, *supra* note 37. Additionally, the judiciary suffers from several cognitive weaknesses in policing administrative agencies including overconfidence, availability, and text fetishism. *See* Eskridge & Ferejohn, *supra* note 190, at 631.

195. Indeed, *any* policy decision is a political one and perhaps we should simply applaud this political choice. For more on the political nature of the decision, see, for example, Mike Allen, *Bush Staff Acted to Appease Conservatives*, WASH. POST, Aug. 11, 2001, at A11, 2001 WL 23186446.

politically motivated policymaker to an administrative agency with relevant technical knowledge and a vested interest in reaching a satisfactory policy outcome, reduces the incentive to obscure debate. Opening the debate will have the added benefit of reducing policy entrenchment in a field that must remain responsive to ongoing scientific discovery. The President can rest easier knowing that the growing trend of centralized regulatory review will prevent him from losing control over an important policy issue.

Stem cell policy is necessarily political, requires informed debate, and thus presents a classic case of responsive efficiency versus deliberation. But regardless of the need for political decisionmakers to control the debate, most would agree that stem cell policy should not be governed by sound bytes or news flashes. It should not be decided through vagueness and obscurity. It should not be incapable of adapting to changes in public and scientific understanding. Most importantly, stem cell policy needs a watchdog and that watchdog must be properly informed. The present policy meets none of these requirements.

Bush is committed to a stem cell policy position derived from commitment to a moral bright line, and a refusal to fully consider the scientific side of the debate. In limiting stem cell research to stem cell lines in existence as of August 2001, Bush declared that more investigation was necessary before plunging ahead into a research area fraught with moral and ethical perils. The irony in that justification is that in declaring the need for further reflection and debate, the President has simultaneously perpetuated an institutional entrenchment that obscures proper debate, limits the policy discussion to a rubber stamp forum, inhibits drivers for reform, and makes future adaptation more costly. Consequently, this Note concludes on a somber note for stem cell research advocates. Despite the potential for endogenous change, it will require an exogenous change, a discovery of enormous proportions, before the government alters its stance. By then, it may well be too late.