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LIMITING EXECUTIVE BRANCH JUDO IN FEDERAL STEM CELL RESEARCH POLICIES AND REGULATIONS

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Human embryonic stem cell research has tremendous potential for treating or curing many diseases that cause human suffering. Nevertheless, federal funding for stem cell research has had a controversial history in the United States. While many Americans believe that stem cell research will lead to the development of critical medical technology, others oppose it because of its association with abortion. These ethical issues have made stem cell research a prime target for political posturing, particularly because of how much power presidents have over stem cell research policies. By using vetoes, directives, or executive orders to manipulate stem cell policies, presidents have engaged in executive branch judo to work around the separation of powers and engage in unauthorized lawmaking activity at the expense of the public.

This note will analyze the history of the United States' stem cell research policies and explain how presidents have interfered with its development. Based on the principles of Youngstown Sheet & Tube Co. v. Sawyer*, presidents have repeatedly manipulated stem cell policies in violation of the Constitution. In light of these violations, this note proposes several methods to curtail the president's unilateral control over an entire field of scientific research. Human embryonic stem cell research represents the next frontier of biomedical science, but its benefits will only reach the American public if the United States puts an end to the presidential practice of using executive branch judo to manipulate it.*

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I. INTRODUCTION

Human embryonic stem cells possess the unique ability to turn into all the different cells of the human body.[1] Given their properties, human embryonic stem cells have become a promising area for creating novel medical therapies for a wide variety of diseases.[2] From cancer to diabetes, almost all the world's untreatable diseases can potentially become curable through human embryonic stem cell research.[3]

However, United States stem cell researchers have often found it challenging to conduct research on human embryonic stem cells because of America's inconsistent stem cell research policy. Since a large proportion of stem cell research utilizes human embryonic stem cells derived from early-stage embryos, portions of the American public strongly oppose federal support for stem cell research.[4] Proponents believe that stem cell research will contribute to the development of new, life-saving medical therapies.[5] On the other hand, opponents believe that stem cell research constitutes an unethical scientific pursuit because of its association with human embryonic stem cells ("hESCs").[6] This public opposition has prevented the United States from adopting a uniform policy for guiding United States stem cell research. As a result, the United States has developed a fragmented funding system for stem cell research that inhibits the development of medical sciences and risks putting the United States behind the international race towards modern medicine.[7]

The problems with the nation's stem cell research policies can largely be attributed to the broad discretion Presidents have over stem cell policies. The controversial nature of stem cell research makes the field a target for political posturing, and Presidents have readily utilized their executive power to pursue diverging stem cell policies to achieve their own aims. While Presidents are not prohibited from pursuing political goals through executive power, the degree to which Presidents have done so is alarming. Using executive-branch judo—meaning a combination of vetoes, directives, and executive orders—to work around

1. John A. Robertson, *Embryo Stem Cell Research: Ten Years of Controversy*, 38 J.L. MED. & ETHICS 191, 192 (2010).
2. *Id.*
3. *Id.* at 198.
4. Dorothy C. Wertz, *Embryo and Stem Cell Research in the United States: History and Politics*, GENE THERAPY 674, 676 (2002).
5. Robertson, *supra* note 1, at 192.
6. *Id.*
7. Robertson, *supra* note 1, at 192.

the law, presidents have engaged in unauthorized policymaking activity at the expense of the public.[8]

If the United States wants to promote the next frontier of medical therapies, Congress must change federal research funding laws or create an independent committee for stem cell regulations. This note will focus on this issue by first discussing the origins of the public debate over stem cell research in the United States. It will then identify the structural problems of the current United States stem cell policy. This note will then conclude by describing solutions that could potentially redress the current state of United States research policies towards stem cell research and future life sciences research.

II. BACKGROUND

America's inconsistent stem cell policy has its roots in America's controversial debate over abortion and embryo status.[9] Fully addressing the current issues of America's stem cell policy requires a discussion of their origins. This section will discuss how the *Roe v. Wade*[10] anti-abortion movement initiated the debate over fetal tissue research in the United States. It will then discuss how different presidents have addressed the fetal tissue research controversy. The section will conclude by discussing how the combined actions of the executive and legislative branches contributed to the current disjointed American stem cell policy.

A. 1973-1980: Roe v. Wade *and the Early Origins of America's Stem Cell Policy*

American stem cell policy has intricate ties with the debate over elective abortion. The debate began in 1973 when the Supreme Court legalized elective abortion through its landmark decision in *Roe v.*

8. Executive branch judo is an original term coined by the author of this article to analogize use of executive power to Judo—"an art of weaponless self-defense developed in China and Japan that uses throws, holds and blows, and derives added power from the attacker's own weight and strength." Principles of Judo have similarly been analogized in other contexts, such as in the term "corporate-judo" which means that a company has taken ". . .advantage of a competitor's inevitable weaknesses when it mergers, acquires, downsizes, or restructures." Bastien et al., *Corporate Judo; Exploiting the Dark Side of Change; When Competitors Merge, Acquire, Downsize, or Restructure*, 1 J. of Mgmt. Inquiry n.3, 261, 262-63.

9. Robertson, *supra* note 1, at 192.

10. Roe v. Wade, 410 U.S. 113 (1973). At the time this note was written, the Supreme Court still recognized Roe v. Wade. It has since overturned Roe v. Wade in Dobbs v. Jackson Women's Health Organization, 597 U.S. ___ (2022).

Wade.[11] Discontent with the Supreme Court's decision, a large and politically active United States anti-abortion movement quickly formed.[12] While the movement primarily focused on reversing *Roe v. Wade*, it also stopped all research involving human embryos or fetal tissue derived from elective abortions.[13]

The heavy political pressure exerted by the anti-abortion movement spurred Congress to begin creating a system for adopting federal regulations on fetal tissue and embryo research.[14] In 1974, Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("NC") to provide recommendations on regulating fetal tissue and embryo experimentation.[15] That same year, the newly established NC released its first recommendations for what ethical guidelines should apply to fetal tissue and embryo research.[16] The NC recommendation requested Congress to form a national Ethics Advisory Board ("EAB").[17] Under the NC guidelines, the proposed EAB would review the acceptability of embryo and fetal tissue research projects that sought funding from the Department of Health and Human Services ("HHS").[18] After receiving the EAB's advice, the HHS would then have the power to decide whether to provide the research project with federal funding.[19]

In 1975, the HHS officially adopted the NC's recommended ethical guidelines for fetal and embryo research.[20] However, Congress took no action on the NC's recommendation to create an EAB.[21] The lack of action restricted the HHS from disbursing federal funds for embryo or fetal tissue research projects because the NC guidelines adopted by the HHS required the non-existent EAB to review the proposed project first.[22] It would take Congress until 1979 to finally create the EAB as a part of the National Institute of Health ("NIH").[23] However, the HHS immediately rejected funding for the first project approved by the

11. Wertz, *supra* note 4, at 676.
12. *Id.*
13. *Id.*
14. *Id.*
15. Ann A. Kiessling, *What Is an Embryo?*, 36 CONN. L. REV. 1051, 1073 (2004).
16. Wertz, *supra* note 4, at 674.
17. *Id.*
18. *Id.*
19. Kiessling, *supra* note 15, at 1073.
20. Wertz, *supra* note 4, at 674.
21. Kiessling, *supra* note 15, at 1073.
22. *Id.*
23. *Id.*

EAB.[24] By 1980, the EAB had run out of funding and its charter expired, leaving no administrative body to approve embryo research protocols.[25]

B. 1980-1988: The Reagan Administration and Stem Cells in Fetal Tissue Research

Following the 1980 dissolution of the EAB, President Reagan's HHS would continue to withhold funds from projects that involved fetal tissue from elective abortions.[26] The anti-abortion movement had strongly supported President Reagan's election campaigns and played a significant role in the President's two successive terms.[27] President Reagan's campaign ran on a strong anti-fetal tissue research platform.[28] During his election, President Reagan had even made a campaign promise to restrict federally funded fetal tissue research during his presidency.[29] Despite this promise, the HHS still funded a substantial number of stem cell-related fetal tissue research projects during President Reagan's two terms.[30] While projects on tissue from elective abortions did not receive HHS funding, the department would continue to fund fetal tissue research on tissue from sources other than elective abortions.[31] Nevertheless, President Reagan would take a stronger stance against fetal tissue research in his final years in office.[32]

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24. Wertz, *supra* note 4, at 674.

25. *Id.*

26. Robin Alta Charo, *"La Pénible Valse Hésitation": Fetal Tissue Research Review and the Use of Bioethics Commissions in France and the United States*, *in* SOCIETY'S CHOICES: SOCIAL AND ETHICAL DECISION MAKING IN BIOMEDICINE 477, 481 (Ruth Ellen Bulger et al. eds., 1995).

27. *Id.*

28. *Id.* (describing how the anti-abortion movement "had expanded the scope of their efforts to include a number of collateral issues," such as the regulation of in-vitro fertilization and mandating contraception for female child abusers).

29. *Id.*

30. *See* Dorothy E. Vawter, *Fetal Tissue Transplantation Policy in the United States*, 12 POL. & LIFE SCI. 79, 80 (1993) (explaining how research on fetal tissue not derived from elective abortions received federal funding before, and during the 1980s).

31. "Federal funding of fetal tissue transplantation research in humans has always been permitted provided that the tissue is obtained from fetuses that died of causes other than elective abortion." *Id.* at 79. In the 1950s, the National Institute of Health (NIH) began supporting fetal tissue research on tissue obtained from elective abortions as well. *Id.* The polio vaccine was developed through this federally funded fetal tissue research. *Id.*; *see also* Meredith Wadman, *Cell Division*, 498 NATURE 422, 422-24 (2013), https://www.nature.com/articles/498422a.pdf (discussing the use of fetal tissue cells in the research and development of vaccines for polio, rubella, rabies, measles, chickenpox, and shingles).

32. *See* Kiessling, *supra* note 15, at 1074 (explaining how embryo related research projects submitted to the NIH would often go through the grant approval process without any hope for final approval because no EAB existed to review the projects).

In 1987, an NIH researcher sought federal funding for a project that involved the transplantation of fetal neural tissue into the brain of a Parkinson's disease patient.[33] When the NIH received the project proposal, it reviewed the proposal and approved the study.[34] However, the Director of the NIH, James Wyngaarden, then did something highly unusual for the NIH: he reached out to the Assistant Secretary of Health, Robert Windom, for advice regarding the ethics of funding fetal tissue research projects.[35]

Windom responded on March 22, 1988, by requesting the NIH to form a special advisory panel to discuss whether fetal tissue transplantation experiments would affect the rate of elective abortions.[36] Until the NIH panel issued its decision, Windom would impose a moratorium on all federal funding for fetal tissue transplant experiments that involved tissue from elective abortions.[37] Per Windom's request, the NIH formed a twenty-five-member panel of scientists, doctors, religious leaders, and anti-abortion activists to answer the Windom question.[38] However, the NIH panel's role in deciding the Windom question quickly became moot.[39]

In the first instance of executive branch judo to control stem cell research policy, the Reagan Administration disclosed a draft of an executive order to the press a week before the NIH panel began its inquiry.[40] In the leaked executive order, the Reagan Administration revealed that President Reagan had already planned on unilaterally banning all fetal tissue experiments, regardless of where the fetal tissue came from.[41] The news indicated that even if the NIH panel decided to provide federal funding for all fetal tissue research, the President would likely ignore its recommendation.[42] The news of the leak did not surprise many because of the President's alignment with the anti-abortion movement.[43] After all, President Reagan had even issued a statement

33. Vawter, *supra* note 30, at 80.
34. *Id.*
35. *Id.*
36. Wertz, *supra* note 4, at 675; Charo, *supra* note 26, at 482.
37. Vawter, *supra* note 30, at 80-81.
38. *See* Charo, *supra* note 26, at 482 (describing the composition of the panel).
39. *See generally id.* at 481 (explaining how the NIH panel only served in an advisory capacity and that the Reagan Administration would likely not follow its decision because of its public stance against federally funding fetal tissue research).
40. *Id.* at 482.
41. *Id.*
42. *Id.* ("From the beginning, then, the efforts of this national panel to provide dispassionate advice leading to a consensus on research regulations had a bit of a farcical quality . . . .").
43. *See id.*

that he would restrict funding for fetal tissue research in his last few years in office.[44]

Nevertheless, the NIH panel proceeded with their inquiry.[45] By December of 1988, the panel reached its decision and conveyed its findings to Assistant Secretary Windom.[46] By an eighteen to three majority, the NIH panel stated two primary conclusions.[47] First, the NIH panel concluded that fetal tissue transplantation experiments would not incentivize women to obtain elective abortions if the federal government enacted procedural guidelines for fetal tissue donation from the medical procedure.[48] Second, the NIH panel concluded that the executive branch should remove Windom's moratorium on fetal tissue research because no evidence suggested that the research would contribute to a rise in elective abortion rates.[49] However, President Reagan made good on his promise to his anti-abortion constituency and wholly ignored the panel's recommendations.[50] Although he never officially issued the leaked executive order to withhold federal funds from all fetal tissue research, President Reagan would neither implement the NIH panel's recommended guidelines nor lift Windom's research moratorium for the remainder of his presidency.[51]

C. 1988-1992: President George H. W. Bush and Changing Public Sentiment

Towards the end of President Reagan's second term, public opinion towards fetal tissue research began to change.[52] George H. W. Bush ("President Bush Sr."), President Reagan's former Vice President,

44. *See* Charo, *supra* note 26, at 481 (explaining that in 1987, President Reagan had also issued a statement through his White House staff that all fetal tissue research would no longer receive federal funding without further review).

45. *See id.* (explaining that the inquiry would become dominated by the discussion of abortion rather than the scientific value and ethics of fetal tissue research).

46. Vawter, *supra* note 30, at 81.

47. Charo, *supra* note 26, at 483.

48. Vawter, *supra* note 30, at 81 (listing the NIH panel's three guidelines that should regulate the donation of fetal tissue from elective abortions to medical research).

49. *See* Charo, *supra* note 26, at 482-84 (summarizing the panel's conclusion that the federal government should not conflate fetal tissue transplantation experiments with the issue of abortion and that no evidence existed to suggest that such experiments had increased elective abortion rates in other countries).

50. Vawter, *supra* note 30, at 81.

51. *See id.* (summarizing how the Reagan Administration took no action on the panel's recommendation); *see also* Charo, *supra* note 26, at 483 (stating that the Reagan Administration ignored the panel's recommendation to lift the research moratorium).

52. *See* Charo, *supra* note 26, at 484-85 (discussing the emergence of various fetal tissue research advocacy groups and expert opinions).

would succeed President Reagan with support from his predecessor's anti-abortion constituency, which continued to have a strong political presence throughout the country.[53] However, a growing number of patient-consumers and provider-advocates had begun to sway the public's opinion towards the Windom moratorium on research that used tissue derived from elective abortions.[54] President Bush Sr.'s actions in response to these changes in public opinion eventually exposed a separation of powers issue over research policymaking decisions in the United States.[55]

After his election, President Bush Sr. quickly established himself as an opponent of fetal tissue research.[56] Within months of President Bush Sr.'s election, the new Secretary of Health and Human Services, Louis Sullivan, issued a statement that would set the tone for the Bush Administration's fetal tissue research policy.[57] In his statement, Sullivan rebuked the findings of the Reagan-era NIH panel and argued that funding research on aborted fetal tissue would incentivize elective abortions and increase its frequency.[58] Although the Bush Sr. Administration could not provide any evidence to counter the NIH panel's opposite conclusion, it extended the Windom moratorium indefinitely.[59]

The executive branch's decision to indefinitely extend the moratorium represented another instance of executive branch judo that left both proponents and opponents of stem cell research dissatisfied.[60] Some critics believed that the Bush Sr. Administration had illegally extended the moratorium because it had not followed the procedures for rulemaking under the Administrative Procedure Act ("APA").[61] According to the APA, the Bush Sr. Administration should have

53. *See id.*

54. *See id.* at 485.

55. Helen M. Maroney, *Bioethical Catch-22: The Moratorium on Federal Funding of Fetal Tissue Transplantation Research and the NIH Revitalization Amendments*, 9 J. CONTEMP. HEALTH L. & POL'Y 485, 497 (1993).

56. Charo, *supra* note 26, at 485.

57. Vawter, *supra* note 30, at 81.

58. *See id.* (summarizing the NIH panel's decades of evidence that indicate that no woman has reportedly aborted her fetus for the purpose of donating its tissue to research).

59. *Id.* (addressing the 1989 extension of Windom's moratorium on fetal tissue research, which the former Assistant Secretary of Health had issued in 1988).

60. *See* Vawter, *supra* note 30, at 83 ("[s]ome have charged that the Bush administration's 'indefinite' extension of the ban was illegal. . .."); *see also* Charo, *supra* note 26, at 485 (discussing how proponents and opponents of stem cell research were both dissatisfied with the federal government's inability to reach a unified stance on whether the country would support or oppose stem cell research).

61. Vawter, *supra* note 30, at 83.

published a proposed rule for extending the moratorium in the Federal Register and field public comment on the rule before issuing the extension.[62] Instead, Sullivan had simply announced that the ban would continue indefinitely.[63] Privately funded advocacy groups, such as the National Advisory Board on Ethics in Reproduction ("NABER") and the American Medical Association ("AMA"), emerged as vocal proponents for the government to end the executive branch's unilateral decision to extend the Windom moratorium.[64] The political pressure exerted by these groups spurred Congress to begin working on bipartisan bills that would curtail the executive branch's control over fetal tissue research policies.[65] However, President Bush repeatedly blocked Congress's efforts, resulting in policy conflicts between the legislative and executive branches.[66]

The fetal tissue research conflict between Congress and the President reached its peak near the end of President Bush Sr.'s first term when he issued a controversial "diverting executive order" to undermine a bipartisan fetal tissue bill.[67] In May of 1992, Congress had passed a bipartisan bill that would have permitted fetal tissue research funding and limited the ability of executive branch officials to ban federal funding for entire fields of research.[68] Both Democrats and Republicans believed that the bill's language would not encourage women to obtain abortions solely to donate the tissue to research.[69] As expected, President Bush Sr. vetoed the bill.[70] However, it quickly became apparent that the bill had enough votes in Congress to override the veto.[71] President Bush Sr. responded by issuing a "diverting" executive order to sway a few crucial votes against the Congressional override.[72] The

62. *Id.*

63. *Id.*

64. Charo, *supra* note 26, at 485.

65. *See* Vawter, *supra* note 30, at 82-83 (describing how Congress passed a bipartisan bill that "limited the authority of officials of the executive branch, such as the secretary of HHS, to ban federal funds for an entire field of research without the support of an ethics advisory board").

66. *See id.* (discussing President Bush's controversial diverting executive order that prevented the passage of a bipartisan fetal tissue research bill between May and June of 1992).

67. *See id.*

68. *Id.* (explaining how the bill would have limited the executive branch authority to ban federal funding for research without the support of an ethics advisory board).

69. *Id.*

70. Vawter, *supra* note 30, at 82.

71. *Id.*

72. *Id.* ("[w]hen it became clear that Congress was close to succeeding [at passing a compromise bill], President Bush [Sr.] issued a diverting executive order that successfully reclaimed a few crucial votes in the House.").

executive order "diverted" House votes by creating an alternative solution to fetal tissue access—specifically, it would establish a fetal tissue bank that provide researchers and patients with fetal tissue collected from spontaneously aborted fetuses and ectopic pregnancies.[73] The Bush Sr. Administration contended that this tissue bank could fully support the needs of fetal tissue researchers and patients while simultaneously avoiding the use of tissue from elective abortions.[74] As a result, the congressional bill lost the votes necessary to guarantee an override because supporters no longer saw the bill as necessary.[75]

In June of 1992, Congress quickly came back with a compromise bill that included the proposed tissue bank of President Bush Sr.'s diverting executive order.[76] The compromise bill gave the administration a year to determine whether the fetal tissue bank would work as the Bush Administration had proposed.[77] After one year, any researcher who could not timely obtain suitable tissue from the NIH tissue bank would have the option of receiving the tissue from elective abortions.[78] However, President Bush Sr. subsequently failed to support the compromise bill, retroactively casting his executive order in a controversial light because it "suggested that the administration was less than fully confident the fetal tissue bank would succeed."[79] In addition, it "lent credence to the suspicion that establishing the tissue bank was a diversion designed solely to appease the radical minority in the Republican party who insisted on holding fetal tissue transplantation hostage to abortion politics."[80] By the end of his first term, President Bush Sr.'s diverting executive order had caused the compromise bill to lose too much support, and a congressional filibuster would eventually ensure that the bill did not reach the oval office for the remainder of President Bush Sr.'s term.[81]

By the end of 1992, President Bush Sr.'s stance on fetal tissue research became unpopular for two reasons. First, the President's actions had lost him congressional support because he had exposed a separation of powers issue surrounding policymaking decisions for

73. *Id.*
74. *See id.* at 82-83 (explaining how the tissue bank could address the lack of usable tissue for research).
75. *See id.*
76. Vawter, *supra* note 30, at 82-83.
77. *Id.* at 82.
78. *See id.*
79. *See id.*
80. *See id.*
81. *Id.*

controversial research areas.[82] The President's use of executive orders and vetoes to stall the passage of bipartisan bills caused many to consider his actions unreasonable.[83] Congress had become frustrated over the President's discouragement of bipartisan solutions to the fetal tissue research issue and disliked how much control the President had over the NIH's funding actions.[84]

Additionally, the President had lost public support on the issue of fetal tissue research because three factors had made the public more receptive to plans for federally funding fetal tissue research during his presidency.[85] First, the moratorium had resulted in a lack of federal regulation over privately funded fetal tissue research because it had discouraged federal involvement in the field.[86] Second, the moratorium had drastically reduced United States fetal tissue transplantation research progress compared to other countries.[87] Lastly, doctors had actually demonstrated that fetal tissue transplants could treat specific diseases, which showed the public the promises of medical fetal tissue research for the first time.[88] Although these factors had changed the public's opinion on fetal tissue research, President Bush Sr. chose to remain opposed to its funding.[89] The President wanted to run for reelection, and withholding federal funds from fetal tissue research could help garner

82. Vawter, *supra* note 30, at 82-83.

83. *See id.* (describing how some members of President Bush's party saw his actions as an appeal to a small minority of anti-abortion voters).

84. *See id.*

85. *See* Vawter, *supra* note 30, at 82-83.

86. To fill in the lack of federal guidance, many states began to apply the Uniform Anatomical Gift Act (UAGA) to the donation of fetal tissue. *See id.* This would lead to a wide range of fetal tissue procurement and research practices because each state began to implement different approaches for applying the UAGA. *Id.* at 83. For example, some states would permit healthcare professionals to have full discretion over the use of fetal tissue from aborted fetuses while other states merely required a healthcare professional to obtain verbal consent at the time of the abortion. *Id.* at 83.

87. *See id.* at 82.

88. *See id.* (summarizing the highly publicized 1991 story of the Walden family's attempt to get a fetal tissue transplant for their unborn child in order to prevent the fetus from dying of Hurler's syndrome, a fatal genetic liver disease). Reverend Guy Walden, pastor of the Broadway Baptist Church in Houston, and his wife, Terri Walden, held fervent anti-abortion views. Steven Maynard-Moody, *Managing Controversies over Science: The Case of Fetal Research*, 5 J. PUB. ADMIN. RES. & THEORY 5, 15 (1995). However, after losing two children to a genetic liver disease, the Waldens chose to take part in an experimental therapy that utilized stem cells from fetal tissue. *Id.* The family would testify about their experience with stem cell therapy and fetal tissue transplants to Congress in 1991. *Id.* at 16. Their testimony "broke the hold that the antiabortion movement had held on fetal research for twenty years," leading to bipartisan support for federally funding fetal tissue research in the last years of President Bush's first term. *Id.*

89. *Id.*

the support of anti-abortion movement voters in the 1992 Presidential Election.[90]

D. 1992-2000: The Clinton Administration and the Dickey-Wicker Amendment

President Bush Sr.'s reelection platform ultimately proved ineffective when voters chose to replace him with Arkansas Governor William Jefferson Clinton and a Democrat-leaning Congress.[91] President Clinton characterized himself as a proponent of fetal and embryonic tissue research, but his efforts to promote the field would eventually become complicated by political concerns and legislative hurdles.[92] By the end of Clinton's two terms, two significant pieces of legislation would change the course of the United States' stem cell policy: the National Institutes of Health Revitalization Act of 1993 and the 1996 Dickey-Wicker Amendment.[93]

On January 22, 1993, President Clinton issued an executive order overturning the Reagan-Bush era moratorium on fetal tissue research.[94] Five months later, the Clinton-aligned Congress passed the National Institutes of Health Revitalization Act of 1993 ("NIHRA").[95] The NIHRA revoked the 1975 regulation that had prohibited the NIH from funding any embryo and fetal tissue research project unless an EAB approved the project.[96] Even though this regulation remained effective throughout the Reagan-Bush Administrations, neither President had formed an EAB to approve fetal tissue and embryo research during their terms.[97]

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90. *See* JAMES T. PATTERSON, RESTLESS GIANT: THE UNITED STATES FROM WATERGATE TO BUSH V. GORE 251-52 (David M. Kennedy ed., 2005) (describing President Bush's 1992 reelection campaign strategy where he ran on a platform that "called for the restoration of prayer in the public schools, and denounced abortion" to appeal to religiously conservative voters).

91. *Id.*

92. Robertson, *supra* note 1, at 194.

93. *See* Kiessling, *supra* note 15, at 1074 (discussing the enactment of the NIHRA); *see also* Robertson, *supra* note 1, at 194 (discussing the enactment of the Dickey-Wicker Amendment).

94. Vawter, *supra* note 30, at 83 (explaining how President Clinton had made a campaign promise to end the moratorium).

95. KIRSTIN R.W. MATTHEWS & ERIN H. YANG, POLITICS AND POLICIES GUIDING HUMAN EMBRYO RESEARCH IN THE UNITED STATES 15-17 (2019), https://www.bakerinstitute.org/media/files/files/a9096889/chb-pub-greenwall-hesc-011519.pdf.

96. *Id.*

97. *See supra* Parts II.B-C; *see also* MATTHEWS & YANG, *supra* note 95, at 13-14 (explaining how the Reagan-Bush Administrations pursued efforts to establish an EAB in 1985, but never took any action to officially form one).

The revocation of the 1975 regulation paved the way for the NIH to finally approve funding for fetal tissue and embryo research by removing ethics board oversight.[98] Following the revocation, President Clinton ordered his newly appointed NIH Director, Harold Varmus, to develop guidelines for embryo research.[99] Director Harold Varmus formed the NIH Human Embryo Research Panel ("HERP") to establish the guidelines and released its conclusions in 1994.[100] The HERP's conclusions recommended that certain instances of embryo research should receive federal funding.[101] Controversially, HERP also recommended that federal funding should go to projects that created embryos solely for research purposes.[102]

In a surprising response, President Clinton issued a presidential directive prohibiting the NIH from funding projects that created an embryo for research purposes.[103] President Clinton qualified his decision by stating that moral and ethical considerations weighed against funding such projects.[104] However, some commentators believe that political factors also played a part in his decision.[105] The 1994 Congress had become much more conservative, and the directive could help him politically by silencing his political opponents on the issue of embryo research.[106]

Regardless of President Clinton's reasoning, Congress did not believe the presidential directive did enough and began working on legislation to establish more stringent controls over embryo research.[107] This legislation would become known as the Dickey-Wicker Amendment and establish two quintessential aspects of the United States' stem cell research policy.[108] Passed as part of the appropriations

98. MATTHEWS & YANG, *supra* note 95, at 15.

99. Robertson, *supra* note 1, at 194. President Clinton had actually ordered Varmus to begin developing the guidelines in 1992, before President Clinton assumed office. *See id.* President Clinton likely ordered Varmus to develop these guidelines in order to make good on his campaign promise to end the fetal tissue research moratorium and to support the advancement of the field. *See* Vawter, *supra* note 30, at 83.

100. Robertson, *supra* note 1, at 194.

101. *Id.*

102. *Id.*

103. Kiessling, *supra* note 15, at 1077.

104. *Id.*

105. John C. Fletcher, *U.S. Public Policy on Embryo Research: Two Steps Forward, One Large Step Back*, 10 HUM. REPROD. 1875, 1877 (1995).

106. *Id.*

107. *Id.*

108. Nefi D. Acosta & Sidney H. Golub, *The New Federalism: State Policies Regarding Embryonic Stem Cell Research*, 44 J.L. MED. & ETHICS 419, 420 (2016).

bill for the HHS, the relevant portions of the Dickey-Wicker Amendment provided that:

> (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 . . . .
>
> (b) For purposes of this section, the term "human embryo or embryos" shall include any organism, not protected as a human subject . . . that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.[109]

The Dickey-Wicker Amendment had two immediate effects.[110] First, it prohibited the National Institute of Health ("NIH") from providing federal funding for research that resulted in the destruction of a human embryo.[111] Second, it prohibited the NIH from issuing federal funds for research that involved creating a human embryo for research purposes.[112] In 1996, President Clinton signed the Dickey-Wicker Amendment into law.[113] The Amendment, which Congress has renewed every year since 1996, continues to curtail embryo research by codifying prohibitions on funding from all agencies within the HHS.[114]

In 1998, the Clinton Administration would oversee another critical event in the development of the United States' stem cell policy: the isolation of human embryonic stem cells.[115] Dr. James Thomson had discovered the method of isolating human embryonic stem cells at the University of Wisconsin by splitting five and six-day-old, fertilized eggs.[116] Since the Dickey-Wicker Amendment prohibited the federal funding of Dr. Thomson's discovery, the Geron Corporation had financed the discovery.[117] The news of Dr. Thomson's work had two effects. First, it directly linked stem cell research to embryonic and fetal

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

110. MATTHEWS & YANG, *supra* note 95, at 8.

111. *Id*.

112. *Id.*

113. *Id.* at 5.

114. *Id.* at 17. The prohibition was once again renewed in a recent omnibus spending bill on March 15, 2022, and remains effective as of August 2022. *See* Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, § 737, 136 Stat. 94 (2022).

115. Robertson, *supra* note 1, at 192.

116. *Id.*; MATTHEWS & YANG, *supra* note 95, at 17.

117. *See* Michael Mintrom, *Competitive Federalism and the Governance of Controversial Science*, 39 PUBLIUS 606, 608 (2009).

tissue research.[118] Up until the isolation of human embryonic stem cells, the public and the government had not actually addressed human embryonic stem cells.[119] Dr. Thomson's discovery would finally ignite the discussion of regulating human embryonic stem cell research as a distinct yet related field to fetal tissue and embryo research.[120]

Second, the isolation of human embryonic stem cells raised the question of whether the government should become an active participant in the research and discovery of new human embryonic stem cell lines.[121] Some policymakers expressed concern over the isolation of human embryonic stem cells because it involved separating five and six-day-old fertilized eggs.[122] Others believed that the discovery could lead to new medical therapies and advocated for the federal government to begin funding human embryonic stem cells research that used embryos left over from in-vitro fertilization treatments.[123] The Clinton Administration sided with the latter group and eventually issued a series of research funding guidelines through the NIH in 2000.[124] However, because human embryonic stem cells involved the destruction of human embryos, the Dickey-Wicker Amendment prohibited the Clinton Administration from using their funding guidelines for any embryo research projects.[125]

E. 2000-2008: President George W. Bush and the Decentralized "Compromise" Policy

While President Clinton had initially indicated an interest in promoting stem cell research, he ultimately decided to withhold federal funding for stem cell research due to political pressure and the passage of the Dickey-Wicker Amendment.[126] Following Clinton's two terms, the United States' stem cell policy would fall into the hands of President George W. Bush ("President Bush Jr.").[127] Unlike his predecessor,

118. MATTHEWS & YANG, *supra* note 95, at 17.
119. *See id.*
120. *See* Allen M. Spiegel, *The Stem Cell Wars: A Dispatch from the Front*, 124 TRANSACTIONS AM. CLINICAL & CLIMATOLOGICAL ASS'N 94, 101 (2013) (describing how the Clinton Administration issued the first series of guidelines regulating human embryonic stem cell research).
121. *See* MATTHEWS & YANG, *supra* note 95, at 17-18 (discussing the different views of the National Bioethics Advisory Commission and the Human Embryo Research Panel on funding the creation of new stem cell lines).
122. *Id.* at 17.
123. *Id.*
124. Spiegel, *supra* note 120, at 101.
125. *Id.* at 100-01.
126. *See supra* Part II.D.
127. MATTHEWS & YANG, *supra* note 95, at 18.

George W. Bush had to handle both the country's fetal tissue and embryo research issues and the new issue of human embryonic stem cell research.[128] Although President Bush Jr. assumed office on a platform opposed to both human embryo and human embryonic stem cell research, he would end up taking on a more conciliatory approach to funding human embryonic stem cell research.[129] The Bush Jr. Administration's stem cell policies would encompass two key events: the oral directive for a "compromise" policy[130] and the founding of state funding programs for stem cell research.[131]

On August 9, 2001, President Bush Jr. announced his human embryo and embryonic stem cell research policy in an oral directive read during a televised address to the country.[132] Instead of banning all human embryonic stem cell research funding, President Bush Jr. declared that he would pursue a "compromise" policy that only permitted federal funding for hESC research conducted on twenty-one hESC lines that had already been created before August 9, 2001.[133] The President would also allow private or nonfederal funding of the research areas without oversight or regulation, essentially continuing the policy of previous administrations that did not restrict the private sector or states from investing in fetal and embryo research.[134]

Although President Bush Jr. permitted embryonic stem cell research funding, the policy still did not satisfy embryonic stem cell research supporters for two reasons.[135] First, supporters believed that limits on funding would discourage new and established scientists from entering the stem cell research field.[136] Several private investors had already patented methods for creating certain stem cell lines.[137] If stem cell researchers could not obtain federal funding to develop workarounds to these patented methods, they would have to obtain licenses from private investors to conduct their research.[138] Supporters believed that

128. *Id.*

129. *Id.*

130. Press Release, George W. Bush, President, President Discusses Stem Cell Research (Aug. 9, 2001), https://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html [hereinafter Bush Press Release].

131. Mintrom, *supra* note 117, at 617-19.

132. MATTHEWS & YANG, *supra* note 95, at 18; *see* Bush Press Release, *supra* note 130.

133. MATTHEWS & YANG, *supra* note 95, at 18; *see* Bush Press Release, *supra* note 130.

134. MATTHEWS & YANG, *supra* note 95, at 18.

135. *Id.*

136. *See* Jeanne Loring, *A Patent Challenge for Human Embryonic Stem Cell Research*, NATURE REP. STEM CELLS (2007), https://doi.org/10.1038/stemcells.2007.113.

137. *Id.* (discussing how Geron and the Wisconsin Alumni Research Foundation had already obtained patents for several stem cell lines and the methods for creating them).

138. *Id.*

this financial burden would dissuade researchers from entering the field and hinder scientific progress.[139]

Second, the restriction on funding for embryo research and the creation of new stem cell lines limited research prospects.[140] Since the existing stem cell lines came from only a few donors, the stem cell lines did not have genetic or ethnic diversity.[141] Therefore, restricting research to the existing lines would make it impossible to study how specific diseases develop in different ethnicities and minority groups.[142] Additionally, supporters believed that the then-existing stem cell lines could die out because the stem cell lines could become genetically unstable.[143]

In reaction to the restraints of the Bush Jr. policy, several states began to push for state-funded stem cell research programs.[144] New Jersey and California were the leading states in the state stem cell revolution.[145] While New Jersey became the first state to pass legislation that incentivized stem cell research, California became the first state to provide funding for the field.[146]

In November 2004, California voters passed Proposition 71 to issue a three billion dollar bond measure to establish the California Institute for Regenerative Medicine ("CIRM") to oversee and fund stem cell research projects.[147] In addition, the Proposition amended the state constitution to make stem cell research a constitutional right.[148] California's approach quickly inspired other states to follow suit.[149] Following the establishment of CIRM, New Jersey, Connecticut, Maryland, and several other states would also set up state agencies to fund stem cell research.[150]

These state agencies would become the bedrock for the United States' stem cell research efforts during President Bush Jr.'s time in office.[151] Like his predecessors, President Bush Jr. used his veto power

139. *See id.*
140. Spiegel, *supra* note 120, at 104.
141. Varnee Murugan, *Embryonic Stem Cell Research: A Decade of Debate from Bush to Obama*, 82 YALE J. BIOLOGY & MED. 101, 101 (2009).
142. *Id.*
143. Spiegel, *supra* note 120, at 104.
144. Acosta & Golub, *supra* note 108, at 420-22.
145. *Id.* at 426-27.
146. *Id.*
147. *Id.* at 423.
148. *Id.*
149. *Id.* at 426.
150. Acosta & Golub, *supra* note 108, at 426-27.
151. *See* Mintrom, *supra* note 117, at 614.

to control the United States' stem cell policy.[152] In 2006 and 2007, President Bush Jr. vetoed bipartisan bills that would expand the set of human embryonic stem cell lines eligible for federally funded research.[153] However, President Bush Jr. took no further action to nationally regulate stem cell research.[154] The effect of President Bush Jr.'s decentralized approach ultimately invited states to fill the stem cell regulatory gap and has become credited for the rise of state-sponsored stem cell programs.[155]

F. 2008-2016: President Obama and The Stem Cell Policy Shift

In 2009, President Obama assumed office and quickly did away with President Bush Jr.'s decentralized stem cell research policy.[156] In place of his predecessor's policy, President Obama attempted to pursue a policy that promoted and controlled stem cell research.[157] However, the Dickey-Wicker Amendment's prohibitions required President Obama to employ more executive branch judo to open federal funding for hESC research.

President Obama began enacting his stem cell policy by issuing an executive order that instructed the NIH to "support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research."[158] The order marked a turning point for the nation's stem cell research policy in two ways. First, it effectively removed the Bush II-era policy restrictions on funding for research on hESC lines created after August 9, 2001.[159] Second, it caused the NIH to reinterpret the Dickey-Wicker Amendment as permitting an expanded funding policy for hESC research.[160]

These departures from previous administrations relied on the NIH's new belief that not all hESC research resulted in the destruction of a human.[161] While the NIH continued to acknowledge that hESC research aimed at deriving new hESC lines involved the destruction of human

152. *Id.* at 613.
153. *Id.*
154. *Id.*
155. *Id.*
156. MATTHEWS & YANG, *supra* note 95, at 5.
157. *Id.* at 18-19 (describing the various pro-stem cell research policies that the Obama Administration pursued).
158. Exec. Order No. 13,505, 74 Fed. Reg. 10667, 10667 (Mar. 9, 2009).
159. MATTHEWS & YANG, *supra* note 95, at 18.
160. *Id.* at 19.
161. *See* Sherley v. Sebelius, 644 F.3d 388, 395 (D.C. Cir. 2011) ("In the 2009 Guidelines the NIH expressly distinguished between the derivation of ESCs and 'research involving [ESCs] that does not involve an embryo nor result in an embryo's destruction.' ").

embryos,[162] a substantial amount of hESC research merely involved the use of hESC lines to study areas such as disease pathology.[163] Since some kinds of hESC research utilized established hESC lines and did not directly result in the destruction of a human embryo, the NIH believed that it could legally provide federal funding for the projects in accordance with the Dickey-Wicker Amendment.[164]

Based on this new view of hESC research, the NIH created new guidelines for disbursing federal funds for stem cell research in the United States. The new guidelines of the Obama Administration still prohibited funding for the creation of new hESC lines.[165] But, it opened up federal funding for research that used *new* hESC lines created after August 9, 2001 if the hESC lines had been derived from privately funded human embryo research.[166] Many scientists, biotech companies, and political figures saw these efforts as a positive sign that the United States would finally have a stem cell policy that separated science from politics.[167] Despite this praise, the Obama Administration would ultimately need to justify its pro-stem cell research policy decisions in court.[168]

In *Sherley v. Sebelius*, two stem cell researchers James Sherley and Theresa Deisher, joined with other anti-human embryonic stem cell groups to contest the Obama Administration's new NIH guidelines for funding stem cell research.[169] According to the plaintiffs, the new NIH guidelines that permitted federal funding for human embryonic stem cell research clearly violated the Dickey-Wicker Amendment because any human embryonic stem cells *must* have come from the destruction of an embryo.[170] However, since the Dickey-Wicker Amendment did not

162. *See id.* at 95.

163. *See id.*

164. Sherley v. Sebelius, 644 F.3d 388, 389-90 (D.C. Cir. 2011). ("The NIH seems reasonably to have concluded that, although Dickey–Wicker bars funding for the destructive act of deriving an ESC from an embryo, it does not prohibit funding a research project in which an ESC will be used.").

165. *See* Murugan, *supra* note 141, at 102.

166. *Id.* at 101-02.

167. Howard Wolinsky, *The Pendulum Swung: President Barack Obama Removes Restrictions on Stem-Cell Research, but Are Expectations Now Too High?*, 10 EMBO REP. 436, 437 (2009). John Kessler, Professor of Neurology and Director of the Feinberg Neuroscience Institute at Northwestern University, commented on the new Obama policy by stating that "[i]t's nice to see politics are no longer intervening in science, where they never should have been in the first place." *Id.*

168. Sherley v. Sebelius, 776 F. Supp. 2d 1 (D.D.C. 2011), *aff'd*, 689 F.3d 776 (D.C. Cir. 2012).

169. *Id.* at 8.

170. *Id.* at 17.

expressly state that human embryonic stem cell research qualified as research that resulted in the destruction of human embryos, the Court deferred to the NIH's interpretation of the Dickey-Wicker Amendment as not encompassing human embryonic stem cell research.[171] Although the plaintiffs appealed the ruling, they lost the case, and the Supreme Court refused to grant their petition for writ of certiorari.[172]

The Obama Administration's victory allowed it to follow through on its plans to fund human embryonic stem cell research. However, the favorable ruling also showed how stem cell research funding policies stood on precarious footing. If a President could simply open federal funding for stem cell research through executive order, they could just as quickly cut off funding at any time.

G. 2016-2020: President Trump and The Status Quo

Throughout most of President Trump's term in office, the federal government did not take any concrete action on the issue of human embryonic stem cell research.[173] However, in June 2019, the Trump Administration suddenly announced that it would order the HHS to subject research projects that used fetal tissue to additional scrutiny and potentially restrict their funding.[174] Although the order targeted fetal tissue rather than embryonic stem cells, the decision troubled many researchers who study how to make organ replacements from stem cells.[175] In this research, fetal tissue is a reference for how well the stem cell-generated proto-organs replicate natural human tissue.[176] By imposing funding restrictions on projects that involved fetal tissue, the Trump Administration threatened to hamper stem cell research inadvertently.[177] However, with the departure of the Trump Administration and the inauguration of President Biden, these regulations may very well come to an end.

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171. *Id.* at 19 (applying the *Chevron* standard to interpret the NIH's interpretation of the Dickey-Wicker Amendment); *see* Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984) (articulating the standard for judicial review of an agency's interpretation of a statute).

172. *See* Sherley v. Sebelius, 689 F.3d 776 (D.C. Cir. 2012), *cert. denied*, 568 U.S. 1087 (2013).

173. MATTHEWS & YANG, *supra* note 95, at 19.

174. *See* Sara Reardon, *U.S. Government Curtails Fetal-Tissue Research*, 570 NATURE 148, 148 (2019), https://media.nature.com/original/magazine-assets/d41586-019-01783-6/d41586-019-01783-6.pdf.

175. *Id.* (discussing how a researcher, Dr. Andrew McMahon, utilizes fetal tissue to determine how closely his lab's stem cell derived kidney reflects real human tissue).

176. *Id.*

177. *Id.*

III. IDENTIFICATION OF THE LEGAL PROBLEM

The last several decades show that the United States has a fragmented policymaking system for governing controversial sciences like stem cell research.[178] The fragmented system has risen from Congress' inability to make legislation that effectively controls stem cell research while also balancing the ethical concerns of legislators and their constituents.[179] As a result, presidents can use executive orders or directives to exercise unfettered control over the United States' stem cell research and exploit Congress's policy gaps.[180]

IV. ANALYSIS

The president's influence over stem cell research through executive branch judo poses a significant problem for the United States because it makes the federal stem cell research policy too inconsistent and variable.[181] The numerous changes to the nation's stem cell research policies over the last forty years show how presidents can have drastically different views on stem cell research.[182] Given their degree of control over executive agencies that fund research, presidents can exploit weak congressional legislation and shape the progress of stem cell research to suit their political or personal beliefs.[183] The unpredictability of this unilateral policymaking system has disincentivized stem cell research and contributed to a disorganized regulatory framework for emerging stem cell therapeutics.[184]

This section will focus on whether presidents can validly use executive orders and directives to establish federal stem cell research policies and discuss the effects of this policymaking system.[185] First, it

178. *See* James W. Fossett et al., *Federalism and Bioethics: States and Moral Pluralism*, 37 HASTINGS CTR. REP. 24, 24-25 (2007).

179. *Id.* at 25.

180. Yaniv Heled, *On Presidents, Agencies, and the Stem Cells Between Them: A Legal Analysis of President Bush's and the Federal Government's Policy on the Funding of Research Involving Human Embryonic Stem Cells*, 60 ADMIN. L. REV. 65, 90 (2008).

181. Fossett et al., *supra* note 178, at 25.

182. Lawrence Gostin, *The Formulation of Health Policy by the Three Branches of Government, in* SOCIETY'S CHOICES: SOCIAL AND ETHICAL DECISION MAKING IN BIOMEDICINE, 335, 351 (1995).

183. *Id.*

184. *See* Jeffrey L. Furman et al., *Growing Stem Cells: The Impact of Federal Funding Policy on the U.S. Scientific Frontier*, 31 J. POL'Y ANALYSIS & MGMT. 661, 700 (2012) (discussing how lower research paper publications during the early years of President George W. Bush's Administration indicates that uncertainty disincentivizes research); *see also* MATTHEWS & YANG, *supra* note 95, at 7 (discussing how the states have largely had to regulate stem cell research due to the lack of federal guidance).

185. Heled, *supra* note 180, at 106.

will utilize Justice Jackson's *Steel Seizure* three-tier analysis to discuss how the executive branch's regulation of stem cell research verges on the brink of executive lawmaking activity. It will then discuss how permitting the president to make stem cell research policy has affected research efforts and regulation of stem cell therapeutics.

A. Evaluating the President's Authority to Make Stem Cell Research Policies

Over the last few decades, presidents have used executive branch judo—in the form of directives, vetoes, or executive orders—to establish drastically different stem cell research policies.[186] This raises an interesting question: to what degree did presidents have the authority to control stem cell research policies?

A president's authority to act arguably stems from the Take Care Clause of the Constitution. Although the Supreme Court has construed the Clause as placing a strict obligation on the president and their delegates to comply with and execute the statutory directives of Congress,[187] some lower courts have construed the Clause as providing these parties with broad discretion to enforce the law.[188] Nevertheless, a president must "take Care that the Law[] be faithfully executed" once a bill has become law.[189] If a president disregards, amends, or repeals statutory directives from Congress, the president violates the separation of powers because he or she is substituting their own policy choices for those established by Congress.[190] In effect, this would permit the president to go beyond their limited lawmaking power to recommend legislation to Congress,[191] communicate their opposition or support for

186. *See supra* Parts II.A-G (describing the various directives and executive orders that Presidents have used to control research in controversial areas of science).

187. Myers v. United States, 272 U.S. 52, 177 (1926) (Holmes, J., dissenting) ("The duty of the President to see that the laws be executed is a duty that does not go beyond the laws or require him to achieve more than Congress sees fit to leave within his power.").

188. This is particularly evident in cases where the President's discretion to prosecute criminal cases is at issue. *See, e.g.*, Smith v. United States, 375 F.2d 243, 246-47 (5th Cir. 1967) ("The President of the United States is charged in Article 2, Section 3, of the Constitution with the duty to 'take care that the laws be faithfully executed . . . .' . . . The discretion . . . in choosing whether to prosecute or not to prosecute, or to abandon a prosecution already started, is absolute.").

189. U.S. CONST. art. II, § 3.

190. Kendall v. United States *ex rel.* Stokes, 37 U.S. (12 Pet.) 524, 613 (1838) ("To contend that the obligation imposed on the President to see the laws faithfully executed, implies a power to forbid their execution, is a novel construction of the constitution, and entirely inadmissible.").

191. U.S. CONST. art. II, § 3.

legislation under consideration,[192] and sign legislation that meets their approval or veto legislation that they disagree with.[193]

Based on these principles of presidential authority, the regulation of stem cell research by recent presidents seemed to fall outside of presidential authority because all recent presidents have deviated from the confines of Congressional legislation or ignored it entirely. Furthermore, Congress has never granted the president express authority to regulate controversial sciences such as stem cell research.[194] This suggests that the stem cell "policymaking" of last several presidents may have constituted impermissible lawmaking activity that exceeded presidential authority and the law.[195]

Justice Jackson provides the essential source of guidance for determining whether a president has utilized their executive power in a permissible manner.[196] In *Youngstown Sheet & Tube Co. v. Sawyer* (*Steel Seizure*), 343 U.S. 579 (1952), Justice Jackson articulated three "tiers" where the president has the authority to act.[197] The first tier encompasses presidential acts that Congress has expressly or impliedly authorized.[198] In these situations, the president has acted with maximum authority and on sound constitutional footing.[199] The second tier encompasses presidential acts that fall within a "zone of twilight" where Congress has neither authorized nor prohibited the president's actions.[200] If a president operates within the "zone of twilight," the president's independent power to act depends on the "imperatives of events and contemporary imponderables rather than on abstract theories of law."[201] Pursuant to this guiding principle, "congressional inertia, indifference or quiescence" to a president's independent actions may implicitly authorize the president's actions.[202] The third and final tier encompasses presidential acts that expressly or impliedly contravene Congress'

192. *Id.* art. I, § 7.
193. *Id.*
194. *See* Heled, *supra* note 180, at 106.
195. *See id.* at 106.
196. *Id.* at 90-91.
197. *See* Youngstown Sheet & Tube Co. v. Sawyer (*Steel Seizure*), 343 U.S. 579, 635-38 (1952) (Jackson, J., concurring).
198. *Id.* at 635.
199. *Id.*
200. *Id.* at 637.
201. *Id.*
202. *Id.*

will.[203] In this last tier, the president's authority to act stands on the weakest legal footing.[204]

Applying Justice Jackson's tier analysis to policymaking in controversial science research indicates that presidents do not have a solid constitutional basis to control stem cell research.[205] Several presidents actively worked to consolidate executive authority over stem cell research by leveraging their executive power in a manner that essentially amounted to lawmaking.[206] In addition, presidents have frequently used directives to immunize their actions from judicial review.[207] The following sections will address why past presidents have not had the clear authority to control stem cell-related research.

1. President Reagan

The Reagan Administration's approach to controlling controversial areas of science likely constituted a permissible exercise of presidential authority within Justice Jackson's second tier of authority. During his administration, President Reagan pursued a policy that opposed fetal tissue research on tissue from elective abortions.[208] Since no law required or prohibited the Reagan Administration from supporting these research projects,[209] the Reagan Administration operated in the "zone of twilight" when it imposed the moratorium on fetal tissue research.[210] While the moratorium did not directly infringe upon Congress' express or implied will, it also lacked a solid legal basis because Congress had not expressly granted the Reagan Administration the authority to create the policy.[211]

Nevertheless, President Reagan's moratorium was likely permissible under the Take Care Clause. Justice Jackson's approach suggested that congressional "indifference or quiescence" to Presidential action could indicate implicit authorization of a President's actions by

203. *Steel Seizure*, 343 U.S. at 637.

204. *Id.*

205. Heled, *supra* note 180, at 124 (arguing that at least President George W. Bush did not have a constitutional basis to pursue the compromise policy).

206. *See supra* Parts II.C, II.E (discussing how the Bush Administrations vetoed bipartisan legislation that went against their political stances on stem cell research); *see also* Heled, *supra* note 180, at 87 (describing how President George W. Bush vetoed bipartisan legislation that would curtail his control over stem cell research in 2006 and 2007).

207. Heled, *supra* note 180, at 88-89.

208. *See* Charo, *supra* note 26, at 481.

209. *Id.*

210. *See* Youngstown Sheet & Tube Co. v. Sawyer (*Steel Seizure*), 343 U.S. 579, 637 (1952).

211. *See id.*

Congress.[212] As Congress did not oppose President Reagan's mortarium, it may have concluded that the President's actions were permissible with Congress' aims. Regardless of whether Congress actually authorized the Reagan Administration's actions, the Reagan-era did establish a clear precedent: presidents could pursue their own stem cell research policy objectives in the absence of clear legislation.

2. President George H. W. Bush

The first Bush Administration's approach to regulating fetal and embryonic research likely fell within Justice Jackson's third tier of authority because President Bush Sr. went outside of the confines of his presidential authority. During his term, President Bush Sr. pursued an anti-embryo and fetal tissue research policy that clashed with Congress' desire to adopt a more supportive policy.[213] In pursuing his policy objectives, President Bush Sr. directed the NIH to extend the moratorium on fetal tissue research against the protests of the Congressional majority, utilized "diverting" executive orders to breakdown bipartisanship, and vetoed any legislation that would constrain his ability to unilaterally decide embryo and fetal tissue research policy.[214] As discussed above, the extension may have constituted an illegal exercise of executive power because it ignored the restraints on the duration of the moratorium, as well as the proper procedures to enact it.

The Windom moratorium was set to expire when President Bush Sr. assumed office.[215] The procedures for rulemaking under the Administrative Procedure Act should have required the Bush Sr. Administration to publish a proposed extension of the moratorium in the Federal Register and field public comment on the proposal before executing an extension.[216] However, Sullivan simply announced that the ban would continue indefinitely.[217] This meant that the Bush Sr. Administration ignored the Congressional directives for the proper execution of the moratorium and engaged in impermissible lawmaking activity by amending a law to increase its effective duration. These actions indicate that President Bush Sr. went against the implied will and

212. *See id.*
213. Vawter, *supra* note 30, at 82-83.
214. *Id.*
215. *Id.*
216. *See id.* at 83.
217. *Id.*

express will of Congress, which likely places his actions within Justice Jackson's third tier of authority as unconstitutional lawmaking.[218]

3. President Clinton

Like his predecessor, President Clinton's regulation of embryo and fetal tissue research likely fell within Justice Jackson's third tier of authority as well. President Clinton had initially voiced an intention to support embryo and fetal tissue research during his presidency, but he ultimately adopted a moderate approach that retained certain restrictions on funding stem cell research projects.[219] The issue with this moderate approach was that President Clinton accomplished it by blatantly contravening the express will of Congress.[220]

According to *Youngstown*, presidential actions contravene the will of Congress when the actions are incompatible with statutory instructions and fall outside of the President's inherent authority.[221] In the context of President Clinton's administration, the statutory instructions of the NIHRA prevented the NIH from withholding federal funds for ethical reasons unless the NIH had the support of an ethics advisory board.[222] However, when the advisory board recommended President Clinton's NIH to provide funding for essentially all forms of embryo research,[223] President Clinton disregarded the board's decision and immediately issued an oral directive that commanded the NIH to withhold funds for research that would create human embryos specifically for research.[224]

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218. *See* Youngstown Sheet & Tube Co. v. Sawyer (*Steel Seizure*), 343 U.S. 579, 637-38 (1952).

219. *See* MATTHEWS & YANG, *supra* note 95, at 14-18 (discussing how President Clinton issued a "series of orders" that included lifting the ban on federal funding of fetal tissue research, but prohibited federal funding for creating embryos for research purposes).

220. *See* Heled, *supra* note 180, at 119 n.292 (explaining how President Clinton's so-called "Embryo Decision" ran "in clear violation of the NIHRA.") .

221. Heled, *supra* note 180, at 75.

222. *Id.* at 74-75 ("[t]he NIHRA explicitly. . .imposed restrictions on the HHS's ability to withhold funds for research on ethical grounds so that such a withholding could not take place without the recommendation of an independent [Ethics Advisory Board]."); 42 U.S.C. § 289a-1(b) (2018).

223. Heled, *supra* note 180, at 75.

224. Kayla Dunn, *The Politics of Stem Cells* (April 13, 2005), https://www.pbs.org/wgbh/nova/sciencenow/dispatches/050413.html ("President Clinton rejected part of these recommendations and directed the NIH not to allocate funds to experiments that would create new embryos specifically for research."); *see also id*. (discussing how President Clinton issued the directive the day after the advisory board had recommended the NIH to expand funding for embryo research).

The issuance of the oral directive constituted a clear violation of the NIHRA's statutory instructions.[225] The NIHRA only permitted the NIH to withhold funds for embryo research if it had the support of an ethics advisory board.[226] Since the ethics advisory board had not counseled against funding research that would create embryos, the NIHRA should not have allowed President Clinton to withhold the funding. In this regard, Clinton followed the example of his predecessor by actively going against Congress' will by violating statutory instructions and engaging in unconstitutional lawmaking for federal research policies.[227]

4. President George W. Bush

Like the two previous administrations, the Bush Jr. Administration's actions also fall within Justice Jackson's third tier of authority. Like Clinton, President Bush Jr. utilized a directive to prohibit the NIH from funding certain embryo and embryonic stem cell research projects without relying on the recommendation of an EAB.[228] Curiously, President Bush Jr. chose to issue his compromise policy directive orally during a televised event.[229] The directive was neither memorialized nor published in any formal government publication.[230] Due to these characteristics, the directive did not meet the criteria for any known category of a presidential directive.[231] This interesting choice of action meant that the directive was effectively unreachable by judicial review because courts could not throw out the directive for any procedural or formal flaws.[232] Since nothing has made these types of

225. Heled, *supra* note 180, at 119 n.292.

226. Heled, *supra* note 180, at 74-75.

227. *Id.*

228. *Id.* at 89

229. Heled, *supra* note 180, at 89. It is also interesting to note that President Clinton also issued his so-called "Embryo Decision" as an oral executive order, much like his successor, President Bush Jr. *Id.*

230. *Id.*

231. *Id.* at 89-90. Unlike an executive order or proclamation, President Bush's directive also lacked any specific instructions to executive officers and did not bear the conventional titles that would help classify it as one of the generally known forms of presidential directives. *Id.* at 89; *see also* Exec. Order No. 11,030, 27 Fed. Reg. 5847 (June 21, 1962) (describing the general requirements for issuing executive orders and proclamations).

232. *See id.* at 88-89 (explaining how Presidents can avoid the questions about the legality of a directive by tailoring them to not fit within the definition of either an executive order or proclamation). Executive orders and proclamations must be published in the federal registrar and must "contain a citation of the authority under which [they are issued]." Exec. Order No. 11,030, 27 Fed. Reg. 5847 (June 21, 1962). Therefore, by issuing a directive that does not qualify as an executive order or proclamation, Presidents can "avoid having to state the [d]irective's source of authority, which might cast its legal legitimacy in a questionable light." Heled, *supra* note 180, at 89 n.139.

directives illegal, presidents can potentially use similar methods to control stem cell research policies in the future unilaterally.

5. President Obama

The Obama Administration's actions likely fall within Justice Jackson's first or second tier of authority. Obama's executive order that permitted the NIH to fund human embryonic stem cell research observed all the formalities of the NIHRA because it required the NIH to subject research proposals to a strict ethical review.[233] On the other hand, the Obama Administration's interpretation of the Dickey-Wicker Amendment clearly clashed with the Amendment's intended purpose of restricting funds for hESC research. If viewed in isolation, this would likely place President Obama's actions within the "zone of twilight" because it was neither authorized nor expressly denied by the Dickey-Wicker Amendment.[234] However, the Obama Administration's actions would ultimately attain credibility due to the favorable judgment in *Sherley*.[235] This makes it difficult to accurately categorize the Obama Administration's stem cell policy actions under Justice Jackson's approach.

Nevertheless, the Obama Administration's actions still raised some concerns regarding the future of stem cell research in the United States. As seen in *Sherley v. Sebelius*, 689 F.3d 776 (D.C. Cir. 2012), which ruled in favor of the Obama Administration, courts will defer to the NIH's interpretation of the Dickey-Wicker Amendment when deciding on whether to extend funding to stem cell research projects.[236] This implies that future presidents could cut off stem cell research funding by simply stacking the NIH with stem cell research opponents. Through these agents, the president could easily influence the NIH to interpret the Dickey-Wicker Amendment as prohibiting the funding of stem cell research. Therefore, the Obama Administration did not help establish a more consistent framework for stem cell policymaking.

6. President Trump

President Trump's efforts to establish a more rigorous review of fetal tissue project funding in 2019 likely falls within Justice Jackson's

233. MATTHEWS & YANG, *supra* note 95, at 18-19.

234. *See* Youngstown Sheet & Tube Co. v. Sawyer (*Steel Seizure*), 343 U.S. 579, 637 (1952) (Jackson, J., concurring).

235. Sherley v. Sebelius, 689 F.3d 776 (D.C. Cir. 2012) (affirming the district court's deferral to the agency interpretation), *cert. denied*, 568 U.S. 1087 (2013).

236. *See id.* (describing how the court deferred to the NIH interpretation of the Dickey-Wicker Amendment and President Obama's Executive Order 13,505).

second tier of authority. While the NIHRA does permit the executive branch to establish ethics review boards for NIH research proposals,[237] the Trump Administration's directive appears to impose an undue burden on the approval of fetal tissue research. Under the Trump directive, ethics review of NIH proposals could last up to six months.[238] The increased approval time creates an obstacle for many stem cell scientists who rely on fetal tissue for their research.[239] Therefore, the Trump Administration's directive likely falls within Justice Jackson's second tier of authority because it hampers Congress' intent to make NIH funding more accessible in a statutorily permissible manner.[240]

B. The Effects of President's Policymaking Authority Over Stem Cell Research

The analysis of presidential actions to control stem cell research shows that almost all presidents have acted outside the scope of their authority to some degree. Even if Congress tries to pass a statute to curtail the president's control over federal research policies, presidents can simply use their veto power to block the legislation as President Bush Sr. did during his term.[241] Permitting the executive branch to control the United States' stem cell research policy unilaterally has affected stem cell research in three ways.

1. Discouraging Research and Development

Uncertain federal support from the executive branch undoubtedly affects research progress and development.[242] As an initial matter, the lack of steady funding can deter students from investing themselves in stem cell research.[243] The lack of federal support also makes investment in stem cell research facilities and faculty much more expensive for universities.[244] While stem cell researchers can turn to either state

237. 42 U.S.C. § 289a-1(b) (2018).

238. Jocelyn Kaiser & Meredith Wadman, *Trump administration releases details on fetal tissue restrictions*, SCIENCE (July 26, 2019), https://www.sciencemag.org/news/2019/07/trump-administration-releases-details-fetal-tissue-restrictions.

239. *See id.*

240. *See* Youngstown Sheet & Tube Co. v. Sawyer (*Steel Seizure*), 343 U.S. 579, 637 (1952).

241. Vawter, *supra* note 30, at 82-83.

242. *See* Furman et al., *supra* note 184.

243. *See* J. Benjamin Hurlbut & Jason Scott Robert, *Stem Cells, Science, and Public Reasoning*, 31 J. POL'Y ANALYSIS & MGMT. 707, 709 (2012).

244. Federal funding provides "more than half of the total amount U.S. universities and colleges spend on R&D each year." Laurie A. Harris & Marcy E. Gallo, Cong. Research Serv., R44774, *Federally Funded Academic Research Requirements: Background and Issues in Brief* 1 (2017), https://sgp.fas.org/crs/misc/R44774.pdf; *see generally* Acosta & Golub, *supra*

funding agencies or private investors for financial backing, both of these options have drawbacks.[245] Certain states, like California and Massachusetts, may currently provide state funding for stem cell research.[246] However, these funding agencies rely on bonds from state voters.[247] Therefore, state agencies cannot guarantee consistent funding because state voters may one day decide that stem cell research is not worth the costs.[248]

Additionally, private investors do not provide a meaningful alternative either. First, investors typically do not invest in early-stage sciences like hESC research because it is generally "too far upstream from marketable products."[249] As investors are uncertain of whether their funding will lead to a marketable product, they have less of an incentive to invest in the research.[250] Second, private investors view stem cell research as a risky venture.[251] This stems from the fact that stem cell technology companies face the chronic risk of becoming banned by executive policy actions.[252] The uncertainty of this system discourages scientists from pursuing stem cell research.[253]

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note 108, at 419-20 (discussing the difficulty of conducting university research on stem cells with and without federal funding restrictions).

245. Mintrom, *supra* note 117, at 617; *see* Acosta & Golub, *supra* note 108, at 420-21. Some states have found it difficult to provide continuous state funding for stem cell research because their citizens do not always want to vote for more government spending. *Id.; see also* Robertson, *supra* note 1, at 194 (discussing reluctance from private investors to support research efforts because hESC is generally "too far upstream from marketable products.").

246. *Id.* at 429-27.

247. *Id.* at 423. The California state funding agency relied on funds generated by the sale of general obligation bonds, which the state would repay with revenue primarily derived from "state personal and corporate income taxes and the sales tax." Secretary of State, *2004 Official Voter Information Guide* 69 (2004), https://vig.cdn.sos.ca.gov/2004/general/english.pdf.

248. Mintrom, *supra* note 117, at 617. In 2005, New Jersey became one of the first states to fund stem cell research. In 2007, however, New Jersey voters refused to support a ballot initiative that would have issued $450 million in state bonds to further support stem cell research. The failure of the 2007 New Jersey ballot initiative has largely been attributed to "voter reluctance to see their state, already heavily indebted, initiate yet another bond issue." *Id.* at 618. At the time of the ballot initiative, New Jersey was $30 billion in debt. *New Jersey Rebuffs Loan to Fund Stem-Cell Research*, 450 NATURE 332, 332 (2007), https://www.nature.com/articles/450332a.pdf.

249. Robertson, *supra* note 1, at 194.

250. *Id.*

251. *See* Amanda Warren-Jones, *Realising New Health Technologies: Problems of Regulating Human Stem Cells in the USA*, 20 MED. L. REV. 1, 571 (2012).

252. *See id.*

253. *See id.*

2. Contribution to Patent Monopolies

A lack of federal funding initiatives from the executive branch can also lead to patent monopolies. Just five months before the Bush policy announcement, Dr. Thomson successfully obtained a patent for his 1998 discovery of isolating human embryonic stem cells.[254] Later that year, Dr. Thomson assigned the rights to the patent to the Wisconsin Alumni Research Foundation. Geron obtained an exclusive license to the patent to create several major stem cell lines and commercialize the discovery through the Wisconsin Alumni Research Foundation.[255]

Through Dr. Thomson's work, Geron and the Wisconsin Alumni Research Foundation would create several major stem cell lines and license their use to researchers.[256] However, the license required researchers to grant Geron and the Wisconsin Alumni Research Foundation the rights to any discovery that came from using the stem cell lines. This licensing structure created problems for researchers in the Bush policy. If it became effective, the policy would financially inhibit scientists from working around the Geron and the Wisconsin Alumni Research Foundation by creating new stem cell lines.[257] In effect, the Bush policy would force scientists to license stem cell lines from Geron or the Wisconsin Alumni Research Foundation, which few scientists wanted to do because their inventions would all belong to Geron or the Wisconsin Alumni Research Foundation.[258]

Future restrictions on stem cell research funding could recreate this dilemma. As of now, no law prohibits an incoming President from reinstituting the Bush-era policies regarding what stem cell lines can receive federal funding. If the United States wants to avoid patent monopolies that kill innovation and competition, it must establish a consistent funding protocol for the derivation and creation of new stem cell lines.

3. Unpredictability Contributes to a Disorganized Regulatory Framework for Stem Cell Discoveries and Therapeutics

Due to the everchanging executive policies for stem cell research, many states and private entities have had to fill in policy gaps to regulate

254. Primate Embryonic Stem Cells, U.S. Patent No. 6,200,806 (filed June 26, 1998) (issued Mar. 13, 2001).

255. *See* Loring, *supra* note 136.

256. *Id.*

257. Sheryl Gay Stolberg, *Patent on Human Stem Cell Puts U.S. Officials in Bind*, N.Y. TIMES, Aug. 17, 2001, at A1, https://timesmachine.nytimes.com/timesmachine/2001/08/17/745014.html?pageNumber=1.

258. *Id.*

the development of stem cell therapies.[259] This has two significant disadvantages. First, the results of the research may not become publicly disclosed or available for peer review.[260] This can lead to unnecessary duplications of research and the publication of unsubstantiated claims that stem cell research has developed some miracle therapy.[261] In fact, some have even attributed the rise of underregulated stem cell clinics to the lack of a centralized federal regulatory structure for stem cell research.[262]Second, the current policymaking structure fails to involve the public in discussions over stem cell research policies. Since the executive branch typically appoints ethics committees to review stem cell policies, they largely leave the public out of the policymaking process. This creates a mismatch between the public's expectation of stem cell regulations and the government's efforts to regulate the field.

V. PROPOSAL

The United States could pursue three courses of action to establish a more consistent federal stem cell research policy. All three courses of action aim to achieve the same goal: limiting the executive branch's influence over stem cell research policy.

A. Rewrite the Dickey-Wicker Amendment Clarify Federal Funding Protocols

By spurring Congress to rewrite the Dickey-Wicker Amendment or enact new legislation to clarify funding for stem cell research, the United States could develop a better policymaking system for controversial areas of scientific research. The executive branch has too much control over stem cell research because of ambiguities surrounding research funding statutes. Congress could fix this problem by creating more detailed legislation that defines how scientists may conduct stem cell research. Although this would be difficult because legislators have different political and social views on stem cell research, clearer legislation would be the most effective method of curtailing the executive branch's control over federal research policies.

259. Warren-Jones, *supra* note 251, at 565.

260. *Id.* at 555; Vawter, *supra* note 30, at 82.

261. Acosta & Golub, *supra* note 108, at 420-21.

262. The federal funding controversy has spurred some fervent supporters of hESC research to "unrealistically raise expectations for the cures sure to come." Spiegel, *supra* note 121, at 106. The fervor surrounding these unproven and unrealistic expectations have led to a "proliferation of 'charlatan' stem cell clinics promising treatments for a multitude of diseases, but in fact, using unproven and in many cases unsafe methods." *Id.*

B. Involve the Public in the Policymaking Process

Another way to address the United States' stem cell policy issue would be to establish a new category of state representatives and involve them in the stem cell policymaking process.[263] This approach would have two benefits.

First, involving representatives from each state in the policymaking process could make stem cell research and regulations more transparent.[264] Each state would choose its own representative to represent their state's interests in a permanent national committee.[265] The committee would function as a public forum for the controversial research policies, inform the American public about the nation's collective view of stem cell research, and provide the president with suggested policy decisions. The president would not have to pursue the committee's policy suggestions. However, it would prevent the president from hiding their unwillingness to serve the public interest and potentially affect the president's performance in reelection years. Furthermore, electing laypersons as public representatives to the national committee could also spur beneficial public discourse on stem cell research.[266] Evidence suggests that laypeople spend the bulk of their time communicating with other laypeople.[267] If laypeople join in the policymaking process and have a positive experience, they are more likely diffuse what they learn to the public, which can help promote a greater trust in policymaking decisions.[268] In effect, they would become public representatives of stem cell policymaking decisions, increasing the transparency of stem cell policy decisions, and influencing the growth of grassroots groups that trust in the government's ability to regulate stem cell research properly.[269]

Second, involving state representatives and members of the public in federal policymaking decisions would help create more well-rounded federal stem cell policies.[270] Many states already have experienced stem cell regulators and administrators with experience in managing state

263. Myrisha S. Lewis, *Innovating Federalism in the Life Sciences*, 92 TEMP. L. REV. 383, 413 (2020).

264. *Id.* at 416.

265. *Id.*

266. Michael Mintrom & Rebecca Bollard, *Governing Controversial Science: Lessons from Stem Cell Research*, 28 POL'Y & SOC'Y 301, 311 (2009).

267. *Id.* at 312.

268. *Id.*

269. *Id.*

270. *See id.* ("[t]he breaking down of barriers between members of the public and members of the decision-making body can promote more open dialogue and the development of trust. . ..increas[ing] the odds that good decisions will be made.").

funding agencies for stem cell research policymaking.[271] If the federal government wants to pursue a policy that genuinely reflects the stem cell interests of the states, it should leverage the expertise of state administrators and allow them to contribute to the national policymaking process.[272] This could either take the form of an independent advisory board to executive agency that engage in decision making or legislation.[273] Either method would ensure that each state has some say in the creation of federal stem cell policies.[274]

C. Establishing an Independent Commission for Research Policymaking

The alternative course of action would be to establish an independent research policy commission that mirrors the Federal Trade Commission ("FTC"). Although presidents appoint the Commissioners of the FTC, the president has limited influence over the five-member Commission because of three reasons. First, the Senate must confirm the president's selections, which could potentially place a check on the President's ability to select an official that would pursue the President's policy interests.[275] Second, the president would not have the power to remove a commissioner because of political or policy differences.[276] Third, the FTC restricts the influence of political parties because no more than three commissioners can come from the same political party.[277] Once appointed and confirmed, each commissioner serves seven-year terms, which enables the FTC to maintain a more consistent policy stance even when a new president assumes office.[278]

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271. Mintrom & Bollard, *supra* note 266, at 312-13 (discussing how officials from the California Institute of Regenerative Medicine could "become diffusers of incremental improvements and innovations in regulatory compliance across the science system.").

272. *Id.*

273. *Id.*

274. *Id.* at 485.

275. U.S. CONST. art. II, § 2, cl. 2.

276. *See* 15 U.S.C. § 41 (West 2022) ("Any commissioner may be removed by the President for inefficiency, neglect of duty, or malfeasance in office."). The President may not remove an FTC commissioner for any other reason. Humphrey's Executor v. United States, 295 U.S. 602, 628 (1935) (holding that a President could not remove a FTC Commissioner based on the belief that "the aims and purposes of the Administration. . .can be carried out most effectively with personnel of my own selection."); *see generally* Remarks of J. Thomas Rosch, Thoughts on the FTC's Relationship (Constitutional and Otherwise) to the Legislative, Executive, and Judicial Branches 8 (Sept. 19, 2009), https://www.ftc.gov/sites/default/files/documents/public_statements/thoughts-ftcs-relationship-constitutional-and-otherwise-legislative-executive-and-judicial-branches/090919roschberlinspeech.pdf (discussing the administrative framework after *Humphrey's Executor*).

277. 15 U.S.C. § 41 (2018).

278. *Id.*

Modelling a stem cell research commission after the FTC could potentially solve many of the current issues with federal stem cell research funding policies. Like the FTC, this stem cell research commission would follow a similar governance structure whereby the commission would exercise quasi-legislative and quasi-judicial power over stem cell research policies. In effect, the commission would assume control over stem cell research and prevent presidents from changing the nation's policies each time they change office. By having a multi-member commission, the president's appointees would have less power to enforce the president's personal views or agendas. Furthermore, the appointees could exercise more independent judgment because the president would not have the power to remove the commissioners based solely on political or policy differences.

VI. CONCLUSION

The way the executive branch has handled the stem cell research policies must change for the United States to realize the benefits that stem cell research can provide. With the inauguration of the forty-sixth President of the United States and the start of the 118th United States Congress, funding for stem cell research has become uncertain once again. Hopefully, the new administration will help build a more sustainable framework for future stem cell research.