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Administrative Law—The Wholesale Human: The Ineffectuality of Responsive Regulation to Advancements in Reproductive Biotechnology Post Roe v. Wade

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THE WHOLESALE HUMAN: THE INEFFECTUALITY OF RESPONSIVE REGULATION TO ADVANCEMENTS IN REPRODUCTIVE BIOTECHNOLOGY POST *ROE V. WADE*

I. INTRODUCTION

> *When we wish to see an oak with its massive trunk and spreading branches and foliage, we are not content to be shown an acorn instead. So too, Science, the crown of a world of Spirit, is not complete in its beginnings.*[1]

During the last week of November 2018, the University of Hong Kong hosted the Second International Summit on Human Genome Editing.[2] Nobel laureate David Baltimore chaired the summit, gathering the world's leading biotechnological experts to discuss the implications of rapid advancements in the field.[3] Around noon on November 28, a little-known Chinese scientist by the name of Jiankui He of China's Southern University of Science and Technology took the floor.[4] Dr. He claimed he had successfully used a recent biotechnological breakthrough to modify the genetic makeup of two human embryos that were subsequently implanted via in vitro fertilization (IVF).[5] The experiment resulted in a successful pregnancy and live birth of twin babies.[6]

By the end of the day, the scientific community at large expressed general condemnation and moral outrage at the news of Dr. He's presentation.[7] Dr. He's actions were seen as a direct violation of the bioethical boundaries that the summit sought to address.[8] In response to the revelation, the National Institutes of Health (NIH) Director, Dr. Francis S. Collins, stated unequivocally that "[i]t is profoundly unfortunate that the first apparent application of this powerful technique to the human germline has been carried out

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1. G.W.F. HEGEL, HEGEL'S PHENOMENOLOGY OF SPIRIT 7 (A.V. Miller trans., Oxford University Press 1977) (1807).

2. *Second International Summit on Human Genome Editing Agenda*, NAT'L ACADS. OF SCIS., ENG'G, & MED., http://www.nationalacademies.org/hk/index.html (last visited Aug. 1, 2019).

3. *Id.*

4. *Id.*

5. Pam Belluck, *Chinese Scientist Who Says He Edited Babies' Genes Defends His Work*, N.Y. TIMES (Nov. 28, 2018), https://www.nytimes.com/2018/11/28/world/asia/gene-editing-babies-he-jiankui.html.

6. *Id.*

7. *Id.*

8. *Id.*

so irresponsibly."[9] As the biomedical community clamored against Dr. He's experiment, a distinct bioethical and geopolitical moment had undoubtedly arrived.

The most pressing biotechnological breakthrough that the summit sought to address is known as CRISPR-Cas9.[10] CRISPR-Cas9 is a revolutionary tool that can be used to extract and replace undesirable portions of an organism's genetic sequence through a process that is heretofore unsurpassed in accuracy, efficiency, and affordability.[11] In its less controversial applications, CRISPR-Cas9 enables agricultural researchers to genetically modify crops to make them resistant to pathogens or to extend their normal lifespans.[12] Brought to its theoretical apex by application to the human genome in the context of disease eradication,[13] the CRISPR debate primarily centers on federal funding for clinical trials involving human embryos.[14]

Most known diseases are, at least in part, attributable to genetics.[15] To date, the primary method for preventing undesirable genetic traits in human offspring is to select embryos without those traits to implant via IVF.[16] Because the IVF universe remains largely unregulated in the United States,[17]

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9. Francis S. Collins, *Statement on Claim of First Gene-Edited Babies by Chinese Researcher*, NAT'L INSTS. HEALTH (Nov. 28, 2018), https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-claim-first-gene-edited-babies-chinese-researcher ("Lest there be any doubt, as we have stated previously, NIH does not support the use of gene-editing technologies in human embryos.").

10. *See generally* Martin Jinek et al., *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCI. MAG. 816 (2012).

11. *See CRISPR Timeline*, BROAD INST., https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-timeline (last visited Aug. 1, 2019). This article provides a rudimentary discussion of the origin of the clustered regularly interspaced short palindromic repeat (CRISPR)-associated system (Cas) (CRISPR-Cas9).

12. *See, e.g.*, Eric E. Williams, *CRISPR: Redefining GMOs—One Edit at a Time*, 39 U. ARK. LITTLE ROCK L. REV. 437, 445–446 (2017).

13. In the interest of limiting the scope of this note to the framework of current regulatory limitations on embryonic research generally, the prospect of genetic enhancement via CRISPR-Cas9 will not be considered.

14. *See generally* COMMITTEE ON HUM. GENE EDITING: SCI., MED., & ETHICAL CONSIDERATIONS, HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE 7 (2017) [hereinafter HGE Report] ("In the United States, authorities currently are unable to consider proposals for this research because of an ongoing prohibition on the U.S. Food and Drug Administration's (FDA's) use of federal funds to review 'research in which a human embryo is intentionally created or modified to include a heritable genetic modification.'").

15. *Frequently Asked Questions About Genetic Disorders*, NAT'L HUM. GENOME RES. INST., https://www.genome.gov/19016930/faq-about-genetic-disorders/ (last visited Aug. 1, 2019).

16. *See* Daniel J. Kevles, *The History of Eugenics*, *in* INT'L SUMMIT ON HUMAN GENE EDITING, A GLOBAL DISCUSSION: COMMISSIONED PAPERS 9 (2015).

17. Tamar Lewin, *Industry's Growth Leads to Leftover Embryos, and Painful Choices*, N.Y. TIMES (June 17, 2015), http://www.nytimes.com/2015/06/18/us/embryos-egg-donors-difficult-issues.html.

un-implanted embryos are often donated, frozen, or discarded.[18] In response to the prospect of researchers using these embryos for experimental purposes, Congress passed what is commonly known as the Dickey-Wicker Amendment.[19] The amendment effectively regulated human embryonic research by restricting federal funding for projects that subjected the embryo to greater risks than were allowable for research on fetuses in utero.[20]

Limiting federal funding is often preclusive for any commercially inviable research set.[21] Moreover, the impact of the current federal regulatory framework on the prospects of a human application of CRISPR-Cas9 is severe to the point of prohibition.[22] Even assuming commercial viability in the absence of federal funding, the risk is that the technology would be available only to those who could afford it.[23] Given the inherent ethical implications of embryonic research coupled with the risk of inequitable access, the time for an overhaul is past due. The issue is how to conceptualize these developments to offer an ethical way forward and, thereby, prevent the unnecessary destruction of human embryos and exclusionary consumerism in embryonic research. This note begins to address that issue by identifying the extent to which the current regulatory framework restricts CRISPR research. Then, this note proposes a limited expansion of funding to allow for research only if that research can be defined as interventional medicine.

Part II of this note provides background information on the history of legislation and regulation in response to advancements in biotechnology over the half-century since the Supreme Court's ruling in *Roe v. Wade*. By analyzing the measures taken by the legislature to confront these advances, this note will illustrate how current regulation is merely reactionary and inadaptive to future challenges. Part III summarizes the current federal regulatory scheme that effectively bars federal funding for embryonic applications of CRISPR. Part IV argues for (1) the discontinuation or repeal of the Dickey-Wicker Amendment as a rider to any subsequent appropriations bills because it fails to address advancements in biotechnology; (2) substantive

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18. Laura Beil, *The Fate of Frozen Embryos*, PARENTING, https://www.parenting.com/article/the-fate-of-frozen-embryos (last visited Aug. 1, 2019).

19. *See* The Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 34 (1996). The Dickey-Wicker Amendment has been included in every appropriations act since 1996, and, by its inclusion, it has effectively prohibited the use of federal funding for any form of embryonic research.

20. *Id.*

21. Richard D. McCullough, *The Lack of Funding is a Tragedy for Bold Scientific Breakthroughs*, N.Y. TIMES (Sep. 20, 2016), https://www.nytimes.com/roomfordebate/2016/09/20/the-cost-of-corporate-funded-research/the-lack-of-funding-is-a-tragedy-for-bold-scientific-breakthroughs ("In other words, decreased funding hampers bold science, and hampering bold science jeopardizes the solutions that we need most.").

22. HGE Report, *supra* note 14, at 7.

23. Kevles, *supra* note 16, at 12.

legislation to ban all applications of CRISPR-Cas9 to the human genome through embryonic research; and (3) the development of ethically sound research strategies to target otherwise untreatable genetic disorders.

II. BACKGROUND

On January 22, 1973, the Supreme Court of the United States issued its opinion in *Roe v. Wade*.[24] That same day, nearly 3,000 miles away, a group of biomedical scientists gathered at the Asilomar Conference Center in Monterey, California to discuss recent developments in the use of recombinant deoxyribonucleic acid.[25] The significance of *Roe* hardly warrants recapitulation here. Its confluence with the landmark advancements in biotechnology examined at Asilomar, however, marked the inception of meaningful debate in America as it relates to human embryonic research.[26] This important moment framed the discussion that ultimately led to the current legislative and regulatory schema governing the prospective uses of CRISPR-Cas9 for the purposes of embryonic research.[27] Part II of this note traces this development by considering three biotechnological breakthroughs and the subsequent federal legislative, judicial, and executive reactions thereto that shaped current law: recombinant DNA, IVF, and embryonic stem cell research.[28]

A. Recombinant DNA, Asilomar, and the National Institutes of Health

A fitting place to begin is with the building blocks of life. DNA is the hereditary material of all multi-cell organisms.[29] From its rudimentary beginnings in a laboratory at Columbia University, DNA sequencing for the purpose of understanding its connection to the heritability of traits and diseases has long been a particularly engaging scientific inquiry.[30] Resulting

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24. *See generally*, 410 U.S. 113 (1973).

25. Adam D. Sheingate, *Promotion Versus Precaution: The Evolution of Biotechnology Policy in the United States*, 36 BRIT. J. POL. SCI. 243, 246 (2006); Donald S. Fredrickson, *Asilomar and Recombinant DNA: The End of the Beginning*, *in* BIO-MEDICAL POLITICS (1991).

26. Ira H. Carmen et al., *Bioconstitutional Politics: Toward an Interdisciplinary Paradigm*, 5 POL. AND THE LIFE SCI. 2, 193, 203 (1987).

27. See Russell A. Spivak et al., *Germ-line Gene Editing and Congressional Reaction in Context: Learning from Almost 50 Years of Congressional Reactions to Biomedical Breakthroughs*, 30 J.L. & HEALTH 20, 22–23 (2017).

28. *Id.*

29. *An Overview of the Human Genome Project*, NIH: NAT'L HUM. GENOME RES. INST., https://www.genome.gov/12011238/an-overview-of-the-human-genome-project/.

30. *See* David Stairs, *The Visual Representation of the Human Genome*, DESIGN ISSUES, Autumn 2012, at 59–61.

from an increased understanding of the ways in which DNA could be manipulated, molecular biologists developed a technique in the late 1960s by which they could create new genetic material by using enzymes to break DNA strands and recouple the broken fragments into new combinations.[31] The result was termed recombinant DNA, more often known in the scientific community as simply rDNA.[32]

Even though the prospective benefits of rDNA research were far-reaching, regulators and scientists alike feared that microorganisms with transplanted genes could pose hazards to humans and to other forms of life on earth.[33] In light of these concerns, the biomedical community sought to define the problem and establish a system of self-regulation to avoid what appeared to be imminent governmental regulation.[34] As has been mentioned, the forum was the Asilomar Convention Center on January 22, 1973.[35]

The first Asilomar Conference in 1973 involved a predominantly American group of biomedical professionals, and the discussions served mainly to frame the issue that would become the focus of ethical and regulatory debate.[36] The conference resulted in a voluntary moratorium on the use of rDNA technology to allow for more thorough consideration of its potential risks.[37] Two years later, in February 1975, a decidedly more international group[38] of biologists, lawyers, medical professionals, government officials, and journalists[39] convened at Asilomar, producing certain guidelines and initiating a voluntary ban on any research that could be viewed as potentially hazardous.[40] In response to the recommendations of the Asilomar at-

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31. David A. Jackson, Robert H. Symons & Paul Berg, *Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40: Circular SV40 DNA Molecules Containing Lambda Phage Genes and the Galactose Operon of Escherichia Coli*, 69 PROC. NAT'L ACAD. SCI. U.S. AM. 2904, 2904–09 (1972); Janet E. Mertz & Ronald W. Davis, *Cleavage of DNA by R1 restriction endonuclease generates cohesive ends*, 69 PROC. NAT'L ACAD. SCI. U.S. AM. 3370, 3370–74 (1972); Stanley N. Cohen, Annie C. Y. Chang, Herbert W. Boyer & Robert B. Helling, *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT'L ACAD. SCI. U.S. AM. 3240, 3240–44 (1973).

32. *Recombinant DNA (rDNA)*, NIH: NAT'L HUM. GENOME RES. INST., https://www.genome.gov/genetics-glossary/Recombinant-DNA (last visited Aug. 1, 2019).

33. Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902, 27,904 (July 7, 1976).

34. Sheingate, *supra* note 25, at 246.

35. Fredrickson, *supra* note 25.

36. *Id.*

37. Editors, *Considerations in the Regulation of Biological Research*, 126 U. PA. L. REV. 1420, 1422 (1978).

38. *Id.*

39. Spivak, *supra* note 27, at 24.

40. *Considerations in the Regulation of Biological Research*, *supra* note 37, at 1422 ("These guidelines provide for both physical and biological containment requirements of increasing severity depending on the perceived level of danger. The physical guidelines en-

tendees, the Director of the NIH convened an Advisory Committee for the purposes of codifying the scientific consensus.[41] On July 7, 1976, the committee issued its own guidelines,[42] which generally deferred to the collective judgment of the scientific community.[43] The guidelines established the conditions upon which the NIH would provide federal funding for rDNA research.[44] Nevertheless, in the absence of Congressional action to prohibit privately funded research, contravention of those guidelines carried no penalty beyond peer condemnation.[45]

Having garnered significant public attention, rDNA research became a substantial point of discussion at all levels of government.[46] Local governments in the vicinities of the nation's most prestigious universities exercised limited regulatory agency over the research, enacting rDNA-focused ordinances by operation of various municipal health boards.[47] Additionally, the state governments of Maryland and New York enacted legislation geared toward addressing the risks of rDNA research through the enforcement of strict licensing requirements.[48] The federal government, unable to reach a national consensus beyond continued reliance on the NIH guidelines to curtail the sources of funding, never passed a single piece of legislation.[49]

As will be shown in the following subparts, the hesitance of public officials to enact meaningful legislation to address the risks of scientific inquiry into rDNA established a precedent of deference to scientific decision-making in the realm of American bioethics.[50] Carried forward through the last half-century of bioethical debate, this model exemplifies Congress's general unwillingness to apply moral and ethical principles to define the outer boundaries of science.[51] The NIH's adoption of the Asilomar rDNA guidelines, therefore, represented a shift in the public's relationship to sci-

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sure that no dangerous organism will escape the laboratory; the biological requirements ensure that no organism which does escape will be able to survive outside the laboratory.").

41. Spivak, *supra* note 27, at 24.

42. Recombinant DNA Research Guidelines, 41 Fed. Reg. 27902–27904 (July 7, 1976).

43. Paul Berg et al., *Potential Biohazards of Recombinant DNA Molecules*, 185 SCI. 303 (1974) (providing recommendations regarding the potential hazards of emerging DNA research capabilities).

44. *Id.*

45. Bernard Talbot, *Development of the National Institutes of Health Guidelines for Recombinant DNA Research*, 98 PUB. HEALTH REP. 361, 365 (1983).

46. Spivak, *supra* note 27, at 24.

47. Talbot, *supra* note 45, at 365.

48. Sheldon Krimsky & David Ozonoff, *Recombinant DNA Research: The Scope and Limits of Regulation*, 69 AM. J. PUB. HEALTH 1252, 1252 (1979).

49. Spivak, *supra* note 27, at 24.

50. O. Carter Snead, *Science, Public Bioethics, and the Problem of Integration*, 43 U.C. DAVIS L. REV. 1529, 1554 (2010).

51. *Id.*

ence that has had a significant and lasting effect.[52] In the end, the federal government's response merely defined the kind of research it would pay for, leaving the underlying questions of ethics and risk mitigation largely unanswered.

B. In Vitro Fertilization

On July 25, 1978, Louise Brown was introduced to the world.[53] Her birth was the result of IVF, a biomedical procedure that had captivated scientists for most of the century.[54] The two British doctors responsible for the success of the procedure received both praise and reproach from a public that had not shown such an invested interest in a scientific advancement since the introduction of the atomic bomb.[55] Essentially, IVF is the ability to fertilize a human egg outside a woman's body to produce a viable human embryo that can withstand assisted uterine implantation, resulting in a healthy pregnancy.[56] For many couples who could not otherwise conceive, IFV provided boundless hope.[57] Despite the generalized fear and anxiety of those who criticized the procedure, Louise's health and her incontestably routine birth alleviated much of the public concern that placed the safety of IVF in question.[58] Because the continued success of the procedure widely dispelled primary concerns about the health and safety of babies and mothers,[59] the focus of the bioethical debate turned to the disposition of excess embryos that would likely never be implanted.[60] Even so, in similar fashion to the federal government's response to rDNA research, IVF research would not have the full benefit of federal funding until nearly fifteen years after the birth of baby Louise with the enactment of the NIH Revitalization Act of 1993.[61] As such, contextualization of the delay in federal funding requires

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52. *See* Sheila Jasanoff et al., *CRISPR Democracy: Gene Editing and the Need for Inclusive Deliberation*, 32 ISSUES IN SCI. & TECH. 1, 25–32 (2015).

53. J. BENJAMIN HURLBUT, EXPERIMENTS IN DEMOCRACY: HUMAN EMBRYO RESEARCH AND THE POLITICS OF BIOETHICS 39 (2017).

54. *Id.*

55. *Conceiving the Inconceivable*, N.Y. TIMES (July 28, 1978), https://www.nytimes.com/1978/07/28/archives/conceiving-the-inconceivable.html.

56. *Id.*

57. *Id.*

58. *Id.*

59. Charis Thompson, *IVF Global Histories, USA: Between Rock and a Marketplace*, 2 REPROD. BIOMEDICINE & SOC'Y ONLINE 130–131 (2016), https://www.sciencedirect.com/science/article/pii/S2405661816300235 (detailing the first clinical success of IVF in the United States in 1981 with the birth of Elizabeth Carr).

60. Hurlbut, *supra* note 53, at 39.

61. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103–43, § 121, 107 Stat. 122, 133 (1993).

attention to two important bioethical events: *Roe v. Wade* and the National Research Act of 1974.[62]

With respect to the legal status of a human embryo, *Roe v. Wade* forms the backdrop against which bioethical debate has played itself out over the course of the last fifty years.[63] In *Roe*, the Supreme Court placed the point of compelling government interest at viability, meaning the point at which it is feasible for a fetus to survive outside the womb.[64] The lesser pre-viability interest established the basis for the Court's preservation of what it found to be a fundamental right to abortion.[65] Because the Court did not need to comment on the disposition of aborted fetuses, it did not address the practice of post-abortive fetal research.[66] Resultantly, even though fetal research had received little legislative or regulatory attention prior to *Roe*,[67] its inherent connection to the abortion debate roused the mechanisms of legislative action to fill the gap.[68]

In part, as a response to public concern over the post-abortive disposition of fetuses, Congress enacted the National Research Act of 1974.[69] The Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("National Commission") as part of the Department of Health, Education, and Welfare (HEW),[70] the precursor to today's Department of Health and Human Services. As its initial act, the National Commission placed a provisional four-month moratorium on federal funding for fetal research pending the results of a statutorily prescribed study on the topic.[71] Additionally, HEW invited public comment to discuss what, if any, future research would receive federal funding.[72] The National Commission's findings identified an existing body of regulation[73] under which it recommended fetal research continue, thereby adopting a policy that limited the research to instances in which a fetus would be exposed to no more than minimal risk.[74] When the National Commission is-

62. *See* Hurlbut, *supra* note 53, at 39; *see generally* National Research Act, Pub. L. No. 93–348, 88 Stat. 342, 42 U.S.C. § 289 (1974); Roe v. Wade, 410 U.S. 113 (1973).

63. *See* John A. Robertson, *In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437, 484 (1991).

64. Roe v. Wade, 410 U.S. 113, 163 (1973).

65. *Id.*

66. *Id.* at 113.

67. Steven Maynard-Moody, *Managing Controversies over Science: The Case of Fetal Research*, 5 J. PUB. ADMIN. RES. & THEORY 1, 10 (1995).

68. *Id.* at 10, 12; Hurlbut, *supra* note 53, at 49.

69. Pub. L. No. 93-348, 88 Stat. 342 (codified as amended at 42 U.S.C. §§ 201 to 300aaa-13 (1994)).

70. Hurlbut, *supra* note 53, at 48.

71. *Id.* at 49.

72. *Id.* at 54.

73. 45 C.F.R. § 46.101, *et seq.* (2018).

74. Hurlbut, *supra* note 53, at 50.

sued its final regulatory proposal in 1975, a remnant of HEW's prior deliberations on the topic of IVF remained in the language.[75] Even though IVF was beyond the scope of the commission's charge and bore only nominal relation to fetal research generally, the proposal maintained a requirement for future IVF research initiatives to obtain approval from a HEW created Ethics Advisory Board (EAB).[76] When reports of the birth of Louise Brown captured the national interest three years later, HEW exercised its oversight by energizing the EAB to control what appeared to be inevitable public demand for the procedure.[77]

After considering the underlying ethical and moral implications of IVF, the EAB delivered its report to the HEW Secretary, essentially reinforcing its regulatory approval authority for funding any form of IVF research.[78] Beginning with the replacement of the National Commission with the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in late 1978,[79] what followed was a seemingly unintended *de facto* moratorium on IVF research throughout the 1980s and into the early 1990s.[80]

Due to a change in HEW leadership in conjunction with a shift in departmental prioritization of its regulatory affairs in preparation for an impending change in presidential administration, IVF research initiatives decreased in priority toward the end of 1979.[81] Furthermore, in the transition of responsibility for EAB funding from the national commission to the newly formed presidential commission, ineffectual departmental communication with Congress resulted in a lack of appropriations to fund the EAB.[82] Without funding, the EAB, for all intents and purposes, ceased to exist.[83] In retrospect, the ineffectuality of executive and legislative coordination is tragicomic. On the one hand, IVF researchers could only access federal funding through the approval of the EAB.[84] On the other, there was no EAB through which researchers could apply for and receive approval.[85] This remained the

75. *Id.* at 54.
76. *Id.*
77. Spivak, *supra* note 27, at 28.
78. *See generally* ETHICS ADVISORY BOARD, U.S. DEP'T HEALTH, EDUC. & WELFARE, REPORT AND CONCLUSIONS: SUPPORT OF RESEARCH INVOLVING HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER (1979) [hereinafter EAB REPORT]; Spivak, *supra* note 27, at 28; Hurlbut, *supra* note 53, at 76.
79. Hurlbut, *supra* note 53, at 77; *see generally* National Research Act, Pub. L. No. 93-348, 88 Stat. 342, 42 U.S.C. § 289 (1974).
80. Spivak, *supra* note 27, at 28; Hurlbut, *supra* note 53, at 77–78.
81. Hurlbut, *supra* note 53, at 76–77.
82. *Id.* at 77–78.
83. Spivak, *supra* note 27, at 28.
84. *Id.*
85. *Id.*

state of affairs until the enactment of the NIH Revitalization Act of 1993, which removed the EAB approval requirement and reopened access to federal funding.[86]

Confronted with the prospect of providing federal funding for the creation of embryos through IVF and the likelihood of the embryos being used for research purposes, Congress enacted what, to date, has been the single most influential and important piece of legislation with respect to embryonic research: the Dickey-Wicker Amendment.[87] The amendment has been reenacted as an appropriations rider every year since 1996. Part III of this note will discuss the amendment in detail.[88] In short, the amendment has, for more than two decades, effectively prohibited federal funding for the "creation of a human embryo or embryos for research purposes" and "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."[89] In light of the funding restrictions imposed by the Dickey-Wicker Amendment, NIH initially interpreted the statute to proscribe federal funding for any form of human embryonic research, including equipment to support research.[90] Nonetheless, in response to the development of embryonic stem cell research, NIH's interpretation would be critiqued, argued, and honed by every branch of the federal government.[91]

C. Embryonic Stem Cell Research

In November 1998, researchers from both Johns Hopkins University and the University of Wisconsin-Madison unveiled the results of their unaffiliated studies that collectively demonstrated the power and potential of the human embryonic stem cell.[92] By deriving cells from both an aborted fetus[93] and an excess embryo produced in the process of IVF[94] respectively, the research teams were able to culture cell lines that could be used for a variety

86. Pub. L. No. 103-43, 107 Stat. 122 (1993); *see also* Spivak, *supra* note 27, at 29–30.

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

88. *See infra* Part III.A.

89. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 508, 132 Stat 348 (2018).

90. R. Alta Charo et al., *Stem Cell Research: A Legal History of the Federal Funding Ban on Destructive Human Embryo Research 1995 to the Present*, 20110126 AM. HEALTH LAW. ASS'N SEMINAR PAPERS 75 (2011).

91. *See infra* Part II.C.

92. Toni Marzotto & Patricia M. Alt, *The Ups and Downs of Stem Cell Research: The Impact of Policy Uncertainty*, 35 J. OF HEALTH AND HUMAN SERV. ADMIN. 3, 334–35 (2012).

93. The Johns Hopkins team led by Dr. John Gearhart utilized aborted fetuses. *Id.*

94. The Wisconsin-Madison team led by Dr. James Thomson utilized excess embryos produced in the process of IVF. *Id.*

of promising therapeutic and regenerative medical purposes.[95] As described by Dr. Thomson of the University of Wisconsin-Madison, advanced research using human embryonic stem cells would "provide a potentially limitless source of cells for drug discovery and transplantation therapies."[96] Despite the purported benefits of the research, the enigmatic restrictions of the Dickey-Wicker Amendment left the biomedical community, once again, to question its fiscal limits.[97]

The initial response to the introduction of human embryonic stem cell (hESC) research at the federal level came in the form of a presidential request for information to the National Bioethics Advisory Commission (NBAC).[98] In 1995, an executive order had created the NBAC to offer policy-driven advice on matters of bioethical import.[99] Initial recommendations from the NBAC included federal funding for embryonic stem cell research that involved the products of IVF as well as enhanced regulatory oversight by the Department of Health and Human Services (HHS) in the form of a National Stem Cell Oversight and Review Panel.[100] Although no panel was ever convened, NIH, in response to the recommendations of the NBAC, assumed the role of bioethics watchdog and began the process of evaluating the legality of funding in the context of the Dickey-Wicker Amendment.[101] In August 2000, after having received and reviewed approximately 50,000 comments from Congress, patient advocacy groups, scientific societies, religious organizations, and private citizens,[102] NIH published its guidelines.[103] The guidelines opened the door to federal funding for research on human pluripotent stem cells derived from embryos, provided the "human embryos . . . were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment."[104] Despite what appeared to be a complete and comprehensive set of rules governing embryonic stem cell research, the political battle had just begun.

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95. *See* Thomas Banchoff, *Path Dependence and Value Driven Issues: The Comparative Politics of Stem Cell Research*, 57 WORLD POL. 200, 203 (2005).

96. James A. Thomson et al., *Embryonic Stem Cell Lines Derived From Human Blastocysts*, 282 SCI. 1145, 1146–47 (1998).

97. Marzotto & Alt, *supra* note 92, at 340-341.

98. *Id.* at 340.

99. Exec. Order No. 12975, 60 Fed. Reg. 52062 (Oct. 3, 1995); *see also* Elisa Eiseman, *The National Bioethics Advisory Commission: Contributing to Public Policy*, RAND SCI. & TECH. POL'Y INST., at iii (2003).

100. Marzotto & Alt, *supra* note 92, at 340–341.

101. *Id.* at 340.

102. *Id.* at 342.

103. *Guidelines for Research Using Human Pluripotent Stem Cells*, NAT'L INST. HEALTH, 65 Fed. Reg. 166 (Aug. 25, 2000).

104. *Id.* at § II(A)(2).

The change in presidential administration in 2001 initiated a categorical restructuring of the framework for hESC research on the national level. While, under the NIH guidelines, there existed no restriction on the creation of new stem cell lines as long as those lines were produced using the products of IVF, a new executive policy hamstrung the biomedical community's momentum in the field by limiting federal funding to stem cell lines already in existence.[105] The NIH assessed that the newly imposed limitation would confine research to 64 existing stem cell lines.[106] Over the next five years, bipartisan Congressional backlash to the executive restrictions resulted in two enactments expanding access to funding.[107] Both were vetoed outright,[108] leaving the administration's restrictions in place to be formally imposed by executive order in 2007.[109]

Two years later, as a result of yet another change in presidential administration, an executive order[110] rescinded the funding restrictions imposed by the previous administration. In order to define the limits of the Dickey-Wicker Amendment, the NIH reincorporated its previous findings into a new set of guidelines.[111] By distinguishing between human embryos as *organisms* and stem cells as *sub-organisms* incapable of human life, the guidelines allowed federal funding for hESC research on stem cell lines derived from embryos created through privately funded IVF procedures.[112] Although the bureaucratic processes necessary to distribute funds lagged at first, researchers eventually began to reap the benefits of the NIH's relaxed standards.[113] Having lost executive support, opponents of stem cell research turned to the judiciary.[114]

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

106. *New Limits on Funding of Stem Cell Research Questioned*, 18 ISSUES IN SCI. & TECH., 29–30 (2001).

107. *See generally*, Stem Cell Research Enhancement Act, H.R. 810, 109th Cong. (2005); Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, H.R. 3043, 110th Cong. (2008); Spivak, *supra* note 27, at 36.

108. Stem Cell Research Enhancement Act, H.R. 810, 109th Cong. (2005); Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, H.R. 3043, 110th Cong. (2008); Spivak, *supra* note 27, at 36.

109. Exec. Order No. 13435, 72 Fed. Reg. 34591 (June 20, 2007).

110. Exec. Order No. 13505, 74 Fed. Reg. 10667 (Mar. 9, 2009).

111. National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170.

112. *Id.*

113. Marzotto & Alt, *supra* note 92, at 345.

114. *See* Sherley v. Sebelius, 776 F. Supp. 2d 1, 4 (D.D.C. 2011), *aff'd,* 689 F.3d 776 (D.C. Cir. 2012), *cert. denied* 568 U.S. 1087 (2013).

In *Sherley v. Sebelius*, an hESC opposition group challenged the revised NIH guidelines as contrary to the Dickey-Wicker Amendment.[115] The group sought declarations "that the [g]uidelines [were] not in accordance with law, were promulgated without the observance of required procedures, [were] arbitrary and capricious, and that past acts by the NIH pursuant to the Guidelines, including previous decisions to fund embryonic stem cell research projects, [were] null and void."[116] Because the group included researchers engaging in a competitive enterprise of adult stem cell research that was subject to decreased funding if guidelines were affirmed, the court found that the group had successfully established Article III standing.[117] In an opinion largely guided by the Supreme Court's ruling in *Chevron U.S.A. Inc. v. Natural Resources Defense Council*,[118] the Court granted summary judgment in favor of the NIH, holding that the guidelines were based on a reasonable interpretation of the Dickey-Wicker Amendment and entitled to deference.[119] The ruling was affirmed by the United States Court of Appeals for the District of Columbia Circuit[120] and denied certiorari before the United States Supreme Court.[121] With the legal challenge put to rest, hESC research found its footing. Nonetheless, in her prescient concurrence to the appellate opinion, Judge Janice Rogers Brown effectively framed the issue going forward:

> The challenging—and constantly evolving—issues presented by bioethics are critical and complex. Striking the right balance is not easy and not, in the first instance, a task for judges. What must be defended is "the integrity of science, the legitimacy of government, and the continuing vitality" of concepts like human dignity. Given the weighty interests at stake in this encounter between science and ethics, relying on an increasingly Delphic, decade-old single paragraph rider on an appropriations bill hardly seems adequate.[122]

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115. *Id.* at 8.
116. *Id.* at 8–9.
117. *Id.* at 12.
118. *See generally* Chevron, U.S.A, Inc. v. NRDC, Inc., 467 U.S. 837 (1984). This case is widely understood to have created the doctrine of deference to an administrative interpretation of a statute when the statute is found to be ambiguous and the agency's interpretation presents a permissible construction of the statute. Under these circumstances, a court will decline to substitute its own interpretation for that of the appropriate administrative body. *Id.* at 2793.
119. *Sherley*, 776 F. Supp. 2d at 25.
120. Sherley v. Sebelius, 689 F.3d 776 (D.C. Cir. 2012), *cert. denied* 568 U.S. 1087 (2013).
121. Sherley v. Sebelius, 568 U.S. 1087 (2013).
122. *Sherley*, 689 F.3d at 790 (D.C. Cir. 2012) (Brown, J., concurring).

Nearly two years later, her words would strike at the heart of the issues surrounding biotechnology's next major development—CRISPR-Cas9. This warning is perhaps more relevant now than ever in light of the current regulatory framework's restrictions on federal funding for any form of embryonic research using CRISPR technology.

III. CURRENT REGULATORY FRAMEWORK

As previously indicated, the Dickey-Wicker Amendment remains the primary regulatory construct through which the federal government actively restricts federal funding to embryonic research.[123] As will be shown in the following subsection, standing alone, the amendment is not an absolute bar to funding for applications of CRISPR-Cas9.[124] Perhaps in recognition of the amendment's inadequacy to confront the rapid advancement of biotechnology in relation to gene editing systems, the NIH has expressly refused to fund any use of gene editing technologies in human embryos.[125] Further, because protocol proposals for human germline genetic modification are summarily rejected by the Department of Health and Human Services without review,[126] no federal funding is presently available to use CRISPR-Cas9 for purposes of human germline editing in embryos.

A. Dickey-Wicker Amendment and CRISPR-Cas9

The extent to which the Dickey-Wicker Amendment precludes federal funding of human germline editing via CRISPR is limited. Under section 508 of the Consolidated Appropriations Act of 2018,[127] the amendment states:

> (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

123. *See supra* Part II.B.

124. *See infra* Part III.A.

125. Collins, *supra* note 9.

126. NAT'L INSTS. OF HEALTH, NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES 100 (2016) ("The NIH will not at present entertain proposals for germ line alterations but will consider proposals involving somatic cell gene transfer.").

127. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 508, 132 Stat 348 (2018).

> utero under 45 CFR 46.204(b)[128] and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).[129]

Under the D.C. Circuit's interpretation of the amendment with respect to embryonic stem cells, "research" is a "discrete endeavor," severable from the extended processes through which the cells are derived.[130] Therefore, if stem cells are derived from embryos destroyed as a result of a private enterprise, current law does not bar federal funding for research using the cells because the two-staged process constitutes separate, discrete endeavors.[131] The stem cell extraction process, considered independently of the subsequent stem cell research, is considered a distinct process, and, as such, separate "research" altogether from the handling of the stem cells after extraction.[132] Even so, *Sherley* appears to reinforce the proposition that the amendment's prohibition is absolute against funding any direct manipulation of an embryo for scientific purposes resulting in the destruction or discarding of the embryo.[133]

Because the court did not address the third disjunctive phrase of § 508(a)(2), the *Sherley* decision offers little help in discerning the extent to which the amendment prohibits funding for research in which an embryo is subjected to no more risk than is allowed for research on fetuses in utero. By reference to 45 C.F.R. § 46.204(b) as it pertains to fetuses in utero, a plain reading of the amendment effectively limits embryonic research to "interventions or procedures that hold out the prospect of direct benefit for . . . the [embryo]."[134] Federal regulation defines "intervention" as "physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are

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128. 45 C.F.R. § 46.204(b) (2018) ("Pregnant women or fetuses may be involved in research if all of the following conditions are met . . . (b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means . . . .").

129. 42 U.S.C. § 289g(b) (2018) ("In administering regulations for the protection of human research subjects which— (1) apply to research conducted or supported by the Secretary; (2) involve living human fetuses in utero; (3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations; or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.").

130. Sherley v. Sebelius, 689 F.3d 776, 781 (D.C. Cir. 2012).

131. *Id.*

132. *Id.*

133. *Id.*

134. 45 C.F.R. § 46.204(b) (2018).

performed for research purposes."[135] Neither federal statutes nor regulations define "procedure," and, thus, by the generally accepted cannons of statutory construction, the ordinary meaning of the term may clarify the ambiguity.[136] A "procedure" is "a series of steps followed in a regular definite order."[137] Under this interpretation, the NIH has, as recently as 2010, provided funding for fetal research to treat non-life threatening illnesses.[138]

The NIH recently funded a study involving an in utero procedure to treat spina bifida in fetuses.[139] As evidenced by the study, the risk of fetal death does not preclude funding under 45 C.F.R. § 46.204(b).[140] During the seven-year study, partially funded by the NIH's *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, 183 women participated in a randomized trial comparing the results of prenatal and postnatal repairs of spinal abnormalities in fetuses and infants respectively.[141] Although the life expectancy of those born with spina bifida is approximately 40 years,[142] the in utero procedure typically results in increased mobility and self-sufficiency whereas, untreated, spina bifida can otherwise result in paralysis and severe bowel and bladder dysfunctions.[143] Of the fetuses that underwent the procedure in utero to correct the abnormality, two died.[144] This equaled the mortality rate of the postnatal research group.[145] Upon completion, the study found that prenatal outcomes were generally more favorable than postnatal outcomes.[146] As a result, researchers determined that prenatal intervention was a preferable mode of treatment.[147]

Thus, if the use of CRISPR-Cas9 to effectively target and treat genetic disorders can be viewed as an "intervention or procedure," the Dickey-

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135. 45 C.F.R. § 46.102(e)(2) (2018).

136. *See* Pittston Coal Group v. Sebben, 488 U.S. 105, 113 (1988) (interpreting the word "criteria" under an interim HEW regulation by reference to Webster's Ninth New Collegiate Dictionary).

137. *Procedure*, WEBSTER'S COLLEGIATE DICTIONARY (11th ed. 2011).

138. *See generally* N. Scott Adzik et al., *A Randomized Trial of Prenatal Versus Postnatal Repair of Myelomeningocele*, 364 NEW ENG. J. MED. 993 (2011) (discussing the results of fetal research partially funded by the NIH); *Surgery on Fetus Reduces Complications of Spina Bifida*, NIH (2011), https://www.nichd.nih.gov/newsroom/releases/020911-MOMS.

139. Adzik, *supra* note 139, at 993.

140. *Id.* at 997.

141. *Id.*

142. C.M. Dillon et al., *Longevity of Patients Born with Myelomeningocele*, 10 EUR. J. PED. SURG. 33 (2000) ("Our data extend life expectancy for patients with MM and hydrocephalus to age 40 years with some reliability for those treated from 1957 to 1974, but only 24 years for those treated with modern techniques after 1974.").

143. Adzik, *supra* note 139, at 994.

144. *Id.* at 997.

145. *Id.*

146. *Id.*

147. *Id.*

Wicker Amendment is inadequate to prohibit federal funding because the technology holds out the prospect of a direct benefit to the embryo. Currently, however, the NIH's interpretation of the amendment, as expressed by the NIH Director, explicitly prohibits federal funding for "any use of gene-editing technologies in human embryos."[148]

B. The Federal Food, Drug, and Cosmetic Act in Relation to CRISPR-Cas9

Perhaps in recognition of the inadequacy of the Dickey-Wicker Amendment to effectively prohibit funding for all applications of CRISPR-Cas9, the 2016 House of Representatives passed a supplementary rider to the annual appropriations bill to directly address gene editing systems.[149] The rider categorizes CRISPR-Cas9 as a biological product subject to the Public Health Service Act.[150] As such, the law prohibits the Department of Health and Human Services and the Food and Drug Administration (FDA) from acknowledging receipt of submissions for investigational use of the technology "in research in which a human embryo is intentionally created or modified to include a heritable genetic modification."[151] Under this new law, CRISPR-Cas9 can be considered an enzymatic protein within the broad statutory definition for biological products as listed under 42 U.S.C. § 262(i).[152] As a result, this restriction not only prohibits funding but also precludes even privatized clinical trials,[153] effectively banning human genome editing one year at a time.[154] Under this statutory scheme, the FDA stands as a stalwart of the legislature's two-tiered system of regulation, and likely will

148. Collins, *supra* note 9.

149. Consolidated Appropriations Act, Pub. L. No. 114-113, § 749, 129 Stat. 2242, 2283 (2016).

150. *Id.*; *see also* 42 U.S.C. § 262(i)(1) (2018) ("The term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, *protein* (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.") (emphasis added).

151. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 734, 132 Stat 348 (2018).

152. *Id.*

153. *What are Clinical Trials and Studies*, NIH: NAT'L INST. ON AGING, https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies (last visited March 10, 2019) ("Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device (for example, a pacemaker) is safe and effective in people. Often a clinical trial is used to learn if a new treatment is more effective and/or has less harmful side effects than the standard treatment.").

154. HGE Report, *supra* note 14, at 136.

remain so unless supplanted by a successful initiative for an overhaul in biotechnological governance.

IV. ARGUMENT

Part IV of this note argues that the historical approaches to regulating biotechnology are outdated and inadequate to address the gene editing uses of CRISPR. The following analysis, therefore, calls for enactment of substantive legislation under the Commerce Clause to ban all applications of CRISPR to the human embryo. Once in effect, federal oversight and funding should be used to pursue technological development within the already established scientific norms derived from the First and Second International Summits on Human Genome Editing.[155] Thus, by requiring the NIH to approve and control all projects related to human embryonic testing of CRISPR, limited funding should be targeted at eradicating heritable genetic disorders such as Tay Sachs disease, in line with currently funded in utero fetal research studies as described in Part III.[156]

A. The Historical Reactive Models in Relation to rDNA, IVF, and hESC Should Be Abandoned as Outdated and Inadequate

As was arguably intended by the biomedical community at Asilomar, proactive self-governance in the realm of biomedicine and biotechnology has historically warded off restrictive legislation in response to scientific advancements.[157] To be sure, as Dr. Baltimore averred upon the conclusion of the First International Summit on Human Genome Editing in 2015, "consideration of the path forward is not solely the responsibility of scientific researchers."[158] Nonetheless, the Asilomar model, while seemingly including broad perspectives, is essentially geared toward consensus-making to ensure freedom of action in a self-imposed ethical construct.[159] As evidenced by the verbatim assimilation of the recommendations of Asilomar into a regulatory framework to address the inherent risks of rDNA,[160] political ac-

155. *See* Press Release, Nat'l Acads. of Scis., Eng'g, & Med., On Human Gene Editing: International Summit Statement (Dec. 3, 2015), http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=12032015a; Press Release, Nat'l Acads. Of Scis., Eng'g, & Med., On Human Gene Editing II: International Summit Statement (Nov. 29, 2018), http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11282018b.

156. *See supra* Part III.A.

157. Jasanoff, *supra* note 52, at 29.

158. David Baltimore, *Why We Need a Summit on Human Gene Editing*, 32 ISSUES IN SCI. & TECH. 3, 36 (2016).

159. *See* Jasanoff, *supra* note 52, at 26.

160. *See* Snead, *supra* note 50, at 1554.

tion in response to biotechnological breakthroughs in the United States has largely been subservient to the will of science.[161]

While the outcomes most feared did not materialize with respect to rDNA applications,[162] there can be little doubt that, in light of the unknown economic, social, and political implications of biotechnology at the time,[163] the reliance on a strictly scientific perspective lacked both depth of analysis and social conscience. The outcome-based approach to biotechnological governance often leaves many unanswered questions in the wake of a singular good result.[164] With respect to CRISPR, though the issue admittedly has been addressed by the scientific community, the wealth-based access to unregulated genetic modification is a primary concern that the biomedical field is particularly inept to address.[165] Especially telling in this regard is the National Academies' acceptance of the risk simply because inequity in healthcare is not a problem unique to gene editing.[166] Although the scientific community at large has striven to provide reasonable and measured approaches to developing CRISPR technology,[167] ethical gaps and a general reluctance to accept societal harm as a meaningful boundary exemplify the need for regulation outside the biomedical community.[168]

Further, the likelihood of leaving private industry to its own devices in regulating gene editing has already been precluded by Congress's reliance on the FDA to stem clinical trials.[169] As has been discussed previously,[170] the IVF model, representative of a conglomeration of bureaucratic and legislative miscommunication resulting in regulatory uncertainty, recommends nothing to the current CRISPR debate.[171] A moratorium on public funding without substantial restrictions on private enterprise is unlikely to suit the public appetite for development of human applications of CRISPR, and "the

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161. J. Benjamin Hurlbut, *Limits of Responsibility: Genome Editing, Asilomar, and the Politics of Deliberation*, 45 HASTINGS CTR. REP. 5, 12 (2015) ("Forty years later, the legacy of Asilomar lives on in the notion that society is not in a position to judge the ethical significance of scientific projects until scientists can declare with certainty what is realistic: in effect, until the imagined scenarios are already upon us.").

162. *See supra* Part II.A.

163. Jasanoff, *supra* note 52, at 31.

164. See *supra* Part III.B.

165. *See, e.g.*, HGE Report, *supra* note 14, at 128.

166. *Id.*

167. *See generally*, Adam P. Cribbs & Sumeth M.W. Perara, *Science and Bioethics of CRISPR-Cas9 Gene Editing: An Analysis Towards Separating Facts and Fiction*, 90 YALE J. BIO. AND MED. 625 (2017).

168. See Hurlbut, *supra* note 162, at 13.

169. *See supra* Part III.B.

170. *See supra* Part II.B.

171. *See supra* Part II.B.

already-existing level of congressional interest and the fears associated with gene editing"[172] make long-term inaction a relative impossibility.

Finally, as ethical boundaries have potentially already been crossed with regard to Dr. He's widely condemned experiment, substantive legislation is the most appropriate response to clearly identify the limitations of future CRISPR applications to the human genome within a workable and ethical construct.

B. Legislation Under the Commerce Clause Coupled with an NIH-Funded Regulatory Program for Limited CRISPR Research is Necessary to Define and Implement Ethical Approaches to Scientific Inquiry

General applications of biotechnology, and CRISPR in particular, substantially affect interstate commerce, and, as such, Congress has the power to enact laws to impose reasonable restrictions on the use of biotechnology.[173] The Constitution grants Congress the power to "regulate Commerce."[174] This power has been interpreted to include regulation of the "channels of interstate commerce," "persons or things in interstate commerce," and "those activities that substantially affect interstate commerce."[175] In its use of this power, Congress maintains the authority to anticipate the effects that an economic activity will have on commerce.[176]

As a subset of the biotechnological industry, the top ten most productive companies dedicated to the application of CRISPR technology in both public and private settings have reported annual revenue in excess of $700 million.[177] Although American companies, due to the FDA's clinical trial restrictions, are not currently in the business of applying CRISPR to the human genome through embryonic research, the potential effect of allowing this research would almost certainly entail a redistribution of assets and materials through interstate commerce.[178] Taken in the aggregate, this activity

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172. Spivak, *supra* note 27, at 38.

173. Natalie Ram, *Science as Speech*, 102 IOWA L. REV. 1187, 1218–19 (2017). While arguing against a ban on CRISPR under the First Amendment, the author generally acknowledges that constitutional power exists at both the state and federal level to regulate and prohibit the use of CRISPR technology.

174. Art. I, § 8, cl. 3.

175. United States v. Morrison, 529 U.S. 598, 609 (2000).

176. Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 557 (2012) (citing Consolidated Edison Co. v. NLRB, 305 U.S. 197 (1938) (labor practices of utility companies); Heart of Atlanta Motel, Inc. v. United States, 379 U.S. 241 (1964) (discrimination by hotel operators); Katzenbach v. McClung, 379 U.S. 294 (1964) (discrimination by restaurant owners)).

177. Alex Philippidis, *Top 10 Companies Leveraging Gene Editing*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (2018), https://www.genengnews.com/lists/top-10-companies-leveraging-gene-editing.

178. *See* Ram, *supra* note 174, at 1218.

is sufficiently connected to interstate commerce to justify congressional regulation.[179]

Nevertheless, a likely challenge to congressionally mandated restrictions on germline editing may be presented in terms of substantive-due-process.[180] As with equal protection analysis, substantive-due-process analysis requires strict scrutiny of any legislative action that "impermissibly interferes with the exercise of a fundamental right."[181] Fundamental rights are "explicitly or implicitly guaranteed by the Constitution."[182] For a right to be considered "fundamental" it must be susceptible to a "careful description of the asserted fundamental liberty interest," and "deeply rooted in this Nation's history and tradition . . . and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [the right was] sacrificed."[183]

Recognizing that procreation is "fundamental to the very existence and survival of the [human] race" and a "basic civil right[ ] of man,"[184] the right of access to genetic modification of embryos, if it exists at all, belongs to the sources of genetic material from which an embryo is conceived (i.e. a biological man and a biological woman).[185] It is argued, therefore, that this right is inextricably tied to the concept of a right to privacy underlying procreative and parental choice.[186] This premise informs both prongs of the *Glucksburg* substantive-due-process analysis.

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179. *See* Gonzales v. Raich, 545 U.S. 1, 22 (2005)("We need not determine whether respondents' activities, taken in the aggregate, substantially affect interstate commerce in fact, but only whether a 'rational basis' exists for so concluding."); *see also*, Ram, *supra* note 174, at 1218–1219 ("Moreover, federal power tied to the Commerce Clause almost certainly provides the jurisdictional hook required for federal legislation. Modern science, particularly science involving human biological materials, is very often a venture that involves moving research materials, funds, or people across state lines. Where that is so, the Commerce Clause permits the federal government to exercise lawmaking authority.").

180. *See e.g.*, Tandice Ossareh, *Would You Like Blue Eyes with That? A Fundamental Right to Genetic Modification of Embryos*, 117 COLUM. L. REV. 729 (2017).

181. Morrisey v. United States, 871 F.3d 1260, 1268 (11th Cir. 2017) (quoting Massachusetts Bd. of Retirement v. Murgia, 427 U.S. 307, 312) (internal quotations omitted).

182. San Antonio Indep. Sch. Dist. v. Rodriguez, 411 U.S. 1, 33 (1973).

183. Washington v. Glucksburg, 521 U.S. 702, 720–21 (1997) (citations omitted) (internal quotations omitted).

184. Skinner v. Oklahoma, 316 U.S. 535, 541 (1942).

185. *See*, Jason C. Glahn, *I Teach You the Superman: Why Congress Cannot Constitutionally Prohibit Genetic Modification*, 25 WHITTIER L. REV. 409, 431 (2003) ("The [Supreme] Court, through such decisions as Meyer and Pierce, should be construed as having articulated a general right of parents to inculcate positive traits in their children, traits which the state 'can neither supply nor hinder.'").

186. Amber Stine, *The Implications of the Due Process Clause on the Future of Human Embryonic Gene Therapy*, 45 ARIZ. L. REV. 507, 515–17 (2003); *see also*, Ossareh, *supra* note 181, at 755–56.

As to the first prong, the right at issue can be described as that of a parent to choose the circumstances under which that parent is willing to engage in reproduction without governmental interference.[187] The constitutionally recognized rights of privacy and parental autonomy provide the conceptual underpinnings of a right to genetic modification of embryos.[188] Here lies significant precedential tension, highlighted by both Justice Scalia[189] and Justice Stevens[190] in their concurring and dissenting opinions to the Supreme Court's decision in *McDonald v. City of Chicago, Ill*. Justice Stevens aptly framed the issue:

> I acknowledge that some have read the Court's opinion in *Glucksburg* as an attempt to move substantive due process analysis, for all purposes, toward an exclusively historical methodology–and thereby to debilitate the doctrine. If that were ever *Glucksburg*'s aspiration, *Lawrence* plainly renounced it. As between *Glucksburg* and *Lawrence*, I have little doubt which will prove the more enduring precedent.[191]

Despite this tension, *Glucksburg* remains good law, and a court must seek "a careful, specific description of the right at issue in order to determine *whether that right, thus narrowly defined,* [is] *fundamental*."[192]

In evaluating a description that ties a right to genetically modify embryos to procreative choice and parental autonomy, a primary concern is the uncertainty surrounding the legal status of an embryo. Some courts that have considered the issue have done so in the context of marital disputes regarding *custody* or *possession* of frozen embryos.[193] These courts have struck a delicate balance, acknowledging that "pre-embryos are not, strictly speaking, either 'persons' or 'property,' but occupy an interim category that entitles them to special respect . . .."[194] At least one court has explicitly stated that pre-embryos are not children.[195] Mindful of the fact that "[i]f the right of privacy means anything, it is the right of the individual, married or single, to

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187. Ossareh, *supra* note 181, at 755–58.

188. *See id.* at 756; *see also*, Stine, *supra* note 187, at 517.

189. McDonald v. City of Chi., 561 U.S. 742, 797 (Scalia, J., concurring) (2010) ("The threshold step of defining the asserted right with precision is entirely unnecessary, however, if (as Justice Stevens maintains) the 'conceptual core' of the 'liberty clause,' includes a number of capacious, hazily defined categories.") (citations omitted).

190. *Id.* at 858–912 (Stevens, J., dissenting).

191. *Id.* at 873 n.16 (Stevens, J., dissenting).

192. *Id.* at 797 (Scalia, J., concurring) (emphasis in original).

193. In re Marriage of Rooks, 429 P.3d 579, 591 (Colo. 2018) (citing Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992)); *see, e.g.*, Davis v. Davis, 842 S.W.2d 588, 597–98 (Tenn. 1992); McQueen v. Gadberry, 507 S.W.3d 127, 149–50 (Mo. Ct. App. 2016).

194. *Davis*, 842 S.W.2d at 597.

195. McQueen, 507 S.W.3d at 148–49 ("Accordingly, the trial court did not err in failing to classify the frozen pre-embryos as children . . .).

be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child,"[196] it is unclear how genetic modification of embryos, at least in the experimental phase, implicates this decision. It seems a logical aberration to conclude that a person can be a parent of a non-child. Of course, the alternative entitles the embryo constitutional protections that would solve the equation altogether.[197] Thus, in line with *Glucksburg*, perhaps, the right at issue is more carefully and more specifically described as that of a person to engage in genetic experimentation on and modification of embryos constituting "property of a special character"[198] without governmental interference.

Turning to the second *Glucksburg* prong, it is necessary to assess whether this right, as described, is one of "those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed."[199] Unless a court were to adopt a description of the right at issue that ties it inextricably to privacy, procreative choice, and parental autonomy, it is doubtful that history would prove helpful in terms of a substantive-due-process analysis.[200] Unknown complexities, moral and ethical issues, and ongoing political dialog surrounding assisted reproductive technologies counsel against a finding of historical rootedness.[201] Remembering that the Supreme Court "[has] always been reluctant to expand the concept of substantive due process because guideposts for responsible decisionmaking [sic] in this unchartered area are scarce and open-ended,"[202] a court is constitutionally bound to allow the democratic process to govern such new and unexplored territory.[203]

Nonetheless, assuming *arguendo* that a court would find *Glucksburg* satisfied by some variation of this analysis, it would then apply strict scruti-

196. Eisenstadt v. Baird, 405 U.S. 438, 453 (1972).

197. Roe v. Wade, 410 U.S. 113, 156–57 (1973) ("If this suggestion of personhood is established, the appellant's case, of course, collapses, for the fetus' right to life would then be guaranteed specifically by the [Fourteenth] Amendment.").

198. In re Marriage of Rooks, 429 P.3d 579, 591 (Colo. 2018) ("Thus, we agree with courts that have categorized pre-embryos as marital property of a special character.").

199. Washington v. Glucksburg, 521 U.S. 702, 720–21 (1997).

200. *See* Morrissey v. United States, 871 F.3d 1260, 1269–70 (11th Cir. 2017) (finding "[h]istory and tradition provide no firm footing" to establish the rootedness of IVF, egg donation, and gestational surrogacy because they are decidedly "modern phenomena").

201. *Id.*

202. *Glucksburg*, 521 U.S. at 720 (quoting Collins v. City of Harker Heights, Tex., 503 U.S. 115, 125 (1992) (internal quotation marks omitted)).

203. McDonald v. City of Chi., 561 U.S. 742, 805 (Scalia, J., concurring) (2010) ("And the Court's approach intrudes less upon the democratic process because the rights it acknowledges are those established by a constitutional history formed by democratic decisions; and the rights it fails to acknowledge are left to be democratically adopted or rejected by the people, with the assurance that their decision is not subject to judicial revision.").

ny to determine if any law regulating genetic modification of embryos is "narrowly tailored to serve a compelling state interest."[204] The Supreme Court has consistently held that the state has an important and legitimate interest in protecting the potentiality of human life.[205] To date, however, that interest has primarily been assessed in the context of abortion jurisprudence, necessitating a balancing of interests between "preserving and protecting the health of a pregnant woman" and "protecting the potentiality of human life."[206] Outside that context, a court would be obligated to assess the state's interest in protecting nascent human life independent of the complicating factors that pertain to the health and safety of a mother.[207] Under these circumstances, it would be necessary to address the embryo-specific risk factors such as off-target effects as well as the difficulties of eliciting informed consent on behalf of the offspring because "'the unforeseeable effects' may be greater than the actual level of genetic interference."[208] Although the outcome of such an analysis remains uncertain, it is probable that these distinguishing factors would be sufficient to elevate the state's already important interest to the level of compelling interest necessary to withstand strict scrutiny in the event that a court would see fit to apply it.[209]

Once a congressional ban is in place, the NIH should only allow research that meets the current acceptability criteria for applications of CRISPR to the human genome through embryonic research. Such restrictions would significantly limit discretion within the biomedical community and focus research within a specified ethical and moral construct to decrease both individual and societal risk.[210] A position paper issued by the American Society of Human Genetics (ASHG) lays out the scientific community's current attitude toward gene editing.[211] Professional organizations

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204. *See Glucksburg,* 521 U.S. at 721 (quoting Reno v. Flores, 507 U.S. 292, 302 (1993)).

205. Roe v. Wade, 410 U.S. 113, 162–63 (1973); *see also* Planned Parenthood v. Casey, 505 U.S. 833, 875–76 (1992) (joint opinion) (discussing relevant interests); *see, e.g.*, Gonzales v. Carhart, 550 U.S. 124, 146 (2007) (discussing the level of interest that the state has in potential life); Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 508, 132 Stat 348 (2018) (affording protections to embryos identical to those afforded to fetuses in utero).

206. *Roe*, 410 U.S. at 162–63; *see also* Ram, *supra* note 174, at 1219–20.

207. *Roe*, 410 U.S. at 162–63.

208. Cribbs, *supra* note 168, at 629–30.

209. Ram, *supra* note 174, at 1220.

210. *See* Snead, *supra* note 50, at 1534 ("Procedurally, delegating bioethical questions to scientists creates serious problems for democratic accountability, and thus legitimacy. More importantly, this model fails in principle because key premises and methods of scientific reasoning are incommensurable with the humanistic principles that comprise the currency of public bioethical deliberation.").

211. Kelly Ormond et al., *Human Germline Genome Editing*, 101 AM. J. HUM. GENETICS 167, 167 (2017).

from six continents have reviewed and endorsed this statement.[212] The statement effectively offers solutions for the ethical issues raised by CRISPR/Cas9 germline gene editing.[213] Essentially, "[f]uture clinical application of human germline genome editing should not proceed unless, at a minimum, there is (a) a compelling medical rationale, (b) an evidence base that supports its clinical use, (c) an ethical justification, and (d) a transparent public process to solicit and incorporate stakeholder input."[214]

Under these parameters, a potential target for NIH-funded and supervised research would be embryos produced as a result of IVF that have been confirmed to carry genetic markers for a disease known as Tay Sachs. Tay Sachs is an inheritable neurodegenerative disease for which there is currently no cure or effective treatment options.[215] The most common form of Tay Sachs disease onsets during the first months of life and results in the loss of both muscle and mental functions.[216] Generally, children afflicted with Tay Sachs disease do not survive beyond the age of five years.[217] To date, the most reliable method of conception for parents who have recessive genes that carry the risk of producing offspring with Tay Sachs is through IVF with preimplantation genetic diagnosis (PGD).[218] As a result, seventy-five percent of these Tay Sachs prone embryos produced through IVF will have the genetic predisposition for Tay Sachs disease.[219]

In terms of a compelling medical rationale for the application of CRISPR to Tay Sachs embryos produced as a result of IVF with PGD, the lack of viable curative options presents a unique situation among any of the heritable disorders.[220] Because Tay Sachs cannot be treated, and infants born with the disease have, on average, a life expectancy of no more than five years,[221] the application of CRISPR with the goal of refining the technology for purposes of eventual implantation arguably qualifies as an intervention

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212. *Id.*

213. *Id.* at 169–174.

214. *Id.* at 167.

215. *Tay Sachs Disease*, NIH, https://rarediseases.info.nih.gov/diseases/7737/tay-sachs-disease (last visited Mar. 10, 2019).

216. *Id.*

217. *Id.*

218. HGE Report, *supra* note 14, at 113; *Preimplantation Genetic Diagnosis: PGD*, AM. PREGNANCY ASS'N, https://americanpregnancy.org/infertility/preimplantation-genetic-diagnosis/ (last visited July 21, 2019) ("Preimplantation genetic diagnosis (PGD) is a procedure used prior to implantation to help identify genetic defects within embryos. This serves to prevent certain genetic diseases or disorders from being passed to the child. The embryos used in PGD are usually created during the process of in vitro fertilization (IVF).").

219. *Id.* at 114 ("In these situations, only one in four embryos would be free of a disease-causing mutation.").

220. *Tay Sachs Disease*, *supra* note 216.

221. *Id.*

or procedure similar to those previously funded for research in fetuses in utero.[222]

Of course, the risks of embryonic destruction far exceed that of fetal mortality with respect to spina bifida treatment in utero.[223] Nevertheless, the difference in life expectancy changes the risk-benefit calculus in such a way as to provide an ethical justification in line with the ASHG's criteria.[224] Although it may be difficult to estimate with any certainty the number of negative embryonic outcomes that will result from CRISPR interventions, it is unlikely that, without intervention, any of the PGD identified embryos will ever be knowingly implanted to produce a healthy pregnancy. Thus, even one positive outcome in the effort to refine and perfect the CRISPR procedure in Tay Sachs embryos would arguably justify the endeavor.

As the sole conduit through which applications for the use of CRISPR would be approved, the NIH is well positioned to facilitate a transparent public process at every stage of development. To the end of soliciting stakeholder input across the board, the NIH should pursue public comment and continue to seek counsel from future International Summits and the global scientific community. By targeting Tay Sachs disease with the goal of producing a healthy pregnancy, the NIH will be able to develop the CRISPR technology in an ethically acceptable manner, and, once perfected, selectively target successive therapeutic applications without the risk of consumerism and inequitable wealth-based access.

V. CONCLUSION

This note has traced the development of biotechnology over the last half-century with the aim of showing the inadequacies of reactive federal regulation. In recognition of those inadequacies, this note further argued that the current regulatory scheme should be replaced by substantive legislation under the Commerce Clause to avoid the risks of abuse and misappropriation of CRISPR technology. Even though genetic modification using CRISPR technology presents numerous opportunities for the eradication of disease and increasing the quality of human life, substantive legislation will ensure that the ethical boundaries of science are clearly defined in pursuit of

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222. *See supra* Part III.A (discussing in utero spina bifida interventional treatments approved under the auspices of the NIH).

223. Antonio Regalado, *US Scientist Who Edited Human Embryos with CRISPR Responds to Critics*, MIT TECH. REV. (Aug. 8, 2018), https://www.technologyreview.com/s/611837/us-scientist-who-edited-human-embryos-with-crispr-responds-to-critics/. A scientist at Oregon Health Sciences University in Portland, Oregon claimed to have repaired a genetic mutation in dozens of human embryos that were later destroyed upon the conclusion of the research.

224. *See supra* Part III.A (discussing life expectancy of those born with spina bifida.)

those goals. In spite of a long history of inaction and uncertainty in response to the hardest questions involving the human relationship to nature and mastery of biology, this is not a time for governmental hesitancy. As Hegel understood, science is incomplete in its beginnings, but the suitability of an end will always depend largely on where it starts.

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