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Genetically Customized Generations—A Need for Increased Regulatory Control over Gene Editing Technology in the United States

Morgan Mendicino

Southern Methodist University, Dedman School of Law, mmendicino@smu.edu

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GENETICALLY CUSTOMIZED
GENERATIONS—A NEED FOR
INCREASED REGULATORY CONTROL
OVER GENE EDITING TECHNOLOGY
IN THE UNITED STATES

*Morgan Mendicino**

ABSTRACT

Gene editing technology, once a far-fetched scientific fantasy, has become a tangible reality. One emerging form of gene editing in particular, human germline genome editing, possesses revolutionary capabilities that warrant cautious examination. Recent advancements in research have demonstrated that such biotechnology could be used to alter the genetic makeup of unborn children and the hereditary genes of future generations. This biotechnology may possess the ability to save countless human lives, but we must ask—What happens when the line between preventing disease and “playing God” becomes blurry? Human germline genome editing raises a multitude of widespread and deeply rooted questions surrounding the fate of humanity, all of which thwart justifying its present-day use. Despite such concerns, this field of biotechnology generally remains unregulated in the United States. This Comment thoroughly examines the potential benefits and consequences of human germline genome editing and provides a brief overview of the current means of government oversight and the lack of regulatory control. Ultimately, this Comment proposes a new regulatory scheme that emphasizes moral considerations for human germline genome editing and other high-risk biotechnology.

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* Associate Managing Editor, SMU Law Review Association. Candidate for Juris Doctor, SMU Dedman School of Law, 2021; B.S., Biomedical Engineering, University of Texas at Austin, 2018. With special thanks to my family and friends for their endless love and support in all that I do.

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I. INTRODUCTION

TO many, gene editing technology seems foreign and inconsequential to their individual lives. However, genetically modified organisms and products are more prevalent than most realize. A significant portion of the produce available at grocery stores has been genetically modified to stay fresh longer, to have increased nutritional value, and to be more resistant to insect and chemical damage.¹ The vaccines people choose to accept as adults or have administered to children are largely genetically modified versions of the viruses or bacteria that the vaccines aim to protect against.² And even more surprising, some of the clothes people wear are made from genetically modified cotton.³ But with the recent advancements in gene editing research and technology, its application is no longer confined to the things we consume, wear, and use. Rather, this technology can now be used to manipulate the DNA in living and unborn human beings.⁴ Research suggests that gene editing may have the potential to treat and eventually eradicate deadly diseases

1. See Theresa Phillips, *Genetically Modified Organisms (GMOs): Transgenic Crops and Recombinant DNA Technology*, NATURE EDUC. (2008), <https://www.nature.com/scitable/topicpage/genetically-modified-organisms-gmos-transgenic-crops-and-732/> [https://perma.cc/DH2A-U2XJ].

2. Jeff Bessen, *GMOs Could Save Your Life—They Might Have Already*, NEW REPUBLIC (July 28, 2016), <https://newrepublic.com/article/135617/gmos-save-lifethey-might-already> [https://perma.cc/6EVD-D2YK].

3. Lydia Ramsey Pflanzler, *7 Everyday Items That Wouldn't Exist as We Know Them Without GMOs*, BUS. INSIDER (Aug. 11, 2015, 8:32 AM), <https://www.businessinsider.com/things-that-wouldnt-exist-without-gmos-2015-8> [https://perma.cc/YU9Z-6UEL].

4. Kelly E. Ormond et al., *ASHG Position Statement: Human Germline Genome Editing*, 101 AM. J. HUM. GENETICS 167, 169 (2017).

such as HIV/AIDS, sickle-cell anemia, cancer, and some cardiovascular diseases.⁵ Gene editing technology could even make it possible to customize the gender, height, strength, intelligence, and other physical and mental attributes of future generations.⁶

Research involving human genes dates back to 1953, when two historic scientific figures, James Watson and Francis Crick, discovered the double helix structure of DNA.⁷ Many breakthroughs followed this discovery, and by the 1980s scientists had harnessed gene editing technology to create vaccines, genetically engineer drugs, and genetically modify crops.⁸ Shortly after, in 1996, the first mammal cloned from an adult cell was created—a sheep known as Dolly.⁹ It is indisputable that Dolly's creation was a monumental scientific accomplishment; nonetheless, it generated some unease in society.¹⁰ Despite the apprehension toward the future of gene editing, research continued to advance and shifted focus to human application.¹¹ However, human application is not without controversy—with the power to modify and improve future human lineages, we must ask, Whose vision of the future are we going to construct?

This Comment aims to inspire discussions over the extraordinary potential and unprecedented ethical ramifications of human germline genome editing and to encourage policymakers to think critically about the future of this technology in the United States. Part II of this Comment provides a brief overview of what human germline genome editing technology is and how it works, highlighting the first controversial use of the technology in China that stimulated both global excitement and apprehension. Part III addresses the safety and ethical concerns associated with the use of human germline genome editing, including concerns arising from both the potential failure and the potential success of the technology. Part IV discusses the current forms of legislation and regulation in the United States that pertain to gene editing technology, as well as the role of patent law in controlling the advancement of biotechnology. Lastly, Part V of this Comment argues that there exists an imminent need for increased control over the development and commercialization of human germline genome editing in the United States and suggests that such reform be pursued through specialized regulations with enforceable consequences and revised patentability requirements.

5. *See id.* at 168; NAT'L ACADS. SCIS., ENG'G, & MED., HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE 67 (2017).

6. *See* NAT'L ACADS. SCIS., ENG'G, & MED., *supra* note 5, at 137–44.

7. *History of Genetic Engineering and the Rise of Genome Editing Tools*, SYNTHEGO, <https://www.synthego.com/learn/genome-engineering-history> [<https://perma.cc/V2SR-LB26>].

8. *Id.*

9. *Id.*

10. Brian Donnelly, *Two Decades on, Dolly the Sheep Still Remains a Source of Controversy*, HERALD (July 3, 2016), <https://www.heraldsotland.com/news/14595633.two-decades-on-dolly-the-sheep-still-remains-a-source-of-controversy/> [<https://perma.cc/B9VS-KAKA>].

11. *History of Genetic Engineering and the Rise of Genome Editing Tools*, *supra* note 7.

II. SCIENTIFIC BACKGROUND

A. WHAT IS HUMAN GERMLINE GENOME EDITING?

Miraculous research achievements have been made in the world of human gene editing, and such research has recently been implemented into practice. Several gene therapy products are now approved by the Food and Drug Administration (FDA) and available for patients in the United States,¹² and nearly 1,000 clinical trials incorporating gene therapy have been approved for health conditions as serious as heart disease, HIV/AIDS, and many forms of cancer.¹³ Under the broad umbrella of gene editing, there are two separate forms of gene editing: somatic and germline.¹⁴ The gene therapy techniques that are currently approved in the United States for human application are all *somatic*,¹⁵ the most well-known being CRISPR-Cas9—a gene editing tool that essentially allows scientists to remove, add, or alter sections of human DNA.¹⁶ While somatic gene editing continues to advance and commercialize, germline genome editing possesses distinct features that differentiate it from somatic gene editing in ways that create substantial ethical and legal barriers to its further development.

Before discussing its implications and the need for more extensive regulation, a basic understanding of the science behind human germline genome editing is warranted. Somatic gene editing involves edits to DNA located in adult cells called somatic, or non-germline, cells.¹⁷ These edits alter only the treated individual, and the genetic changes will not pass to the offspring of that individual.¹⁸ By contrast, germline genome editing involves edits to DNA located in germ cells which are held in sperm, eggs, and embryos.¹⁹ Such edits not only alter the treated individual but also can be passed on to offspring.²⁰ The genetic change resulting from the procedure, whether intended or not, can carry into the patient's children, their grandchildren, their great-grandchildren, and so on.²¹ Consequently, germline genome editing carries the potential of creating a genetically modified human lineage.

Investigation into germline genome editing began with the embryos of various species, other than humans, for purposes such as enhancing nutri-

12. For a complete list of FDA-approved gene therapy products, see *Approved Cellular and Gene Therapy Products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products> [<https://perma.cc/M87H-L6AX>] (last updated July 24, 2020).

13. *Gene Therapy Clinical Trials in the United States*, U.S. NAT'L LIBR. MED., <https://clinicaltrials.gov/search?term=%22gene+Therapy%22> [<https://perma.cc/NHV8-Z33Q>].

14. See generally Melody Redman et al., *What is CRISPR/Cas9?*, 101 ARCHIVES DISEASE CHILDHOOD: EDUCATION AND PRACTICE 213, 213–15 (2016).

15. See *Approved Cellular and Gene Therapy Products*, *supra* note 12.

16. See generally Redman et al., *supra* note 14, at 213–15.

17. Ormond et al., *supra* note 4, at 169.

18. *Id.*

19. *Id.*

20. *Id.*

21. See *id.*

tion and resistance in crops and livestock, as well as for observation purposes in model organisms.²² Germline editing has proven successful in the embryos of several mammals including mice, rats, and monkeys.²³ Moreover, a groundbreaking 2015 study²⁴ demonstrated the feasibility of germline editing in human embryos and led to an immediate acceleration in research.²⁵ Although many safety, ethical, and legal concerns restrained this research to mice and petri dishes for many years, it eventually broke free—introducing Lulu and Nana, the world’s first gene-edited babies.²⁶

B. THE WORLD’S FIRST GENE-EDITED BABIES

On November 25, 2018, He Jiankui, a Chinese researcher startled the world with a YouTube video, in which he claimed that he and his fellow researchers had created the first genetically altered babies.²⁷ Dr. He’s experiment aimed to create immunity in humans to HIV by editing the DNA of human embryos and then implanting the modified embryos into the uterus of five female participants in the study.²⁸ Dr. He’s experiment was “successful” in the sense that it resulted in two twin babies born with modified genes; nevertheless, “for *neither* twin did the [experiment] do exactly what it was intended to do.”²⁹ The goal of Dr. He’s research was to inject a gene-editing construct that would cause a single “32-base-pair deletion in a gene called CCR5. . . . This deletion would make the gene produce non-functional copies of the CCR5 protein,”³⁰ which is generally needed for the HIV virus to attach to and infect T-cells. The experiment ultimately resulted in the production of nonfunctional CCR5 protein; however, the results demonstrated that the targeted string of 32 base pairs was *not* deleted.³¹ In fact, several other unintentional changes, the consequences of which remain uncertain, were made to the twins’ genes.³² In all, although Dr. He’s experiment may appear to have been a

22. *See id.* at 168.

23. *Id.*

24. Puping Liang et al., *CRISPR/Cas9-Mediated Gene Editing in Human Triprounuclear Zygotes*, 6 *PROTEIN & CELL* 363 (2015).

25. *See* Ormond et al., *supra* note 4, at 168.

26. Henry T. Greely, *CRISPR’d Babies: Human Germline Genome Editing in the ‘He Jiankui Affair’*, 6 *J. L. & BIOSCIENCES* 111, 116–18 (2019).

27. Jing-ru Li et al., *Experiments That Led to the First Gene-Edited Babies: The Ethical Failings and the Urgent Need for Better Governance*, 20 *J. ZHEJIANG U. SCI. B* 32, 33 (2019).

28. Greely, *supra* note 26, at 116.

29. *Id.* at 117.

30. *Id.* at 116–17 (emphasis omitted).

31. *Id.* at 117.

32. *Id.* Scientists have been attempting to study the effects of the particular genetic mutations in the twins, and there is a great deal of speculation and debate surrounding the potential consequences. Some contend that the mutations will result in “enhanced memories and learning abilities,” while others argue that the mutations will make the twins more likely to die young. Jon Cohen, *Did CRISPR Help—or Harm—the First-Ever Gene-Edited Babies?*, *SCIENCE* (Aug. 1, 2019, 11:30 AM), <https://www.sciencemag.org/news/2019/08/did-crispr-help-or-harm-first-ever-gene-edited-babies> [<https://perma.cc/8UZH-35TC>].

success, in reality it brought about changes that were not intended, “changes that had never been seen in humans before.”³³

Dr. He’s experiment was initially met with praise by Chinese media; however, it was not long before strong criticism surfaced worldwide from the scientific community and the general population.³⁴ Following Dr. He’s public announcement of his experiment, scientific leaders forming the Committee of the Second International Summit on Human Genome Editing released a condemning statement, calling Dr. He’s actions “deeply disturbing” and claiming “[Dr. He’s] procedure was irresponsible and failed to conform to international norms.”³⁵ Over one year later, in December of 2019, Dr. He was found guilty of “illegal medical practices” and was sentenced to three years in prison along with a \$429,000 fine.³⁶ Dr. He’s bold leap to make human germline genome editing research a reality served as a wake-up call to many countries and individuals. Dr. He’s navigation into uncharted waters is now compelling countries, if they have not already, to plan ahead and to control the development and ramifications of this revolutionary technology. As a result, many profound safety and ethical concerns are being brought to the world’s attention, stimulating heated debates surrounding morality and the future of humanity.

III. THE SAFETY AND ETHICAL CONCERNS WITH HUMAN GERMLINE GENOME EDITING

The most notable characteristic in germline genome editing that segregates it from other modern biotechnology is the ability of its results to be inherited by future generations.³⁷ This hereditary aspect has sparked both excitement and fear in society. It is undeniable that human germline genome editing possesses an astounding potential for greatness. It may have the ability to eradicate deadly genetic diseases, create immunity to certain infections such as HIV/AIDS, and even suppress human genes known for increasing the risks of cancer and heart disease.³⁸ But while this technol-

33. Greely, *supra* note 26, at 117.

34. See, e.g., *Statement by the Organizing Committee of the Second International Summit on Human Genome Editing*, NAT’L ACADS. SCIS., ENG’G, & MED. (Nov. 28, 2018), <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11282018b> [<https://perma.cc/Y7W4-CKHK>].

35. *Id.*

36. Dennis Normile, *Chinese Scientist Who Produced Genetically Altered Babies Sentenced to 3 Years in Jail*, SCIENCE (Dec. 30, 2019, 8:15 AM), <https://www.sciencemag.org/news/2019/12/chinese-scientist-who-produced-genetically-altered-babies-sentenced-3-years-jail> [<https://perma.cc/HZ5W-XX9C>]. Without explicit laws prohibiting Dr. He’s experiment, China was forced to take an alternate route in prosecuting Dr. He: a court in Shenzhen held that Dr. He’s forgery of ethical review documents, misleading of doctors involved in administering the procedure, and deliberate violation of national regulations on scientific research constituted “illegal medical practice[.]” *Id.*

37. See Ormond et al., *supra* note 4, at 169.

38. *Id.* at 168; Michael Walsh, *How Can CRISPR Genome Editing Shape the Future of Cancer Research?*, CANCER RES. UK (Jan. 12, 2018), <https://scienceblog.cancerresearchuk.org/2018/01/12/how-can-crispr-genome-editing-shape-the-future-of-cancer-research/> [<https://perma.cc/CBL8-6KET>].

ogy may appear to be the answer to problems society never thought fixable, in its present state of development it carries its own far-reaching and unprecedented problems. The primary concerns associated with human germline genome editing can generally be separated into two broad categories: (1) the safety and ethical concerns stemming from its potential failure, and (2) the ethical concerns stemming from its potential success.³⁹

A. THE SAFETY AND ETHICAL CONCERNS STEMMING FROM THE
POTENTIAL FAILURE OF HUMAN GERMLINE GENOME
EDITING

One of the greatest safety concerns with the human germline genome editing technology itself is the possibility of off-target edits. Off-target edits, sometimes described as collateral damage,⁴⁰ occur when genetic modifications are accidentally made to an unintended region of DNA.⁴¹ Some off-target edits may be harmless, while others could result in physical and potentially detrimental changes in the offspring, including the accidental activation of genes known to cause cancer.⁴² It is known that off-target edits have resulted in genetic variations “that are rare or not known to exist in human populations,”⁴³ yet the precise short-term, long-term, and toxic effects of these off-target edits in humans remain unknown.⁴⁴

Another significant safety concern with the human germline genome editing technology itself is the possibility of mosaic embryos. Mosaic embryos are created when the intended modifications reach only *some* of the cells in the developing embryo and not others.⁴⁵ As a result, the embryo

39. Ormond et al., *supra* note 4, at 169. The American Society of Human Genetics (ASHG) Workgroup on Human Germline Genome Editing structured its discussion of the ethical concerns into these two broad categories in its 2017 explanatory paper on human germline genome editing. *Id.*

40. See Dana Carroll, *Collateral Damage: Benchmarking Off-Target Effects in Genome Editing*, *GENOME BIOLOGY* 1 (June 3, 2019), <https://genomebiology.biomedcentral.com/track/pdf/10.1186/s13059-019-1725-0> [<https://perma.cc/FUP8-K32V>].

41. Ormond et al., *supra* note 4, at 169.

42. See *id.* Off-target edits “could affect the entire body of the offspring” and, in a hypothetical yet realistic extreme case, “could result in the child developing cancer.” Tetsuya Ishii, *Germ Line Genome Editing in Clinics: The Approaches, Objectives and Global Society*, 16 *BRIEFINGS FUNCTIONAL GENOMICS* 46, 49 (2015); see also Tanya Lewis, *New Gene-Editing Tool Could Fix Genetic Defects—With Fewer Unwanted Effects*, *SCI. AM.* (Oct. 21, 2019), <https://www.scientificamerican.com/article/new-gene-editing-tool-could-fix-genetic-defects-with-fewer-unwanted-effects/> [<https://perma.cc/M44B-K3PT>].

43. Ormond et al., *supra* note 4, at 173.

44. Diane Catherine Wang, *Off-Target Genome Editing: A New Discipline of Gene Science and a New Class of Medicine*, 35 *CELL BIOLOGY & TOXICOLOGY* 179, 180 (2019). Many scientific leaders in the United States who do not yet support the use of human germline genome editing, without further scientific research and ethical considerations, have recognized “minimum standards for measuring off-target mutagenesis” and a “[c]onsensus regarding the likely impact of, and maximum acceptable thresholds for, off-target mutations” as “minimum necessary developments.” Ormond et al., *supra* note 4, at 173.

45. Michael Le Page, *Mosaic Problem Stands in the Way of Gene Editing Embryos*, *NEWSIDENTIST* (Mar. 15, 2017), <https://www.newsidentist.com/article/mg23331174-400-mosaic-problem-stands-in-the-way-of-gene-editing-embryos/> [<https://perma.cc/DEP7-JLU7>].

contains a mixture of both cells containing properly mutated DNA and cells containing the original unmodified DNA.⁴⁶ This can generate false-positive results, meaning testing on an embryo prior to its implantation could reveal that the experiment was a success, yet the offspring could be born without the intended mutation.⁴⁷ This risk transforms mosaicism into not only a safety concern but also an ethical concern. Its uncertainty carries great weight when considering the time, money, and commitment that would go into making the decision to genetically enhance future offspring. And even more so when considering the psychological distress that would result from discovering a false-positive when it is too late to start over.

Although many scientists contend that germline gene editing would only be implemented in humans once the technology is refined to perfection, accidents still happen, and serious ethical concerns arise with the potential failure of the technology. If germline gene editing does not work as intended and results in unwanted harmful mutations, the effects of the mistake do not stop at the modified child. These genetic errors may be passed on to an infinite number of generations, and thus, it seems as though “[t]he only way to prevent the future transmission of germline edits is to prevent the person whose genes have been edited from reproducing.”⁴⁸ As one could imagine, this “solution” would encounter significant legal barriers as it presumably would impede one’s constitutionally protected reproductive rights.⁴⁹

B. THE ETHICAL CONCERNS STEMMING FROM THE POTENTIAL SUCCESS OF HUMAN GERMLINE GENOME EDITING

Many of the concerns driving people’s disapproval of human germline genome editing do not originate from its safety risks or its potential biological consequences, but rather originate from the societal ramifications that may arise if it functions as intended. A large portion of the ethical debates over human germline genome editing has been dedicated to the distinction between treatment and enhancement. Uses of this technology for treatment would include modifying DNA to create offspring immune to particular diseases, while uses for enhancement would include modifying DNA to create taller, stronger, or more intelligent offspring.⁵⁰ Society

46. *Id.*

47. See Maryam Mehravar et al., *Mosaicism in CRISPR/Cas9-Mediated Genome Editing*, 445 *DEVELOPMENTAL BIOLOGY* 156, 158 (2019). Mosaicism may also lead to inaccurate results when testing for unintentional off-target edits. See *id.*

48. Sarah Ruth Bates, *Rewriting Our Genes Is Easier Than Ever. That Doesn’t Mean We Should Do It*, *WBUR* (Jan. 3, 2020), <https://www.wbur.org/cognoscenti/2020/01/03/germline-prime-gene-editing-sarah-ruth-bates> [<https://perma.cc/XW98-ESRT>] (“If germline gene editing goes wrong, there’s no ethically sound way to stop the resulting domino effect. . . . [T]here is no precedent—nor should there be—for preventing a person who hasn’t even been born yet from reproducing as an adult.”).

49. Although the U.S. Constitution does not explicitly mention a right to reproduce, the Supreme Court has deemed reproductive rights “fundamental.” *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942).

50. See *NAT’L ACADS. SCIS., ENG’G, & MED.*, *supra* note 5, at 137–45.

is beginning to see an increasingly passionate struggle over the acceptance of the idea of commercial human enhancement, especially with the introduction of unsettling labels such as “designer babies,” “super humans,”⁵¹ and “mutants.”⁵²

Societal unease is not derived solely from the troubling nature of the labels frequently given to future genetically enhanced generations, but it is also deeply rooted in concerns about eugenics.⁵³ Among the several eugenic concerns expressed by the general public is the fear that heritable genetic enhancement will transform our sense of humility and diminish our humanity.⁵⁴ Human awareness that our genetic makeups—and thus many of our qualities, talents, and abilities—are given and beyond our control instills a degree of meekness in our character. Inheritable genetic enhancement erodes this idea of chance by allowing us to pick and choose the most desirable human genes and dispense with the less favorable genes.⁵⁵ Consequently, some traits and some individuals would be identified not merely as disadvantaged but also as “unfit.”⁵⁶ And the predetermined fitness of people’s traits would inevitably “reflect[] on the worth and value of people who have that trait in our society.”⁵⁷ Inheritable genetic enhancement would thus endorse defining and rejecting inferiority, creating “a world inhospitable to the unbidden, a gated community writ large.”⁵⁸

The arguably most controversial societal concerns are centered around the deepening of social inequalities. If human germline genome editing were developed to the point of commercialization, it is reasonable to assume that treatment with this biotechnology would be expensive, not universally available, and potentially contrary to different religious beliefs.⁵⁹

51. Kathleen M. Vogel, *Crispr Goes Global: A Snapshot of Rules, Policies, and Attitudes*, BULL. ATOMIC SCIENTISTS (June 5, 2018), <https://thebulletin.org/2018/06/crispr-goes-global-a-snapshot-of-rules-policies-and-attitudes/#> [<https://perma.cc/LL58-87MD>].

52. Heidi Gardner, *Real-Life X-Men: How CRISPR Could Give You Superpowers in the Future*, SYNTHGO: THE BENCH (Sept. 14, 2018), <https://www.synthgo.com/blog/could-crispr-make-x-men-a-realistic-possibility> [<https://perma.cc/7ZBX-YVEL>].

53. *Eugenics* is defined as “the practice or advocacy of controlled selective breeding of human populations . . . to improve the population’s genetic composition.” *Eugenics*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/eugenics> [<https://perma.cc/5A3W-NS8E>].

54. Michael J. Sandel, *The Case Against Perfection*, ATLANTIC, Apr. 2004, at 50.

55. In addition to provoking strong eugenic concerns, this erosion of the idea of chance also threatens our capacity “to consider ourselves responsible—worthy of praise or blame—for the things we do and for the way we are.” Sandel, *supra* note 54. This transformation in our fundamental sense of responsibility would in turn alter our expectations for ourselves and for others. *See id.* (“The more we become masters of our genetic endowments, the greater the burden we bear for the talents we have and the way we perform.”). Note that this position has been countered by bioethicist John Harris, who believes that this notion is “inescapable” since “the burdens of responsibility are our fate as choosing autonomous beings” and “because choosing not to act is still a choice for which we are responsible.” JOHN HARRIS, ENHANCING EVOLUTION: THE ETHICAL CASE FOR MAKING BETTER PEOPLE 118 (2007).

56. Sandel, *supra* note 54.

57. Ormond et al., *supra* note 4, at 172.

58. Sandel, *supra* note 54.

59. *See* Ormond et al., *supra* note 4, at 172.

Access to this novel technology would then be determined by factors such as wealth, location, disability, and religious affiliation.⁶⁰ And with such correlation, “[g]enetic disease, once a universal common denominator, could instead become an artifact of class, geographic location, and culture.”⁶¹ The concerns regarding social inequalities are just as, if not more, prevalent with respect to enhancement as they are with treatment. Many share the worry that genetic enhancement will create “two classes of human beings: those with access to enhancement technologies, and those who must make do with their natural capacities.”⁶² And now, with the ability to make such enhancements inheritable, there exists the possibility that these two classes will transform into species and subspecies.⁶³ Furthermore, the American population has struggled for many years to overcome—and continues to feel the sting of—the societal consequences of identifying separate classes of individuals as superior to others, as in the case of racial classifications. And if species and subspecies were created on the basis of genetic enhancement, it could be argued that society would be back to square one, confronting a new harmful stigma that attaches only to a particular group of people.

Despite these widely accepted and deeply rooted concerns, some maintain the position that human commercial genetic enhancement is beneficial for humanity.⁶⁴ John Harris is highly regarded in the field of bioethics for his permissive approach to human enhancement taken in his book entitled *Enhancing Evolution: The Ethical Case for Making Better People*.⁶⁵ Harris begins his book with the broad idea that “an enhancement is by definition an improvement on what went before,” and “[i]f it wasn’t good for you, it wouldn’t be enhancement.”⁶⁶ He points out that many of us have already enhanced ourselves in several ways (e.g., wearing glasses) and virtually all of us have benefitted from enhancement (e.g., vaccinations creating “herd immunity” in society).⁶⁷ Harris takes his position even further, asserting that society and the government have not only a “freedom” to pursue genetic enhancement but also an “obligation” to do so.⁶⁸

Among many other influential arguments, Harris counters the unease associated with the possibility that enhancement will lead to the identification of unfit traits or unfit individuals and thus, discrimination, while noting its critical importance, by arguing that genetic enhancement to re-

60. *See id.*

61. *Id.*

62. Sandel, *supra* note 54.

63. *Id.*

64. *See generally, e.g.,* HARRIS, *supra* note 55.

65. *See id.*; Sarah Chan, *Enhancing Evolution: The Next Step?*, 9 EMBO REPS. 227, 227 (2008) (book review).

66. HARRIS, *supra* note 55, at 9. Critics have argued that this simplistic view proposed by John Harris “neatly sidesteps some of the practical difficulties associated with the potential use of enhancement technologies—such as possible harm or unforeseen adverse consequences.” Chan, *supra* note 65, at 227.

67. *See* HARRIS, *supra* note 55, at 8.

68. *Id.* at 9.

move disabilities does not demonstrate “existential preference.”⁶⁹ In other words, choosing to create children without disabilities is not the same as preferring individuals without disabilities over those who are disabled, and it simply does not imply that those with disabilities are in any way of lesser value.⁷⁰ In that regard, Harris suggests that genetic enhancement’s “subjective costs” to the disabled (or unenhanced) of feeling disvalued and its “objective costs” to society of the possibility of the disabled (or unenhanced) being viewed as of lesser value to the community are both costs that should be eliminated as much as possible given the technology’s ability to prevent harm, pain, and suffering.⁷¹ The core of Harris’s position advocating for human genetic enhancement is the notion that enhancements “do good” and “make us better people.”⁷² In particular, “[enhancements] make us less the slaves to illness and premature death, less fearful because we have less to fear, [and] less dependent, not least upon medical science and on doctors.”⁷³ And thus, exploiting this technology for our own benefit and the benefit of others, under the fundamental moral principle that humans are to do no harm, is humanity’s “moral duty.”⁷⁴

Although there are many well-grounded arguments favoring the use of human germline genome editing technology, the ethical concerns are too widespread and too deeply rooted in the fate of our humanity to justify its present-day use. Moreover, given the fact that the genetic results, intended or not, good or bad, will be passed onto future generations, the safety concerns are too far-reaching and sobering in nature, and their chances of manifestation are undeniable at this stage in the technology’s development. Some of these safety and ethical concerns will necessarily be resolved in time by advances in research and the evolution of society’s ethical perspectives, however, numerous others will require careful implementation of new laws and regulations.

IV. LEGAL LANDSCAPE IN THE UNITED STATES

A. CURRENT LEGISLATION AND REGULATION OF HUMAN GERMLINE GENOME EDITING

In the United States, there is currently no federal legislation implementing an outright ban on experimentation with heritable human genomes.⁷⁵ However, absent explicit laws directed to the research itself, the

69. *Id.* at 96 (internal quotation marks omitted).

70. *See id.* To illustrate his point, Harris uses the analogy: “To set badly broken legs does not constitute an attack on those confined to wheelchairs.” *Id.* at 95–96 (footnote omitted).

71. *See id.* at 100–08.

72. *Id.* at 185–86.

73. *Id.* at 185.

74. *Id.* at 185, 188–89.

75. *See* RUMIANA YOTOVA, *THE REGULATION OF GENOME EDITING AND HUMAN REPRODUCTION UNDER INTERNATIONAL LAW, EU LAW AND COMPARATIVE LAW* 45 (2017), <https://www.nuffieldbioethics.org/assets/pdfs/GEHR-report-on-regulation.pdf> [https://perma.cc/5JAP-QWGG]. Given the variations in legislation from state to state, this Com-

United States government has found alternative means to exercise control over human germline genome editing. The federal government contributes financially to most developing biotechnologies and regulates the safety and effectiveness of medical products available to the public.⁷⁶ With such influence, the federal government maintains the ability to “impose requirements on research as a condition for receiving either federal funding or FDA premarket review of a new medical product (such as a drug, device, or biologic).”⁷⁷ However, whether this degree of control is sufficient is controversial.

Since human germline genome editing currently remains confined to its early stages of research in the United States, the government’s predominant method of control exists in the form of funding restrictions.⁷⁸ In 1996, Congress passed the Dickey–Wicker Amendment as a bill rider to the appropriations bill for the Department of Health and Human Services.⁷⁹ The amendment prohibited federal funding for creating, destroying, or knowingly injuring human embryos.⁸⁰ This amendment has been reenacted each year, hindering the advancement of scientific research involving human embryos.⁸¹

In addition to restricting funding, should human germline genome editing develop beyond the stages of mere research in the United States, the federal government has also taken preemptive measures to confront this

ment focuses solely on the limits imposed on human germline genome editing by federal laws and regulations.

76. See MARCY E. GALLO ET AL., CONG. RESEARCH SERV., R44824, ADVANCED GENE EDITING: CRISPR-CAS9 8, 17–19 (2018).

77. *Id.* at 17.

78. It is worth noting that the current standards for government regulation of research on human subjects are grounded in the Federal Policy for the Protection of Human Subjects, generally known as the “Common Rule.” See generally Joseph L. Breault, *Protecting Human Research Subjects: The Past Defines the Future*, 6 OCHSNER J. 15, 17–19 (2006). The Common Rule focuses on the reasonableness of the risks to the human subjects, the anticipated benefits to the subjects, and the value of the knowledge expected to be gained. See *id.* at 17–18. And if the Common Rule applies to certain research on human subjects, it requires such research to be reviewed and approved by an Institutional Review Board. See *id.* at 18. But, as promising as this baseline standard of ethics may seem, it is applicable only to federally funded or federally sponsored research and research that will submit data to a federal agency for approval. See *id.* Consequently, the Common Rule would rarely have any authority over human germline genome editing. See *id.*

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

80. See *id.*

81. See Megan Kearl, *Dickey-Wicker Amendment, 1996*, EMBRYO PROJECT ENCYCLOPEDIA (Aug. 27, 2010), <https://embryo.asu.edu/pages/dickey-wicker-amendment-1996> [<https://perma.cc/AU35-W9TB>]. Recognizing the Dickey–Wicker Amendment, the Director of the National Institutes of Health (NIH) published a statement in 2015, stating that the NIH “will not fund any use of gene-editing technologies in human embryos” due to the “unquantifiable safety issues, ethical issues presented by altering the germline in a way that affects the next generation without their consent, and a current lack of compelling medical applications justifying the use of [these technologies].” Francis S. Collins, *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, NAT’L INSTS. HEALTH (Apr. 28, 2015), <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos> [<https://perma.cc/SRQ4-HDEV>].

technology at the testing and commercialization stages. Human germline genome editing falls within the broader category of “gene therapy” and would be regulated by the FDA.⁸² To obtain premarket approval from the FDA, any new gene therapy treatment must prove its safety and efficacy through clinical trials on human volunteers.⁸³ And prior to any clinical studies in the United States, an applicant must submit an Investigational New Drug application.⁸⁴ Following clinical trials and investigation, any new gene therapy product requires, among many other requirements, the submission of a biologics license application and FDA approval before it can be marketed to the general public.⁸⁵ These burdensome FDA hurdles are far more impractical to overcome than they seem, as current federal law prohibits the FDA from reviewing—let alone approving—the aforementioned applications for human germline genome editing.⁸⁶

In 2016, the House of Representatives enacted a bill rider amendment to the Consolidated Appropriations Act, narrowly tailored to address germline gene therapy research.⁸⁷ The bill rider prohibits the FDA from acknowledging any applications submitted “for an exemption for investigational use of a drug or biological product . . . in research in which a human embryo is intentionally created or modified to include a heritable genetic modification.”⁸⁸ This precautionary measure taken by Congress effectively creates a future roadblock at the clinical study and marketing

82. NAT'L ACADS. SCIS., ENG'G, & MED., *supra* note 5, at 35; *see also* Yotova, *supra* note 75, at 45 (“[T]he US Food & Drug Administration (FDA) has the authority under the Public Health Service Act and the Federal Food, Cosmetic and Drug Act to regulate products and drugs involving genome editing, including human genome editing on the federal level.”).

83. Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53248 (Oct. 14, 1993).

84. The FDA’s regulations on investigational new drugs are described in Title 21 of the Code of Federal Regulations, parts 50, 56, and 312. *See* 21 C.F.R. pts. 50, 56, 312 (2020).

85. 21 C.F.R. § 601.2 (2020). For a new gene therapy product to obtain a biologics license under section 351 of the Public Health Service Act, allowing the product to be marketed to the general public, FDA regulations state that the manufacturer of such biological products

shall submit an application[;] . . . shall submit data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed requirements of *safety, purity, and potency*; . . . [and shall submit] statements regarding each clinical investigation involving human subjects contained in the application, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements[;] and was conducted in compliance with requirements for informed consent set forth in part 50 of this chapter.

Id. § 601.2(a) (emphasis added).

86. Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 749, 129 Stat. 2242, 2283 (2015).

87. *See* Jocelyn Kaiser, *Update: House Spending Panel Restores U.S. Ban on Gene-Edited Babies*, SCIENCE (June 4, 2019, 1:45 PM), <https://www.sciencemag.org/news/2019/06/update-house-spending-panel-restores-us-ban-gene-edited-babies> [<https://perma.cc/HV6E-SUTW>].

88. Consolidated Appropriations Act, 2016 § 749.

stages for germline gene therapy research.⁸⁹ The 2016 bill rider was initially removed from the 2020 spending bill as leaders of the spending panel expressed that they “wanted to spur a fuller debate on how the U.S. government should regulate the genetic modification of human sperm, eggs, or embryos” and that they were “concerned that the FDA rider might also hinder the development of potentially helpful therapies.”⁹⁰ However, the Appropriations Committee revisited the issue the next month and restored the bill rider language to the 2020 bill, suggesting that the issue be addressed by Congress more comprehensively than through the annual appropriations process.⁹¹

Although these federal funding restrictions and FDA regulations tie many hands, scientists are not explicitly prohibited from conducting the germline gene therapy research itself and are not entirely out of options when it comes to resources. Researchers may still receive funds for their research from private foundations, organizations, or individuals.⁹² Such funding is free of federal oversight, “which means that the government is limited in its ability to control the research plans of these studies should researchers choose to ignore consensus-driven ethics in the field of genomic editing.”⁹³

B. HUMAN GERMLINE GENOME EDITING AND PATENT LAW

In addition to federal legislation and regulation, patent law also plays a crucial role in innovation within the United States and elsewhere in the world. The patent system incentivizes the development and disclosure of technology and knowledge by granting inventors a potential financial reward, in the form of a temporary statutory right to exclude others, in exchange for revealing the inventor’s discoveries to the public.⁹⁴ In theory, the public then possesses enough information to expand upon and advance the original technology for the benefit of society.⁹⁵ This guarantee of protection, backed by federal law, is what drives inventors to risk vast amounts of time, research, and resources.⁹⁶

Patent law derives its power directly from Article I, Section Eight, Clause Eight of the Constitution which grants Congress the power “[t]o

89. See Jennifer M. Gumer, *Why Human Germline Editing Might Never Be Legal in the U.S.*, HASTINGS CTR.: BIOETHICS FORUM (Aug. 9, 2019), <https://www.thehastingscenter.org/why-human-germline-editing-might-never-be-legal-in-the-u-s/> [https://perma.cc/LL48-4HJE].

90. Kaiser, *supra* note 87.

91. *Id.*

92. Tracey Tomlinson, *A CRISPR Future for Gene-Editing Regulation: A Proposal for an Updated Biotechnology Regulatory System in an Era of Human Genomic Editing*, 87 *FORDHAM L. REV.* 437, 457 (2018).

93. *Id.*

94. 35 U.S.C. § 154(a)(1) (2018) (“Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States”); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974).

95. *Kewanee*, 416 U.S. at 480–81.

96. *Id.* at 480.

promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁹⁷ Under this grant of authority, Congress created and has continued to amend federal patent law, which is currently codified under Title 35 of the United States Code. To obtain a patent on a new invention (or innovation), the invention must meet certain patentability qualifications: it must be useful,⁹⁸ novel,⁹⁹ nonobvious,¹⁰⁰ and the specification portion of the application must adequately disclose the invention.¹⁰¹ Further, the subject matter of the invention must be eligible for patenting.¹⁰² The current standard for subject matter eligibility has been criticized for its lack of clear boundaries and has led to major roadblocks in the biotechnology and life sciences industries.¹⁰³ Thus, human germline genome editing will undoubtedly encounter hurdles in the patenting process when it comes to the subject matter eligibility requirement. However, given the ambiguity and controversy associated with the governing subject matter eligibility standards, this Comment largely focuses on this technology’s interplay with a separate patentability requirement, utility.

New inventions brought before the United States Patent and Trademark Office (USPTO) are dissected and evaluated in every which way, but moral and ethical considerations have been removed from the process for decades. The utility requirement for patent applications once encompassed “judicially identified standards of morality.”¹⁰⁴ Justice Story’s opinion in *Lowell v. Lewis* first articulated what is historically known as the moral utility doctrine.¹⁰⁵ He established the connection between morals and patent law by explaining that “[a]ll that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful,’ therefore, is incorporated into the act in contradistinction to mischievous or immoral.”¹⁰⁶ The moral utility doctrine was put to good use throughout the twentieth century as it prevented patent protection for numerous ethically questionable inventions.¹⁰⁷ Nonetheless, the moral utility doctrine’s

97. U.S. CONST. art. I, § 8, cl. 8.

98. See 35 U.S.C. § 101 (2018).

99. See *id.* § 102.

100. See *id.* § 103.

101. See *id.* § 112.

102. See *id.* § 101.

103. PRACTICAL LAW INTELLECTUAL PROP. & TECH., EXPERT Q&A ON PATENT ELIGIBILITY OF LIFE SCIENCES INVENTIONS (2019), Westlaw W-022-4626 (“Some experts have called the standards for determining patent eligibility under [s]ection 101 of the Patent Act incoherent. This ‘incoherence’ is particularly challenging for the life sciences industry . . .”).

104. Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 489 (2003).

105. *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568).

106. *Id.*

107. See Bagley, *supra* note 104, at 489. Some examples of ethically questionable inventions that were rejected based on the morality doctrine include “gambling machines and fraudulent articles.” *Id.* (footnotes omitted).

force slowly declined until the infamous case *Juicy Whip v. Orange Bang* solidified its obsolescence.¹⁰⁸ However, the emergence of ethically controversial technologies such as human germline genome editing will likely provide new support for restoring the moral utility doctrine.

Under the present patentability regime, numerous human *somatic* gene editing systems have succeeded in receiving patent protection, such as the CRISPR-Cas9 technology.¹⁰⁹ On the other hand, human *germline* genome editing will surely endure the same obstacles as, if not more than, those traditionally confronted by new biotechnology in achieving patent protection. But absent clarification of or amendment to the current patentability standards, it will likely be eligible for patent protection despite its highly controversial ethical, legal, and social concerns.¹¹⁰

V. PROPOSALS FOR INCREASED REGULATION

Gene editing technology was once viewed as a far-fetched scientific vision. It is now, however, a tangible reality. Human germline genome editing research has reached a significant point in development where human implementation may be considered by scientists as the next step. As such, there is now a need for increased and particularized regulation to control the future advancement and exposure of this biotechnology. Numerous countries have in place more restrictive heritable gene editing laws and regulations than the United States, with many even enforcing outright bans on such experiments.¹¹¹ While an outright ban would be the easiest way to put the flood of ethical and safety concerns at bay, it is not the

108. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366–67 (Fed. Cir. 1999) (“[T]he principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years. For example, years ago courts invalidated patents on gambling devices on the ground that they were immoral, but that is no longer the law.” (citations omitted)).

109. See, e.g., *Two Issued U.S. Patents Granted to Collectis for CRISPR Use in T-Cells*, BUS. WIRE (Feb. 13, 2018, 12:01 AM), <https://www.businesswire.com/news/home/20180212006461/en/> [<https://perma.cc/E7LU-BQH8>]. It is important to note that although many patents have already been granted on human somatic gene editing technology, the technology is not per se patent-eligible, and its eligibility status can still be changed. Patents are given a presumption of validity, see 35 U.S.C. § 282(a) (2018), however, that validity can be challenged in the courts. That said, there has not yet been a case challenging the patent eligibility of the CRISPR-Cas9 technology, so there exists the possibility that it could be judicially deemed ineligible for patent protection. See Noah C. Chauvin, *Custom-Edited DNA: Legal Limits on the Patentability of CRISPR-Cas9’s Therapeutic Applications*, 60 WM. & MARY L. REV. 297, 330–31 (2018).

110. Part V of this Comment discusses the application of the America Invents Acts (AIA) to human germline genome editing.

111. A 2014 survey reveals that “at least 29 countries around the world” enforce an outright ban on heritable gene editing experiments, with speculation that “the number of countries may be as high as 38 since the survey’s authors found that nine had ambiguous legal status.” Pete Shanks, *Moratorium on Germline Gains Momentum*, CTR. FOR GENETICS & SOC’Y (May 9, 2019), <https://www.geneticsandsociety.org/biopolitical-times/moratorium-germline-gains-momentum> [<https://perma.cc/K7TV-JM6H>]. Canada enforces one of the strictest bans on human germline genome editing under its 2004 Assisted Human Reproduction Act, which criminalizes such research and imposes fines of up to 500,000 Canadian dollars and the possibility of imprisonment for up to ten years. Assisted Human Reproduction Act, S.C. 2004, c 2, §§ 60–61 (Can.); see also Vogel, *supra* note 51.

only way and it may not be the best. Human germline genome editing possesses an astonishing potential for greatness, particularly the ability to eradicate many deadly genetic diseases, and imposing an outright ban would eliminate that potential. Rather, this potential can be preserved and the ethical and safety concerns can be addressed by implementing more restrictive and specialized regulations as opposed to an outright ban.

A. SPECIALIZED REGULATIONS FOR HUMAN GENE EDITING RESEARCH

The United States could exercise regulatory control and oversight over human germline genome editing through the use of specialized regulations tailored to specifically address research involving hereditary human gene editing. The government's current means of control are inadequate to effectively control the advancement of such unique and controversial biotechnology. The FDA is currently not permitted to acknowledge, let alone approve, applications relating to human germline genome editing.¹¹² However, the bill rider that imposes this restriction is losing more and more support, and it is possible that this restriction on the FDA will not be renewed in the upcoming year.¹¹³ That said, the only remaining restrictions on human germline genome editing would be the generalized FDA regulations for clinical testing and marketing, and that will not suffice. Furthermore, even if the bill rider is perpetually renewed, this technology carries with it highly controversial safety and ethical concerns that warrant specialized regulations.

One example of such specialized procedures that the federal government could use as a guide in developing its own regulations are those proposed by China's National Health Commission (NHC). Not long after Chinese researcher Dr. He shocked the world with the first gene-edited babies, China took remedial measures and drafted new regulations to increase oversight in this area of biotechnology.¹¹⁴ In February 2019, China's NHC released a draft of proposed new regulations for commentary which, among other things, would require any research on "high risk" biomedical technology, including human gene-editing, to be reviewed and approved by China's National Health Agency.¹¹⁵ In addition, the proposed regulations would require consideration of "the scientific necessity and rationale of the research, the qualifications of the researcher and the institution, and the protocols to mitigate public health

112. See Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 749, 129 Stat. 2242, 2283 (2015).

113. The bill rider amendment was initially removed from the 2020 bill as panel members expressed a need for "a fuller debate on how the U.S. government should regulate" human genome germline editing. Kaiser, *supra* note 87.

114. See *China Tightens Regulations After Gene-Editing Scandal*, TELESUR (Feb. 27, 2019), <https://www.telesurenglish.net/news/China-Tightens-Regulations-After-Gene-Editing-Scandal-20190227-0010.html> [<https://perma.cc/DB74-TPFM>].

115. *Id.*

risks.”¹¹⁶

The United States would benefit greatly from implementing similar regulations. Research that involves hereditary human gene editing or modifying human embryos should be required to be reviewed and approved by the National Institutes of Health (NIH), or any other suitable regulatory agency.¹¹⁷ The NIH’s review should go beyond the FDA’s evaluation for safety and efficacy and incorporate the considerations proposed by China’s NIC into a balancing test. This balancing test would reach so far as to weigh the ethical and societal consequences of the use of high-risk biotechnology, and for human germline genome editing in particular, it would identify, among other things, the risks and consequences of off-target edits and mosaicism. Moreover, the current system employed by the Department of Health and Human Services Office for Human Research Protections (OHRP)¹¹⁸ for specific oversight of research involving human subjects could continue to perform its present functions, as well as assume the responsibility of ensuring compliance with the proposed regulations.¹¹⁹

Regulations tailored specifically to address research involving hereditary human gene editing or modifying human embryos could also serve as a means to address the treatment-versus-enhancement matter. Supplemental provisions could be added to delineate the distinction between the two technological uses and to impose more stringent restrictions on, or to prohibit entirely, the research and use of germline genome editing for enhancement purposes. For example, the regulations could include language mirroring India’s Ethical Guidelines for Biomedical Research on Human Subjects, which prohibits eugenic genetic modification “for selection against personality, character, formation of body organs, fertility, intelligence[,] and physical, mental and emotional characteristics.”¹²⁰ The United States could also take a reverse approach in regulating the treatment-versus-enhancement matter, similar to that taken by the French government. This would involve regulations prohibiting the modification

116. Letter from Douglas A. Melton, President, Int’l Soc’y for Stem Cell Research, to Ma Xiaowei, Dir., Nat’l Health Comm’n & Med. Admin. Bureau (Mar. 27, 2019), <https://www.isscr.org/docs/default-source/policy-documents/isscr-comments-re-china’s-new-bio-medical-technology-rules-27-march-2019.pdf?sfvrsn=2> [https://perma.cc/29XW-9PLU] [hereinafter Letter from Douglas A. Melton].

117. The NIH currently serves as a major funding vehicle for a wide range of innovative biomedical research and could serve as a gatekeeper for approval of high-risk biotechnology research. See *About NIH: What We Do*, NAT’L INSTS. HEALTH, <https://www.nih.gov/about-nih/what-we-do> [https://perma.cc/F6D3-MM8X].

118. The OHRP presently, among other things, “provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research.” *Office for Human Research Protections*, U.S. DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/ohrp/> [https://perma.cc/6MH5-5SXV].

119. Letter from Douglas A. Melton, *supra* note 116.

120. INDIAN COUNCIL MED. RESEARCH NEW DELHI, ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH ON HUMAN SUBJECTS 45 (2000), http://www.rimsalabad.yolasite.com/resources/HSD_Resources_Ethical_Guidelines_for_Biomedical_Research_on_.pdf [https://perma.cc/N3AW-DFD8].

of human germline genomes but invoking an exception to the prohibition specifically for human germline genome editing research having a legitimate purpose of treating or preventing genetic diseases.¹²¹

To further emphasize the seriousness of the medical and ethical risks at stake with human germline genome editing, the proposed specialized regulations should include penalties, punishments, or both for their violation. Consequences would be determined based on the scope of the violation and could range from fines and blacklisting from grant applications to criminal prosecution.¹²² Lastly, given the degree and nature of concerns associated with human germline genome editing, the proposed regulations should be formed through a transparent, public process. Incorporating the public in the creation of the proposed regulations would allow a general consensus to be formed as to values that would be later emphasized by the reviewing regulatory body. Public opinions need to be considered at such a beginning stage because the proposed reviewing regulatory body is unlikely to look to the public for its input on a case-by-case basis, but it will rely on the public's prioritized moral standards and values when making regulatory decisions.¹²³ Overall, transparency would allow "the international community to harmonize rules to prevent rogue scientists from performing additional unethical experiments involving the modification of the human germline,"¹²⁴ and it would respect fundamental democratic values by giving society the opportunity to participate, albeit in a limited form, in the creation of the regulatory system that arguably will determine the genetic makeup of future human lineages.¹²⁵

B. REGULATION THROUGH PATENT LAW

Another avenue through which the federal government could exercise control over the future advancements in human gene editing technology

121. See CODE CIVIL [C. CIV.] [CIVIL CODE] art. 16-4 (Fr.); see also Yotova, *supra* note 75, at 60 ("[Article 16-4 of the French Civil Code] prohibits the modification of genetic traits with the purpose of modifying the germ line, creating an exception from the prohibition for research aimed at the prevention or treatment of genetic diseases.").

122. The regulations proposed by China's NHC suggest consequences of the same nature for violations of the regulations. See Jef Akst, *China Proposes New Gene-Editing Regulations*, SCIENTIST (Feb. 27, 2019), <https://www.the-scientist.com/news-opinion/china-proposes-new-gene-editing-regulations-65544> [<https://perma.cc/H4JB-HATX>]. The possible violations should be equal to or harsher than those imposed for FDA violations (since this argument largely relies on the idea that FDA regulation is not strict enough or in-depth enough for this controversial level of biotechnology). For information on the types of enforcement actions taken for FDA violations, see *Types of FDA Enforcement Actions*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions> [<https://perma.cc/CPG5-6EQU>] (last updated Nov. 6, 2017).

123. As with the proposed regulatory scheme, the public currently does not have the ability to participate on a case-by-case basis in the FDA's approval processes because "the FDA does not have a statutory mandate to consider public views on the intrinsic morality of a technology when deciding whether to authorize clinical trials." NAT'L ACADS. SCIS., ENG'G, & MED., *supra* note 5, at 134.

124. Letter from Douglas A. Melton, *supra* note 116.

125. See Cary Coglianese et al., *Transparency and Public Participation in the Federal Rulemaking Process: Recommendations for the New Administration*, 77 GEO. WASH. L. REV. 924, 926-34 (2009).

is patent law. Patent law has long been used to shape the path of technological development and to control the introduction of groundbreaking research. While patent law may not afford the full degree of control necessary, it could provide an indirect means for Congress to prevent the premature advancement of human germline genome editing. Patents are critically important in the biotechnology industry since this field is primarily research-based. Generally, a much greater amount of costs and effort are put into the research and development (R&D) phase in the biotechnology industry than in other industries.¹²⁶ As a result, substantial funding becomes crucial in recoup the amounts expended in developing the biotechnology. Additionally, copying by competitors is a weighty concern in this industry because the technology that required extreme amounts of resources for its original inventor can typically be easily duplicated, or reverse engineered, at a comparably negligible cost to any competitor.¹²⁷ This leads to great importance placed on patents to protect the underlying research and ensure that the entities invested in the biotechnology's original development are those that reap its commercial benefits in the market.¹²⁸ For human germline genome editing in particular, this concept is amplified since the prohibition on federal funding forces researchers to rely on funding solely from private sources or the states.¹²⁹ Ultimately, this critical interplay supports the proposition that patent law can be utilized to slow down and control the advancement of human germline genome editing by diminishing the opportunity for commercial investment and protection of research, at least until the safety and ethical concerns are resolved.¹³⁰

1. A Limited Revival of the Morality Doctrine

With the abrupt advances in human germline genome editing research, the scientific community and general public have been overwhelmed with profound ethical concerns. It is inevitable that this controversial technology will soon seek patent protection and one way the courts, or even Congress, can utilize the patent system to control its development is through the revival of the moral utility doctrine. The reestablishment of a limited role of morality in our patent system would further align the United States' patent laws with those of foreign countries. For example,

126. Studies have shown that the ratio of total R&D expenditures to total revenue is between approximately 40% and 50% in the biotechnology industry, while the ratio hovers around 13% for the pharmaceutical industry and 5% for the chemical industry. MICHAEL SZYCHER, *COMMERCIALIZATION SECRETS FOR SCIENTISTS AND ENGINEERS* 239 (2017).

127. *Why Patents Are the Lifeblood of Biotech Companies*, BIOSPACE (Apr. 26, 2016), <https://www.biospace.com/article/around-the-web/why-patents-are-the-lifeblood-of-biotech-companies/> [<https://perma.cc/3VQS-2LGD>].

128. *Id.*

129. See Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 749, 129 Stat. 2242, 2283 (2015).

130. This approach has already been taken in Russia, which in 2014 modified its Civil Code to prohibit the patentability of methods of modifying the genetic integrity of the human germline. GRAZHDANSKII KODEKS ROSSIISKOI FEDERATSII [GK RF] [Civil Code] art. 1349(4)(2) (Russ.).

the European patent system does not allow patents to be granted for “inventions the publication or exploitation of which would be contrary to *ordre public* or morality.”¹³¹ Negligible guidance is provided in the European Patent Office’s Guidelines for Substantive Examination,¹³² yet examiners have successfully worked under this morality provision since its enactment in 1973.¹³³ Critics may argue that the invocation of moral considerations into United States patent law is impractical or would disrupt the functioning of the current system. But those arguments can be settled simply by observing the success of, and even the benefits afforded to, other countries who have longstanding laws excluding from patentability inventions contrary to morality.¹³⁴

Renewal of the moral utility doctrine would impact human germline genome editing technology at the outset of its course through the patenting process. If this technology was presented to the USPTO today and evaluated under the moral utility doctrine, it would likely not be deemed patentable. The concept of editing heritable human genes raises ethical concerns as extreme as the undermining of our humanity.¹³⁵ Moreover, these ethical controversies extend beyond just the individual treated or even present-day society; instead, they implicate the future of all of humanity. And given the nature and quantity of moral concerns, it would be improper for human germline genome editing technology to be granted patent protection under the moral utility doctrine. This is not to say that such novel technology would never be eligible for patent protection. Rather, if the majority of the scientific community and general public came to a consensus regarding the ethical concerns, and the federal and state governments ironed out a means to effectuate the details of that consensus, human germline genome editing could eventually surmount the boundaries to patent protection imposed by the moral utility doctrine.

The moral utility doctrine could also be used to draw the line between treatment and enhancement. Many people are comfortable with the idea of using human germline genome editing to eradicate deadly diseases; however, when it comes to using this technology to enhance human traits (i.e., height, strength, intelligence), a new level of unease forms in the pits

131. Convention on the Grant of European Patents (European Patent Convention) art. 53(a), Oct. 5, 1973, 1065 U.N.T.S. 16208.

132. EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE, pt. G, ch. II, § 4.1 (2019), [http://documents.epo.org/projects/babylon/eponet.nsf/0/8654640290C2DBE7C12584A4004D2D9A/\\$File/epo_guidelines_for_examination_2019_hyperlinked_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/8654640290C2DBE7C12584A4004D2D9A/$File/epo_guidelines_for_examination_2019_hyperlinked_en.pdf) [<https://perma.cc/SM33-PU3X>] (explaining that the morality provision “is likely to be invoked only in rare and extreme cases”).

133. See Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL’Y 247, 257 (2000).

134. Examples of countries that implement patent systems containing morality-based patent eligibility bars include Egypt, France, India, Japan, Mexico, Thailand, members of the African Intellectual Property Organization, members of the European Patent Convention, and many others. See Shamnad Basheer et al., *Exclusions from Patentability and Exceptions and Limitations to Patentees’ Rights*, WORLD INTELL. PROP. ORG., annex IV, 43–73 (2010), https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex4.pdf [<https://perma.cc/3HPL-99LL>].

135. Sandel, *supra* note 54.

of many stomachs. Should the technology develop and societal concerns fade, allowing the human germline genome editing for the treatment and prevention of genetic diseases to become eligible for patent protection, the moral utility doctrine could still be utilized to reject patent applications for forms of the technology that serve the purpose of human enhancement rather than treatment.

The general proposition of reviving the moral utility doctrine in patent law is not a new one.¹³⁶ Scholars have been publishing opinions and theories on the subject since the downfall of the doctrine following the case of *Juicy Whip*,¹³⁷ and one of the most prominent arguments against reintroducing moral considerations in patent law is worth discussing.¹³⁸ There is inherent difficulty in defining what is morally acceptable and what is morally unacceptable.¹³⁹ One individual's moral standards and beliefs will inevitably be diametrically opposed to another individual's moral perspectives. And with this comes the concern that situations will arise in which the subjective perspectives of those making the patentability decisions may not align with the perspectives of society as a whole.¹⁴⁰ Strong opinions and judgment will always be present when morals are at issue, but this has not been and should not be the reason for discarding moral considerations entirely.

Courts and legislatures could restore the moral utility doctrine in a limited manner and could implement a system of oversight to assure final impartial and appropriate decision making. Under the current system, when a patent application for new technology is rejected, the applicant has the option to appeal the patent examiner's final decision to the Patent Trial and Appeal Board (PTAB) and present an argument for why the technology does in fact qualify for patent protection.¹⁴¹ If the moral utility doctrine were revived, this appeal system could be altered, just slightly, to address the concern around the subjective moral perspectives of the patent examiner. In cases where an application is rejected based on the moral utility doctrine, the PTAB could invite outside experts to submit their opinions to the panel in amicus briefs.¹⁴² The group of experts

136. See generally Bagley, *supra* note 104, at 488–93; Andrew R. Smith, *Monsters at the Patent Office: The Inconsistent Conclusions of Moral Utility and the Controversy of Human Cloning*, 53 DEPAUL L. REV. 159, 199–201 (2003).

137. See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366–67 (Fed. Cir. 1999).

138. See Benjamin D. Enerson, Note, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 708 (2004); Gary Gregory, Note, *What's Immoral About Monsanto?: Strengthening the Roots of the Moral Utility Requirement by Amending the U.S. Patent Act*, 21 CARDOZO J. INT'L & COMP. L. 759, 771 (2013).

139. See Bagley, *supra* note 104, at 489.

140. See Enerson, *supra* note 138, at 690.

141. See 35 U.S.C. § 134(a) (2018).

142. The current patent system does not explicitly contemplate a procedure involving the submission of third-party amicus briefs during appeals to the PTAB, though there has been one instance in which the PTAB invited amicus briefing before a hearing. See *Mylan Pharms. Inc. v. Saint Regis Mohawk Tribe*, No. IPR2016-01127, 2017 WL 5067421, at *1 (P.T.A.B. Nov. 3, 2017) (“[W]e authorize briefing from any other *amici curiae*, which shall be no more than 15 pages . . .”). Although the invitation for briefing was for an *inter*

would ideally be composed of both those with extensive knowledge of the particular technology in the case and those qualified in the areas of ethics and morals.¹⁴³ The PTAB's final decision would thus be aided by those most educated in the relevant fields of technology and ethics. The revival of the moral utility doctrine and the accompanying adjustments to the current appeal process may add another layer of complexity to the already complicated structure of the patent system. But as technology advances, the legal system should be responsive and adapt when necessary to ensure justice.

2. Patent Ineligibility Under the America Invents Act

It is worth mentioning that there is another area in patent law that could potentially be utilized for control over human germline genome editing. The Leahy–Smith America Invents Act (AIA) is a federal statute that reformed United States patent law in 2011.¹⁴⁴ The AIA removed human organisms from patent-eligible subject matter by including a provision that states, “no patent may issue on a claim directed to or encompassing a human organism.”¹⁴⁵ It can be argued that human germline genome editing would not be patent-eligible subject matter under this provision because with germline editing specifically, the substantial DNA mutations are expressed not only in the treated germ cell but also in every single cell in the offspring.¹⁴⁶ Thus, by altering the DNA in every future cell in the offspring's body, the technology is arguably directed to a human organism.¹⁴⁷ However, unlike with the revival of the moral utility doctrine, a ruling that human germline genome editing is not patent-eligible subject matter under this provision of the AIA would permanently prevent this technology from receiving patent protection. Overall, while patent law may not afford the full degree of control necessary, it could

partes review (the PTAB's review of the validity of a granted patent) rather than for review of a patent application rejection, it nonetheless demonstrates the PTAB's ability and willingness to administer such action. See Kevin E. Noonan, *Amicus Briefs Filed in Mohawk Tribe's Motion to Dismiss IPRs*, PATENT DOCS (Jan. 28, 2018, 11:59 PM), <https://www.patentdocs.org/2018/01/amicus-briefs-filed-in-mohawk-tribes-motion-to-dismiss-iprs.html> [<https://perma.cc/C4RT-PTF8>] (noting that “everyone (including the Patent Trial and Appeal Board) consider[ed]” the invitation for briefing “an unprecedented administrative action”); Dennis Crouch, *PTAB Request Amicus Support for its Decision on Immunity*, PATENTLY-O (Nov. 6, 2017), <https://patentlyo.com/patent/2017/11/request-decision-immunity.html> [<https://perma.cc/X25M-8PZD>] (reporting that “[i]n what appears to be a first, the Patent Trial & Appeal Board (PTAB) has requested briefing from [amici curiae]”).

143. For human germline genome editing in particular, experts would likely be needed in the areas of human genetics, reproductive medicine, etc.

144. See Leahy–Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat. 340 (2011).

145. *Id.*

146. See Chauvin, *supra* note 109, at 330–31. In arguing that human germline genome editing should not be patentable, Chauvin writes that “[a]n invention designed to fundamentally alter the DNA in every cell in the body is clearly ‘directed to . . . a human organism.’” *Id.* (quoting Leahy–Smith America Invents Act § 33(a)). Chauvin goes on to hypothesize that “serious ethical concerns will likely prevent the USPTO from issuing patents on any technology that could so fundamentally alter a person's genetic code.” *Id.*

147. See *id.*

provide an indirect means for Congress to prevent the premature advancement of human germline genome editing.

VI. CONCLUSION

The potential value of human germline gene editing technology is undeniable as it possesses the ability to manipulate human DNA and create certain traits that are inheritable to future generations. However, it is this precise ability that renders the technology so troubling and serious. Without carefully defined laws and regulations, scientists may step outside the bounds of society's current comfort zone. And the results of any such premature experimentation would have a permanent presence in the genetic makeup of future lineages.

With great power comes great responsibility. And awareness of future responsibility entails present consideration of the means of control available and needed. This Comment argues that the United States currently lacks sufficient laws and regulations to oversee the development of human germline genome editing technology. The Dickey-Wicker Amendment's restriction on funding would apply to this technology but would be limited only to research and experiments that utilize federal funding. Consequently, privately funded research and experiments are outside this form of governmental control. Moreover, the FDA regulations that impose barriers on gene therapy products in reaching clinical trials and the marketing stages are burdensome but do not cover the early stages of experimentation and do not impose the harsh level of scrutiny necessary for such controversial technology. Additionally, without more clarification on the patentability standard for biotechnology, or the application of the AIA to human germline genome editing technology, the current patent system will fuel the technology's premature expansion by allowing it to receive patent protection and thus funding.

The regulations proposed in this Comment would ensure that the potential benefits and harms of human germline genome editing and other high-risk biotechnology are carefully evaluated in the early stages of its development. The proposed regulations involve considerations of moral and ethical implications and take into account the collective viewpoints of society. The morality analyses would either be based on society's predetermined ethical values or involve a process that invites the outside assessments of experts who have extensive knowledge of society's opinions. Additionally, under the proposed regulations, any initial opposition to human germline genome editing would not function as a permanent bar. If societal perspectives evolve and the current safety and ethical concerns become a thing of the past, human germline genome editing research could be approved, and the technology could be eligible for patent protection. As explained by a transnational group of experts on the ethical implications of scientific advancements worldwide, "[s]ocieties have the authority to regulate science, and scientists have a responsibility to obey

the law.”¹⁴⁸ Human germline genome editing raises a multitude of widespread and deeply rooted questions surrounding the fate of humanity, all of which thwart justifying its present-day use. This Comment hopes to encourage individuals and the government to think critically about the future of this technology in the United States and to consider prompt implementation of regulations to control its development and exposure.

148. HINXTON GRP., CONSENSUS STATEMENT (Feb. 24, 2006), <http://www.hinxtongroup.org/docs/Hinxton%202006%20consensus%20document.pdf> [<https://perma.cc/VK2C-8BCY>].

