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Gene Editing and the Rise of Designer Babies

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NOTES

Gene Editing and the Rise of Designer Babies

ABSTRACT

Nearly as long as human beings have existed on this earth, many people have sought out the ideal of perfecting their population: infanticide in Sparta during the Hellenistic era; compulsory sterilization in the 1920s in the United States; and the unimaginable atrocities of the Holocaust in the 1940s in Europe. The goal of alleged perfection leaves many hesitant to repeat the mistakes of our past. Today, a new frontier of science has emerged, gene editing using CRISPR-Cas9, reigniting ethical debate as to how far humans should go in manipulating the population.

While many proponents herald this technology as a potential for eradicating devastating genetic disease, some critics fear that it presents an opportunity to pre-select “desirable” traits in offspring, which is expounded by a lack of clear scientific and ethical regulations in the United States and abroad. Though the National Academies of Science and Medicine recently began an initiative to address the implications of this technology, this body can only provide a recommendation. This Note looks to the technology, historical eugenics’ concerns, domestic and foreign law, and the recommendations of the Academies, in proposing a two-part solution to address the concerns surrounding “designer babies”: reinforcing United States research laws and revising the Universal Declaration on the Human Genome and Human Rights.

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I. INTRODUCTION

Like the genetically “perfect” society in the film *Gattaca*¹ or the genetically modified “Indominus Rex” in *Jurassic World*,² gene editing inundates popular culture.³ How can science make individuals stronger, eradicate disease, and obtain societal perfection? While such concepts seem best suited for the science-fiction genre, editing human genes is no longer a hypothetical scenario. Rather, the reality of modern gene editing now focuses not on whether science *could*

1. GATTACA (Jersey Films 1997).

2. JURASSIC WORLD (Amblin Entertainment, Legendary Pictures 2015).

3. This Note uses “gene editing” or “genetic modification” to refer to the narrower concept of genome editing or human germline gene editing, also referred to as human germline modification, “deliberating changing the genes passed on to children and future generations . . .”. *About Human Germline Gene Editing*, CTR. FOR GENETICS AND SOC'Y, <http://www.geneticsandsociety.org/article.php?id=8711> (last visited Feb. 6, 2017) [<https://perma.cc/PYZ9-RYQJ>] (archived Feb. 6, 2017).

genetically “perfect” an individual, but instead, whether science *should* do so.

Modern gene editing evolved, in part, from a variety of scientific advancements in embryonic research. Previously, gene editing conversations, in terms of potential offspring, often centered on the techniques of pre-implantation genetic screening (PGS) and pre-implantation genetic diagnosis (PGD)—two techniques physicians use during in vitro fertilization (IVF) to achieve pregnancy in patients.⁴ These processes screen “embryos for genetic predispositions to rare disorders as well as prevalent and treatable diseases. . . .”⁵ The screening results determine whether abnormalities are present in the embryos and allow the prospective parents to determine whether to implant specific embryos.⁶

On the one hand, the advantage of such technology is obvious: it eliminates much of the risk of having a child born with a devastating debilitating disease,⁷ which could present the parents with an unanticipated emotional and/or financial hardship. On the other hand, some critics argue that purposefully avoiding the implantation of embryos that are genetically predisposed to evolve into a child with a disability only perpetuates misconceptions that individuals with disabilities have a lesser quality of life.⁸ Despite this discord among

4. For a background on Preimplantation Genetic Diagnosis and Screening, including its uses and limitations, see Jaime King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL’Y & ETHICS 283, 290–301 (2008).

5. Gregory Katz & Stuart O. Schweitzer, *Implications of Genetic Testing for Health Policy*, 10 YALE J. HEALTH POL’Y L. & ETHICS 90, 93 (2010).

6. See King, *supra* note 4, at 291 (“After getting the test results, the clinician usually transfers two to three embryos that meet the parents’ approval to the uterus in hopes of establishing pregnancy. Embryos with undesired genes are typically discarded or donated to research.”).

7. See, e.g., JOYCE HARPER, PREIMPLANTATION GENETIC DIAGNOSIS 151 (2d ed. 2009):

PGD, followed by implantation of disease-free embryos, offers couples at high risk of transmitting a serious genetic disorder a possibility of seriously diminishing or avoiding the risk of disease in their offspring. Also, couples at high risk for (repeated) spontaneous pregnancy loss because of a structural chromosome abnormality in one of the spouses may benefit from PGD. Finally, many couples opt for PGD because they experience a combined genetic and fertility problem and require medically assisted reproduction anyway.

8. Several groups have criticized PGD for a variety of reasons. Feminists feared women would be prosecuted for declining the technology or that a child born with disabilities could sue his or her mother for failing to undergo testing. Additionally, disability activists and scholars worry that the technology may continue “to perpetuate negative myths about the quality of life for people with disabilities and their families.” See Kimberly M. Mutcherson, *Making Mommies: Law, Pre-Implantation Genetic Diagnosis, and the Complications of Pre-Motherhood*, 18 COLUM. J. GENDER & L. 313, 324 (2008).

bioethicists and disability activists in this arena, gene editing has moved beyond the immensely complex area of disability prevention to include the pre-selection of a child's gender by determining the sex prior to implantation.⁹ Still the most astonishing recent development occurred in April 2015, when Chinese scientists revealed that they used a new technology known as CRISPR-Cas9 to, for the first time, edit deoxyribose nucleic acid (DNA) in human embryos.¹⁰

With such capabilities, many critics of the CRISPR-Cas9 technology are concerned that it will eventually lead to a market for *designer babies*, children whose traits, including height, eye color, and even athletic ability, are pre-selected by their parent-consumers.¹¹ In discussing the implications of this technology, bioethicist George Annas noted that “[w]hen we talk about [sic] ‘better,’ we’re making very real value judgments about our genetic code and its worth.”¹² Perhaps shockingly to some, such a concern is not just theoretical conjecture. In one study, 12 percent of parents surveyed claimed they would abort a fetus that was predisposed to being obese.¹³

The international community lacks uniformity in regulating gene-editing technology, no more so than the three countries at the forefront of the discussion. In 2015, within the confines of a federal spending bill, the U.S. Congress effectively prohibited such technology in federally-funded research.¹⁴ The United Kingdom, by contrast, formally granted

9. See Gautam Naik, *A Baby, Please. Blond, Freckles – Hold the Colic*, WALL ST. J. (Feb. 12, 2009, 12:01 AM), <http://www.wsj.com/articles/SB123439771603075099> [<https://perma.cc/2ZKL-9AF2>] (archived Jan. 22, 2017) (discussing a Los Angeles clinic claiming that it would be offering couples the ability to pick gender and certain physical attributes for their future children).

10. David Cyranoski & Sara Reardon, *Chinese Scientists Genetically Modify Human Embryos*, NATURE (Apr. 22, 2015), <http://www.nature.com/news/chinese-scientists-genetically-modify-human-embryos-1.17378> [<https://perma.cc/JTE9-ESAC>] (archived Jan. 22, 2017).

11. See Rob Stein, *British Scientists Seek Permission To Edit DNA In Human Embryos*, NPR (Sept. 18, 2015 11:44 AM), <http://www.npr.org/sections/health-shots/2015/09/18/441408880/british-scientists-seek-permission-to-edit-dna-in-human-embryos> [<https://perma.cc/H6E7-SXMQ>] (archived Jan. 22, 2017) (“Critics say that could open the door to accidentally introducing a new disease or to trying to genetically engineer the human race and create ‘designer babies,’ in which parents pick the traits of their children.”).

12. Kevin Loria, *It's Time for an Uncomfortable Discussion about What it Really Means to Engineer a 'Designer Baby'*, BUS. INSIDER AUSTL. (Aug. 13, 2015, 12:49 AM), <http://www.businessinsider.com.au/what-the-designer-baby-discussion-really-means-2015-8> [<https://perma.cc/6Q5N-76QZ>] (archived Jan. 22, 2017).

13. LORI B. ANDREWS ET AL., GENETICS: ETHICS LAW AND POLICY 247 (4th ed. 2015).

14. See Mike Orcutt, *The Unintended Consequences of Congress's Ban on Designer Babies*, TECH. REV. (Aug. 26, 2016), <https://www.technologyreview.com/s/602219/the-unintended-consequence-of-congresss-ban-on-designer-babies/> [<https://perma.cc/53B2-5D8M>] (archived Jan. 22, 2017) (discussing the effects of the United States' regulation of gene-editing techniques); see also Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 749, 129 Stat. 2283 (2015) (“None of the funds made available by this Act may be used . . . in research in which a human embryo is intentionally created or modified to include a heritable genetic modification.”).

Kathy Niakan of the Francis Crick Institute in London permission to conduct gene-editing research in human embryos.¹⁵ The research team underwent two separate approval processes, one from the Human Fertilisation and Embryology Authority in February 2016, and one from the National Health Service Health Research Authority in May 2016.¹⁶ Meanwhile, the country that sparked the recent designer-baby conversation, China, remains limited only by non-binding national guidelines prohibiting “the implantation of modified human embryos for reproductive purposes since 2003.”¹⁷

Such rapidly changing technological advances and the lack of an international consensus on how to regulate these advances have moved science and society into uncharted territory. Consequently, in December of 2015, the United States National Academy of Sciences and the National Academy of Medicine, along with the Chinese Academy of Sciences and the Royal Society of the United Kingdom, hosted the International Summit on Human Gene Editing (International Summit), “conven[ing] experts from around the world to discuss the scientific, ethical, and governance issues associated with human gene-editing research.”¹⁸ Upon concluding the International Summit, the second phase, a consensus study, commenced, which resulted in a report that came out in February 2017.¹⁹ This study demonstrates the importance of international uniformity and cooperation in determining the scientific and ethical limits of the technology, and the study may act as a tool to guide the future development of gene-editing regulations.

This Note conducts a comparative analysis of foreign law and, more importantly, critiques the current lack of an international consensus. Part II provides an overview of the CRISPR-Cas9 technology and its potential benefits, as well as the varying opinions in the scientific community of the technology’s capabilities. Part III

15. Fergus Walsh, *Gene editing technique could transform future*, BBC HEALTH (June 6, 2016), <http://www.bbc.com/news/health-36439260> [<https://perma.cc/8VEY-JJLB>] (archived Jan. 22, 2017).

16. See Ben Spencer, *British scientists will genetically modify embryos by the end of the year in bid to understand why women miscarry*, DAILY MAIL (May 27, 2016), <http://www.dailymail.co.uk/health/article-3613080/British-scientists-genetically-modify-embryos-end-year-bid-understand-women-miscarry.html> [<https://perma.cc/2UQ6-KTFW>] (archived Jan. 22, 2017) (outlining the approval process and research of the Francis Crick Institute and anticipated upcoming research).

17. See Douglas Sipp & Duanqing Pei, *Comment: Bioethics in China: No wild east*, 534 NATURE 465 (June 22, 2016), <http://www.nature.com/news/bioethics-in-china-no-wild-east-1.20116> [<https://perma.cc/SMY3-Y68Y>] (archived Jan. 22, 2017) (discussing the perception that China is without regulation for embryonic-stem-cell research).

18. *International Summit*, NAT’L ACADS. SCIS., ENG’G, & MED., <http://nationalacademies.org/gene-editing/Gene-Edit-Summit/> (last visited Jan. 26, 2017) [<https://perma.cc/5V8M-AFXX>] (archived Jan. 26, 2017).

19. *Id.*

briefly discusses some of the ethical concerns surrounding gene editing by looking at two of the more infamous eugenics movements, the forced sterilization laws of the early 1900s in the United States and Hitler's attempt to promote a "superior race" in Nazi Germany. Part IV compares the current gene-editing laws in the United States, the United Kingdom, and China in order to illustrate the legal variance and complexity in regulations among nations. Part V then discusses the International Summit and Consensus Study of the National Academies of Science.

In recognizing the variance in the international regulations, concerns of the scientific community, and ambiguity in the Academies' recommendation, Part VI proposes a two-part solution to remedy the lack of enforceable gene-editing regulations, both within the United States and internationally. First, the United States should revise its laws to promote the progress of scientific research in this field while restricting ethical concerns. Second, given the administrative difficulties in enacting a binding treaty and the current political climate, a more flexible mechanism for establishing an international consensus should be employed: the revision of the Universal Declaration on the Human Genome and Human Rights.

II. THE CRISPR-CAS9 TECHNOLOGY: BACKGROUND, BENEFITS, AND LIMITATIONS

CRISPR-Cas9 inundates current news coverage in both the scientific and mainstream media. A simple Google search of "CRISPR-Cas9" as of January 2017 will render some 481,000 results,²⁰ and the technology has even appeared on popular television shows. In the series finale of the "X-Files" reboot, CRISPR-Cas9 played a role in a dramatic alien conspiracy.²¹ While a CRISPR-Cas9 alien conspiracy may seem laughable to many, the fear of the rise of designer babies does not, creating tension and debate among scientific scholars and ethicists. David King, director of Human Genetics Alert, claims that permitting the use of this technology in research experiments "is the first step in a well mapped-out process leading to [genetically edited] babies, and a future of consumer eugenics."²² But, supporters of the technology believe that the information gained from further CRISPR-

20. Author search of "CRISPR-Cas9" conducted on January 26, 2017.

21. Rebecca Harrington, *The creator of 'The X-Files' says this is the coolest real science fact he learned from the reboot*, BUS. INSIDER (June 9, 2016, 1:07 PM), <http://www.businessinsider.com/x-files-creator-chris-carter-crispr-2016-6> [<https://perma.cc/EWN9-MTVQ>] (archived Jan. 26, 2017) (discussing how the recent season of X-Files tied CRISPR-Cas9 technology into its alien conspiracy plotline).

22. James Gallagher, *Scientists get "gene editing" go-ahead*, BBC (Feb. 1, 2016), <http://www.bbc.com/news/health-35459054> [<https://perma.cc/L3NT-6FXB>] (archived Jan. 26, 2017).

Cas9 research will provide invaluable insight as to which genes are vital for healthy development in humans.²³ In order to address the disagreement, this Part first briefly describes the CRISPR-Cas9 technology, then looks at its purported benefits, and finally discusses the debate among scientists as to the limitations of the technology.

A. *The CRISPR-Cas9 Technology and Gene Editing*

CRISPR, Clustered Regulatory Interspaced Short Palindromic Repeats, are a critical component of an individual's defense system against bacteria.²⁴ In simplistic terms, CRISPR contain "sequences of genetic code," which include interim sequences known as spacer sequences, which code for past bacterial invaders in the body.²⁵ These spacer sequences help "the cell detect and destroy [past bacterial] invaders" upon their return,²⁶ with CRISPR acting as a guide to specific sequence of DNA.²⁷ Cas9, "a CRISPR-associated protein. . . that is programmed by small [ribonucleic acids] to cleave DNA,"²⁸ commences the actual gene editing. It binds to the sequence of DNA of interest "and cuts it, shutting the targeted gene off."²⁹

Scientists are able to program these sequences so precisely that commentators have likened the technology "to a word processor, capable of effortlessly editing a gene down to the level of a single letter."³⁰ CRISPR can find the right sequence even when searching through billions of DNA pairs, and can do so extremely accurately.³¹

23. See JV Chamary, *GM Human Embryos Won't Create Designer Babies*, FORBES (Feb. 16, 2016, 10:00 AM), <http://www.forbes.com/sites/jvchamary/2016/02/16/embryo-gene-editing/#563151661e40> [<https://perma.cc/9AZM-YGXC>] (archived Jan. 26, 2017) (quoting Dr. Kathy Niakan of the Francis Crick Institute in London to whom the United Kingdom Human Fertilisation and Embryology Authority recently granted a license in order to edit genes in embryos).

24. *Questions and Answers About CRISPR*, BROAD INST., <https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/questions-and-answers-about-crispr> (last visited Jan. 26, 2017) [<https://perma.cc/9WXY-95BP>] (archived Jan. 26, 2017).

25. *Id.*

26. *Id.*

27. *Id.*

28. Alex Reis et al., *CRISPR/Cas9 and Targeted Genome Editing: A New Era in Molecular Biology*, NEW ENGLAND BIOLABS INC. (2014), <https://www.neb.com/tools-and-resources/feature-articles/crispr-cas9-and-targeted-genome-editing-a-new-era-in-molecular-biology> [<https://perma.cc/Y9YR-LQVC>] (archived Feb. 19, 2017).

29. BROAD INST., *supra* note 24.

30. Jennifer Kahn, *The Crispr Quandary*, N.Y. TIMES (Nov. 9, 2015), http://www.nytimes.com/2015/11/15/magazine/the-crispr-quandary.html?_r=0 [<https://perma.cc/7JFS-BQ4N>] (archived Jan. 26, 2017).

31. Robert Sanders, *CRISPR-Cas9 gene editing: check three times, cut once*, BERKELEY NEWS (Nov. 12, 2015), <http://news.berkeley.edu/2015/11/12/crispr-cas9-gene->

Further, the Cas9 editing process is believed to have three different checks to ensure the correct gene is cut out.³² First is the precursory scan, discussed above, which allows Cas9 to locate the appropriate gene. The second check corrects possible errors from Cas9 binding to incorrect genes. The Cas9 protein binds on to the DNA base pairs only when they precisely match the RNA base pairs of the Cas9.³³ If incorrect binding occurs, it only lasts for “milliseconds to seconds before the Cas9 moves on” to the correct match.³⁴ Finally, since some incorrect matches can occur, particularly to off-target sequences that only differ by a few mutations, the actual cutting will only occur if there is a precise match with the DNA sequence, otherwise the Cas9 protein inhibits it.³⁵ However, despite these checks, researchers have faced difficulty in using the technology precisely enough to prevent unintended edits through incorrect binding.³⁶

Alleviating some of the fear of incorrect binding, scientists recently discovered an “off-switch” for CRISPR-Cas9: “anti-CRISPR proteins” that can be used to turn off gene edits.³⁷ The ability to turn off edits could provide researchers with “a fail-safe to quickly block any potential harmful uses of the technology.”³⁸ While researchers are continuing to unwind the intricacies of this technology, it nonetheless has the potential to revolutionize the scientific and medical fields. Yet with such revolutionary capabilities, the debate now centers on what diseases CRISPR-Cas9 could alleviate and when researchers will be ready to use the technology.

B. Benefits of CRISPR-Cas9

CRISPR-Cas9 has the potential to change the world. From a clinical standpoint, since there are over six thousand diseases linked to genes, the technology could have vast implications for the overall human population.³⁹ Researchers, and even organizations tied to

editing-check-three-times-cut-once/ [https://perma.cc/Z4QR-7YF8] (archived Jan. 26, 2017).

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.*

36. *Off-switch for CRISPR-Cas9 gene editing system discovered*, PHYS.ORG (Dec. 29, 2016), <https://phys.org/news/2016-12-off-switch-crispr-cas9-gene.html> [https://perma.cc/CTN4-9U2F] (archived Jan. 26, 2017).

37. *Id.*

38. *Id.*

39. See Simon Wilson, *Gene editing: A Cut-and-Paste Cure for Cancer*, MONEYWEEK (Nov. 14, 2014), <http://moneyweek.com/gene-editing-a-cut-and-paste-cure-for-cancer/> [https://perma.cc/AYM2-5Z96] (archived Jan. 26, 2017) (noting that “gene editing’s scope could be vast” given the number of genetics-based diseases).

specific genetic diseases, are consequently working to determine if CRISPR-Cas9 will provide long-awaited treatments and cures.

One example of an area for treatment is cystic fibrosis, a disease caused by a gene mutation “that causes persistent lung infections and limits the ability to breathe over time.”⁴⁰ Possible treatment would use the CRISPR-Cas9 technology to replace the mutated gene with the correct one,⁴¹ although there are nearly 1,800 mutations in the cystic fibrosis gene.⁴² The Cystic Fibrosis Foundation Therapeutics, associated with the Cystic Fibrosis Foundation, entered into an agreement with Editas Medicine to provide Editas up to \$5 million to develop a medicinal treatment.⁴³ Preliminary studies in intestinal stem cells have shown promise.⁴⁴ Another example is CRISPR-Cas9’s promising potential for treating hemophilia, a well-known blood disorder that causes excessive bleeding. Like cystic fibrosis, genetic mutations in an individual’s DNA cause hemophilia.⁴⁵ Researchers at the University of Pennsylvania developed a treatment for hemophilia using CRISPR-Cas9 and delivered it to hemophilic mice.⁴⁶ The preclinical study results demonstrated that this treatment method may be translatable to treat hemophilia in humans.⁴⁷

C. Debate among the Scientific Community

While CRISPR-Cas9 may revolutionize the way the scientific community approaches, and the medical community treats genetic diseases, some critics fear that the technology will usher in a generation of designer babies and “a dystopia of superpeople.”⁴⁸ On the one hand, it is relatively easy to understand society’s unease about the extreme scenarios that could result from CRISPR-Cas9 gene editing,

40. *About Cystic Fibrosis*, CYSTIC FIBROSIS FOUND., <https://www.cff.org/What-is-CF/About-Cystic-Fibrosis/> (last visited Jan. 26, 2017) [<https://perma.cc/9M6D-G75T>] (archived Jan. 26, 2017).

41. *CRISPR/Cas9 Approach for Cystic Fibrosis Treatment*, CYSTIC FIBROSIS NEWS TODAY, <https://cysticfibrosisnewstoday.com/crisprcas9-approach-for-cystic-fibrosis/> (last visited Jan. 26, 2017) [<https://perma.cc/9LWF-ATBK>] (archived Jan. 26, 2017).

42. *Id.*

43. *Id.*

44. *Id.* (noting that a recent study used “a model of intestinal stem cell organoids from [cystic fibrosis] patients” and the researchers were able to replace the defective gene and restore function).

45. *CRISPR/Cas9 for Hemophilia*, HEMOPHILIA NEWS TODAY, <https://hemophilia.newstoday.com/crispr-cas9-hemophilia/> (last visited Jan. 26, 2017) [<https://perma.cc/LUT7-D4N2>] (archived Jan. 26, 2017).

46. *Id.*

47. *Id.*

48. Antonio Regalado, *Engineering the Perfect Baby*, TECH. REV. (Mar. 5, 2015), <https://www.technologyreview.com/s/535661/engineering-the-perfect-baby/> [<https://perma.cc/4Z95-N87G>] (archived Jan. 26, 2017).

scenarios that could catapult the world into an era that now seems more appropriately confined to science fiction films.⁴⁹ Yet, while these extreme scenarios should be considered and are reviewed in Part III, the true dispute lies in what CRISPR-Cas9 currently is, or will shortly be capable of. Some companies and researchers believe that this technology will allow individuals to choose at least some traits of their offspring. OvaScience, a Cambridge, Massachusetts-based company, argues that this technology will allow parents to choose not only “when and how they have children [but also] how healthy those children are going to be.”⁵⁰ David Sinclair, a geneticist at Harvard University and co-founder of OvaScience, stated at a commercial presentation in December 2016 that “there is no reason to expect” that the ability to remove defective genes, referring to those in genetic diseases, “won’t be possible in coming years.”⁵¹

On the other hand, other members of the scientific community believe that the idea of genetically engineering a “perfect” society is nowhere close to being attainable.⁵² Dr. Stuart Kim, a genetics professor at Stanford, argued that the notion of making an individual faster or more resilient is “still far enough off, [that it] might as well be the stuff of science-fiction [sic].”⁵³ Similarly, Rudolf Janeisch, a biologist at the Massachusetts Institute of Technology, stated that any “attempts to edit human embryos [are] ‘totally premature.’”⁵⁴ In fact, in studies that use CRISPR-Cas9 editing in animal subjects, researchers noted that the reality of obtaining an embryo with both genes edited as desired is actually only a one in twenty chance.⁵⁵ Further, researchers are only beginning to study the use of the technology as a treatment for single-gene disorders, but many traits, such as increasing resistance to muscular injury, involve multiple

49. See Claire Brownell, *From curing diseases to making designer babies, human gene editing is coming*, FIN. POST (July 22, 2016), <http://business.financialpost.com/executive/smart-shift/from-curing-diseases-to-making-designer-babies-human-gene-editing-is-coming> [<https://perma.cc/T3VJ-DNZ5>] (archived Jan. 26, 2017) (“If CRISPR is used irresponsibly, it’s possible to imagine all sorts of extreme scenarios: parents creating designer babies; Hitler-like figures wiping out entire races; the entire Jurassic Park franchise coming to life.”).

50. Regalado, *supra* note 48.

51. *Id.*

52. See Erin Beresini, *Could CRISPR Genetically Tailor Athletes? It’s a Nice Idea*, OUTSIDE (Jan. 7, 2016), <http://www.outsideonline.com/2045666/could-crispr-genetically-tailor-athletes> [<https://perma.cc/T3BS-FX3V>] (archived Mar. 25, 2017) (discussing the limitations of the gene-editing technology).

53. *Id.*

54. Regalado, *supra* note 48.

55. *Id.* (“Only about half the embryos will lead to live births, and of those that do, many could contain a mixture of cells with edited DNA and without. If you add up the odds, you find you’d need to edit 20 embryos to get a live monkey with the version you want.”).

genes.⁵⁶ Before being able to genetically modify an individual with the trait, scientists would need to determine how the genes interact.⁵⁷

Nonetheless, this disagreement regarding the capabilities of CRISPR-Cas9 in gene editing illustrates the uncertainty as to what doors the Chinese research opened and what realms of genetic modification are possible currently and in the future. Without proper regulations and research, there are many technical and ethical issues that the international community must address to avoid exploitation—particularly given the eugenics problems of the past.

III. HISTORICAL REVIEW OF PERFECTION THROUGH EUGENICS

Many in the scientific community, as well as speakers at the National Academies' Summit, recommend that scientists take a more cautious approach in implementing this technology, and some explicitly believe that researchers should not pursue gene editing in human embryos, even for clinical practices.⁵⁸ This reluctance for allowing or facilitating changes in an individual's genetic traits can be seen not only in modern ethical debates, but also throughout history. As one scholar aptly noted

[w]e recognize ourselves, measured against such goals and ideals, to be imperfect creatures. We wish to be more generous, more mathematically able, more musical, more altruistic – less like brutes and more like gods. . . [y]et as noble as our aspirations for shedding our failings might be, our history also suggests that, being flawed as we are, we can never blindly trust our own aspirations to reshape ourselves.⁵⁹

It is the desire for this illusive perfection that has etched a path of atrocities throughout history. As another speaker at the International Summit stated, “not everything that is technically feasible is ethically desirable.”⁶⁰ Although genetic modification through the gene editing of

56. See Beresini, *supra* note 52 (“[I]ncreasing resistance to muscular injury or stress fractures, for example, would likely involve multiple genes, and figuring out how altering one might affect the behavior of others is a puzzle that could take decades to put together.”).

57. See *id.* (noting that current research is mainly focused on single gene disorders as opposed to those in which multiple genes interact).

58. See, e.g., John P. Holdren, Dir. White House Office of Sci. & Tech. Pol’y, Opening Remarks (Dec. 1, 2015), <https://vimeo.com/album/3703972/video/149179773> [<https://perma.cc/YWJ2-A8E6>] (archived Jan. 26, 2017) (presenting Holdren’s belief that using the CRISPR technology to modify the gene line should not be done even for clinical practices while the technology still has many uncertainties).

59. CELESTE M. CONDIT, *THE MEANINGS OF THE GENE: PUBLIC DEBATES ABOUT HUMAN HEREDITY* 245 (1999).

60. Ismail Serageldin, *The Librarian of Alexandria, Context Through Three Lenses: Scientific, Historical, Legal* (Dec. 1, 2016) (<https://vimeo.com/album/3703972/video/149182559> [<https://perma.cc/A77G-3EWR>] (archived Jan. 26, 2017)).

embryos is only in the beginning stages of development, society's concerns stem in part from the horrors associated with human experimentation in the past.

These concerns arise from certain historical periods including the sterilization laws of the United States and the eugenics practices of the Nazi party during the Holocaust—and these examples are neither the earliest nor the only instances of society's drive towards perfection at the cost of innocent life and human rights. In the Hellenistic period of Ancient Greece, for instance, the goal to perfect male soldiers drove the nation-state of Sparta to practice infanticide in order to eliminate those perceived to be weak.⁶¹ While these examples may differ from gene editing on their face, they underlie the ethical apprehension that modification to eliminate alleged flaws will go too far. Therefore, scientists and legal ethicists should be cognizant of this past in determining how to move forward.

A. Sterilization Laws in the United States

Due to the appalling scope of the atrocities attributed to the Holocaust, many members of the American public may be unaware that eugenic policies flourished in the early-twentieth century in the United States.⁶² At the turn of the twentieth century, most of the American scientific and medical community hypothesized that infirmities, such as “feble-mindedness, epilepsy, drunkenness, criminality and insanity,” were hereditary and passable to offspring.⁶³ Scientist believed that individuals with these conditions represented the lowest social sphere in society, reflecting undesirable traits that should be eliminated from the population. The movement gained holding, and, by 1913, fourteen states had active involuntary sterilization programs.⁶⁴ However, *every* court faced with the issue of whether these programs violated the Constitution invalidated the laws—often on Due Process grounds.⁶⁵

Nonetheless, sterilization laws resurged in the 1920s and eventually a case regarding the forced sterilization of a mentally

61. WALTER BERNS, MAKING PATRIOTS 12 (2001) (“[A]nd whose infants, if they chanced to be puny or ill-formed, were exposed in a chasm (the Apothetae) and left to die.”).

62. *See generally* PHILIP R. REILLY, EUGENICS, ETHICS, STERILIZATION LAWS 204, 204–08, in 1 ENCYCLOPEDIA OF ETHICAL, LEGAL, AND POLICY ISSUES IN BIOTECHNOLOGY (Thomas H. Murray & Maxwell J. Mehlman eds., 2000) (discussing the sterilization laws of the United States and the rationales behind their enactment).

63. *Id.*

64. *Id.*

65. *See id.* (“In every instance (Indiana, Iowa, Michigan, Nevada, New Jersey, New York, and Washington) in which the constitutionality was put at issue, the courts invalidated the laws, usually on the grounds that they violated the requirements of the Due Process Clause of the Fourteenth Amendment.”).

handicapped individual, Carrie Buck, went to the United States Supreme Court in 1927.⁶⁶ The resulting case, *Buck v. Bell*, has been called “the single most important event in the history of sterilization laws in the United States.”⁶⁷ Justice Holmes’ majority opinion held that “in order to prevent our being swamped with incompetence. . . [i]t is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind.”⁶⁸ In reference to perceived disabilities of Buck’s mother and one of Buck’s children, the opinion went on to astonishingly note that “[t]hree generations of imbeciles are enough.”⁶⁹ Although sterilization has mostly fallen out of favor, largely due to the immense backlash following the Holocaust—discussed in the next Section—states retain the right to enforce sterilization laws.⁷⁰ As of 2004, seven states still had laws allowing for compulsory sterilization, and there are some estimates that over sixty thousand Americans have undergone forced sterilization.⁷¹ Even the Patient Protection and Affordable Care Act included sterilization as a “preventive care” service.⁷²

B. The Nazi Regime and Hitler’s Eugenic Movement

As the eugenics movement began to build more strength, the United States’ sterilization measures eventually made their way overseas to Germany.⁷³ Henry Hamilton Laughlin, a major eugenics advocate and director of the Eugenic Records Office, had developed sterilization laws that bypassed due process concerns.⁷⁴ When his work

66. See *id.* (discussing the resurgence of sterilization laws in 1923 and the infamous Supreme Court case of *Buck v. Bell*).

67. *Id.*

68. *Buck v. Bell*, 273 U.S. 200, 207 (1927). *Buck v. Bell* has never explicitly been overturned.

69. *Id.*

70. See Ariel S. Tazkargy, *From Coercion to Coercion: Voluntary Sterilization Policies in the United States*, 32 LAW & INEQ. 135, 135 (2014) (“Physicians, in the absence of state laws that mandate otherwise, still retain unfettered authority to prescribe or refuse sterilization procedures.”).

71. Michael G. Silver, Note, *Eugenics and Compulsory Sterilization Laws: Providing Redress for the Victims of a Shameful Era in United States History*, 72 GEO. WASH. L. REV. 862, 863 (2004) (discussing the impact and current status of sterilization laws in the United States).

72. Tazkargy, *supra* note 70, at 135.

73. See REILLY, *supra* note 62 (noting that the model sterilization laws of Henry Laughlin “found their way to Nazi Germany” where he was held in “high regard”).

74. Henry Laughlin, originally a high school teacher and highly respected biologist, provided “scientific legitimacy” to eugenics and analyzed laws to draft model laws that would not suffer the same constitutional invalidity of the sterilization laws of the 1910s. See *id.*

reached Nazi Germany, it was so well regarded that the University of Heidelberg awarded Laughlin an honorary degree in 1934.⁷⁵ Throughout the Holocaust and Hitler's overt goal to proliferate a superior race, the Nazi regime deemed millions of European Jews along with many Russians, Gypsies (Romani), Poles, and disabled individuals, undesirable.⁷⁶ Nazi-regime physicians participated in programs that involved coercive sterilization, harmful and barbaric experimentation, and the killing of impaired children and allegedly defective adults from mental hospitals, institutions, and concentration camps such as Auschwitz.⁷⁷

Physicians conducted these experiments, according to the Nazis, "for 'the advancement of science.'"⁷⁸ The experimentations included sterilization, "exposure to low temperature and atmospheric pressure," and "deliberate wounding with infection to test antibiotics."⁷⁹ The Nazi regime considered the extermination of the Jewish population a "program of racial hygiene" premised on the belief that a non-Aryan race created "a public health threat," and, therefore, elimination "was medically akin to excising a dangerous tumor."⁸⁰ Gideon Hausner, the chief prosecutor at the 1961 trial of Nazi war criminal Adolf Eichmann, stated that "[t]he Nazis regarded Auschwitz as the ideal place for experimentation, for the creation of supermen."⁸¹ One statistic notes that "over 400,000 Germans had been sterilized including 200,000 deemed mentally deficient; 100,000 with mental illness; 60,000 epileptics; 10,000 alcoholics; 20,000 with body deformities; and others afflicted with Huntington's chorea, hereditary blindness or deafness."⁸² The Nazi Regime also ordered the killings of numerous infants born with deformities or brain damage.⁸³

75. *Id.*

76. *See, e.g.,* JOSHUA A. PERPER & STEPHEN J. CINA, *WHEN DOCTORS KILL: WHO, WHY, AND HOW* 61 (2010) (discussing the populations affected by the eugenics movement in Germany during the Holocaust).

77. *See id.* at 58 ("Nazi physicians also participated in other progressively injurious or murderous programs including coercive sterilization, the killing of 'impaired' children in hospitals, and the eradication of 'defective' adults mostly from mental hospitals or institutions in special centers.").

78. *Id.*

79. *See* Howard Brody, *The Origins and Impact of the Nuremberg Doctors' Trial*, in *HUMAN SUBJECTS RESEARCH AFTER THE HOLOCAUST* 163–64 (Sheldon Rubinfeld & Susan Benedict eds., 2014) (providing an overview of the different types of experimentations individuals were subjected to under the Nazi regime).

80. *Id.* at 164.

81. Jonathan Broder, *Auschwitz Survivors Recall Horror of Nazi Experiments*, CHI. TRIB. (Feb. 7, 1985), http://articles.chicagotribune.com/1985-02-07/news/8501080137_1_josef-mengele-israel-and-west-germany-auschwitz [<https://perma.cc/LWB3-AV9G>] (archived Jan. 27, 2017).

82. PERPER & CINA, *supra* note 76, at 58.

83. *See id.* ("In the end, 70,000 German children thought to be abnormal were forcefully taken from their homes, institutionalized, and eventually killed.").

This rapid and extreme escalation from sterilization to genocide sparked outrage, discrediting and shaming eugenics;⁸⁴ but, many of those involved in the Nazi movement, including physicians, believed they were promoting science.⁸⁵ Their claimed goal was improving the human race by manipulating genetic traits—discouraging and eliminating negative traits, known as negative eugenics, and promoting positive and desirable traits, known as positive eugenics.⁸⁶

While dissimilar in how they obtain this goal, clinicians use a version of genetic manipulation in pre-natal testing and screening, and in genetic counseling.⁸⁷ Against this historical backdrop, many in the scientific and medical communities worry that the current advancements in gene editing could eventually overstep the ethical limits of science.⁸⁸ One example of such an inappropriate use would be the proliferation of designer babies.⁸⁹

IV. THE CURRENT STATE OF LAWS: THE UNITED STATES, THE UNITED KINGDOM, AND THE PEOPLE'S REPUBLIC OF CHINA

The capabilities of CRISPR-Cas9 described in Part II, along with the historical concerns reviewed in Part III, enforce the belief that, despite any uncertainty as to the full extent of the technology's capabilities, the time for a global discussion on ethical limitations is now. As noted previously, three players are at the forefront of gene editing: the United States, the United Kingdom, and China. In order to devise a recommendation for regulating gene editing, this Note analyzes the current laws and regulations in place in these countries. Arguably, this subject would benefit from a review of the laws of additional countries in formulating a proposed solution, but such an endeavor is beyond the scope of this Note. Because these three countries co-hosted the International Summit and they are making the

84. See Ana Romero-Bosch, *Lessons in Legal History—Eugenics & Genetics*, 11 MICH. ST. J. MED. & L. 89, 99–100 (2007) (“Nazi racial hygiene programs radically changed from controlling reproduction and marriage to the massive murder and gassing of thousands of innocent people. . . . Ultimately, the Holocaust served to discredit and shame eugenics practitioners worldwide.”).

85. See PERPER & CINA, *supra* note 76, at 62 (providing an overview for the argued medical justifications for the experimentation).

86. See *id.* at 59 (discussing the reason behind physician involvement in the mass killings and experimentations).

87. See *id.* at 62 (noting that “in modern times, [eugenics] has played a formative role in pre-natal testing and screening, genetic counseling and molecular correction of genetic diseases”).

88. See Mike Steere, *Designer Babies: Creating the Perfect Child*, CNN (Oct. 30, 2008, 10:38 AM), <http://www.cnn.com/2008/TECH/science/10/30/designer.babies/> [<https://perma.cc/SY8F-7SDX>] (archived Jan. 27, 2017) (questioning whether the idea of designing your child is a “scary thought”).

89. See *id.* (describing the concept behind designer babies).

most leeway in research, it is likely that other countries will look to their actions in deciding how to regulate gene editing domestically.

A. The United States

Shortly after the news spread of the Chinese researchers' gene-editing experiments, the National Institutes of Health (NIH) issued a statement that it would "not fund any use of gene-editing technologies in human embryos."⁹⁰ The NIH proclaimed that not only is the use of this technology "a line that should not be crossed," but also that "there are multiple existing legislative and regulatory prohibitions" which prohibit such work.⁹¹

One such regulatory barrier to gene editing of human embryos is the Dickey-Wicker amendment.⁹² The amendment prohibits the Department of Health and Human Services (HHS) from using any appropriated funds for both "the creation of a human embryo or embryos for research purposes" and "research in which human embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero"⁹³ according to applicable federal law.⁹⁴ Pursuant to this legislation, the most recent NIH guidelines state that "[t]he NIH continues to explore the issues raised by the potential of *in utero* gene transfer clinical research. However, the NIH concludes that, at present, it is premature to undertake any *in utero* gene transfer clinical

90. *Statement on NIH funding of research using gene-editing technologies in human embryos* U.S. DEPT OF HEALTH & HUMAN SERVS., NAT. INSTS. OF HEALTH, (2015), <http://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos> [https://perma.cc/LT9M-BNMF] (archived Jan. 28, 2017).

91. *See id.* (discussing the prohibitions within a variety of legislative and regulatory materials including the Dickey-Wicker amendment, NIH guidelines, and the authority of the Food and Drug Administration).

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

93. *Id.*

94. In March 2009, President Obama issued an executive order removing this restriction for the purposes of stem cell research if the research did not destroy the stem cells and researchers did not create stem cell lines. *See* Exec. Order No. 13,505, 74 F.R. 10667 (2009); *see also* *Sherley v. Sebelius*, 680 F.3d 776 (D.C. Cir. 2012) (holding that the NIH guidelines in response to Executive Order 13505 remained in line with the Dickey-Wicker Amendment as they only permitted the use of already-derived embryonic stem cells, which are not themselves embryos, and thus no embryos would be destroyed).

trial.”⁹⁵ Still, there is some suggestion that the United States may be moving towards eliminating some of these restrictions.⁹⁶

The organizational structure for regulating gene editing, which does not relate to the banned research on human embryos, is multifaceted. The NIH’s Recombinant DNA Advisory Committee (RAC) determines whether to approve gene-editing proposals that seek government funding.⁹⁷ Recently, the RAC approved “the first clinical protocol to use CRISPR/Cas9-mediated gene editing”⁹⁸ in an effort to treat multiple kinds of cancer.⁹⁹ The second key federal player in the gene-editing realm is the Food and Drug Administration (FDA), whose “Center for Biologics Evaluation and Research (CBER) has a well-established program and policies in place to evaluate gene therapy products.”¹⁰⁰

Despite this seemingly thorough federal structure, David Magnus, the Director of the Stanford Center for Biomedical Ethics, and Nicole Martinez, a lecturer and fellow at Stanford University, have criticized the United States regulatory control of gene editing “as a ‘wild west’ of reproductive technology.”¹⁰¹ Although HHS and the NIH limit what

95. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, U.S. DEP’T OF HEALTH AND HUMAN SERVS., NAT. INSTS. OF HEALTH, (2016), http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html [<https://perma.cc/QBN4-EEEXL>] (archived Jan. 28, 2017) (emphasis in original).

96. See Zachary Brennan, *Congressional Hearings Focus on Compassionate Use, FDA Issues*, REG. AFFAIRS PROF’LS SOC’Y (Feb. 25, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/02/25/24410/Congressional-Hearings-Focus-on-Compassionate-Use-FDA-Issues/> [<https://perma.cc/4RBS-759F>] (archived Jan. 28, 2017) (noting that some members of Congress question the extent of U.S. restrictions on genetic modification of human embryos including Representative Sam Farr of California who said that the provision was aimed “to stop designer babies though he thought that the actual language of it went too far and would mean the US will lose research opportunities”) (internal quotations omitted).

97. Robert M. Califf & Ritu Nalubola, *FDA’s Science-based Approach to Genome Edited Products*, U.S. FOOD & DRUG ADMINISTRATION, DEP’T OF HEALTH & HUM. SERVS. (Jan. 18, 2017), <http://blogs.fda.gov/fdavoices/index.php/2017/01/fdas-Science-based-approach-to-genome-edited-products/> [<https://perma.cc/2NGT-SR6J>] (archived Jan. 28, 2017).

98. *Id.*

99. Sharon Begley, *Federal panel approves first use of CRISPR in humans*, STAT (June 21, 2016), <https://www.statnews.com/2016/06/21/crispr-human-trials/> [<https://perma.cc/PB72-V5EJ>] (archived Jan. 28, 2017) (“A federal biosafety and ethics panel on Tuesday unanimously approved the first study in patients of the genome-editing technology CRISPR-Cas9, in an experiment that would use [CRISPR] to create genetically altered immune cells to attack three kinds of cancer.”).

100. Califf & Nalubola, *supra* note 97.

101. See David Magnus & Nicole Martinez, *In Embryo Research We Need Laws First, Then Science*, TIME (Feb. 2, 2016), <http://time.com/4204059/crispr-regulation/> [<https://perma.cc/Z6A4-RK2C>] (archived Jan. 28, 2017) (discussing the inefficiencies of embryonic research regulations in the United States, particularly in reference to the United Kingdom and China).

research may receive funding, there is no government agency or authority that regulates privately funded projects.¹⁰² Therefore, unlike the United Kingdom (discussed in the subsequent Section), it is not illegal in the United States to implant a genetically modified embryo to begin a pregnancy.¹⁰³ Further, based on the vital Separation of Powers Doctrine in the United States, some states are looking to their laws and guidelines to see if it is permissible to fund research on the gene editing of human embryos.¹⁰⁴ The California Institute for Regenerative Medicine is considering whether to fund such an endeavor, and it would do so with California taxpayer dollars.¹⁰⁵ Such a gap in regulations between federal and state researchers illustrates the worrisome inefficiencies in the current U.S. gene-editing regulatory scheme.

B. *The United Kingdom*

Discussions of reproductive medicine have often focused on the United Kingdom, perhaps more so than any other region in the world.¹⁰⁶ England was the first country to have a test-tube baby, to use pre-implantation genetic diagnostics, and to clone a higher vertebrate.¹⁰⁷ It also has been a leader “in human embryonic stem cell derivation and banking.”¹⁰⁸ These many achievements influenced the United Kingdom’s “creation of rigorous legislation and policy strictly limiting [the] technological manipulation of human fertilisation and embryology.”¹⁰⁹ This legislation and policy allows the United Kingdom to have “a uniquely-robust-but-flexible” approach to embryological

102. See *id.* (“In contrast, privately funded gene-editing projects are not regulated by a central agency or framework that can address concerns of safety and efficacy, or balance the interests of research with the protection of patients.”).

103. See Melody Peterson, *California stem cell agency may fund tests to edit genes in human embryos*, L.A. TIMES (Feb. 12, 2016, 3:00 AM), <http://www.latimes.com/business/la-fi-human-gene-editing-20160212-story.html> [<https://perma.cc/RU5N-KCSG>] (archived Jan. 28, 2017) (noting the differences in the acceptability of embryonic genetic modification in the legal standards of the United States and the United Kingdom, specifically Britain).

104. See *id.* (discussing California’s investigation into whether its ethical guidelines allow its agencies to use taxpayer funds to support research regarding genetically modifying human embryos).

105. See *id.* (“The state’s stem cell institute is reviewing its ethics guidelines to determine whether they are strong enough to safely allow studies in which scientists would attempt to edit the genes of embryos.”).

106. See SARAH FRANKLIN & CELIA ROBERTS, *BORN AND MADE: AN ETHNOGRAPHY OF PREIMPLANTATION GENETIC DIAGNOSIS 2* (2006) (“Britain has in many respects been at both the center and forefront of the controversies surrounding a cluster of new technologies associated with reproductive biomedicine.”).

107. *Id.*

108. See *id.* (discussing all the “firsts” in reproductive medicine that Britain accomplished) (internal quotations omitted).

109. *Id.* (internal quotations omitted).

testing, with the enforcement of criminal law, the presence of a licensing body, and the allowance for revisions in the legislation by Parliament.¹¹⁰

The Human Fertilisation and Embryology Act (“The Act”) governs the Human Fertilisation & Embryology Authority (HFEA), which regulates all research involving human embryos in the United Kingdom.¹¹¹ The Act imposes strict limitations, including an outright ban on the use of modified embryos for pregnancy, stating that the Act only permits implantation of an embryo if “no nuclear or mitochondrial DNA of any cell of the embryos has been altered and no cell has been added to it other than by division of the embryo’s own cells.”¹¹² The regulations noticeably do provide a possible exception if researchers process the embryo “to prevent the transmission of serious mitochondrial disease.”¹¹³ Additionally, researchers may apply for licenses if they are able to meet strict requirements including educational standards, two years practical experience related to the activity, and payment of a fee.¹¹⁴

Parliament recently amended the Act in 2008 to address some of the evolving aspects of genetic research. The explanatory notes discuss the changing of definitions such as “embryo,” which Parliament modified to “no longer assume[] that an embryo can only be created by fertilisation” and to bring the definition “up to date with technologies that have been developed since the time of enactment of the 1990 Act.”¹¹⁵ The notes further acknowledge that the limitation on implantation “ensures embryos created by artificial gametes or genetically modified gametes could not be placed in a woman.”¹¹⁶ The previous 1990 Act strictly prohibited alteration of the genetic structure of an embryo unless Parliament enacted specific regulations; however, Parliament made no such regulations.¹¹⁷ The removal of this

110. See *id.* at 3 (noting that Britain’s system is “backed up by criminal law, enforced through a licensing body, and subject to constant revision, while being bound by the ‘will of Parliament’”).

111. *Human embryo research*, HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY (UK), <http://www.hfea.gov.uk/161.html> (last visited Feb. 20, 2017) [<https://perma.cc/BLX4-2L2Y>] (archived Jan. 29, 2017).

112. Human Fertilisation and Embryology Act 2008, 2008 c. 22, §3(5)(4)(b-c) (UK).

113. *Id.* at §3(5)(5).

114. *Id.* at §16.

115. Human Fertilisation and Embryology Act 2008, c.22, Explanatory Notes ¶ 23 [hereinafter Explanatory Notes].

116. *Id.* ¶ 29.

117. *Id.* ¶ 65 (discussing previous paragraph 3(4) of Schedule 2 to the 1990 Act and its prohibitory language).

prohibition paved the way for the licensure requirements to now govern embryonic modification research.¹¹⁸

London researchers used this licensing scheme recently to gain permission to genetically edit human embryos.¹¹⁹ A couple donated the embryos, which doctors or researchers could never legally implant per regulations, from their surplus after IVF treatment.¹²⁰ The HFEA granted the license on February 1, 2016.¹²¹ The research license allows for the keeping, use, and storage of embryos for a period of three years, with the option of renewal.¹²² The license notes that these activities are for the purpose of “developing treatments for serious disease or other serious medical conditions,” “increasing knowledge about the development of embryos,” and “promoting advances in the treatment of infertility.”¹²³ Nonetheless, the HFEA committee reiterated the prohibition that the research project can never involve placing non-permitted embryos, eggs, or sperm in a woman, or keeping or using embryos after fourteen days from the date of creation or upon the appearance of a primitive streak¹²⁴.¹²⁵ Additionally, no research using gene editing can take place until the research receives an ethics approval.¹²⁶ Although China was the first to use CRISPR-Cas9 for gene-editing purposes, this licensure approval represents the first endorsement worldwide of research of this kind by a national regulatory authority, and many scholars believe that it has established a strong precedent for this type of research.¹²⁷

118. See *id.* (discussing the removal of prohibitions on all genetic modification absent regulations and instead allowing for HFEA approved licensure).

119. See Ewen Callaway, *UK scientists gain license to edit genes in human embryos*, NATURE (Feb. 1, 2016), <http://www.nature.com/news/uk-scientists-gain-licence-to-edit-genes-in-human-embryos-1.19270> [<https://perma.cc/JQ4B-GFDG>] (archived Jan. 29, 2017) (discussing the HFEA’s approval of the Francis Crick Institutes license request).

120. See Ian Sample, *UK scientists seek permission to genetically modify human embryos*, GUARDIAN (Sept. 17, 2015, 7:01 PM), <http://www.theguardian.com/science/2015/sep/18/uk-scientists-seek-permission-to-genetically-modify-human-embryos> [<https://perma.cc/MRD6-TLDM>] (archived Jan. 29, 2017).

121. Callaway, *supra* note 119.

122. HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY, LICENSE COMMITTEE – MINUTES (Jan. 14, 2016), <http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5966> [<https://perma.cc/6CTQ-BECZ>] (archived Jan. 29, 2017) [hereinafter License Committee].

123. *Id.*

124. A primitive streak is a structure that arises during embryologic development that is considered the beginning of the neural tube and nervous system. *Primitive Streak*, MERRIAM-WEBSTER ONLINE DICTIONARY (2016), <http://www.merriam-webster.com/dictionary/primitive%20streak> [<https://perma.cc/U6B2-U8EK>] (archived Mar. 25, 2017).

125. License Committee, *supra* note 122.

126. *Id.*

127. See Callaway, *supra* note 119 (discussing the international impact of the HFEA’s approval of the research).

C. The People's Republic of China

Like the United Kingdom, China theoretically has an outright legislative ban on gene editing of human embryos.¹²⁸ Yet despite this legislation, commentators have referred to China's stem cell treatment and research as "wild"¹²⁹ as China has "one of the most unrestrictive regulatory regimes . . ."¹³⁰ Despite enacted regulations, no real legal enforcement mechanism exists and loopholes in the guidelines are widespread.¹³¹ It is through one of these loopholes—the researchers' use of non-viable embryos that could never be implanted—that the Chinese researchers were able to become the first country in the world to edit the genes of a human embryo.¹³²

Similar to the United Kingdom, researchers cannot develop embryos past fourteen days, and the government strictly prohibits the implantation of modified embryos into humans.¹³³ The only ethical guidelines for regulating this type of research arise from a 2003 joint issuance from the Ministry of Science and Technology and the Ministry of Health, *The Guidelines for Ethical Principles in Human Embryonic Stem Cell Research*.¹³⁴ These guidelines permit the use of embryonic stem cells in research from specified sources such as unwanted embryos from IVF, miscarriages, and voluntarily induced abortions, as well as donated germ cells.¹³⁵ Still, the guidelines dictate a complete ban on "[u]sing human egg plasma and nuclear transfer technology for the purposes of reproduction, and [the] manipulation of the genes in human gametes, zygotes or embryos for the purposes of reproduction are prohibited."¹³⁶

128. See Skye Gould & Kevin Loria, *This map shows where researchers might design the first genetically engineered baby*, BUS. INSIDER (Oct. 20, 2015, 12:48 PM), <http://www.businessinsider.com/what-countries-allow-researchers-to-edit-human-embryos-2015-10> [https://perma.cc/UPY5-DNRC] (archived Jan. 29, 2017) (providing an overview of foreign law regulations on genetic modification).

129. Shan Juan, *Health authority announces step to rein in 'wild' stem cell treatment*, CHINA DAILY (Aug. 21, 2015), http://www.chinadaily.com.cn/china/2015-08/21/content_21662613.htm [https://perma.cc/DJL7-RLJA] (archived Jan. 29, 2017) (discussing changes made by the Chinese Health authority to stem cell treatments and experimentation).

130. Laney Zhang, *Bioethics Legislation in Selected Countries*, LAW LIBRARY OF CONG. (2012), https://www.loc.gov/law/help/bioethics_2012-008118FINAL.pdf [https://perma.cc/HNY3-7QF4] (archived Jan. 29, 2017) [hereinafter *Bioethics Legislation*].

131. See Gould & Loria, *supra* note 128.

132. See *id.*

133. *Bioethics Legislation*, *supra* note 130.

134. *Id.*

135. *Id.*

136. Zihong Xu, Professor, Peking University & Chinese Academy of Sciences, PowerPoint Presentation at the International Summit on Gene Editing: Human Embryos and Gene-Editing Research and Regulation in China (<http://www.nationalacademies>).

Other agencies involved, or potentially involved, in regulating gene editing in China include the National Health and Family Planning Commission (NHFPC) and the Chinese Food and Drug Administration (CFDA). The NHFPC is charged with the guidance and formation of scientific programs related to health and family planning.¹³⁷ The CFDA regulates genetic testing and had previously banned prenatal DNA testing in 2014.¹³⁸ However, the ban allowed clinical applications of gene sequencing to continue if they were approved by the NHFPC and were done according to regulations.¹³⁹ Given the country's restrictive guidelines prohibiting gene editing for the purpose of reproduction, much speculation arose as to how the Chinese research team was able to conduct this research experiment.¹⁴⁰ Two theories have emerged.¹⁴¹ First, the researchers used non-viable embryos—those unable to develop into humans because they were fertilized by two sperm.¹⁴² Second, China's regulatory bans actually “consist mostly of guidelines,” which are considered “soft laws,” leaving sanctions ambiguous and possibly unenforceable.¹⁴³

org/cs/groups/genesite/documents/webpage/gene_169524.pptx [https://perma.cc/ZN8R-GVFZ] (archived Jan. 29, 2017)).

137. *About Us*, NAT'L HEALTH AND FAMILY PLANNING COMM'N OF THE PRC, http://en.nhfpc.gov.cn/policies_2.html (last visited Jan. 29, 2017) [https://perma.cc/AZM4-AYPY] (archived Jan. 29, 2017).

138. See Sophie Hohn, *China Imposes Restrictive Regulation of Genetic Testing*, INT'L RARE DISEASES RESEARCH CONSORTIUM (Apr. 1, 2014), <http://www.irdirc.org/china-imposes-restrictive-regulation-of-genetic-testing/> [https://perma.cc/69GR-HFG3] (archived Jan. 29, 2017) (discussing the CFDA's regulatory constraints on clinical genetic tests).

139. See Shu-Ching Jean Chen, *China Cracks Down on DNA Testing*, FORBES (Mar. 3, 2014, 10:06 AM), <http://www.forbes.com/sites/shuchingjeanchen/2014/03/03/china-cracks-down-on-dna-testing-2/> [https://perma.cc/BL2W-YVV7] (archived Jan. 29, 2017) (“From now on, clinical applications of gene-sequencing technology can be offered only at locations approved as pilot trial points by the National Health and Planning Commission . . . [a]nd they have to be done according to regulations.”).

140. See Lauren F. Friedman, *These are the countries where it's 'legal' to edit human embryos (hint: the US is one)*, BUS. INSIDER (Apr. 23, 2015, 2:15 PM), <http://www.businessinsider.com/china-edited-human-genome-laws-2015-4> [https://perma.cc/X2ZF-XPAB] (archived Jan. 29, 2017) (commenting on the debate as to whether the Chinese research was allowed).

141. *Id.*

142. *Id.*

143. *Id.*

V. THE NATIONAL ACADEMIES' SUMMIT AND REPORT

A. *The International Summit Recommendation*

After reviewing the individual policies of these three nations, it would be amiss not to evaluate the recommendations put forth after the International Summit on gene editing. The International Summit consisted of several days of discussions, debates, and even appeals from the general public affected by genetic disorders. Approximately five hundred “scientists, ethicists, legal experts and advocacy groups” represented more than twenty countries.¹⁴⁴ The summit addressed multiple topics at length: the scientific, historical, and legal context; the scientific background of gene editing technologies; the application of gene editing technology to change the genetic makeup of offspring; the societal impacts; the limitations; the application of gene editing technology to research; governance, regulation, and control; and international perspectives.¹⁴⁵

After several presentations and panel discussions over the three-day event, it became apparent that there was a disagreement as to the scope of the technology’s potential for genetic editing and modification. Despite this disagreement on certain topics, a common theme of caution and ethical concern emerged. The committee addressed the different uses of the CRISPR-Cas9 gene-editing technology in their closing recommendations.¹⁴⁶ The organizing committee, comprised of twelve biologists and bioethicists, endorsed the use of CRISPR-Cas9 to alter “DNA sequences of human eggs, sperm, or embryos” but did not recommend the implantation of embryos through in vitro fertilization “because of ongoing safety concerns and a lack of societal consensus.”¹⁴⁷

In addition to the committee’s general recommendation, the committee first addressed the need for “intensive basic and preclinical research” that should be conducted according to all the applicable legal,

144. Sara Reardon, *Global summit reveals divergent views on human gene editing*, NATURE (Dec. 8, 2015), <http://www.nature.com/news/global-summit-reveals-divergent-views-on-human-gene-editing-1.18971> [<https://perma.cc/8TWU-ZVNU>] (archived Jan. 29, 2017).

145. *Summit Draft Agenda*, NAT’L ACADS. OF SCIS, ENG’G, & MED., http://nationalacademies.org/cs/groups/genesite/documents/webpage/gene_168809.pdf (last visited Jan. 29, 2017) [<https://perma.cc/32QX-HFTX>] (archived Jan. 29, 2017).

146. David Baltimore, California Inst. of Tech., *Going Forward: Closing Thoughts* (Dec. 3, 2015) (unpublished presentation), http://nationalacademies.org/cs/groups/genesite/documents/webpage/gene_169560.pptx [<https://perma.cc/5RFL-H9UM>] (archived Jan. 29, 2017) [hereinafter *Closing Presentation*].

147. See John Travis, *Inside the Summit on Human Gene Editing: A Reporter’s Notebook*, SCI. MAG. (Dec. 4, 2015, 3:45 PM), <http://www.sciencemag.org/news/2015/12/inside-summit-human-gene-editing-reporter-s-notebook> [<https://perma.cc/G476-2H72>] (Jan. 29, 2017) (providing a brief overview of the International Summit’s conclusions).

ethical, and regulatory rules.¹⁴⁸ The research should address the technologies for gene editing, “potential benefits and risks of proposed clinical uses,” and a further biological understanding of human embryos and germ lines.¹⁴⁹ However, the committee recommended that any cells modified through gene editing should not be used for implantation “to establish a pregnancy.”¹⁵⁰ Second, the committee discussed somatic clinical use. Somatic cells are those that cannot be transmitted through progeny.¹⁵¹ Regardless of the cells’ inability to have a hereditary effect, the committee noted that there is a risk of inaccurate editing¹⁵² but recognized that the “existing and evolving regulatory frameworks for gene therapy” allow regulators to determine whether to approve clinical trials and therapies.¹⁵³

Most important to the ethical debate is the committee’s third recommendation. The committee recognized that it would be “irresponsible” to continue with clinical uses of germline editing absent further research and consideration.¹⁵⁴ It discussed the need for gathering additional information on the safety and efficacy of the technology, particularly in relation to the “risks, potential benefits, and alternatives.”¹⁵⁵ The committee also referenced the need to wait until “there is broad societal consensus about the appropriateness of the proposed application.”¹⁵⁶ Additionally, it proposed that clinical uses should be utilized only when conducted “under appropriate regulatory oversight.”¹⁵⁷ While the committee noted that none of those criteria were presently met, they recognized that it may change over time:

Moreover, any clinical use should proceed only under appropriate regulatory oversight. At present, these criteria have not been met for any proposed clinical use: the safety issues have not yet been adequately explored; the cases of most compelling benefit are limited; and many nations have legislative or regulatory bans on germline modification. However, as scientific knowledge advances and societal views evolve, the clinical use of germline editing should be revisited on a regular basis.¹⁵⁸

In the last line of this statement, the committee kept the door open for possible future use of germline editing and did not mention how to address the variance in laws among the international community.

148. Closing Presentation, *supra* note 146.

149. *Id.*

150. *Id.*

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.*

B. *The Consensus Report*

The International Study released its consensus study report, *Human Genome Editing: Science, Ethics, and Governance*, in February of 2017. The report “permit[s] clinical research trials [using gene editing] only for the compelling purposes of treating or preventing serious disease or disabilities, and only if there is a stringent oversight system able to limit uses to specified criteria.”¹⁵⁹ However, the report notes that “[m]ore research is needed before any germline intervention could meet the risk/benefit standard for authorizing clinical trials” but maintains that “caution does not mean that [such trials] must be prohibited.”¹⁶⁰ Figure 1 below represents the report’s recommendation and the suggestions for regulatory oversight.

RECOMMENDATION 5-1. Clinical trials using heritable germline genome editing should be permitted only within a robust and effective regulatory framework that encompasses

- the absence of reasonable alternatives;
- restriction to preventing a serious disease or condition;
- restriction to editing genes that have been convincingly demonstrated to cause or to strongly predispose to that disease or condition;
- restriction to converting such genes to versions that are prevalent in the population and are known to be associated with ordinary health with little or no evidence of adverse effects;
- the availability of credible pre-clinical and/or clinical data on risks and potential health benefits of the procedures;
- during the trial, ongoing, rigorous oversight of the effects of the procedure on the health and safety of the research participants;
- comprehensive plans for long-term, multigenerational follow-up that still respect personal autonomy;
- maximum transparency consistent with patient privacy;
- continued reassessment of both health and societal benefits and risks, with broad on-going participation and input by the public; and
- reliable oversight mechanisms to prevent extension to uses other than preventing a serious disease or condition.

Figure 1: Human Genome Editing Report Recommendation¹⁶¹

159. *Summary of Recommendations, Human Genome Editing: Science, Ethics, and Governance*, NAT’L ACADS. OF SCIS. AND NAT’L ACAD. OF MEDICINE, http://nationalacademies.org/cs/groups/genesite/documents/webpage/gene_177259.pdf (last visited Feb. 19, 2017) [<https://perma.cc/N298-4ZP8>] (archived Feb. 19, 2017).

160. THE NATIONAL ACADEMIES, *HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE* 102 (2017).

161. *Id.* 102–03

While the report represents a pro-gene-editing stance for the prevention of a serious disease or condition, it is less favorable for possible enhancements of human genome. The report puts forth two recommendations: (1) that clinical trials for such enhancement purposes “should not at this time” be authorized by regulatory agencies; and (2) that “[g]overnment bodies should encourage public discussion and policy debate regarding governance of somatic human genome editing for purposes other than treatment or prevention of disease or disability.”¹⁶²

This summarization is merely a simplistic representation of an extremely complex, thorough, and well-reasoned report. Consequently, an in-depth analysis of the report and its recommendations is beyond the scope of this Note. This Note, instead, makes one critical claim in response to, and disagreement with, the report: the report’s use of “at this time” in the first recommendation. The prohibition on enhancement treatments is ill advised as it adds further ambiguity to an already contentious topic. As Part III discussed, enhancement often leads to the belief that some individuals are superior while others are inferior. While, this may not result in a Gattaca-like situation,¹⁶³ history evidences that the threat of misuse is not a path that society should take lightly.¹⁶⁴ Therefore, properly addressing this concern requires explicit language prohibiting gene-editing technology for the purpose of enhancement, which Part VI details.

VI. REFORMING LAWS DOMESTICALLY AND INTERNATIONALLY

The world of genetic modification has the potential to develop rapidly,¹⁶⁵ and currently both the domestic and international fronts display serious ambiguities. In order to address these issues, this Note proposes a two-step solution. First, the gaps between private versus public and state versus federal regulations on genetic modification in the United States should be closed.¹⁶⁶ To best correct these faults, the United States should use its constitutional authority to create a federal

162. *Id.* at 123.

163. GATTACA, *supra* note 1.

164. *See supra* Part III.

165. *See* John Farrell, *How Brave New World Is Sneaking Up On Us*, FORBES (Feb. 28, 2016, 9:33 AM), <http://www.forbes.com/sites/johnfarrell/2016/02/28/how-brave-new-world-is-sneaking-up-on-us/#1a839d841700> [<https://perma.cc/X3YJ-25R6>] (archived Jan. 29, 2017):

[G]iven the speed with which genomes can be sequenced and the massive amount of personal genomic Big Data this will represent, it may not be long before the deep interconnections between sequences are indeed well enough understood to embolden scientists and prospective parents to attempt direct modification of gene sequences for purely optional design changes in their offspring.

166. *See infra* Section IV.A.

law that mirrors that of the United Kingdom, with the National Institutes of Health (NIH) handling the licensing.¹⁶⁷ Second, in order to strengthen the recommendations of the Academies and create an international consensus, the Declaration on the Human Genome and Human Rights should be revised to reflect a prohibition of gene editing, at least until the technology and ethical implications can be better understood.

A. Establishing a Licensing System in the United States

The United States prohibition of funding embryonic genetic modification traces back to a provision placed into an appropriation bill in 1993, and the legislature has renewed it every year thereafter.¹⁶⁸ However, given the advances in science and the successes of the international research community, this stance no longer seems appropriate. As previously discussed, the United States has good reason to be cautious. The government and courts upheld an era of sterilization justified by the noble aim of the betterment of society.¹⁶⁹ Nonetheless, these concerns should not “entail wholesale rejection of a technology that can teach us a great deal about how living creatures develop and how cells specialize and function.”¹⁷⁰ Rather, Congress should pass legislation allowing the research to go forward, with several restrictions.

Under its Commerce Clause power, Congress can arguably regulate both private and public research of genetic modification, as both involve interstate commerce.¹⁷¹ As CRISPR-Cas9 research develops, consumers may seek out the technology to genetically modify

167. Although not discussed in this Note due to the complexity of the issue, establishing a federal law in the United States is of particular importance. In *Medellin v. Texas*, 552 U.S. 491, 504–05 (2008), the Supreme Court held that “not all international law obligations automatically constitute binding federal law enforceable in United States Court.”

168. See Farrell, *supra* note 165.

169. See *supra* Section III.A.

170. Stephen Latham, *Proceed With Caution*, U.S. NEWS & WORLD REPORT (Feb. 8, 2016, 1:45 PM), <http://www.usnews.com/opinion/blogs/policy-dose/articles/2016-02-08/nih-wont-fund-human-embryo-gene-editing-but-others-will> [<https://perma.cc/QPL7-X96V>] (archived Jan. 29, 2017).

171. Although an in-depth discussion of the federal government’s Commerce Clause authority is outside of the scope of this Note, the Commerce Clause states that Congress shall have power “[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.” U.S. CONST. art. I, § 8, cl. 3. Embryonic research likely falls under such commerce as it can lead to cures for disease and disorders which could have a financial impact on millions, or even billions of dollars. For a further discussion on the legislative authority to regulate research, see Lauren Thuy Nguyen, Comment, *The Fate of Stem Cell Research and a Proposal for Future Legislative Regulation*, 46 SANTA CLARA L. REV. 419, 439 (2006).

their embryos, whether it be to remove a genetic disorder or even to choose their child's eye color. Such consumer-parents may travel across state lines to seek out doctors and facilities with such CRISPR-Cas9 capabilities, causing a large amount of money to flow across state lines. While writing legislation on such a medically heavy and contentious topic may seem daunting, the framework for the law is already in existence. The FDA previously commissioned a report on mitochondrial replacement techniques, a method of modifying the germline, which outlined recommendations for the FDA.¹⁷² Several contents of this report, in particular the precursory stipulations to initial investigations, should be combined with the licensing system and limitations of the United Kingdom's regulation. Prohibition of implantation of any genetically modified embryos eliminates the fear of the rise of the "designer baby," as does the requirement to destroy the embryo after fourteen days. Implementing a licensing system ensures that regulatory oversight is in place, which the NIH will control.¹⁷³ Further, the general legislation should control all research initiatives, whether private or public, regardless of funding.

One obvious concern in regard to this proposal, however, is the current attitude of the Supreme Court in interpreting the Commerce Clause. Recent decisions, including *Morrison*, illustrate that the Court has moved away from "the post-New Deal permissiveness" in interpreting the Commerce Clause.¹⁷⁴ The Court's current stance is that the federal government should leave truly local, noneconomic conduct to the states.¹⁷⁵ In *Morrison*, examples of such conduct included "marriage, divorce, and childrearing," leading some critics to believe that Commerce Clause restrictions on certain types of genetic research would be deemed unconstitutional.¹⁷⁶ Further, while

172. See Zachary Brennan, *Expert Committee: FDA Should Allow Mitochondrial Replacement Trials Under Certain Conditions*, REG. AFFAIRS PROF'L SOC'Y (Feb. 3, 2016), <http://raps.org/Regulatory-Focus/News/2016/02/03/24245/Expert-Committee-FDA-Should-Allow-Mitochondrial-Replacement-Trials-Under-Certain-Conditions/> [<https://perma.cc/MVU8-TVAK>] (archived Jan. 29, 2017). The recommendations will not be discussed in length as they are numerous and speak specifically to MRT. Rather, they can be incorporated into a new law focused more generally on embryonic genetic editing.

173. One subgroup that the National Institutes of Health could have control the licensing function is the already existing National Human Genome Research Institute which "has funded and conducted research to uncover the role that the genome plays in human health and disease." *National Human Genome Research Institute (NHGRI)*, THE NIH ALMANAC, NAT. INSTS. OF HEALTH, <http://www.nih.gov/about-nih/what-we-do/nih-almanac/national-human-genome-research-institute-nhgri> (last visited Jan. 29, 2017) [<https://perma.cc/8JNM-D6HJ>] (archived Jan. 29, 2016).

174. Robert A. Burt, *Constitutional Restraints on the Regulation of Cloning*, 9 YALE J. HEALTH POL'Y, L. & ETHICS 495, 504 (2009).

175. *Id.*

176. *Id.* ("Prohibition of reproductive cloning is clearly nothing more than identification of an impermissible technique of 'childrearing'; and the destruction of

scientific endeavors such as the cloning of embryos arguably suffice as economic activity because they create a commodity,¹⁷⁷ gene editing merely modifies an embryo.

Nonetheless, if a court held such a restriction to be constitutional, then, by imposing explicit limitations, it can placate the fears of the public and scientific community that this research will lead to the selection of eye-color or height, and instead focus on the research's capabilities to cure diseases. Updating the U.S. stance on gene editing ensures that the country can remain at the forefront of scientific advances, in an ethical manner, and closes the loopholes that have existed because of the regulatory division based on whether the researchers receive federal funding.

B. *Establishing an International Consensus*

In a utopian world, key countries involved in gene editing could collaborate and enact a multilateral or plurilateral treaty, prohibiting gene editing until further research occurs and the ethical implications can be better understood. Ideally, a stand-alone treaty involving China, the United Kingdom, and the United States would eliminate any fear that gene editing will bypass ethical concerns to the detriment of society. This would allow for explicit language and purposeful drafting premised on the current state of affairs. Further, a new treaty provides an opportunity to delineate specific enforcement or revision provisions. A treaty could be attempted under the purview of the World Trade Organization. As gene editing implicates patent law, fertility treatments, and the development of medicine, one could make an argument, albeit a reach, that CRISPR-Cas9 implicates trade. But, a link to trade is too attenuated and few countries are willing to adopt binding measures,¹⁷⁸ perhaps more so in the scientific realm: each country wants to be the first to make a breakthrough in the newest field of research, whether it be for financial opportunities or pure prestige. Further, the current political climate hinders the likelihood of negotiating such a treaty. U.S. President Donald Trump is currently deciding whether to sign the executive order, *Moratorium on New Multilateral Treaties*, which "calls for a review of all current

embryos involved in cloning research is based on the progenitor's decision to refrain from childrearing—that is, from carrying embryos to term.”).

177. See Russell Korobkin, *Stem Cell Research and the Cloning Wars*, 18 *STAN. L. & POL'Y REV.* 161, 178–79 (2007) (“Under Raich, creating an embryo would presumably be considered an ‘economic’ activity because it entails the production of a commodity, even if the production is for a non-commercial purpose such as basic scientific research.”).

178. *Brochure of the Declaration: Universal Declaration on Bioethics and Human Rights*, UNESCO (2006), <http://unesdoc.unesco.org/images/0014/001461/146180E.pdf> [<https://perma.cc/4FHS-C769>] (archived Feb. 3, 2017).

and pending treaties with more than one other nation . . . that are not directly related to national security, extradition or international trade.”¹⁷⁹ Still, the international community cannot allow countries to continue ethically questionable research absent any guidelines or measures.

In order to balance the goal of instituting some protective measures against the reality that countries like China and the United States are unlikely to submit to binding restraints, modifying an already existing declaration, specifically the Universal Declaration on the Human Genome and Human Rights, presents a practical and realistic solution.¹⁸⁰

1. The Universal Declaration on the Human Genome and Human Rights

Shortly after the establishment of the United Nations post-World War II, a U.N. Conference convened in November of 1945 to found an organization reflecting “the intellectual and moral solidarity of mankind.”¹⁸¹ Thirty-seven countries, including China, the United Kingdom, and the United States, consequently established the United Nations Educational, Scientific and Cultural Organization (UNESCO).¹⁸² Nearly fifty years later, with the publicized emergence of genetic research, UNESCO adopted The Universal Declaration on the Human Genome and Human Rights on November 11, 1997.¹⁸³ The Declaration sets “out universal ethical standards on human genetics research and practices, standards that seek to balance the freedom to carry out genetic research with a need to shield human rights and protect people from potential abuses deriving from such research.”¹⁸⁴

While the Declaration contains several provisions to which gene editing may be applicable, this Note argues that the key provision in solving the current gene-editing dilemma is Article 11:

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international

179. Max Fisher, *Trump Prepares Orders Aiming at Global Funding and Treaties*, N.Y. TIMES (Jan. 25, 2017), <https://www.nytimes.com/2017/01/25/us/politics/united-nations-trump-administration.html> [<https://perma.cc/BLR7-GSUA>] (archived Feb. 3, 2017).

180. *The Organization's History*, UNESCO, <http://www.unesco.org/new/en/unesco/about-us/who-we-are/history/> (last visited Feb. 3, 2017) [<https://perma.cc/V3TD-VT7H>] (archived Feb. 3, 2017).

181. *Id.*

182. *Id.*

183. See Harry Rothman, *Disseminating the Principles of the Universal Declaration on the Human Genome and Human Rights*, 19 NEW GENETICS & SOC'Y 89, 90 (2000).

184. *Id.*

organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.¹⁸⁵

One argument is that the language in the first sentence of Article 11 is extremely broad, prohibiting undefined “practices” if they “are contrary to human dignity.” This use of “such as”, in providing the example of cloning, further evidences this breadth. As Part III discussed, historical precedence dictates, or at least strongly suggests, that modifications of the human population undertaken to maintain or establish an ideal would be “contrary to human dignity” because such modifications relay that those who do not meet the prescribed ideal are inferior. Thus, gene editing is arguably exactly the kind of practice that Article 11 intends to cover. Further, the International Summit and the Consensus Study align with the recommendation provided in the second sentence of the provision. Holding a forum to discuss gene editing and its ethical implications, co-sponsored by the three prominent countries in the research field, reflects “co-operat[ion] in identifying such practices and . . . taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.”¹⁸⁶

This approach has an obvious limitation: it relies on an implicit interpretation. While one can readily argue for gene-editing’s inclusion, it is inadvisable to leave something so ethically important to mere interpretation. Countries may differ in their interpretations of “human dignity.” While many disability advocates caution against a method of eliminating mental disabilities,¹⁸⁷ some countries may view such treatment as beneficial for society. With the possibility of such differing interpretations, a more explicit approach is preferred.

2. Revising Article 11 of the Declaration

Rather than relying on an ambiguous interpretation of an already unenforceable declaration, UNESCO should revise Article 11 to contain an explicit provision prohibiting gene editing to eliminate any ambiguity of the international consensus. This Note proposes amending the first sentence to read, “Practices that are contrary to

185. UNESCO, RECORDS OF THE GENERAL CONFERENCE: TWENTY-NINTH SESSION: RESOLUTIONS 44 (1997), <http://unesdoc.unesco.org/images/0011/001102/110220e.pdf> [https://perma.cc/BBK5-TTZ6] (archived Feb. 20, 2017).

186. *Id.*

187. See Erika Check Hayden, *Should you edit your children’s genes?*, NATURE (Feb. 23, 2016), <http://www.nature.com/news/should-you-edit-your-children-s-genes-1.19432> [https://perma.cc/8XYC-2XP6] (archived Feb. 3, 2016) (discussing gene editing as a possible treatment to eliminate future instances of mental disabilities).

human dignity, such as *germline genetic modifications* and reproductive cloning of human beings, shall not be permitted.” In order to make such a change, several steps would need to be taken.

The process for modifying a pre-existing declaration is relatively straightforward. First, the General Conference determines whether an elaboration of a current declaration should address a certain question.¹⁸⁸ Genetically modifying offspring easily should arise to such a level. It is highly publicized and contested and has already led to an international review via the International Summit. Second, the General Conference must request that the Director-General submit a draft declaration on a specified date.¹⁸⁹ Due to the minor scale of this change, the Director-General should easily meet any deadline. Third, the General Conference “reviews and discusses the draft declaration,” which is “adopted by a resolution of the General Conference.”¹⁹⁰ The third step is theoretically the most contentious but nonetheless is quite feasible. Most countries, particularly those at the forefront of gene editing, prohibit or severely restrict gene editing. Additionally, a group of independent experts has already requested that UNESCO ban gene editing.¹⁹¹ Such a minor change in the phrasing of Article 11 is unlikely to illicit a large amount of backlash. As the General Conference is likely to adopt this revision, the only remaining step is that the Director-General then has the responsibility of disseminating the declaration “as widely as possible.”¹⁹²

3. The Practicality of a Declaration

As previously noted, a treaty would likely be unsuccessful at remedying the lack of an international consensus on gene editing, but a declaration provides a solution far less adverse to a country’s autonomy. An obvious advantage of a declaration over a treaty is that a declaration is not subject to ratification and is not binding on Member States. “However, in view of the greater solemnity and significance of a ‘declaration,’ it may be considered to impact, on behalf of the organ adopting it, a strong expectation that Members of the international

188. *Multi-stage procedure for the elaboration, examination, adoption and follow-up of declarations, charters and similar standard-setting instruments adopted by the General Conference*, UNESCO, http://portal.unesco.org/en/ev.php-URL_ID=31286&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited Feb. 28, 2017) [<https://perma.cc/9WK9-MSPU>] (archived Mar. 25, 2017) [hereinafter *Multi-stage procedure*]

189. *Id.*

190. *Id.*

191. *UNESCO panel of experts calls for ban on “editing” of human DNA to avoid unethical tampering with hereditary traits*, UNESCO, <http://en.unesco.org/news/unesco-panel-experts-calls-ban-editing-human-dna-avoid-unethical-tampering-hereditary-traits> (last visited Feb. 3, 2017) [<https://perma.cc/7YBK-6PMX>] (archived Feb. 3, 2017).

192. *Multi-stage procedure*, *supra* note 188.

community will abide by it.”¹⁹³ Thus, a declaration can indicate international consensus,¹⁹⁴ absent the complexities and complications necessary in drafting, enacting, and ratifying a treaty.

Despite the apparent benefits of a declaration, it would be amiss for this Note to fail to address that such an instrument remains “soft law.” Many scholars consider declarations “soft law” because of their non-binding nature;¹⁹⁵ there is nothing truly stopping countries from non-compliance. Unlike a treaty, declarations lack any enforcement mechanism. There is no option to bring those who have violated the instrument to a court, such as the International Court of Justice, nor a method of resolving disputes, such as the Dispute Resolution process of the World Trade Organization. However, treaties suffer from their own limitations. The most glaring limitation is that there is nothing stopping a country from withdrawing from a specific treaty if they no longer wish to abide by it. Further, hard law is expensive to enact and can be “difficult to adapt to changing circumstances,” which scientific research falls under.¹⁹⁶

Therefore, while the Declaration on the Human Genome and Human Rights may lack the teeth of a more binding instrument, it affords flexibility in a rapidly advancing field and a faster method for establishing an international norm against gene editing.

VII. CONCLUSION

Technological advances in gene editing and modification over the past few years have been astonishing.¹⁹⁷ Research suggests that these advances could provide a myriad of societal benefits—including the elimination of certain diseases and disorders. Still, many have reason to be weary of jumping into a world of gene editing and modification when there are few limits and little regulation on just how far it can go. Should scientists eliminate blindness, deafness, and mental

193. *General Introduction to the Standard-Setting Instruments*, UNESCO, http://portal.unesco.org/en/ev.phpURL_ID=23772&URL_DO=DO_TOPIC&URL_SECTION=201.html#name=3 (last visited Feb. 3, 2017) [<https://perma.cc/HC72-P4DX>] (archived Feb. 3, 2017).

194. See Noëlle Lenoir, Comment, *Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level*, 30 COLUM. HUM. RTS. L. REV. 537, 550 (1999) (“The purpose of a declaration is therefore to help achieve international consensus. UNESCO’s decision to draft a declaration sought to facilitate agreement among states in the sensitive and complex field of bioethics.”).

195. See Jacob E. Gersen & Eric A. Posner, *Soft Law: Lessons from Congressional Practice*, 61 STAN. L. REV. 573, 575 (2008) (noting the non-binding nature of soft law).

196. Gregory C. Shaffer & Mark A. Pollack, *Hard vs. Soft Law: Alternatives, Complements, and Antagonists in International Governance*, 94 MINN. L. REV. 706, 719 (2010).

197. See Cyranoski & Reardon, *supra* note 10.

handicaps if they are able to? To some, this seems all too similar to other attempts at removing imperfections in society. As discussed, this is not the first time that the desire to enhance genetics has resulted in ethical offenses. In the United States, Congress enacted, and the Supreme Court upheld, sterilization laws.¹⁹⁸ The legislation's main purpose was to eradicate certain infirmities—criminality, mental illness, *et cetera*—from the population. However, *ex post*, society and science now better understand these “infirmities,” particularly mental illnesses, and even provides treatments that allow these individuals to prosper. Another example discussed was the horrific actions under the Nazi regime and the Holocaust. Yet again, society and a culture decided that certain traits were polluting the race—including Judaism.¹⁹⁹ Both of these historical examples show that societal, cultural, scientific, and ethical values can change.

The International Summit and the Consensus Study acted as a promising first step in looking at the gene-editing technology thoroughly to determine the next move transnationally. However, the United States needs to address the ambiguities and holes within its own laws and the international community must develop a consensus against gene editing in embryos, at least for now. The Universal Declaration on the Human Genome and Human Rights provides an opportunity to establish such a consensus in an already existing instrument. Further, the non-binding nature of declarations, and the ease in their adoption and revision, eliminates the hesitation many countries have in entering more formal instruments, such as binding treaties, and provides flexibility to modify the declaration. This solution ensures that ethical obligations will not unnecessarily hinder science, but also that the international research community will not take them lightly. Relying on soft law ensures that the international consensus on gene editing can adapt as researchers better understand the technology. This may not only prevent a resurgence of the mistakes of our past, but may also allow for a future in which this new and exciting technology could eradicate detrimental disabilities.

*Tara R. Melillo

198. See *supra* Section III.A.

199. See PERPER & CINA, *supra* note 76.

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