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# REHABILITATION OR ENHANCEMENT? FDA & THE GENE THERAPIES OF TOMORROW

*Alexander Harding*∗

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## I. INTRODUCTION

In November 2018, a Chinese scientist named He Jiankui walked across a stage in a crowded Hong Kong conference hall and announced that he had created the world's first genetically engineered babies.[1] Dr. He claimed to have used a genetic engineering tool called "CRISPR" to edit the embryos of twin girls, allegedly making them HIV-resistant

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∗ Harvard Law School, J.D. Class of 2019; Dalhousie University, B.Eng. Class of 2016. I would like to thank Article Editor Crystal Lee for her efforts and valuable comments and the Harvard Journal of Law & Technology ("JOLT") for humoring me with this Note. Finally, I would like to thank Peter Barton Hutt for inspiring this article — as well as for his excellent taste in ties.

1. *See* Rob Schmitz, *Gene-Editing Scientist's "Actions Are a Product of Modern China*," NPR (Feb. 5, 2019, 1:05 PM), https://www.npr.org/2019/02/05/690828991/gene-editing-scientists-actions-are-a-product-of-modern-china [https://perma.cc/RXK8-HQ3Z].

before implanting them for live births via in vitro fertilization.[2] Dr. He's work was met with immediate condemnation by the scientific community, as well as the Chinese government, which has since vowed to punish him.[3]

If all goes well in this ongoing experiment, Dr. He will have created children who are resistant to the HIV infection. But the mutations he generated in the girls' DNA have never been tested in animals.[4] The dilemmas write themselves. What if the mutations introduced into the girls' DNA produce a toxic protein that harms them and future generations?[5] Does an unborn child have a right to refuse genetic modification?[6] How should the law treat illegally modified children, such as those in Dr. He's study? Should these children be able to recover damages from their genetic designers? From their parents?

How does Dr. He's work change the calculus for the United States Food and Drug Administration ("FDA") as it races to adapt its rules for an exploding gene editing industry? There is still no international framework to regulate human genome editing,[7] save for perhaps the Declaration of Helsinki in 1964.[8] That resolution, largely a reaction to the Nazis' bone-chilling experiments on humans in World War II,[9] is

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2. *See id.*

3. *Id.* But new evidence suggests the Chinese government may not have been as unaware of He Jiankui's research as previously reported. *See* Jane Qiu, *Chinese Government Funding May Have Been Used for "CRISPR Babies" Project, Documents Suggest*, STAT (Feb. 25, 2019), https://www.statnews.com/2019/02/25/crispr-babies-study-china-government-funding [https://perma.cc/U9TV-89SN] ("The documents examined . . . list three funding sources for the study that led to the twins' birth: the Ministry of Science and Technology; Shenzhen Science and Technology Innovation Commission, part of the municipal government; and Southern University of Science and Technology, where He worked.").

4. Kevin Curran, *How on Earth Are We Currently Regulating Human Genetic Modification?*, RISING TIDE BIOLOGY (Jan. 23, 2020) https://www.risingtidebio.com/human-gene-therapy-regulations-laws [https://perma.cc/8T66-JKRN].

5. Mutant proteins have been tied to neurodegenerative disorders such as amyotrophic lateral sclerosis. *See* Jeffrey N. Agar, *What Makes (and Doesn't Make) a Mutant Protein Toxic? Exploring Nonpathogenic Variants of Amyotrophic Lateral Sclerosis-Associated Cu,Zn Superoxide Dismutase*, RISE (2015), https://www.northeastern.edu/rise/presentations/what-makes-and-doesnaet-make-a-mutant-protein-toxic-exploring-nonpathogenic-variants-of-amyotrophic-lateral-sclerosis-associated-cuzn-superoxide-dismutase [https://perma.cc/KK78-JDZ7].

6. For a discussion of consent concerns in germline gene editing, see Robert Ranisch, *Germline Genome Editing and the Functions of Consent*, 17 AM. J. BIOETHICS 27, 27–29 (2017).

7. Kathleen M. Vogel et al., *CRISPR Goes Global: A Snapshot of Rules, Policies, and Attitudes*, BULL. ATOMIC SCIENTISTS (June 5, 2018), https://thebulletin.org/2018/06/crispr-goes-global-a-snapshot-of-rules-policies-and-attitudes [https://perma.cc/Y2SN-7DQ9] ("To date, no internationally agreed-upon regulatory framework for gene editing exists . . . .").

8. *See* World Med. Ass'n, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 79 BULL. WORLD HEALTH ORG. 373, 373–74 (2001) (stating "ethical principles for medical research involving human subjects" in general).

9. *See* Robert V. Carlson et al., *The Revision of the Declaration of Helsinki: Past, Present and Future*, 57 BRIT. J. CLINICAL PHARMACOLOGY 695, 696 (2004).

no longer referenced by FDA in any guidance as of 2006.[10] Without an international framework, FDA must design its own rules to balance the anticipated benefits of gene therapy with the risks of irreversible genetic change.[11]

To date, outrage among geneticists towards Dr. He's study is directed primarily at his use of *germline* gene therapy in his research — that is, the editing of an embryo's genome to alter a child's entire genetic makeup.[12] This reaction is certainly rational; an unborn child, after all, cannot consent to a procedure.[13] Nearly forgotten, however, is the fact that Dr. He claims to have granted his subjects an enhanced genetic immunity to an otherwise incurable disease.[14]

Certainly, the goal of eliminating HIV is a noble one. This Note does not argue for a blanket prohibition against enhancing therapies like Dr. He's. But there are social risks at play with enhancement-based therapies not previously seen in medicine. We must make a formal distinction between enhancement-based gene therapies and therapies that aim merely to rehabilitate. Social risk factors must be incorporated into such a distinction, and they will inform the policy steps advocated for by this Note. First, FDA must establish readily identifiable criteria for researchers to know which FDA category their work falls into. Second, because of the positive feedback loop generated by enhanced individuals being more likely to afford further enhancement, FDA should consider cost-balancing options for any treatment falling into that category.

### *A. Scientific Background — What is CRISPR?*

Before we explore the current regime for regulating genetic research in the United States, we should understand a little about the science behind the technology. CRISPR technology allows scientists to

10. Howard Wolinsky, *The Battle of Helsinki*, 7 EMBO REP. 670, 670 (2006).

11. For a discussion of the risks of irreversible genetic change, see Jeantine Lunshof, *Regulate Gene Editing in Wild Animals*, 521 NATURE 127, 127 (2015) (noting that "[o]nce introduced, these genetic changes are self-propagating" and "if released beyond the laboratory, the effects would spread with every new generation and would quickly run out of control").

12. *See On Human Gene Editing: International Summit Statement*, NAT'L ACAD. SCI., ENGINEERING & MED., (Dec. 3, 2015), https://www.nationalacademies.org/news/2015/12/on-human-gene-editing-international-summit-statement [https://perma.cc/7ZET-ZJ8Z].

13. *See* Ransich, *supra* note 6, at 27.

14. Indeed, most criticism of Dr. He's work seems to focus exclusively on issues of consent and sexual transmission of traits. *See, e.g.*, Schmitz, *supra* note 1 ("What if this introduced mutations in the girls' DNA that could pass on genetic diseases to future generations? And is it ethical to create gene-edited babies, who could never be willing participants in such a risky experiment?").

delete, cut, copy, and paste genetic code in DNA.[15] This ease of manipulation can facilitate replacement of undesirable genes with theoretically superior ones.[16]

In 2008, commentators branded genetic tools like CRISPR an "Uncertain Peril."[17] In 2017, CRISPR was promoted to an "Unthinkable Power,"[18] and, in 2018, "More Dangerous than Nuclear Weapons."[19] Scholarship is consistently cataclysmic on the issue of human augmentation through genetic engineering, even while the technology behind it advances at a breakneck pace, all without thorough regulatory instruction. After a decade of alarm bells, there is still no official guidance on the human augmentation capacity of technologies such as CRISPR. Under FDA's current regime, there is still no formal difference in rules for research to treat genetic defects of the Achilles tendon and research that could turn a patient *into* Achilles.[20]

On the other hand, FDA has taken some measures to contain the risks associated with human genetic research more generally. For example, in 2018, FDA put the brakes on an early human trial for a CRISPR-based sickle cell disease therapy until it had resolved "certain questions" about the treatment.[21] This year, it finalized guidance documents on the development of certain rehabilitative gene therapies.[22] FDA has also preemptively — and with good reason — put a pause on

15. *See* Mark Shwartz, *Target, Delete, Repair*, 35 STAN. MED. 20, 24 (2018) (explaining that CRISPR can "target and delete any sequence of DNA in the human genome" and "insert . . . DNA sequence[s] into the edited gene"); Nat'l Inst. of Standards & Tech., *Taking CRISPR from Clipping Scissors to Word Processor*, PHYS.ORG (May 7, 2018), https://phys.org/news/2018-05-crispr-scissors-word-processor.html [https://perma.cc/K5DU-Q3Z2] ("[T]he new platform [MAGESTIC] makes CRISPR . . . like a word processor by enabling an efficient 'search and replace' function for genetic material.").

16. *See* Shwartz, *supra* note 15, at 24.

17. CLAIRE HOPE CUMMINGS, UNCERTAIN PERIL: GENETIC ENGINEERING AND THE FUTURE OF SEEDS (2008).

18. JENNIFER DOUDNA & SAMUEL STERNBERG, A CRACK IN CREATION: GENE EDITING AND THE UNTHINKABLE POWER TO CONTROL EVOLUTION (2017).

19. Nick Bilton, *The "Black Ball" Hypothesis: Is Gene Editing More Dangerous than Nuclear Weapons?*, VANITY FAIR (Nov. 28, 2018), https://www.vanityfair.com/news/2018/11/is-gene-editing-more-dangerous-than-nuclear-weapons [https://perma.cc/57CQ-CKZC].

20. *See Regulation of Genetic Tests*, NAT'L HUMAN GENOME RES. INST. (Nov. 20, 2019), https://www.genome.gov/10002335/regulation-of-genetic-tests [https://perma.cc/W48U-KZPT].

21. Kristin Houser, *The FDA Puts the Brakes on a Major CRISPR Trial in Humans*, FUTURISM (May 31, 2018), https://futurism.com/human-crispr-trial-fda-stops [https://perma.cc/S2BF-YTYF].

22. Zachary Brennan, *FDA Finalizes 6 Gene Therapy Guidances*, *Unveils a New Draft*, REGULATORY AFFAIRS PROF'L SOC'Y (Jan. 28, 2020), https://www.raps.org/news-and-articles/news-articles/2020/1/fda-finalizes-6-gene-therapy-guidances-unveils-a [https://perma.cc/A2B8-ZG7R] ("The six final guidance documents . . . finalize drafts from July 2018 and focus on developing hemophilia, rare disease and retinal disorder gene therapies.").

certain research for germline gene therapies.[23] The decision came on the back of dozens of scientific and ethics papers calling for a specific distinction between somatic and germline treatments with robust ethical arguments and empirical data to back up such a move.[24] Embryos cannot consent, one essay warned.[25] Some argued that unintended effects of germline editing may not be reversible.[26] These arguments latched on to well-known socio-ethical issues like consent and sustainability.

But the sensationalist journalism on the disruptive capability of CRISPR, even when used somatically, has been less useful. Lofty proclamations that CRISPR "could precipitate the end of life as we know it"[27] when used to enhance, rather than rehabilitate, aren't necessarily useful for American regulators, who should aim to regulate the technology without hamstringing domestic innovation in the field, particularly in the face of surging Chinese investment in gene editing.[28]

## II. GENETIC RESEARCH REGULATION, TODAY & TOMORROW

Currently, there is no federal legislation that dictates protocol or restricts subject matter in human engineering research in the United States.[29] FDA, however, oversees human genetic research through: (1) allotting federal funding for research, (2) approving gene therapy clinical trials, and (3) awarding market approval for therapies to be sold

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23. For example, germline genetic therapy research is not eligible for federal research funding from FDA. *See infra* Section II.A.

24. *See* Jeremy Sugarman, *Ethics and Germline Gene Editing*, 16 EMBO REP. 879, 879 (2015); Tetsuya Ishii, *Germline Genome-Editing Research and Its Socioethical Implications*, 21 TRENDS MOLECULAR MED. 473, 473 (2015) ("[R]epresentatives of the Alliance for Regenerative Medicine, a group of interested stakeholders including Cas9 developers and the International Society for Stem Cell Research (ISSCR), have called for a voluntary moratorium on research into and/or the clinical application of human germline genome editing owing to increasing bioethical concern.").

25. Joanna Smolenski, *CRISPR/Cas9 and Germline Modification: New Difficulties in Obtaining Informed Consent*, 15 AM. J. BIOETHICS 35, 35–37 (2015).

26. *See* Elliot Hosman, *CRISPR Gene Editing: Proofreaders and Undo Buttons, but Ever "Safe" Enough?*, BIOPOLITICAL TIMES (Nov. 19, 2015), https://www.geneticsandsociety.org/biopolitical-times/crispr-gene-editing-proofreaders-and-undo-buttons-ever-safe-enough [https://perma.cc/TL3R-PMXG] (stating that "even if the promised safeguards [of reversal gene drives] function as advertised, they wouldn't necessarily prevent gene editing tools from effecting unforeseeable and irreversible changes to human genomes or ecological systems"); *see also* Kenneth A. Oye et al., *Regulating Gene Drives*, 345 SCIENCE 626, 626 (2014) ("Reversal drives . . . could overwrite unwanted changes introduced by . . . genome engineering, even restoring the original sequence. However, ecological effects would not necessarily be reversed.").

27. Bilton, *supra* note 19.

28. *Id.* ("China . . . spent $254 billion on genetic research last year, racing to catch up to the U.S. without any of our ethics laws. . . . [W]hatever our hesitance, the future of these technologies becomes clear: America will have no choice but to play along, or else fall behind.").

29. Curran, *supra* note 4.

to consumers.[30] Geneticist Kevin Curran reports that, as of April 2019, FDA has granted market approval to six gene therapy products:[31]

Table 1: FDA-Approved Gene Therapy Treatments[32]

| Treatment | Description |
|---|---|
| Imlygic | A herpes virus modified to infect and kill melanoma cancer cells |
| Kymriah | T-cells genetically modified to kill acute lymphoblastic leukemia cells |
| Yescarta | T-cells genetically modified to kill non-Hodgkin's lymphoma |
| Provenge | Immune cells modified to kill prostate cancer cells |
| Luxturna | RPE65 gene delivered via adeno-associated virus ("AAV") to modify a genetic defect that leads to a rare eye disease |
| Zolgensma | SMN1 gene delivered via AAV to modify motor neurons of spinal muscular atrophy patients |

### *A. Today: Somatic Versus Germline*

Before we dive any deeper, it is important to understand the difference between two major types of genetic engineering because the two are regulated differently. The first and less controversial is called "somatic" gene therapy.[33] A somatic cell is an adult human cell that is unrelated to reproduction.[34] The effects of somatic gene therapy are limited to those cells.[35] Somatic therapies are performed on consenting adults and their effects do not transfer to a patient's offspring.[36] Most, but not all, scientists are comfortable with somatic therapies because they resemble conventional medicine: one adult, one consent form.[37]

30. *Id.*
31. *Id.*
32. *Id.*
33. *See id.*
34. *Id.*
35. *Id.*
36. *Id.*
37. *See On Human Gene Editing: International Summit Statement*, *supra* note 12 ("Because proposed clinical uses are intended to affect only the individual who receives them, they can be appropriately and rigorously evaluated within existing and evolving regulatory frameworks for gene therapy, and regulators can weigh risks and potential benefits in approving clinical trials and therapies.").

The second type of genetic engineering treatment is called "germline" gene therapy. These treatments modify the genome of a single sperm cell, egg, or embryo. Any traits that are added to or removed from that cell would alter every cell in the resulting organism and would carry on to further generations via sexual reproduction.[38] The National Institutes of Health ("NIH") acknowledges germline gene therapies as "controversial" because they "might affect the development of a fetus in unexpected ways or have long-term side effects that are not yet known."[39]

Currently, NIH may approve federal funding for somatic cell gene therapy, but not for germline therapy.[40] The quote below was the extent of federal guidance on the matter as of April 2019:

> Current gene therapy research has focused on treating individuals by targeting the therapy to body cells such as bone marrow or blood cells. This type of gene therapy cannot be passed to a person's children. Gene therapy could be targeted to egg and sperm cells (germ cells), however, which would allow the inserted gene to be passed to future generations. This approach is known as germline gene therapy.
>
> The idea of germline gene therapy is controversial. While it could spare future generations in a family from having a particular genetic disorder, it might affect the development of a fetus in unexpected ways or have long-term side effects that are not yet known. Because people who would be affected by germline gene therapy are not yet born, they can't choose whether to have the treatment. Because of these ethical concerns, the U.S. Government *does not* allow federal funds to be used for research on germline gene therapy in people.[41]

FDA's present dilemma is chiefly limited to the difference in risk between somatic and germline gene therapies. Because FDA does not distinguish between gene therapies that seek to augment natural human

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38. *See* Curran, *supra* note 4.

39. *What Are the Ethical Issues Surrounding Gene Therapy?*, NAT'L INST. HEALTH (Jan. 21, 2020), https://ghr.nlm.nih.gov/primer/therapy/ethics [https://perma.cc/223X-LQGD].

40. While FDA handles approval and testing, NIH is often responsible, as here, for public funding into areas of research. *See Balanced Budget Downpayment Act*, Pub. L. No. 104-99, § 128, 110 Stat. 26, 34 (1996) (instructing NIH not to award funding for most germline research projects).

41. *Id.* (emphasis added).

function and those that only cure some acute disorder, all somatic research ostensibly falls under the same set of rules. Admittedly, in one small bullet point, NIH asks: "Should people be allowed to use gene therapy to enhance basic human traits such as height, intelligence, or athletic ability?" but does not provide an answer.[42] This Note will not try to answer this sweeping normative question. It aims simply to provide FDA with a more concrete framework to present to scientists who wish to pursue this sort of research but who currently have almost no guidance on how such enhancement therapies will be regulated.

### *B. Tomorrow: Rehabilitation Versus Enhancement*

While today's regulatory concerns surrounding gene therapies center on the "how" of a procedure — how the therapy is delivered and how we can obtain consent — tomorrow's will almost certainly focus on the "how much." How much stronger or more intelligent can a therapy make the patient who can afford it, and how much will it cost? How much of a class divide is created when wealthy patients can purchase genetic traits to perpetuate their own success?

Many leading scholars have expressed skepticism at the idea of separating enhancement from rehabilitation. Glenn Cohen argues that such line-drawing flows from an overreliance on traditional "ends of medicine and the organization of the medical professions."[43] Augmentation, Cohen tells us, cannot (yet) render a patient any less a "human being" since any traits produced by such augmentation exist naturally in some humans.[44] Whether the treatment renders the patient "inhuman" in some moral sense, however, is not the issue of this Note.

It is clear that enhancement-based therapies present novel risks not shared by rehabilitative therapies. Gene therapies that raise the bar of human performance — rather than simply making the patient "whole" — carry real socioeconomic risks over traditional therapies. Because of these dangers, drawing a distinction between these two types of therapies is useful for FDA when it sets regulations for approving commercial treatments. This Section attempts to divide the risks of enhancement-based therapies into three primary categories to argue that enhancement-based therapies require extra consideration from FDA, whether it be at the testing or market approval stages. First, en-

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42. *Id.*

43. I. Glenn Cohen, *What (If Anything) Is Wrong with Human Enhancement? What (If Anything) Is Right with It?*, 49 TULSA L. REV. 645, 650 (2014).

44. *Id.* at 650–51. But Cohen also gives an excellent example of a pilot who chooses not to enhance himself and thereby puts himself at risk of losing employment opportunities. *See id.* at 659–60. While Cohen "[does] not find that plea all that sympathetic," *id.* at 660, this Note aims to acknowledge that such moral objectors will exist and realistically must receive some level of regulatory protection — or else be forced from every employment opportunity.

hancement in a competitive system such as work or school tends to destabilize the level of competition, whereas rehabilitation tends to correct underperformance. Second, enhancement can create genomes which have never existed; rehabilitation seeks to restore mutated genes to some genetic norm. Third, the likely financial cost of enhancement may make such therapies disproportionately inaccessible to less wealthy individuals, exacerbating current class inequality.

### *C. Raising the Bar Versus Leveling the Playing Field*

First, gene therapies that merely rehabilitate some genetic disorder are limited in power by their very nature. They are designed to return a patient to a state in which where they can perform, intellectually or physically, on some threshold level. For example, if FDA approves CRISPR Therapeutics' pending CTX001 treatment for sickle-cell disease, the ideal result will be that patients receiving the treatment will have a closer-to-normal level of healthy hemoglobin in their red blood cells.[45]

Enhancement gene therapies would go further. For example, a study published in 2019 found 187 genetic loci in the human genome which are associated with overall intelligence.[46] Small changes in the genetic code associated with some of these loci corresponded to measurable differences in the level of education attained among the study's participants.[47] A parent looking to ensure their child's educational success could theoretically use CRISPR to "snip" out the markers in their child's embryonic genome that are implicated by these loci[48] and found to be related to low academic performance, and replace them with versions correlated with high academic performance.[49] Thus, a patient receiving intelligence-enhancing CRISPR treatment would attain levels of intelligence beyond their natural capabilities.

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45. *See A Safety and Efficacy Study Evaluating CTX001 in Subjects with Severe Sickle Cell Disease*, CLINICALTRIALS.GOV (Nov. 21, 2019), https://clinicaltrials.gov/ct2/show/NCT03745287 [https://perma.cc/7GLR-2X9S].

46. *See* W.D. Hill et al., *A Combined Analysis of Genetically Correlated Traits Identifies 187 Loci and a Role for Neurogenesis and Myelination in Intelligence*, 24 MOLECULAR PSYCHIATRY 169, 169 (2019).

47. *See id.* at 170.

48. The Hill paper found 538 genes associated with the 187 independent, intelligence-related loci. *See id.* at 169.

49. And while germline therapy may be a powerful tool for gene editing, it may not necessarily be required. It would be theoretically possible to use somatic therapy for the same ends, although it would be more difficult to do so using current technology, because such therapies can only alter genes in specific types of cells, such as skin cells or blood cells. *See* G. Owen Schaefer, *Why Treat Gene Editing Differently in Two Types of Human Cells?*, ELSEVIER SCITECH (Dec. 18, 2015), http://scitechconnect.elsevier.com/treat-gene-editing-differently-human-cells [https://perma.cc/YQ8J-NUS7].

This dynamic presents a classic prisoner's dilemma. Imagine a classroom of healthy, elementary-aged children. Each child's family knows that for $10,000, their child can outperform each of their peers.[50] But each family cannot prevent the other families from also seeking enhancement therapy for their respective children. If a family pursues treatment for their child, their child's resulting enhanced performance will raise the average performance level of the class slightly. This means that every other child is now performing slightly worse relative to the class average.

The willingness to "enhance" oneself likely varies from person to person.[51] Such a shift would increase the cost of not pursuing enhancement; parents previously on the fence about enhancement might now pursue it to maintain competitiveness for their child. While the effect of a single child's family pursuing intelligence enhancement on the class average may be slight, if many families pursue enhancement, the aggregate effect may be stark. Children from families who cannot afford treatment — or families who choose not to pursue treatment for ethical reasons — would perform measurably worse against the new class average. These students may have to compete for admittances into selective colleges and prestigious scholarships, even though the bar has been raised artificially.

In contrast, the negative externalities of rehabilitative gene therapies are inherently limited. These technologies are unlikely to create a prisoners' dilemma for patients because the treatments are inherently limited to a small subset of the population. The possible effects of each individual treatment are also limited; for example, CTX001 cannot by itself grant a disabled child the athletic ability of a modern Olympic athlete.[52]

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50. The figure $10,000 is chosen as an example, but it reflects a generously low estimate for the cost of gene therapy. The recently approved Luxturna will cost patients an estimated $850,000. *See* Bill Berkrot, *Spark's Price for Luxturna Blindness Gene Therapy Too High: ICER*, REUTERS (Jan. 12, 2018), https://www.reuters.com/article/us-spark-icer/sparks-price-for-luxturna-blindness-gene-therapy-too-high-icer-idUSKBN1F1298 [https://perma.cc/W8XZ-MNF8].

51. Medical preferences have historically varied person-to-person and even culture to culture. Consider, for example, the recent proliferation of alternative medicine against more traditional methods of treatment. *See* Dr. Arthur L. Caplan et al, *Should Doctors Embrace or Reject Alternative Treatments?*, MEDSCAPE (Oct. 18, 2017), https://www.medscape.com/viewarticle/886987 [https://perma.cc/RUL6-DJLC].

52. *See* Joana Cavaco Silva, *CTX001*, SICKLE CELL DISEASE NEWS (Dec. 6, 2019), https://sicklecellanemianews.com/ctx001 [https://perma.cc/XN6C-DQ6A] ("CTX001 was able to . . . achieve about 40 percent of fetal hemoglobin production, which investigators believe is sufficient to improve a patient's symptoms.").

### *D. Rehabilitation Aims for Predictable Results; Enhancement Does Not*

Rehabilitative gene therapies are designed to return a patient to a known state. Taking CTX001 for example again, FDA can take comfort in knowing that, for all the risks associated with gene therapies — somatic or germline — the long-term effects of a normal level of functional hemoglobin are known. Therefore, regulators of the research and commercialization of these therapies can focus on monitoring unwanted side effects, rather than studying the possible long-term harms of the intended effect.

But function-enhancing therapies do not merely aim to restore patients to known physiological states. Take the 187 intelligence loci, for example. Assume, for simplicity's sake, that an individual has an equal chance to naturally inherit either low- or high-performing code for any of these 187 regions.[53] The probability that any given individual will naturally inherit high-performing genetic code for all 187 regions is about 1 in $2 \times 10^{56}$. In other words, the chance of an individual naturally inheriting high performance for every region in their genome is less than the probability of that individual winning the Powerball lottery six times in a row.[54]

There is almost certainly no human alive with high-performing code in all 187 regions identified in the Hill study. A treatment which artificially implements code identified as high-performing in each region will almost certainly lead to a genome that has never naturally occurred, even though each individual region has. We know that genes can interact in unpredictable ways.[55] For example, psychiatric diseases are thought to be "conferred by multiple small effect genetic variants interacting with one another and with the environment."[56] It is plausible that switching 187 areas in a patient's genome to "high intelligence" would, through complex genetic interactions, cause an overall level of

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53. Certainly, each of these loci has more than two states. Each locus might have dozens of variants. For each of these loci, we can assume for simplicity's sake that there is some average level of intelligence performance correlated to each and that roughly half of the variants will perform above average, and half will perform below. But even if an individual were twice as likely to receive high-performing loci from their parents, the probability of naturally inheriting 187 high-performing loci would be roughly 1 in $8.5 \times 1{,}032$.

54. *See* Alicia Adamczyk, *These Are the Odds You'll Win Tonight's $350 Million Powerball Jackpot,* CNBC (June 1, 2019), https://www.cnbc.com/2019/05/31/these-are-the-odds-youll-win-the-350-million-powerball-jackpot.html [https://perma.cc/4NHX-R999].

55. For a discussion on genetic interaction (i.e., when genes interact in ways that produce more change than expected based on the sum of their parts), see generally Tong et al., *Global Mapping of the Yeast Genetic Interaction Network*, 303 SCIENCE 808, 808 (2004) (analyzing a data set containing "~4,000 interactions amongst ~1,000 genes").

56. Andreas Meyer-Lindenberg & Daniel R. Weinberger, *Intermediate Phenotypes and Genetic Mechanisms of Psychiatric Disorders*, 7 NATURE REV. NEUROSCIENCE 818, 818 (2006).

psychotic or mental disability even if the treatment is performed perfectly.

### *E. Enhancement & Social Class: Positive Feedback Loops*

Even if enhancement were proven to be both safe and effective, the latest-and-greatest patented enhancement treatments would not be cheap.[57] Kymriah, a CAR T-cell gene therapy treating lymphoblastic leukemia, was initially priced at $475,000 per treatment following its approval in 2017.[58] Luxturna, which treats certain types of genetic blindness, was also approved in 2017 and priced at $850,000 per patient.[59] Certainly, prices for genetic treatments can be expected to fall as our knowledge of the science improves and companies streamline the development process for therapies.[60] And indeed, a leading cause of the high cost for these treatments is the relatively low number of eligible patients — the blindness treated by Luxturna, for example, is estimated to affect only a few thousand Americans.[61]

This means that, at least initially, the wealthy would have greater access to the fruits of FDA approval for enhancement-based gene therapies. Rehabilitative therapies assist with specific, acute illnesses, and are inherently limited in terms of patient pool. Enhancement, on the other hand, could potentially alter *any* trait that patients deem to be suboptimal.[62]

This would create a troubling positive feedback loop: because wealthy Americans will be able to afford more enhancement therapy

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57. *See* Sterghios Moschos, *Gene Therapy Is Now Available, but Could Cost Millions over a Lifetime, Says Scientists*, INDEPENDENT (Apr. 2, 2018, 11:00 PM), https://www.independent.co.uk/life-style/health-and-families/gene-therapy-cost-rare-genetic-diseases-treatment-expensive-research-a8275391.html [https://perma.cc/6TNG-8XR5].

58. *See* Matthew Herper, *Patient Advocate Says Novartis' $475,000 Breakthrough Should Cost Just $160,000*, FORBES (Feb. 8, 2018, 8:50 AM), https://www.forbes.com/sites/matthewherper/2018/02/08/patient-advocate-says-novartis-475000-breakthrough-should-cost-just-160000 [https://perma.cc/AA4F-EYNM].

59. Or $425,000 per eye — but someone with the disorder will typically have symptoms in both eyes. *See* Berkrot, *supra* note 50. Medical insurance providers are trying to avoid providing coverage for expensive genetic treatments. *See* Michelle Andrews, *Staggering Prices Slow Insurers' Coverage of CAR-T Cancer Therapy*, KHN (July 17, 2018), https://khn.org/news/staggering-prices-slow-insurers-coverage-of-car-t-cancer-therapy [https://perma.cc/HF3T-MWZP].

60. *See* Carla Tardi, *Moore's Law,* INVESTOPEDIA (Sept. 5, 2019) https://www.investopedia.com/terms/m/mooreslaw.asp [https://perma.cc/ADG5-R7B3]. *But see* Jeremy Hall et al., *The Paradox of Sustainable Innovation: The "Eroom" Effect (Moore's Law Backwards)*, 172 J. CLEANER PRODUCTION 3487, 3488 (2018).

61. Berkrot, *supra* note 50.

62. *See, e.g.*, Ya-Ping Tang et al., *Genetic Enhancement of Learning and Memory in Mice*, 401 NATURE 63, 63 (1999); Michelle L. Taylor et al., *The Heritability of Attractiveness*, 17 CURRENT BIOLOGY R959, R959 (2007); Martine A. Thomis et al., *Strength Training: Importance of Genetic Factors*, 30 MED. SCI. SPORTS EXERCISE 724, 724 (1998).

relative to Americans who are poor, the wealthy will gain an even larger advantage in obtaining jobs and securing competitive seats at colleges. If wealth leads to enhancement, and enhancement leads to better performance and therefore greater wealth, then poor Americans may soon find themselves entirely outside of the competitive range of society.

This raises the question of how patent laws might mitigate these negative externalities. The twenty-year limitation on patent protection for any gene therapy — including enhancement-based — inherently limits the social distortion such a therapy can cause. It is not clear that these trends should operate any differently in the market than they do for other forms of medicine. After the patent term expires, generic production of any given enhancement therapy should reduce the cost of the therapy to more affordable levels.[63] But twenty years is a long time in the school or workplace.

If a breakthrough new enhancement therapy for intelligence received FDA approval and were placed on the market today, it could take until at least 2030 for the patent term to expire. It would be little comfort to today's college graduates looking for work to know that the unfair advantage their wealthier counterparts would have access to would only last for the next decade. By 2030, their colleagues may be in supervisory positions or in possession of elite graduate degrees. Worse, there may very well be an even more powerful gene therapy approved in that timeframe that poor Americans would not be able to afford. In short, the current limits of patent protection may dull the blow, but they cannot prevent it.

## III. THE RACE FOR THE HUMAN RACE

Now that we've covered the reasons why gene therapies which enhance rather than merely rehabilitate warrant further scrutiny, we should explore what that "further scrutiny" looks like. Specifically, what exactly is the line between rehabilitation and enhancement?

### *A. Recommended First Steps for FDA*

Scholars have written many warnings for geneticists and lawmakers about the dangers lurking in the nebulous future of genetic science.[64] Because these warnings have too often been lofty prophecies of Rag-

63. *But see* Julia Belluz, *The Absurdly High Cost of Insulin, Explained*, VOX (Nov. 7, 2019, 6:00 AM), https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive [https://perma.cc/6F6W-ZJ8M].

64. *See supra* Part I.

narök without any concrete recommendations, FDA has so far perpetuated little guidance on what, if any, extra scrutiny enhancement-based gene therapies should be subject to.[65]

In an attempt to break that cycle, this Note proposes two modest first steps for FDA to regulate this field. First, FDA should provide a definition of exactly what qualifies as an "enhancement-based" gene therapy versus one which is merely "rehabilitative." Second, FDA should condition commercial approval of any gene therapy falling into the former category on price restrictions.

### *B. Defining Enhancement-Based Versus Rehabilitative*

Until now, this Note has treated enhancement-based and rehabilitative therapies as two completely distinct categories of gene therapy. Reality is not that simple. For example, a therapy which starts as an effort to rehabilitate a genetic muscle condition may end up producing greater-than-natural muscle growth when used to treat healthy patients.[66] If geneticists are to know when their work will be subject to extra scrutiny, they must have a clear definition from FDA on this crucial divide. Since the risks of a genetic arms-race colored by classism are the proposed motivating factors behind extra scrutiny for enhancement-based therapies, it makes sense that those risks should inform the definition of "enhancement" adopted by FDA. This Note proposes two approaches.

### *C. Cautious Approach — Any Measurable Improvement*

If FDA wishes to take a cautious approach, it may define enhancement-based gene therapies as those which produce any measurable improvement of function when used to treat an otherwise healthy patient.[67] This definition allows treatments similar to Luxturna to remain regulated as they are now. Luxturna is designed to correct for a

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65. *See supra* Part II. *But see* Brennan, *supra* note 22.

66. Studies have demonstrated the connection between genetics and muscle hypertrophy in human and mice subjects. *See* Sander A.J. Verbrugge et al., *Genes Whose Gain or Loss-of-Function Increases Skeletal Muscle Mass in Mice: A Systematic Literature Review*, 9 FRONTIERS PHYSIOLOGY 553, 553 (2018). A gene therapy which seeks to help patients with low muscle hypertrophy may operate in a way that not only corrects for any genetic defects in a patient, but which directly codes for the DNA found above which codes for high levels of muscle hypertrophy. *See id.* at 560.

67. "Healthy" in this context means the lack of any acute genetic mutation, such as B-Cell acute lymphoblastic leukemia.

genetic disability by recoding the mutated DNA to return it to its unmutated state.[68] Luxturna therefore cannot provide any measurable improvement to otherwise-healthy patients, because the patients already have a healthy version of the DNA Luxturna fixes.

By defining enhancement-based gene therapies as therapies that provide "any measurable improvement" to healthy patients, FDA can filter out all gene therapies that seek to replace DNA not associated with some acute disorder with a higher functioning version of that DNA, as opposed to therapies that purport to restore mutated DNA. Of course, this approach risks being overinclusive. Many traditional drugs, such as steroids, hormones, or nootropics that we believe to be safe despite their enhancement-based nature would fall into this broad definition of providing "any measurable improvement" to healthy patients.[69]

What makes gene therapies different — and perhaps worthy of such a strict definition — is their potential permanence. Whether administered somatically or via germline, a genetic therapy which changes the DNA of a patient at some level will not necessarily "wear off" in a day or two. So far there has been scarce panic that the rich and powerful will unfairly perpetuate their social class through expensive, performance-enhancing drugs — even if they had a lifetime supply of any given drug, they would likely build such a tolerance and addiction to the drug as to outweigh any potential performance-enhancing effects.[70]

Even more importantly, these drugs are not typically prescribed for their enhancement effect.[71] Human growth hormone ("HGH") — infamously used by baseball player Barry Bonds in 2001 to smash McGwire's single-season home run record by knocking out seventy-three home runs[72] — is usually prescribed for chronic illnesses, such as Prader-Willi syndrome,[73] or chronic kidney disease[74]. Many doctors

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68. *See About LUXTURNA*, LUXTURNA, https://luxturna.com/about-luxturna [https://perma.cc/YM5X-WDAG] ("LUXTURNA provides a working RPE65 gene to act in place of a mutated RPE65 gene.").

69. Anabolic steroids, for example, were infamous for their impact on professional sports in the 80s and 90s. But today, these drugs are used primarily to treat disorders such as immunodeficiency, anemia, and cancer. *See* Shehzad Basaria et al., *Anabolic-Androgenic Steroid Therapy in the Treatment of Chronic Diseases*, 86 J. CLINICAL ENDOCRINOLOGY & METABOLISM 5108, 5108 (2001).

70. *See* Kenneth B. Kashkin, *Hooked on Hormones? An Anabolic Steroid Addiction Hypothesis*, 262 JAMA 3166, 3166 (1989).

71. *See* Basaria et al., *supra* note 69, at 5108.

72. *Book Details Bonds' Steroid Regimen*, ESPN (Mar. 7, 2006), https://www.espn.com/mlb/news/story?id=2358236 [https://perma.cc/TQC8-PB44].

73. *See* Theresa Strong, *Growth Hormone Therapy for PWS*, FPWR (Aug. 24, 2016), https://www.fpwr.org/blog/growth-hormone-therapy-for-pws [https://perma.cc/LR9L-AVPD].

74. *See* Jens Drube et al., *Clinical Practice Recommendations for Growth Hormone Treatment in Children with Chronic Kidney Disease*, 15 NAT. REV. NEPHROLOGY 577, 577 (2019).

will not prescribe treatments that have an overall performance-enhancing effect unless the treatment will be used to counteract the weakening effects of disability.[75] We can use this rationale to inform our second approach to defining enhancement.

### *D. Flexible Approach — Enhancement for Some, Rehabilitative for Others*

If FDA is concerned that an overinclusive definition for classifying enhancement-based therapies might chill innovation, it could also try a flexible approach that would allow a single gene therapy to be defined as enhancement-based or rehabilitative *depending on who the patient is*. Under this model, FDA should ask not only about the subject matter of the treatment, but also its intended audience.

First, does the gene therapy have a noticeable function-enhancing effect on an otherwise healthy person? If not, then the gene therapy will *always* be merely rehabilitative regardless of the target audience because, even if made available for everyone, the treatment could only ever be used to rehabilitate.

If the therapy *does* have a function-enhancing aspect, then FDA should give it heightened scrutiny as an enhancement-based therapy *unless* it is to be approved and marketed only to individuals carrying an acute disorder which the otherwise enhancement-based therapy would treat. This way, researchers who intend to develop a treatment only to treat acute disorders and later discover that the therapy has performance-enhancing characteristics will not find themselves unduly hamstringed in their work. Researchers can develop treatments intended for narrow applications, like Luxturna, without fear of additional regulation or scrutiny, and genetics companies can more accurately predict costs before pursuing development. Moreover, any new regulations implemented to curb the impact of enhancement-based therapies will also have less of a chilling effect on treatments for genetic disorders, since the therapies' designers can always opt to forgo the larger market in exchange for reduced oversight.

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75. *See* Christopher Madden et al., *A Patient's Request for Steroids to Enhance Participation in Wilderness Sport and Adventure*, 16 AMA J. ETHICS 534, 537 (2014) (recommending that doctors advise patients against using performance-enhancing drugs without an underlying disorder). Performance-enhancing drugs are not necessarily illegal — but most sports where they're advantageous have banned their use. *See Professional Sports Leagues Steroid Policies*, SPORTS REFERENCE, https://www.sports-reference.com/blog/professional-sports-leagues-steroid-policies [https://perma.cc/7SD3-CHX7].

### *E. Contract to Establish Price Ceilings*

There is no use in having a discussion on how FDA should define enhancement-based versus rehabilitative gene therapies without an exploration of how they should be treated differently. In Part II, this Note explored the social risks of enhancement-based gene therapies. Classism is one such risk — the shockingly expensive nature of genetic treatments might lead to only wealthier people being able to afford enhancements, giving them and their families exclusive access to tools which allow them to stay ahead.[76] FDA can diminish this risk of entrenchment significantly by requiring sellers of enhancement-based gene therapies to enter into contracts with FDA that establish a fair and accessible pricing scheme for the treatment.[77]

Ideally, an agreed-upon price would be one that would allow the developer of the therapy to recoup its development costs plus a risk premium while capping the cost to consumers near contemporary prices for widely-marketed prescription drugs.[78] Enhancement-based treatments are inherently more tolerant of price ceilings than traditional medicine is. Because the eligible patient pool for such treatments is essentially the entire population of the United States, the recoupment of research and development costs could be spread over more buyers than corresponding costs for developing Luxturna.[79]

This proposal is not meant to dismiss concerns about non-price-dependent social risks of enhancement therapies. There are, for example, many patients who might refuse enhancement therapy altogether based on personal beliefs and values. They certainly have the right to abstain from participating in any genetic treatment, but they might soon find themselves behind their genetically enhanced counterparts.[80] But how do we protect these people? How do we prevent the sort of genetic arms-race contemplated in Part II? These are ambitious questions which deserve their own note or article. But a scheme to condition market approval on equitable pricing can at least begin to address concerns about fairness and accessibility in a post-genetic enhancement future.

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76. *See supra* Part II.

77. For an overview of FDA's contract programs with regulated entities on other matters, see *Contracts*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/funding-opportunities/contracts [https://perma.cc/E3D2-WB4U].

78. Selective Serotonin Reuptake Inhibitors ("SSRIs") such as Zoloft, for example, are usually able to be priced affordably because their market — patients suffering from depression, anxiety and others — is relatively large. *See, e.g.*, *SSRIs*, GOODRX, https://www.goodrx.com/ssris [https://perma.cc/2D7C-BJGP].

79. *See* Berkrot, *supra* note 50.

80. *See supra* Part II.

### *F. Why FDA Likely Cannot Simply Ban Enhancement-Based Therapy*

Regardless of regulatory approach, a flat-out ban on enhancement-based gene therapies in the United States is an unwise remedy. Opponents to restrictions on medical treatments for ethical reasons are quick to point out that any safeguards by FDA on enhancement-based therapies are necessarily limited by the boundaries of the United States.[81] While we might scoff at the idea of genetically modifying embryos or enhancing a patient to superhuman status, the United States cannot presume to enforce its own social norms internationally. Indeed, while the Chinese government initially condemned He Jiankui's work, some reporters now suggest that government institutions were not only aware of Dr. He's work, but also helped fund it.[82] In any event, genetic innovation is not simply limited to the United States and China.[83] This raises the question: if we impede enhancement-based therapies here, what stops patients from just travelling overseas?

Much has been said of medical tourism in the last decade.[84] As the world gets smaller, patients who desire a given medical treatment can travel to receive that treatment, even if it is illegal in the United States. Examples range from assisted suicide[85] to dangerous surgeries to change a patient's eye-color.[86] The United States cannot impose unilateral bans on genetic treatment in other countries. And at least for now, the United States has taken a stance of not criminalizing Americans who seek treatment elsewhere and then return.[87]

As such, hard restrictions on enhancement-based therapies in the United States may send interested patients elsewhere. Already, wealthier families would naturally be more able to afford enhancement-based therapies and therefore perpetuate a heightened status by simply buying

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81. *See* Michael D. Horowitz et al., *Medical Tourism: Globalization of the Healthcare Marketplace*, 9 MEDSCAPE GEN. MED. 33, 33 (2007) ("Medical tourism is becoming increasingly popular, and it is projected that as many as 750,000 Americans will seek offshore medical care in 2007.").

82. *See* Qiu, *supra* note 3.

83. *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), https://www.businessinsider.com/china-edited-human-genome-laws-2015-4 [https://perma.cc/D8DQ-4VXP].

84. *See, e.g.*, I. GLENN COHEN, PATIENTS WITH PASSPORTS, at xv–xxvi (2014) (discussing medical tourism in-depth, with a focus on American patients travelling overseas for procedures which are either illegal or prohibitively expensive domestically).

85. *See id.* at 315.

86. *See Cosmetic Iris Implants Carry Risk of Permanent Eye Damage, Vision Loss*, AM. ACAD. OPHTHALMOLOGY (Oct. 29, 2014), https://www.aao.org/eye-health/tips-prevention/iris-implants-risk-eye-damage [https://perma.cc/WL98-AJM9]. ("Currently, Americans who want [cosmetic iris implants] travel to Panama . . . .").

87. *See* COHEN, *supra* note 84, at 331–33 (addressing whether "home countries can extend prescriptive jurisdiction over home country citizens" who pursue treatment abroad, and, if so, whether countries should adopt a policy of criminalizing such behavior).

better genes.[88] Adding in the obstacle of travel — that is, barring enhancement therapy in the United States while it is offered elsewhere — may prevent FDA from implementing any socially-conscious cost-reducing regulations of its own and yield equitable decisions entirely to other jurisdictions. And with an outright ban, FDA would forfeit all of its own tools to level the playing field in a post-enhancement world.

While this argument will be crucial in guiding FDA policy, it should not preempt the agency from setting a distinction between enhancement-based and rehabilitation-based therapies at the research and commercial licensing levels. Singling out enhancement-based therapies for extra scrutiny is not a ban, but a recognition of the increased risks that they carry.

Here, we can use the example from earlier of a theoretical enhancement therapy for increased intelligence. Special scrutiny for such a therapy would allow FDA to condition commercial approval on some equitable redistribution effort by a therapy's manufacturer. For example, the owner of the intelligence therapy might be required to agree to certain price restraints that allow a wide range of patients to receive the therapy, but at a lower price than the manufacturer would choose to maximize profits. If the enhancement therapy is patented, FDA could condition approval of the therapy on the patent owner shortening their monopoly period post-approval to some acceptable window.[89] For example, if the intelligence therapy were only patent-protected for three years post-approval, the delay between wealthier and poorer patients receiving the treatment would be reduced. These special conditions would alleviate some of the socioeconomic concerns associated with enhancement therapies, while allowing FDA to stem the flow of enhancement-seeking patients to other jurisdictions that would result from a total domestic ban.

On the other hand, this special scrutiny is neither required nor wise for rehabilitative therapies. By their nature, rehabilitative therapies have a limited pool of eligible patients. Luxturna, for example, treats Leber congenital amaurosis,[90] a genetic eye disease that affects only

88. *See supra* Part II.

89. FDA has entangled itself in patent-term adjustments motivated by economic considerations before. In 1984, Congress passed the Drug Price Competition and Pattern Term Restoration Act (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 (2012)), which authorized abbreviated new drug applications that exempt generic drug manufacturers from having to prove the safety and efficacy of their drugs. *See* Gerald Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187–91 (1999). In exchange, pioneer manufacturers of brand-name pharmaceuticals were given slightly longer patent terms. *See id.* at 190.

90. *See* Rachel Lutz, *Luxturna Successfully Used to Treat Inherited Retinal Disease,* HCPLIVE (Mar. 30, 2019), https://www.mdmag.com/medical-news/luxturna-treat-inherited-retinal-disease [https://perma.cc/DR3D-4R9G].

two to three of every 100,000 newborns.[91] This means the eligible patient pool in the United States is likely only around 8,000 people. The cost of developing and testing Luxturna is not publicly available, but it is likely to have been highly expensive.[92] Pharmaceutical companies will not be sufficiently incentivized to develop specialized treatments such as Luxturna unless they expect to extract high prices per patient.

Enhancement-based therapies would have no such limitation on their client pool. The intelligence-based therapy hypothesized previously would deliver genes which have almost certainly never naturally occurred, but which could greatly improve intelligence by influencing myelination and neurogenesis.[93] This means that all 320 million residents in the United States theoretically could be customers for the therapy,[94] requiring a much lower price per patient to recoup geneticists' investments than would a rehabilitative therapy such as Luxturna.

Case-by-case price restraints for enhancement-based therapies over rehabilitative therapies alone will not create the widespread "patients with passports"[95] epidemic that an outright ban of the technology may produce. They would instead allow FDA to infuse social and ethical considerations into the distribution of the resulting therapies, so that any American could receive genetic enhancement if they so chose.

## IV. CONCLUSION

Powerful new tools like CRISPR grant us greater control than ever over the genetic code that makes us "us." Despite the cataclysmic warnings by scientists and journalists around the country, FDA has so far been slow to provide guidance on just how far researchers and pharmaceutical companies should be allowed to go in developing treatments that alter the human genome. To date, much of the guidance has focused on the procedural elements of gene therapies, which revolve around whether the therapy is administered to a consenting adult or to an unborn child.

But with therapies on the horizon that not only treat acute genetic disorders, but also augment human performance, we must consider

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91. *Leber Congenital Amaurosis*, NAT'L. INST. HEALTH (Feb. 11, 2020), https://ghr.nlm.nih.gov/condition/leber-congenital-amaurosis [https://perma.cc/XW4K-5UTF].

92. *See* Ricki Lewis, *What Should Gene Therapy Cost?,* PLOS BLOGS NETWORK (Oct. 26, 2017), https://blogs.plos.org/dnascience/2017/10/26/what-should-gene-therapy-cost [https://perma.cc/Q9DW-H37X] ("Luxturna was in clinical trials for 9 years, and that's expensive. Developing the vector alone can cost $500,000 to $1 million.").

93. *See* Hill et al., *supra* note 46, at 178 (explaining "how genetic differences, via their influence on physiological differences [in neurogenesis and myelination], contribute to variation in intelligence").

94. *See U.S. and World Population Clock*, U.S. CENSUS BUREAU, https://www.census.gov/popclock [https://perma.cc/2RB3-BUWL].

95. COHEN, *supra* note 84.

rules on the subject matter of those treatments. Treatments which enhance human performance — whether it be intelligence, physical ability, or attractiveness — raise new socioeconomic concerns. These concerns need not stifle the entire field of augmentative genetics, but they must inform FDA decision-making in order to ensure the equitable distribution of enhancement therapies, so as not to risk further cementing a hierarchical class structure.