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PREVENTING AN ERA OF "NEW EUGENICS": AN ARGUMENT FOR FEDERAL FUNDING AND REGULATION OF GENE EDITING RESEARCH IN HUMAN EMBRYOS

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I. INTRODUCTION

[1] The 1997 film *Gattaca* is set in a futuristic society in which its members are either "valid," born with the aid of genetic engineering, or "in-valid," conceived by traditional means.[1] While valids qualify for high-level professional employment, in-valids are considered less desirable by society and are relegated to menial jobs.[2] At the time of the film's release, this type of dystopian society, dominated by genetic engineering, seemed far into the future; however, only twenty years later, the concept of manipulating the genes of human embryos is near reality.[3]

[2] The last decade has seen tremendous progression in gene editing technology.[4] In 2011, genome editing was hailed as the Method of the Year by *Nature Methods*,[5] and the newest tool in the gene editing tool belt, the CRISPR/Cas9 system, was named the 2015 Breakthrough of the Year by *Science*.[6] CRISPR/Cas technology has been used in research laboratories to

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[1] *See* GATTACA (Columbia Pictures 1997).

[2] *See id.*

[3] *See* Colin Druce-McFadden, *Gattaca Rising: Humanity Closes in on Designer Babies*, GEEK & SUNDRY (May 27, 2015), https://geekandsundry.com/gattaca-rising-humanity-closes-in-on-designer-babies/ [https://perma.cc/AP9C-MCRK] ("Many of the concepts that were Sci-Fi a decade ago are now fact.").

[4] *See* Ana Nordberg et al., *Cutting Edges and Weaving Threads in the Gene Editing (Я)evolution: Reconciling Scientific Progress with Legal, Ethical, and Social Concerns*, 5 J.L. & BIOSCIENCES 36, 41 (2018).

[5] *See Method of the Year 2011*, 9 NATURE METHODS 1, 1 (2012), https://www.nature.com/articles/nmeth.1852.pdf [https://perma.cc/Y5GM-CJ6G].

[6] *See* John Travis, *Making the Cut: CRISPR Genome-Editing Technology Shows Its Power*, 350 SCI. 1456, 1456 (2015),

edit a cell's DNA,[7] and when used to edit the DNA of an embryo, termed germline editing, it can permanently change the genetic makeup of the resulting individual and its future offspring.[8] Thus, this technology has the potential to eradicate many deadly genetic diseases in humans, such as cystic fibrosis, sickle-cell anemia, and Huntington's disease.[9] Opponents of gene editing of human embryos argue that it will create an era of "new eugenics" and that "designer babies" will foster greater social inequality.[10]

[3] This article argues that by providing federal funding for gene editing research involving human embryos, and by promulgating additional regulations to address pertinent safety and ethical concerns, the U.S. can play an influential role in the direction in which this industry proceeds, thus precluding an era of "new eugenics" while simultaneously benefiting society and the economy. In support of this thesis, this article begins with a

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http://science.sciencemag.org/content/sci/350/6267/1456.full.pdf [https://perma.cc/3U6P-HFRW].

[7] *See, e.g.*, Thomas Gaj et al., *ZFN, TALEN, and CRISPR/Cas-Based Methods for Genome Engineering*, 31 TRENDS IN BIOTECHNOLOGY 397, 402 (2013) (discussing how the CRISPR/Cas system can be used to split DNA sequences by redesigning crRNA and has successfully indicated genome editing in non-human cells).

[8] *See* Sarah Buhr, *CRISPR'd Human Embryos Doesn't Mean Designer Babies Are Around the Corner*, TECHCRUNCH (2017), https://techcrunch.com/2017/07/28/crisprd-human-embryos-doesnt-mean-designer-babies-are-around-the-corner/ [https://perma.cc/SRH3-AQ4G].

[9] *See Cystic Fibrosis, Sickle-Cell Anemia Could Be Corrected in Embryos with New CRISPR Variant*, GENETIC LITERACY PROJECT (Mar. 8, 2017), https://geneticliteracyproject.org/2017/03/08/cystic-fibrosis-sickle-cell-anemia-could-be-corrected-in-embryos-with-new-crispr-variant/ [https://perma.cc/J78P-BZ8X].

[10] *See, e.g.*, Shawna Benston, *CRISPR, a Crossroads in Genetic Intervention: Pitting the Right to Health Against the Right to Disability*, 5 LAWS 1, 4, 10 (2016) (discussing the possibility of selecting-out disability, "designer babies," and the tension between the fear of "new eugenics"); David King, *Editing the Human Genome Brings Us One Step Closer to Consumer Eugenics*, THE GUARDIAN (Aug. 4, 2017, 7:02 EDT), https://www.theguardian.com/commentisfree/2017/aug/04/editing-human-genome-consumer-eugenics-designer-babies [https://perma.cc/29AR-REQZ] (stating the social consequences of a creating a society in which some have biological advantages over others).

recent history of society's attempts at genetic manipulation, describes the modern tools available for editing genomic DNA, and discusses the current regulatory landscape regarding research involving human embryos. The next section addresses the potential benefits and drawbacks of using gene editing technology in human embryos, and the final section argues in favor of federal funding of such research and provides several regulatory guidelines to ensure that safety and ethical concerns are adequately addressed.

II. GENOME MANIPULATION: FROM THEN TO NOW

A. Past Attempts at Genetic Manipulation

[4] On the heels of Charles Darwin's *On the Origins of Species*,[11] the Augustinian monk Gregor Mendel published in 1865 his research describing the fundamental laws of inheritance.[12] However, it was not until the turn of the century that Mendel's work was re-discovered and independently verified, thus launching the "age of genetics."[13] Despite limited knowledge of the molecular mechanisms of genetic inheritance, the first attempts to manipulate society's gene pool occurred in the early 20th century with the eugenics movement.[14] Only during the latter half of the 20th century, with the development of recombinant DNA technologies and

[11] *See* CHARLES DARWIN, ON THE ORIGIN OF SPECIES BY MEANS OF NATURAL SELECTION (D. Appleton and Co. 1859).

[12] *See* Gregor Mendel, Experiments in Plant Hybridization, Address at the Brünn Natural History Society (Feb. 8 & Mar. 6, 1865) (trans. William Bateson & Roger Blumberg), http://www.esp.org/foundations/genetics/classical/gm-65.pdf [https://perma.cc/6Y2G-PSMR].

[13] *See* Sarah A. Leavitt, *Gregor Mendel: The Father of Modern Genetics*, NAT'L INSTS. OF HEALTH, https://history.nih.gov/exhibits/nirenberg/HS1_mendel.htm [https://perma.cc/Y96G-5V96].

[14] *See* 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, 862 (2004).

in vitro fertilization techniques, did the notion of directed and deliberate manipulation of the human genome emerge.[15]

1. Eugenics

[5] The theory of eugenics is based on the notion that selective procreation can lead to the gradual improvement of the human race.[16] While the concept of selective procreation had been contemplated as far back as the time of Plato, the modern eugenics movement is attributed to the British scientist Sir Francis Galton.[17] Based on the science of natural selection,[18] this movement advocated not only for the selective procreation of those with "desirable" traits, but also for the sterilization of "undesirable" individuals.[19] The first sterilization law in the U.S. was enacted in the State of Indiana in 1907,[20] and by 1931, a majority of states had enacted eugenic

[15] *See generally* Russel A. Spivak et al., *Germ-Line Gene Editing and Congressional Reaction in Context: Learning from Almost 50 Years of Congressional Reactions to Biomedical Breakthroughs*, 30 J.L. & HEALTH 20 (2017) (observing that a 2015 federal law prohibiting the FDA from considering applications involving human germ-line modifications was the latest in a long line of laws regulating scientific manipulation of the human genome).

[16] *See* Paul A. Lombardo, *Medicine, Eugenics, and the Supreme Court: From Coercive Sterilization to Reproductive Freedom*, 13 J. CONTEMP. HEALTH L. & POL'Y 1, 1 (1996).

[17] *See* Sara Goering, *Eugenics*, STANFORD ENCYCLOPEDIA PHIL. (July 2, 2014), https://plato.stanford.edu/entries/eugenics/ [https://perma.cc/CT8R-SZK3].

[18] *See* Nicholas W. Gillham, *Cousins: Charles Darwin, Sir Francis Galton and the Birth of Eugenics*, 6 SIGNIFICANCE 132, 133–34 (2009). Sir Francis Galton was a younger cousin of Charles Darwin and was inspired by Darwin's theories of natural selection. *See id.* at 132–33.

[19] *See* Marc D. Brown, *State-Sponsored Sterilization: The Dark History of Eugenics in Oregon*, HOLY NAMES HERITAGE CTR. (June 25, 2018, 7:00 PM), https://www.holynamesheritagecenter.org/history-pub/122-state-sponsored-sterilization-the-dark-history-of-eugenics-in-oregon [https://perma.cc/HFJ4-699X].

[20] *See 1907 Indiana Eugenics Law*, IND. HIST. BUREAU, https://www.in.gov/history/markers/524.htm [https://perma.cc/D2EB-DR49].

sterilization laws.[21] The "undesirability" of those sterilized under eugenics laws was often based on mental or physical infirmities, including epilepsy, insanity, blindness, and physical malformations, but also included "social inadequacies" such as criminality and drug addiction.[22] It is estimated that under such laws, over 60,000 individuals were sterilized and thereby deprived of the right to bear children and forever stigmatized as "feebleminded."[23] The prominence of the eugenics movement in the United States inspired its adoption by the National Socialist party of Germany, which resulted in the sterilization of over 350,000 "defective" persons by the end of World War II.[24] Most states in the U.S. repealed their eugenic sterilization laws by the 1970s and 1980s.[25]

2. Recombinant DNA

[6] Gregor Mendel's work was improved upon by the early 20th century work of Thomas Hunt Morgan, who discovered that genes were the basis for specific traits.[26] It was not until 1953 that the structure of DNA was first described by Watson and Crick,[27] and it took nearly twenty additional years before development of the first tools to manipulate a cell's genetic material.[28] The discovery in the early 1970s of restriction endonucleases, or

[21] *See* Lombardo, *supra* note 16, at note 2.

[22] *See id.* at 3.

[23] *See* Silver, *supra* note 14, at 863.

[24] *See* Garrett Power, *Eugenics, Jim Crow & Baltimore's Best*, 49 MD. B.J. 4, 12 (2016).

[25] *See* Silver, *supra* note 14, at 863.

[26] *See* Asude Alpman Durmaz et al., *Evolution of Genetic Techniques: Past, Present, and Beyond*, 2015 BIOMED RES. INT'L 1, 2 (2015).

[27] *See id.*

[28] *See, e.g.*, David A. Jackson et al., *Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40: Circular SV40 DNA Molecules Containing Lambda Phage Genes and the Galactose Operon of Escherichia Coli*, 69 PROC. NAT'L ACAD. SCI. U.S.A. 2904, 2906 (1972) (explaining an early method for altering DNA); Janet E. Mertz & Ronald W. Davis, C*leavage of DNA by R_I Restriction Endonuclease*

molecular "scissors" that cut DNA at specific sequence sites, allowed scientists to splice and recombine DNA molecules from different sources, thus creating "recombinant DNA."[29]

[7] Restriction endonucleases provided scientists with the tools to create virtually any combination of recombinant DNA.[30] In light of the potential ethical ramifications of "creating" DNA, the scientific community instituted a worldwide moratorium on genetic engineering, and in 1975 scientists and experts held an international conference to assess the risks of recombinant DNA technology and to set research standards that comported with protecting public health.[31] The concerns that led to the moratorium and conference focused primarily on the fear that recombinant bacterial viruses would escape into the environment and cause cancer in those that it infected.[32] Fortunately, those fears were never realized.[33] However, the notion that recombinant DNA technology might one day be used to manipulate the human genome became a possibility with the advent of in vitro fertilization.

Generates Cohesive Ends, 69 PROC. NAT'L ACAD. SCI. U.S.A. 3370, 3371 (1972) (discussing the manipulation of SV40(I) DNA molecules); Peter E. Lobban & A.D. Kaiser, *Enzymatic End-to-End Joining of DNA Molecules*, 78 J. MOLECULAR BIOLOGY 453 (1973) (examining an approach to join naturally existing DNA molecules based on the unique ability of the "calf thymus enzyme terminal deoxynucleotidyltransferase"); Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROC. NAT'L ACAD. SCI. U.S.A. 3240, 3240 (1973) (stating the finding that certain plasmids are susceptible to cleavage by a particular enzyme).

[29] *See* Leslie A. Pray, *Restriction Enzymes*, NATURE EDUC. (2008), https://www.nature.com/scitable/topicpage/restriction-enzymes-545 [https://perma.cc/6599-A6V5].

[30] *See id.*

[31] *See* Paul Berg, *Asilomar 1975: DNA Modification Secured*, 455 NATURE 290, 290 (2008).

[32] *See id.*

[33] *See id.* at 291.

3. In Vitro Fertilization

[8] In 1978, the first "test tube baby," conceived via fertilization outside of the womb, was born.[34] Though controversial at the time, in vitro fertilization (IVF) quickly became an accepted therapy throughout the world and has led to millions of births.[35] The notion that a healthy baby could be born following implantation of an in vitro fertilized egg opened the doorway for pre-implantation manipulation of the embryonic genome. By the 1990s, pre-implantation genetic diagnosis (PGD) of diseases was used to screen fertilized embryos for various diseases, including cystic fibrosis[36] and sickle-cell anemia,[37] to ensure that only unaffected embryos are used for implantation.[38] Mitochondrial replacement therapies (MRT) were also developed to prevent transmission of genetic diseases inherited via maternal mitochondrial DNA.[39]

[9] While PGD and MRT allow prospective parents to prevent transmission of certain genetic diseases, these options have limitations. MRT can only alleviate diseases associated with mitochondrial DNA,

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[34] *See* Tian Zhu, *In Vitro Fertilization*, THE EMBRYO PROJECT ENCYCLOPEDIA (July 22, 2009), https://embryo.asu.edu/pages/vitro-fertilization [https://perma.cc/B4W5-XLJT].

[35] *See* Megan Garber, *The IVF Panic: 'All Hell Will Break Loose, Politically and Morally, All Over the World'*, THE ATLANTIC (June 25, 2012), https://www.theatlantic.com/technology/archive/2012/06/the-ivf-panic-all-hell-will-break-loose-politically-and-morally-all-over-the-world/258954/ [https://perma.cc/8R5K-JN3E].

[36] *See* Alan H. Handyside et al., *Birth of a Normal Girl After in Vitro Fertilization and Preimplantation Diagnostic Testing for Cystic Fibrosis*, 327 NEW ENG. J. MED. 905 (1992).

[37] *See* Kangpu Xu et al., *First Unaffected Pregnancy Using Preimplantation Genetic Diagnosis for Sickle Cell Anemia*, 281 J. AM. MED. ASS'N 1701, 1701–02 (1999).

[38] *See* Molina B. Dayal et al., *Preimplantation Genetic Diagnosis*, MEDSCAPE (Aug. 29, 2018), https://emedicine.medscape.com/article/273415-overview [https://perma.cc/75FS-UW6T].

[39] *See* Steve Connor, *When Replacement Becomes Reversion*, 35 NATURE BIOTECHNOLOGY 1012, 1012 (2017).

which is comprised of a scant thirty-seven genes and accounts for only for 0.1% of the entire human DNA.[40] Moreover, mitochondrial DNA originates solely from the unfertilized egg, thus MRT has no effect on paternally-derived genetic diseases.[41] PGD, while able to detect both maternal and paternal genetic diseases throughout the entire embryonic genome,[42] is limited by the number of viable embryos available for screening.[43]

B. Modern Gene Editing Techniques

[10] Successful editing of genomic DNA essentially involves three steps: the DNA is first cut at a specific site, then small pieces of DNA are added or removed, and finally the loose ends of DNA are rejoined.[44] For the last two steps, scientists rely on the cell's own DNA repair mechanisms, which rejoin the DNA and alter the intervening sequence based on a repair template inserted into the cell.[45] For cutting DNA at a single, specific site, molecular "scissors" far more precise than restriction endonucleases are needed. Currently, scientists have at their disposal several tools for site-specific splicing and editing of genomic DNA: zinc-finger nucleases, TALENs, and the CRISPR-Cas9 system.

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[40] *See Mitochondrial Replacement Therapy*, UNITED MITOCHONDRIAL DISEASE FOUND. (Nov. 2017), http://www.umdf.org/mitochondrial-replacement-therapy/ [https://perma.cc/7KA2-UX2R].

[41] *See id.*

[42] *See* Jason Franasiak & Richard T. Scott, *A Brief History of Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening*, IVF WORLDWIDE, https://ivf-worldwide.com/cogen/oep/pgd-pgs/history-of-pgd-and-pgs.html [https://perma.cc/2GLJ-4GQ7].

[43] *See Preimplantation Genetic Diagnosis: Technical Limitations*, FERTILITY PROREGISTRY, https://www.fertilityproregistry.com/article/lab-techniques/preimplantation-genetic-diagnosis-pgd/preimplantation-genetic-diagnosis-technical-limitations [https://perma.cc/2GLJ-4GQ7].

[44] *See Genome Editing*, ALLELE BIOTECHNOLOGY, http://www.allelebiotech.com/genome-editing/ [https://perma.cc/5LJU-LFKP].

[45] *See* Dana Carroll, *Genome Engineering with Zinc-Finger Nucleases*, 188 GENETICS 773, 774 (2011).

1. Zinc-Finger Nucleases and TALENs

[11] In the mid-1990s, scientists developed new site-specific endonucleases by combining the DNA-binding domain of one protein with a DNA splicing domain of another.[46] Since the DNA-binding domain contained a zinc ion and "gripped" the DNA, the new proteins were dubbed "zinc-finger nucleases" (ZFNs).[47] Unlike traditional restriction endonucleases, ZFNs could be engineered to recognize and cut a single site on the DNA, thus providing the specificity needed to edit genomic DNA.[48] However, ZFNs do not bind all sequences with equal strength and thus work better for some DNA sites than for others, and because ZFNs bind as dimers, proper orientation on the DNA can be difficult to achieve.[49]

[12] In 2009, researchers demonstrated that a DNA binding protein naturally expressed in bacteria could be engineered to specify precisely where the protein binds DNA.[50] Like with ZFNs, these bacterial proteins can be fused to a DNA cutting protein to permit highly targeted splicing of genomic DNA.[51] Termed transcription activator-like effector nucleases, or TALENs, these proteins are comparable to ZFNs in their DNA-cutting

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[46] *See* Yang-Gyun Kim et al., *Hybrid Restriction Enzymes: Zinc Finger Fusions to Fok I Cleavage Domain*, 93 PROC. NAT'L ACAD. SCI. 1156, 1156 (1996).

[47] *See* Aaron Klug, *The Discovery of Zinc Fingers and Their Applications in Gene Regulation and Genome Manipulation*, 79 ANN. REV. BIOCHEMISTRY 213, 215 (2010).

[48] *See id.* at 222, 228.

[49] *See The Challenges of Engineering Zinc-Finger Nucleases*, BARCELONA BIOMEDICAL RES. PARK: REDCEDAR NEWS (Jan. 11, 2012), https://redcedarnews.wordpress.com/2012/01/11/the-challenges-of-engineering-zinc-finger-nucleases/ [https://perma.cc/NX2E-2WUQ].

[50] *See* Jens Boch et al., *Breaking the Code of DNA Binding Specificity of TAL-Type III Effectors*, 326 SCIENCE MAG. 1509, 1509, 1512 (2009); Matthew J. Moscou & Adam J. Bogdanove, *A Simple Cipher Governs DNA Recognition by TAL Effectors*, 326 SCIENCE MAG. 1501, 1501 (2009).

[51] *See* J. Keith Joung & Jeffry D. Sander, *TALENs: A Widely Applicable Technology for Targeted Genome Editing*, 14 NATURE REV. MOLECULAR CELLULAR BIOLOGY 49, 50 (2013).

efficiency, but TALENs are easier to manipulate and synthesize compared to ZFNs, thus making them more attractive to researchers.[52]

2. CRISPR-Cas9

[13] The newest gene editing system is CRISPR-Cas9.[53] Short for "clustered regularly interspaced short palindromic repeats" and "CRISPR-associated protein 9," this system, like TALENs, is a genome editing system naturally occurring in bacteria that provides acquired immunity from viruses:

> The bacteria capture snippets of DNA from invading viruses and use them to create DNA segments known as CRISPR arrays. The CRISPR arrays allow the bacteria to "remember" the viruses (or closely related ones). If the viruses attack again, the bacteria produce RNA segments from the CRISPR arrays to target the viruses' DNA. The bacteria then use Cas9 or a similar enzyme to cut the DNA apart, which disables the virus.[54]

Researchers discovered that the snippets of viral DNA can be replaced with a "guide sequence" to direct the CRISPR-Cas9 system to cleave genomic DNA at unique, sequence-specific sites.[55] The CRISPR-Cas9 system has proven to be more advantageous over ZFNs and TALENs due to its ease of design, high cleavage efficiency, and versatility.[56]

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[52] *See id.* at 50, 53.

[53] *See What Are Genome Editing and CRISPR-Cas9?*, U.S. NAT'L LIBR. OF MED. (Oct. 30, 2018), https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting [https://perma.cc/2M7C-DNYM].

[54] *Id.*

[55] *See* Martin Jinek et al., *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCIENCE MAG. 816, 816 (2012).

[56] *See* Jon Chesnut, *Analyzing TALEN vs CRISPR*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (Oct. 13, 2016), https://www.genengnews.com/gen-exclusives/analyzing-talen-vs-crispr/77900759 [https://perma.cc/ETC6-4AJ3].

[14] While ZFNs, TALENs, and the CRISPR-Cas9 system have all been used extensively in a variety of species and cell types, including human somatic and pluripotent stem cells,[57] only the CRISPR-Cas9 system has been successfully used to edit genes in human embryos. In 2015, Chinese scientists published the first article describing the use of the CRISPR-Cas9 system in human embryos.[58] Prior to that study, it was unclear whether the CRISPR-Cas9 system would be compatible in that context, but this research proved that the system can effectively edit genomic DNA in a human embryo, even if it was less efficient than expected.[59] Although the embryos used in the study were non-viable and could not have progressed to live births,[60] it renewed the debate regarding the ethics of using the gene editing technique in human embryos,[61] as discussed in Section III of this article.

C. Current Regulatory Framework

[15] In anticipation of the release of the Chinese scientists' publication describing the use of the CRISPR-Cas9 system in human embryos,[62] the Director of the National Institutes of Health (NIH) issued a statement on the issue of federal funding for gene editing research in human embryos.[63]

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[57] *See* Zhao Zhang et al., *CRISPR/Cas9 Genome-Editing System in Human Stem Cells: Current Status and Future Prospects*, 9 MOLECULAR THERAPY: NUCLEIC ACIDS 230, 230–31 (2017); *see also* Gaj et al., *supra* note 7, at 398, 402. *See generally* Joung & Sander, *supra* note 51 (describing how ZFNs and TALENs have enabled genetic alteration of multiple organisms).

[58] *See* Puping Liang et al., *CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes*, 6 PROTEIN CELL 363, 363 (2015).

[59] *See id.* at 363–64.

[60] *See id.* at 364.

[61] *See* David Cyranoski, *Embry Editing Divides Scientists*, 519 NATURE 272, 272 (Mar. 19, 2015); *see also* Edward Lanphier et al., *Don't Edit the Human Germ Line*, 519 NATURE 410, 410–11 (Mar. 26, 2015).

[62] *See* Liang et al., *supra* note 58, at 363–64.

[63] *See* Francis S. Collins, *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, NAT'L INSTS. OF HEALTH (Apr. 28, 2015),

While recognizing many of the beneficial uses of genomic editing technology and pointing out that the NIH can and does fund research involving many of these uses, the Director stated that the NIH "will not fund any use of gene-editing technologies in human embryos."[64]

[16] After highlighting several ethical arguments against funding such research, the Director noted that "there are multiple existing legislative and regulatory prohibitions against this kind of work."[65] The current U.S. approach to regulating gene editing research in human embryos is by limiting public funding. The evolution of federal funding bans on research involving human embryos and the current regulatory framework are discussed below.

1. Dickey-Wicker Amendment

[17] The emergence of IVF technologies in the 1970s raised concerns about the use of human embryos in scientific research.[66] To address such concerns, the Department of Health, Education, and Welfare[67] in 1977 promulgated a regulation requiring all federally funded research projects involving human in vitro fertilization to be reviewed by an Ethical Advisory Board.[68] However, the Board was dissolved in 1981 by the Reagan

https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos [https://perma.cc/WAK4-L2TJ].

[64] *Id.*

[65] *Id.*

[66] *See* Ann A. Kiessling, *The History of the Dickey-Wicker Amendment*, BEDFORD STEM CELL RES. FOUND. (Aug. 24, 2010), http://www.bedfordresearch.org/the-history-of-the-dickey-wicker-amendment/ [https://perma.cc/AN4Y-G5NC].

[67] *See HHS Historical Highlights*, DEP'T OF HEALTH & HUM. SERVS. (Feb. 10, 2017), https://www.hhs.gov/about/historical-highlights/index.html [https://perma.cc/G7F2-KL5A] ("The Department of Health, Education, and Welfare (HEW) became the Department of Health and Human Services (HHS) on May 4, 1980.").

[68] *See* Protection of Human Subjects, 45 C.F.R. § 46.204(e) (1977).

administration,[69] resulting in a de facto moratorium on federal funding for research involving human embryos.[70]

[18] In 1993, then-President Clinton signed into law the National Institutes of Health Revitalization Act, which, among other purposes, revised certain programs of the NIH.[71] Section 121(c) of the Act[72] eliminated the 1977 regulation requiring review by an Ethical Advisory Board,[73] thus clearing the path for federal funding of grant applications to study human fertilization.[74] When members of Congress realized that federal funds could possibly be used in research involving human embryos, Representatives Jay Dickey and Roger Wicker drafted a rider to the 1996 NIH budget specifically precluding federal funding for human embryo research.[75] The text of the 1996 rider is as follows:

> Sec. 128. None of the funds made available by Public Law 104-91 may be used for –
>
> (1) the creation of a human embryo or embryos for research purposes; or
>
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for

[69] *See* George J. Annas, *Resurrection of a Stem-Cell Funding Barrier–Dickey-Wicker in Court*, 363 NEW ENG. J. MED. 1687, 1688 (2010).

[70] *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION & RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 128 (2004).

[71] *See* National Instituted of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 1, 107 Stat. 122 (1993).

[72] *See* § 121(c), 107 Stat. at 133.

[73] This section also repealed Executive Order 12806, which mandated that all research projects involving fetal tissue undergo a peer review process. *See* 57 Fed. Reg. 21589 (May 21, 1992).

[74] *See* Kiessling, *supra* note 66.

[75] *See id.*

> research on fetuses in utero under 45 CFR 46.208(a)(2) and 42 U.S.C. 289g(b).
>
> For purposes of this section, the phrase "human embryo or embryos" shall include any organism, not protected as a human subject under 45 CFR 46 as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.[76]

Known as the Dickey-Wicker Amendment, this rider has been attached, largely unchanged, to every appropriations bill for the Departments of Health and Human Services, Education, and Labor since 1996,[77] including the omnibus spending bill signed by President Trump in March of 2018.[78]

2. Stem Cell Research

[19] Embryonic stem cells are capable of developing into nearly every cell type in the body and thus hold great potential for transplantation therapies for a variety of diseases.[79] Stem cell research has led to clinical trials using cells derived from embryonic stem cells to treat Parkinson's disease, diabetes, and macular degeneration, among other conditions.[80] The

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

[77] Megan Kearl, *Dickey-Wicker Amendment, 1996*, THE EMBRYO PROJECT ENCYCLOPEDIA (Aug. 27, 2010), https://embryo.asu.edu/pages/dickey-wicker-amendment-1996 [https://perma.cc/Z6JN-AZLG].

[78] *See* Consolidated Appropriations Act, H.R. 1625, 115th Cong. § 508 (2018) (enacted).

[79] *See* Junying Yu & James A. Thomson, *Embryonic Stem Cells*, NAT'L INSTS. OF HEALTH, https://stemcells.nih.gov/info/Regenerative_Medicine/2006Chapter1.htm [https://perma.cc/CFC5-4D9L].

[80] *See* David Cyranoski, *The Cells That Sparked a Revolution*, 555 NATURE 428, 429 (2018), https://www.depts.ttu.edu/biology/people/Faculty/Held/StemCells2018.pdf [https://perma.cc/N8E4-LD7Q].

derivation of embryonic stem cells from pre-implantation human embryos, however, has generated backlash from religious and anti-abortion groups.[81]

[20] Over the last several presidencies in the U.S., the question of whether stem cell research should be publicly funded has become a game of ping-pong. Near the end of President Clinton's second term in office, the NIH issued guidelines to permit federal funding of "research using human pluripotent stem cell lines derived from embryos or fetal tissue."[82] Less than one year later, then-President Bush reversed course and adopted a policy banning the creation of new stem cell lines and restricting federally-funded research to lines already in existence.[83]

[21] Eight years later and early in his first term, then-President Obama revoked the previous administration's policy in an attempt to expand the number of stem cell lines available for research.[84] Subsequent attempts by both major political parties in Congress to either expand stem cell research or curtail President Obama's Executive Order were not successful,[85] and a district court injunction against federally-funded stem cell research was vacated on appeal.[86] President Trump has not publicly commented on his

[81] *See The Cases For and Against Stem Cell Research*, FOX NEWS (Aug. 9, 2001), http://www.foxnews.com/story/2001/08/09/cases-for-and-against-stem-cell-research.html [https://perma.cc/6SR3-JNEV]. *See generally* Richard A. Pizzi, *The Science and Politics of Stem Cells*, 5 MOD. DRUG DISCOVERY 32 (2002) (discussing the religious and ethical controversies pertaining to stem cell research).

[82] *Approval Process for the Use of Human Pluripotent Stem Cells in NIH-Supported Research*, NAT'L INSTS. OF HEALTH (Aug. 23, 2000), https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-050.html [https://perma.cc/FPQ5-D6M2].

[83] *See* Spivak et al., *supra* note 15, at 36.

[84] *See* Exec. Order No. 13,505, 3 C.F.R § 586 (2009).

[85] *See* Spivak et al., *supra* note 15, at 36.

[86] *See* Sherley v. Sebelius, 644 F.3d 388, 390 (D.C. Cir. 2011).

views of stem cell research.[87] Although President Trump recently signed into law so-called "right-to-try" legislation[88] that would allow terminally ill patients access to experimental treatments, including experimental stem cell therapies,[89] this law does not expand public funding for stem cell research.[90] Moreover, this legislation has been decried by stem cell research groups for putting patients at risk "by providing a route for snake-oil salesman to evade regulation and sell unproven and scientifically dubious therapies to patients."[91]

3. Consolidated Appropriations Act of 2016

[22] The Food and Drug Administration (FDA) has broad authority under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to "regulate cell and gene therapy products as biological products and/or drugs . . . ."[92] While the FDA normally reviews and evaluates new drugs prior to clinical use, occasionally the agency allows researchers to test the safety and effectiveness of investigational new drugs

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[87] *See* Emily Mullin, *Under Trump, Biologists Fear Political Risks of Controversial Research*, MIT TECH. REV. (Nov. 9, 2017), https://www.technologyreview.com/s/609323/under-trump-biologists-seek-a-low-profile-for-controversial-research/ [https://perma.cc/KMD2-4J8L].

[88] *See* Jessie Hellman, *Trump Signs 'Right to Try' Drug Bill*, THE HILL (May 30, 2018, 1:16 PM EDT), http://thehill.com/policy/healthcare/389908-trump-signs-right-to-try-bill-for-terminally-ill-patients [https://perma.cc/5CDB-QVHR].

[89] *See* Jacqueline Howard, *What You Need to Know About Right-to-Try Legislation*, CNN (May 29, 2018, 1:50 PM ET), https://www.cnn.com/2018/03/22/health/federal-right-to-try-explainer/index.html [https://perma.cc/988L-J6NJ].

[90] *See* Right to Try Act of 2017, Pub. L. 115-176, 132 Stat. 1372 (2017).

[91] *ISSCR Responds to President Trump Signing 'Right to Try' Law*, INT'L SOC'Y FOR STEM CELL RES. (June 4, 2018), http://www.isscr.org/professional-resources/news-publicationsss/isscr-news-articles/article-listing/2018/05/22/isscr-troubled-by-%27right-to-try%27-passage-in-u.s.-congress [https://perma.cc/96GD-7TJX]; *see also* Howard, *supra* note 89.

[92] Collins, *supra* note 63.

that have not yet been approved.[93] The Consolidated Appropriations Act of 2016, however, includes a provision that forbids the FDA from reviewing exemption applications involving research with genetically modified human embryos.[94] The pertinent provision is as follows:

> Sec. 749. None of the funds made available by this Act may be used to notify a sponsor or otherwise acknowledge receipt of a submission for an exemption for investigational use of a drug or biological product . . . in research in which a human embryo is intentionally created or modified to include a heritable genetic modification. Any such submission shall be deemed to have not been received by the Secretary . . . .[95]

[23] While this provision does not explicitly ban research involving genetically modified human embryos, the disqualification of this type of research from investigational new drug exemptions stifles new developments in the field.[96] Scholars argue that the provision "adds yet another layer to a complex regulatory and statutory web concerned with human embryo research in general and human germline modification in particular."[97] The rider affects not only genome editing to prevent genetic disorders but also "ongoing efforts of the FDA to review the prevention of mitochondrial DNA diseases through germline modification of human zygotes or oocytes at risk."[98] Thus, Section 749 extends the impact of prior efforts to limit research with human embryos by precluding any corporate

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[93] *See* Kushal Kadakia, *Consolidated Appropriations Act, 2016 (Public Law 114-113)*, DUKE SCIPOL (Nov. 9, 2016), http://scipol.duke.edu/content/consolidated-appropriations-act-2016-public-law-114-113 [https://perma.cc/L8ND-Q2U2].

[94] *See* Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, 129 Stat. 2242, 2283 (2015).

[95] *Id.*

[96] *See* I. Glenn Cohen & Eli Y. Adashi, *The FDA is Prohibited from Going Germline*, 353 SCIENCE MAG. 545, 545 (2016).

[97] *Id.* at 546.

[98] *Id.* at 545.

entity from applying for permission to test cell and gene therapy products.[99] Scholars argue that "this latest congressional intervention appears premature, if not unhelpful,"[100] and that it "undermines ongoing conversations on the possibility of human germline modification . . . ."[101]

III. DISEASE PREVENTION & DESIGNER BABIES

[24] A recent Pew Research Center study demonstrated that the American public is evenly divided on the issue of whether gene editing technology should be used to reduce the risk of serious diseases and conditions in newborn babies.[102] Patients with genetic disorders, their family members, and patient advocates have diverse views on the subject as well.[103] Some with progressive, life-threatening diseases feel strongly that genetic editing should be used to prevent transmission of such diseases.[104] Others with less-debilitating, non-life-threatening conditions do not consider their condition to be a disability and fear that they may no longer be accepted by society should gene editing become commonplace.[105] The fact that patient communities and the public are closely divided on the issue suggests that there are persuasive arguments on both sides of the debate.

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[99] *See id.* at 546.

[100] *Id.*

[101] Cohen & Adashi, *supra* note 96, at 545.

[102] *See Genome Editing*, NAT'L HUMAN GENOME RES. INST. (Aug. 3, 2017), https://www.genome.gov/27569226/what-do-people-think-about-genome-editing/ [https://perma.cc/9U4J-XWME].

[103] *See id.*

[104] *See id.*

[105] *See id.*

A. Eliminating Inheritable Diseases and Improving Quality of Life

[25] The most compelling argument in favor of germline genome editing is that the technology could be used to prevent life-threatening genetic disorders. For prospective parents who suffer from serious genetic diseases or who are carriers for such diseases, the desire to bear genetically related children unaffected by the disease can be overwhelming.[106] Even for those prospective parents who are not known carriers of a genetic disease, the fear of spontaneous genetic abnormalities can cause great angst and anxiety.[107] Over 10,000 medical conditions are caused by inherited genetic mutations,[108] and gene editing offers a solution to permanently rid society of many of those life-threatening diseases and conditions.[109]

[26] Proponents of germline gene editing also point to potential quality of life improvements the technology could provide. Gene editing technology might one day be capable of increasing the human lifespan by manipulating genes known to contribute to the aging process.[110] Some medical conditions or impairments that are not life-threatening might also be amenable to genetic modification. For example, ongoing research in the U.S. is using gene editing tools to correct inherited genetic mutations that

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[106] *See* Gwendolyn P. Quinn et al., *BRCA Carriers' Thoughts on Risk Management in Relation to Preimplantation Genetic Diagnosis and Childbearing: When Too Many Choices Are Just as Difficult as None*, 94 FERTILITY & STERILITY 2473, 2474 (2010).

[107] *See Pregnancy-Related Fears: Know the Facts About Birth Defects*, HCA TODAY BLOG (Jan. 23, 2017), https://hcatodayblog.com/2017/01/23/pregnancy-related-fears-know-the-facts-about-birth-defects/ [https://perma.cc/XUV8-6VPL].

[108] *See* Hong Ma et al., *Correction of a Pathogenic Gene Mutation in Human Embryos*, 548 NATURE 413, 413 (2017).

[109] *See* Thom Patterson, *Unproven Medical Technique Could Save Countless Lives, Billions of Dollars*, CNN (Oct. 30, 2015, 7:28 PM ET), https://www.cnn.com/2015/10/30/health/pioneers-crispr-dna-genome-editing/index.html [https://perma.cc/2RV2-SDG8].

[110] *See* Dom Galeon, *Scientists Uncover Genes That May Help Combat Aging and Disease*, FUTURISM (Feb. 21, 2017), https://futurism.com/scientists-uncover-genes-that-may-help-combat-aging-and-disease/ [https://perma.cc/2RV2-SDG8].

cause hypertrophic cardiomyopathy,[111] a disease which causes ventricle walls of the heart to thicken.[112] For some people, this disease has no effect on their lives, but others suffer "shortness of breath, serious arrhythmias, or an inability to exercise."[113] Thus, while for many this condition is not fatal, eradicating it would vastly improve the quality of their lives. Moreover, gene editing technology might one day be applied to correct mutations associated with non-life-threatening food or environmental allergies[114] or to correct inheritable deficiencies with vision[115] or hearing.[116]

B. Designer Babies and Social Inequality

[27] The greatest concern among opponents of germline genome editing is that it will lead to "designer babies" and thereby foster greater social inequality.[117] The fear is that gene editing technology will place us on "a path toward a dystopia of superpeople and designer babies for those who

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[111] *See* Julia Franz & Katie Hiler, *New Developments in Human Gene Editing Face an Ethical and Regulatory Quagmire in the US*, PUB. RADIO INT'L (Aug. 27, 2017, 10:00 AM EDT), https://www.pri.org/stories/2017-08-27/new-developments-human-gene-editing-face-ethical-and-regulatory-quagmire-us [https://perma.cc/BMT7-97U6].

[112] *See Hypertrophic Cardiomyopathy*, AM. HEART ASS'N (Mar. 31, 2016), http://www.heart.org/HEARTORG/Conditions/More/Cardiomyopathy/Hypertrophic-Cardiomyopathy_UCM_444317_Article.jsp#.WsPBG2aZPdc [https://perma.cc/3EHZ-22SW].

[113] *Id.*

[114] *See* Michael A. Goodman et al., *CRISPR/Cas and the Future of Gene Editing in Allergic and Immunologic Diseases*, 13 EXPERT REV. OF CLINICAL IMMUNOLOGY 5, 6, 8 (2016).

[115] *See Inherited Eye Disease*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/diseases/17130-inherited-eye-disease [https://perma.cc/SQE6-GX5Z].

[116] *See* Lydia Denworth, *Gene Editing Shows Promise for Alleviating Hearing Loss*, SCI. AM. (Dec. 20, 2017), https://www.scientificamerican.com/article/gene-editing-shows-promise-for-alleviating-hearing-loss/ [https://perma.cc/Z3JB-ZVLE].

[117] King, *supra* note 10.

can afford it."[118] According to Dr. Marcy Darnovsky, the executive director of the Center for Genetics and Society, germline modification could one day be offered in fertility clinics as "genetic upgrades," thus creating "a world where some people's children are considered biologically superior to the rest of us."[119] This is the precise bifurcated society of "haves" and "have-nots" that was portrayed in the film *Gattaca*.[120] Dr. Juan Carlos Izpisua Belmonte, a geneticist at the Salk Institute, notes that "[a]ny intervention that goes to the clinic should be for everyone. . . . It shouldn't create inequities in society."[121]

[28] Another concern expressed by opponents to germline editing is that it promotes a new era of eugenics.[122] By eliminating "undesirable" traits and thereby promoting the development of "superior individuals," gene editing is pursuing the same goals as the eugenics movement of the last century.[123] Opponents also argue that altering the germline "affects the next generation without their consent,"[124] another feature that is in line with eugenics theory.[125]

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[118] Antonio Regalado, *Engineering the Perfect Baby*, MIT TECH. REV. (Mar. 5, 2015), https://www.technologyreview.com/s/535661/engineering-the-perfect-baby/ [https://perma.cc/7UL5-LZCC].

[119] Pam Belluck, *Gene Editing for 'Designer Babies'? Highly Unlikely, Scientists Say*, N.Y. TIMES (Aug. 4, 2017), https://www.nytimes.com/2017/08/04/science/gene-editing-embryos-designer-babies.html [https://perma.cc/J9XT-YAZU].

[120] GATTACA, *supra* note 1.

[121] Belluck, *supra* note 119.

[122] *See generally* Felipe E. Vizcarrondo, *Human Enhancement: The New Eugenics*, 81 LINACRE Q. 239 (2014) (stating that "[p]arental selection for specific traits raises significant concerns" one of which being that every consequence is passed on to all subsequent generations in germline editing).

[123] *See id.* at 239.

[124] Collins, *supra* note 63.

[125] *See* Vizcarrondo, *supra* note 122, at 240.

[29] Opponents also argue that there is no medical justification for gene editing of embryos. Through pre-implantation genetic testing, doctors can already avoid propagating certain genetic diseases by not using embryos containing deleterious mutations.[126] Moreover, the money that might be spent on gene editing research "would be much better spent on developing cures for people living with those conditions."[127]

C. Finding Middle Ground

[30] Regardless of which side of the germline-gene-editing-fence one falls, genomic editing of human embryos is currently happening in several parts of the world.[128] Importantly, an outright ban in the U.S. on gene editing research in human embryos would not only fail to curtail research in other countries, but it may also drive scientists to other parts of the world to perform such research.[129] Moreover, existing research involving human embryos has shown that gene editing technology is nowhere near

[126] *See* King, *supra* note 10.

[127] *Id.*

[128] *See* Oscar Holland & Serenitie Wang, *Chinese Scientist Claims World's First Gene-Edited Babies, Amid Denial from Hospital and International Outcry*, CNN (Nov. 27, 2018, 12:56 PM ET), https://www.cnn.com/2018/11/26/health/china-crispr-gene-editing-twin-babies-first-intl/index.html [https://perma.cc/6W5B-Z545]; *see also* Liang et al., *supra* note 58, at 363; Ma et al., *supra* note 108, at 413; Rob Stein, *Breaking Taboo, Swedish Scientist Seeks to Edit DNA of Healthy Human Embryos*, NPR (Sept. 22, 2016, 5:07 AM ET), https://www.npr.org/sections/health-shots/2016/09/22/494591738/breaking-taboo-swedish-scientist-seeks-to-edit-dna-of-healthy-human-embryos [https://perma.cc/KZ9F-7AD7]; Meera Senthilingam, *Gene Editing of Human Embryos in UK Reveals New Fertility Clue*, CNN (Sept. 21, 2017, 10:40 PM ET), https://www.cnn.com/2017/09/21/health/uk-human-embryos-crispr-fertility-study/index.html [https://perma.cc/AF3M-X2VZ].

[129] *See generally* Elizabeth Redden, *Ready to Go Expat?*, INSIDE HIGHER ED (July 26, 2017), https://www.insidehighered.com/news/2017/07/26/several-countries-launch-campaigns-recruit-research-talent-us-and-elsewhere [https://perma.cc/G35Z-2RPC?type=image] (explaining what Britain, Canada, France, and Germany are doing to recruit foreign researchers, including how they are using their funding programs, and how they may capitalize on perceptions of the United States as a less attractive place for research).

perfected.[130] As one scholar has noted, "[c]urrent genome editing technology does not have sufficient efficiency and specificity to be reliably safe . . . and [off-target] effects will not always be benign or predictable . . . ."[131] Thus, more research is needed to ensure that if and when this technology becomes commonplace, it is safe and reliable. Rather than promulgate laws to directly regulate the use and application of gene editing techniques themselves, the U.S. government has chosen to address the issue of gene editing research in human embryos at the level of the purse. If gene editing research was endorsed and adequately funded in the U.S., however, it could be tightly controlled to ensure that it is used for appropriate purposes, thereby satisfying proponents of such research while also addressing relevant ethical concerns.

IV. FUNDING & REGULATING GENE EDITING IN HUMAN EMBRYOS

[31] Congress should enact legislation allowing for federal funding of gene editing research in human embryos. Such legislation should be enacted in concert with additional regulations to ensure that public monies are used appropriately. Funding gene editing research would promote, rather than stifle, innovation, and by providing a proper regulatory framework, Congress can ensure that the safety and ethical concerns associated with this technology are adequately addressed.

A. Permitting Federal Funding for Gene Editing Research in Human Embryos

[32] A major concern for opponents to gene editing research in human embryos is that the absence of oversight could lead to the misuse of the technology and the creation of *designer babies*. However, allowing federal funding for gene editing research in human embryos will drive both regulatory and ethical oversight of this field of research. Issuance of federal grants by the NIH requires that recipients "comply with all applicable

[130] *See* Dana Carroll, *Genome Editing: Past, Present, and Future*, 90 YALE J. BIOLOGY & MED. 653, 654–55 (2017).

[131] *Id.* at 655.

Federal statutes . . . regulations, and policies."[132] Current compliance regulations are extensive and include a wide-range of oversight activities, such as reporting requirements, public welfare protections, and compliance site visits.[133] Additionally, permitting federal funding for this area of research will ensure that the research remains in the public domain, thus allowing for transparency and public oversight through peer-review of research and sharing of data and research resources.[134] In the absence of public funding for gene editing research, however, "there is a risk that research will move offshore and/or to areas where it is subject to fewer regulations and less oversight and where work is done without transparency."[135]

[33] The lack of federal funding for genome editing research in human embryos is also putting the U.S. behind other countries in the quest for knowledge, discovery, and technology. While gene editing in human embryos is not banned in the U.S., the lack of available public funds severely hampers domestic advancement of gene editing technologies.[136] Jennifer Doudna, a leader of the research team holding multiple U.S. patents for CRISPR-Cas9 technology,[137] argues that federal funding of basic research "lays the groundwork for future innovation" and "is critical to encourage our scientists to pursue not just the challenges that are relatively easy, or obviously profitable, but the ones that are fiendishly hard–yet

[132] *Grants Compliance & Oversight*, NAT'L INSTS. OF HEALTH, https://grants.nih.gov/policy/compliance.htm [https://perma.cc/B95X-V65E].

[133] *See id.*

[134] *See* Kelly E. Ormond et al., *Human Germline Genome Editing*, 101 AM. J. HUM. GENETICS 167, 171 (2017).

[135] *Id.* at 173.

[136] *See* Alice Hazelton, *Everything You Need to Know About Gene Editing*, WORLD ECON. F. (June 27, 2017), https://www.weforum.org/agenda/2017/06/everything-you-need-to-know-about-gene-editing-2/ [https://perma.cc/55PW-N8Z5].

[137] *See* Kristin Houser, *UC Berkeley Finally Scores a Win with Two CRISPR Patents*, FUTURISM (June 14, 2018), https://futurism.com/crispr-patents-uc-berkeley/ [https://perma.cc/9SAR-SG6R].

crucial."[138] In addition to promoting innovation, federal funding for gene editing technologies has economic benefits. While some U.S. biotech firms may benefit from the export of the technology to other jurisdictions, the development and improvement of the technology for use in humans is occurring primarily in other countries.[139] Thus, the U.S. is deprived of any economic benefits deriving from the development of such technologies on its own soil and is losing an edge in its ability to recruit the best scientists and researchers in this burgeoning field.[140]

[34] To be sure, CRISPR-Cas9 research in human embryos is currently being conducted in the U.S.;[141] however, such research is funded only by private organizations.[142] This highlights the notion that restrictive federal funding policies "do not necessarily prevent certain research or the development of new technologies from taking place."[143] However, the amount of private funding for biomedical research is dwarfed by public funding levels: it was estimated that in 2015, federal funding for basic research in life sciences was nearly forty times greater than available private funding in that sector.[144] By removing restrictions on funding for gene editing research in human embryos, it is more than likely that funding levels for research in this field will increase several-fold, thereby promoting the rapid development of this technology within U.S. borders.

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[138] Jennifer Doudna & Alex Marson, *Federal Funding for Basic Research Led to the Gene-Editing Revolution. Don't Cut It.*, VOX (Apr. 22, 2017, 8:30 AM EDT), https://www.vox.com/the-big-idea/2017/4/22/15392912/genes-science-march-nih-funding-basic-research-doudna [https://perma.cc/CB6J-VHQT].

[139] *See* Brent M. Eastwood, *Gene-Editing in China: Beneficial Science or Emerging Military Threat?*, ATLANTIC COUNCIL (July 13, 2017), http://www.atlanticcouncil.org/blogs/futuresource/gene-editing-in-china-beneficial-science-or-emerging-military-threat [https://perma.cc/3A5X-Y48F].

[140] *See* Redden, *supra* note 129.

[141] *See* Ma et al., *supra* note 108, at 413 n.1.

[142] *See* Franz & Hiler, *supra* note 111.

[143] Ormond et al., *supra* note 134, at 171.

[144] *See Private Funding for Science*, 13 NATURE METHODS 537, 537 (2016).

[35] There are also international security concerns associated with a failure to fund gene editing research. By not fostering the industry's development in the U.S., the technology is driven overseas where it may one day be used to develop military applications.[145] Countries that fund and permit development of the technology in human embryos may be able to "create 'super soldiers' to dominate future battlefields."[146] Gene editing technology is more likely to be used to develop biological weapons focused on ecological and agricultural issues,[147] and the threat of "super soldiers," if ever realized, is likely a long way off. However, it remains a concern that needs to be taken seriously and closely monitored,[148] even if it borders on science-fiction.

[36] By recognizing that withholding federal funding will not prevent gene editing research in human embryos and will instead drive the industry to other parts of the world, Congress has an opportunity to retain control of this technology's development and ensure that the U.S. remains a leader in this field. Public funding of gene editing research in human embryos will provide economic, military, and social benefits, and by controlling the purse, Congress can maintain tight regulatory control and oversight to ensure that the technology is not used for unethical and socially harmful purposes.

B. Essential Criteria for Gene Editing Regulations

[37] Currently in the United States, the regulatory framework regarding gene modification in humans is sparse. The only federal law that references heritable genetic modification is the Consolidated Appropriations Act of 2016, which merely restricts federal funding for gene modification research

[145] *See* Eastwood, *supra* note 139.

[146] *Id.*

[147] *See Pentagon Revealed as Top Funder of Controversial Gene Editing Tech*, RT (Dec. 5, 2017, 4:57 PM), https://www.rt.com/usa/412019-pentagon-darpa-gene-drive/ [https://perma.cc/BQJ4-F8CG].

[148] *See* Eastwood, *supra* note 139.

in human embryos.[149] If public funding was made available for gene editing research involving human embryos, Congress would also need to enact legislation providing for the regulation of the industry.

[38] On February 14, 2017, the National Academies of Sciences, Engineering, and Medicine published a report titled *Human Genome Editing: Science, Ethics, and Governance* (hereinafter, "the Report").[150] Acknowledging the global interest in genome editing technology, the Report discussed gene-editing technologies, their potential applications in biomedical research and medicine, and the clinical, legal, ethical, and social implications of using gene-editing in humans.[151] Important questions addressed in the Report include "how to balance potential benefits against the risk of unintended harms; how to govern the use of these technologies; . . . and how to respect the inevitable differences, rooted in national cultures, that will shape perspectives on whether and how to use these technologies."[152]

[39] The Report includes recommendations for governance in the U.S. of human genome editing in various contexts, including "laboratory research, preclinical testing, clinical trials, and potential medical uses."[153] While this article focuses on the use of gene editing technology in human embryos in a laboratory research setting[154] rather than for somatic cell-based therapies in a clinical setting, many of the Report's recommendations are applicable to both. However, in the beginning stages of use of this technology in human embryos, several factors play a more significant role in ensuring that the technology is not used inappropriately. In any federal legislation enacted to

[149] *See* Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 508, 129 Stat. 2242, 2650 (2015).

[150] *See* NAT'L ACADS. OF SCIS., ENG'G, MED., HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE (National Academies Press, 2017) [hereinafter THE REPORT].

[151] *See id.* at 273.

[152] *Id.* at 1–2.

[153] *Id.* at 59.

[154] *See id.* at 2.

regulate the use of gene editing technology in human embryos, the following three criteria from the Report's recommendations would be critical to the success of such legislation.

1. Restricting Use to Serious Diseases or Conditions

[40] A criterion restricting the use of gene editing technology to serious diseases or conditions is essential for avoiding the concern that gene editing technology would be used to generate "designer babies." A restriction on the use of gene editing for only serious diseases and conditions forecloses the possibility that the technology will be used to dictate non-life-threatening traits or characteristics, such as hair color or skin tone.

[41] An important aspect of this criterion concerns the definition of the term "serious disease or condition."[155] The term as presented in the Report is purposefully vague to allow the class of permitted maladies to expand or contract as needed.[156] At a minimum, the term should refer to those diseases and conditions that are more likely than not to cause death or severe impairment in function. The FDA defines "serious disease or condition" as:

> a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. . . . Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.[157]

This definition provides a non-exclusive list of factors to be considered in determining which maladies are "serious" and indicates that such determinations should be clinically based.[158] While a certain condition by

[155] *See* THE REPORT, *supra* note 150, at 8.

[156] *See id.*

[157] 21 C.F.R. § 312.300(b) (2018).

[158] *See id.*

itself may be non-life-threatening, in combination with other traits or characteristics, the condition's severity may be elevated and thereby approach life-threatening. Therefore, a clinical determination of whether a disease or condition, either by itself or in combination with other factors, is "serious" is vital. Moreover, as additional cheap and effective medical treatments are developed, some diseases or conditions may no longer be considered "serious" to warrant use of gene editing at the germline stage.[159]

2. Restricting Use to Genes Demonstrated to Cause or Strongly Predispose to the Disease or Condition

[42] Roughly 99.5% of a person's DNA is identical to that of an unrelated person, but there are also over eighty million known variations in the human genome, many of which have unknown or poorly understood functions.[160] By restricting editing of human embryos to genes and variants known to cause or strongly predispose to a disease or condition, this criterion will minimize the risk of unintended and adverse consequences.

[43] Many genetic diseases, conditions, and traits are not caused by a single mutation but instead are influenced by a panoply of genetic changes.[161] For example, as many as sixty-seven genetic variants are thought to contribute to heart disease,[162] and a person's height is estimated to be determined by as many as 93,000 genetic variations.[163] In the absence of substantial scientific data and a general consensus within the scientific and medical communities about the genetic etiology of a disease, there is

[159] *See* Belluck, *supra* note 119.

[160] *See Genetic Variation Program*, NAT'L HUM. GENOME RES. INST. (Dec. 6, 2017), https://www.genome.gov/10001551/genetic-variation-program/ [https://perma.cc/X2YD-TM2Y].

[161] *See* Belluck, *supra* note 119.

[162] *See The Genetics of Heart Disease: An Update*, HARVARD HEALTH PUB. (Sept. 2017), https://www.health.harvard.edu/heart-health/the-genetics-of-heart-disease-an-update [https://perma.cc/8E44-SVC5].

[163] *See* David B. Goldstein, *Common Genetic Variation and Human Traits*, 360 NEW ENG. J. MED. 1696, 1696 (2009).

no way of knowing whether a genetic alteration will effectively prevent the disease or whether other protein functions will be adversely affected. This limitation will also avoid concerns about the use of gene editing to alter traits unrelated to health needs because many of such traits do not arise from an easily identifiable number of genes, nonetheless from a single gene mutation.[164] Without specific knowledge regarding which gene variants are the main drivers for such traits, the possibility of regulating characteristics such as height is next to nonexistent.[165]

3. Restricting the Conversion of Genes to Versions That Are Known to be Associated with Normal Health and That Are Prevalent in the Population

[44] Restricting the conversion of genes to versions that are known to be associated with normal health will ensure that gene alterations do not confer any unintended function(s) on the protein for which the gene encodes. Changing disease-causing variants to versions known to be nonpathogenic would minimize the risk that the new variant will exacerbate the disease or introduce an unintended function. For example, if normal gene function requires an adenine base at a specific location within the gene, whereas the disease-causing variant contains a thymine base at that location, conversion of the thymine to anything other than adenine (e.g. cytosine or guanine) may introduce a new, unknown function. The protein encoded by the modified gene may not function as efficiently as a protein encoded by an adenine-containing version, thereby failing to eradicate the disease or condition. Alternatively, the protein encoded by the modified gene may no longer cause the disease or condition but may instead alter a separate protein function that promotes a different disease. Therefore, only variants known to be associated with normal health should be used.

[45] Restrictions on converting genes to versions that are prevalent in the population will prevent the promotion of "desirable" traits, thereby negating

[164] *See* Belluck, *supra* note 119.

[165] *See id.*

a fear of "new eugenics"[166] or any perceived threat to human evolution.[167] By "[c]hanging a disease-causing mutation to [only] a known . . . nonpathogenic sequence[,]" there would be a "minimal effect on the human gene pool."[168] However, some gene mutations that are known to cause disease also confer a certain level of protection against other diseases.[169] For example, carriers of the gene mutation that causes sickle-cell anemia have been shown to be more resistant to malaria,[170] and those with histories of hay fever and asthma have a lowered mortality risk of pancreatic cancer and leukemia, respectively.[171] Therefore, whether the elimination of a mutation will increase susceptibility to other diseases or conditions and whether alternative treatments for those other diseases or conditions are available should be considered.

V. CONCLUSION

[46] Gene editing technology has progressed dramatically over the last decade, and what was once considered futuristic science fiction is now close to becoming a reality. The U.S. has an opportunity to be a leader in this new reality by properly funding and regulating gene editing research involving human embryos. Public funding of gene editing research will provide economic and social benefits, while also allowing Congress to maintain

[166] *See* Vizcarrondo, *supra* note 122, at 239.

[167] *See* Jim Kozubek, *How Gene Editing Could Ruin Human Evolution*, TIME (Jan. 9, 2017), http://time.com/4626571/crispr-gene-modification-evolution/ [https://perma.cc/9LHB-KZZA].

[168] THE REPORT, *supra* note 150, at 118.

[169] *See* Sarah C.P. Williams, *Genetic Mutations You Want*, 113 PROC. NAT'L ACAD. SCI. 2554, 2254, 2556 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4791022/pdf/pnas.201601663.pdf [https://perma.cc/S8Z6-C57C].

[170] *See* Catherine de Lange, *How Sickle-Cell Carriers Fend Off Malaria*, NEW SCIENTIST (May 5, 2011), https://www.newscientist.com/article/dn20450-how-sickle-cell-carriers-fend-off-malaria/ [https://perma.cc/CX3B-J8TU].

[171] *See* Michelle C. Turner et al., *Cancer Mortality Among US Men and Women with Asthma and Hay Fever*, 162 AM. J. EPIDEMIOLOGY 212, 212, 218 (2005).

tight regulatory control and oversight to ensure that the safety and ethical concerns associated with gene editing technology are appropriately addressed.