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Defusing a Ticking Time Bomb: The Complicated Considerations Underlying Compulsory Human Genetic Editing

by GRANT HAYES FRAZIER[*]

Abstract

Gene editing is a type of genetic engineering that enables scientists to change an organism's DNA by adding, removing, or altering genetic material at particular locations in the human genome. While these editing technologies are in their infancy, they hold great promise for future applications. They also raise many moral, ethical, and legal questions.

Fast forward 10 years. *In utero* gene editing is effective, safe, and inexpensive (or covered by insurance). A couple with strong religious views against gene editing decides to procreate despite knowing, via family history, they are both homozygous dominant for the allele that causes Huntington's disease (an autosomal dominant disease), and therefore the child will have a 100% likelihood of inheriting the disease (barring a highly unlikely, unforeseen mutation eliminating the inherited disorder). The couple undergoes genetic testing of the fetus, which confirms the fetus is homozygous dominant for Huntington's disease. The couple's physician recommends a gene editing treatment to "fix" the fetus's genes. The couple declines the treatment on religious grounds, knowing full well the spectrum of health risks and symptoms their child will face. The child is born with Huntington's disease and suffers the expected health issues. Safe post-birth gene therapy for Huntington's is not available.

In a situation like the one above, what liability do parents face if there is a state statute requiring gene editing in circumstances such as these? If there is no such statute, should courts determine that parents have an affirmative duty, via existing common law principles governing "special relationships," to acquiesce to these procedures during pregnancy to avoid almost certain postnatal injury? If so, what genetic issues are important

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enough for this affirmative duty to be imposed? What criminal liability do parents potentially face under existing causes of action? What types of civil actions might the affected child bring against his or her parent(s)? Does the state or the child even have the standing to bring a suit? If the standing requirement is met, how might courts reconcile parents' potential affirmative duty to acquiesce to gene editing treatment with parents' constitutionally-based arguments in opposition (e.g., free exercise of religion, privacy rights under *Roe v. Wade* and its progeny, etc.)? These questions, and related topics, are addressed below.

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Introduction

Curing a presently irremediable genetic-related disease by "fixing" a "bad gene" might seem like science fiction. However, a group of developing technologies, known as gene editing, enable scientists to change and, therefore, fix an organism's DNA by adding, removing, or altering genetic material at particular locations in the human genome.[1] Collectively, these technologies have the potential to be one of the most significant medical advances in recent history.[2] Experts have suggested

1. *What Are Genome Editing and CRISPR-Cas9?*, GENETICS HOME REFERENCE (Apr. 11, 2018), https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting; *see also How Is Genome Editing Used?*, NAT'L HUM. GENOME RES. INST. (Aug. 3, 2017), https://www.genome.gov/27569224/how-is-genome-editing-used/.

2. Victor Tangermann, *A CRISPR Future*, FUTURISM (Jan. 30, 2018), https://futurism.com/crispr-genetic-engineering-change-world/. Gene-editing has many other potential applications, including the repair of old or damaged organs. *No Pig in A Poke*, ECONOMIST (Oct. 17, 2015), https://www.economist.com/news/science-and-technology/21674493-genome-engineering-may-help-make-porcine-organs-suitable-use-people-no-pig. This technology could save many lives, with an average of 20 people dying each day in the U.S. waiting for

these editing tools may have clinical utility for treating afflictions such as Huntington's disease,[3] sickle cell disease, cystic fibrosis, hemophilia, mental illness, heart disease, HIV/AIDS, and several types of cancer.[4]

While these editing tools are in their infancy, research and development efforts have been accelerated by significant financial commitments from well-respected private sector investors.[5] Recent developments indicate these technologies hold great promise for future applications,[6] and several experts have noted that these technologies' efficacy is rapidly progressing and clinical use is likely not far off.[7]

Beyond its clinical benefits, gene editing holds great promise for halting and reversing the trajectory of skyrocketing medical costs[8] by enabling proactive treatment addressing the root afflictions that cause

viable organ transplants. *Organ Donation Statistics*, ORGAN DONOR, https://www.organdonor.gov/statistics-stories/statistics.html (last visited Apr. 11, 2018).

3. *See* Su Yang et al., *CRISPR/Cas9-Mediated Gene Editing Ameliorates Neurotoxicity in Mouse Model of Huntington's Disease*, 127 J. CLIN. INVEST. 2719, 2719 (2017); *see also CRISPR Reverses Huntington's Disease in Mice*, GEN (June 20, 2017), https://www.genengnews.com/gen-news-highlights/crispr-reverses-huntingtons-disease-in-mice/81254532.

4. *What Are Genome Editing and CRISPR-Cas9*, *supra* note 1; *see also* Edward Lanphier, *Don't Edit the Human Germ Line*, 519 NATURE NEWS 410, 410–11 (2015).

5. In 2015, a group of investors including Bill Gates, Google Ventures, Deerfield Management, Viking Global Investors, and T. Rowe Price Associates participated in a $120 million funding round for Editas, a small company focused on CRISPR gene-editing. Matthew Herper, *Bill Gates and 13 Other Investors Pour $120 Million into Revolutionary Gene-Editing Startup*, FORBES (Aug. 10, 2015, 7:30 AM), https://www.forbes. com/sites/matthewherper/2015/08/10/bill-gates-and-13-other-investors-pour-120-million-into-revolutionary-gene-editing-startup/#15996f886369.

6. *See, e.g.*, Jocelyn Kaiser, *A Human Has Been Injected with Gene-Editing Tools to Cure His Disabling Disease*, SCIENCE (Nov. 15, 2016, 6:00 PM), http://www.sciencemag.org/news/2017/11/human-has-been-injected-gene-editing-tools-cure-his-disabling-disease-here-s-what-you (reporting that the first instance of in vivo gene editing was carried out in November 2017 to treat a 44-year-old man with Hunter's Syndrome - a severe inherited metabolic disorder); *see also* James Gallagher, *DNA Surgery on Embryos Removes Disease*, BBC (Sept. 28, 2017), http://www.bbc.com/news/health-41386849 (reporting that for the first time, Chinese scientists, in September 2017, corrected a gene mutation in a human embryo for the inherited blood disorder beta thalassemia).

7. Jacqueline Howards, *Scientists Edit Gene for Blood Disease in Human Embryos*, CNN (Sept. 29, 2017, 3:30 PM), http://www.cnn.com/2017/09/29/health/gene-edit-beta-thalassemia-study.

8. David Cutler, *JAMA Forum: Rising Medical Costs Mean More Rough Times Ahead*, NEWS@JAMA (June 23, 2017), https://newsatjama.jama.com/2017/06/23/jama-forum-rising-medical-costs-mean-more-rough-times-ahead/.

prolonged medical problems.[9] Some experts estimate that effective gene editing treatments would "save society hundreds of billions of dollars in health care costs every year."[10] New editing tools, like CRISPR, are making the editing process quicker, more precise, and less expensive.[11]

Despite gene editing's many potential positives, it also raises moral, ethical, safety, and legal questions, as it can be used for less ethically-agreeable, therapeutic means, such as enhancing human traits or characteristics.[12]

Fast-forward 10 years. *In utero* gene editing is effective, safe, inexpensive and, perhaps, covered by insurance.[13] A couple with strong religious views against gene editing decides to procreate despite knowing, via family history, they are both homozygous dominant[14] for the allele that

9. Thom Patterson, *Unproven Medical Technique Could Save Countless Lives, Billions of Dollars*, CNN (Oct. 30, 2015), http://www.cnn.com/2015/10/30/health/pioneers-crispr-dna-genome-editing/index.html.

10. *Id.*

11. Amy Dockser Marcus, *DIY Gene Editing: Fast, Cheap—and Worrisome*, WALL ST. J. (Feb. 26, 2017, 11:00 PM), https://www.cnn.com/2015/10/30/health/pioneers-crispr-dna-genome-editing/index.html.

12. *See, e.g.*, *What Are the Ethical Concerns About Genome Editing?*, NAT'L HUM. GENOME RES. INST. (Apr. 17, 2018), https://www.genome.gov/27569225/what-are-the-ethical-concerns-about-genome-editing/ (discussing intelligence, height, or athletic ability as examples of non-therapeutic uses). Some argue there are safer alternatives than *in utero* gene editing, namely preimplantation genetic diagnosis (PGD) and *in vitro* fertilization (IVF). Lanphier, *supra* note 4, at 410-11. PGD and IVF enable scientists to create multiple embryos in a lab, genetically test them, select one that has a "normal" genetic makeup, and implant that embryo into the would-be mother's uterus. *Id.* However, *in utero* gene editing addresses certain issues that PGD and IVF cannot— including when both parents are homozygous (have two copies) for a disease-causing variant, when the disorder is polygenetic (influenced by more than one gene), and for families who have moral, ethical, or religious objections to the PGD/IVF process. *Id.*

13. While not a subject of this paper, there are concerns gene editing will not be covered by medical insurance and, therefore, won't be affordable by many. Jason Koebler, *One Thing that Could Stop the Rise of Gene Editing: Insurance Companies*, MOTHERBOARD (Apr. 12, 2016, 9:10 AM), https://motherboard.vice.com/en_us/article/gv5vm9/will-insurance-companies-cover-crispr-therapies-gene-editing.

14. Because the Huntington's disease trait is autosomal dominant, only one parent would need to be homozygous dominant (DD) for the Huntington's disease trait to be passed on to all offspring, regardless of the status of the other partner. *Huntington Disease*, GENETICS HOME REFERENCE, http://ghr.nlm.nih.gov/condition/huntington-disease#inheritance (last visited Apr. 11, 2018). The mutant allele (DD) would expressively dominate the normal allele (dd) in 100% of progeny receiving it (DD x dd = Dd, Dd, Dd, Dd). *See* Ivan Suarez Robles, *Interactive Punnet[t] Square*, HOPES HUNTINGTON'S DISEASE INFO. (March 8, 2015), http://www.web.stanford.edu/group/hopes/cgi-bin/hopes_test/interactive-punnet-square/. It would not require that both parents be homozygous dominant or that one be heterozygous dominant. If both were heterozygous dominant (Dd), the offspring (Dd X Dd = DD, Dd, Dd, dd) would have a one in four chance of being homozygous dominant for

causes Huntington's disease[15] (an autosomal dominant disease), and therefore the child will have a 99% likelihood of inheriting the disease.[16] The couple undergoes genetic testing of the fetus, which confirms the fetus is homozygous dominant for Huntington's disease. The couple's physician recommends a gene editing treatment to "fix" the fetus's genes. The couple declines the treatment on religious grounds, knowing full well the spectrum of health risks and symptoms their child will face. The child is born with Huntington's disease and suffers the expected health issues. Safe post-birth gene therapy for Huntington's is not available.

What liability do parents face if there is a state statute requiring gene editing in circumstances such as outlined above (hereafter collectively referred to as the "Hypothetical")? If there is no such statute, should courts determine that parents have an affirmative duty, via existing common law principles governing "special relationships," to acquiesce to these procedures during pregnancy to avoid almost certain postnatal injury? If so, what genetic issues are important enough for this affirmative duty to be imposed? What criminal liability do parents potentially face under existing causes of action? What civil actions might the affected child bring against his or her parent(s)? Does the state or the child have standing to bring a suit? If the standing requirement is met, how might courts reconcile the parents' affirmative duty to acquiesce to gene editing treatment with the parents' constitutionally-based arguments in opposition (*e.g.*, free exercise of religion, privacy rights under *Roe v. Wade* and its progeny, etc.)? These questions, and related topics, are addressed below.

Scientific Background

To better understand the topics to be covered, an overview of human genetics and gene editing is useful.

the trait, two in four chance of being heterozygous dominant for the trait, and a one in four chance of being homozygous recessive and not carrying the trait. *Id.*

15. Huntington's disease is characterized by degeneration of nerve cells in the brain. Symptom manifests during an affected individual's 30s and 40s and includes a breadth of motor, cognitive, and behavioral declines. Mayo Clinic Staff, *Huntington's Disease*, MAYO CLINIC (June 13, 2017), https://www.mayoclinic.org/diseases-conditions/huntingtons-disease/symptoms-causes/syc-20356117.

16. Homozygous dominant individuals are rare and experience more severe symptoms than heterozygous individuals. Ferdinando Squitieri et al., *Homozygosity for CAG Mutation in Huntington Disease Is Associated with a More Severe Clinical Course*, 126 BRAIN 946, 946 (2003).

A. Human Genetics

An individual's DNA sequence acts as his or her blueprint for growth, expressed characteristics, and functions.[17] DNA consists of two strands of uniquely ordered nucleotides held together by four types of nitrogenous bases: cytosine (C), guanine (G), adenine (A), and thymine (T).[18] These bases pair together - C with G, and A with T— and allow DNA to maintain its well-known double helix form.[19]

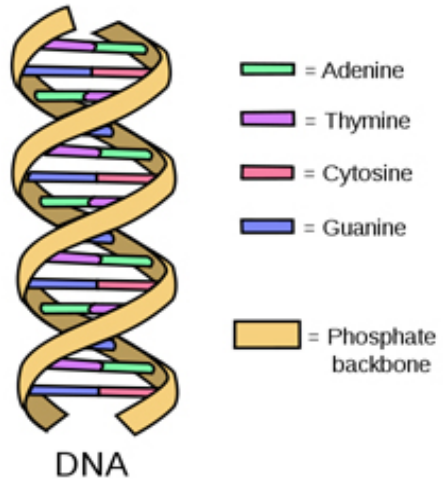

Figure 1. DNA Base Pairs and Structure.

Stretches of these nucleotides comprise genes. There are several types of genes.[20] Some genes that encode messenger RNA (mRNA) code for proteins, [21] while many other non-coding genes specify other types of RNA (e.g., transfer RNA or ribosomal RNA, among many others) that are

17. *What Is DNA?*, GENETICS HOME REFERENCE, https://ghr.nlm.nih.gov/primer/basics/dna (last updated Nov. 28, 2017).

18. *Id.*

19. *Nucleotides and Bases*, GENETICS GENERATION, http://knowgenetics.org/nucleotides-and-bases/ (last visited Apr. 11, 2018).

20. Michele Clamp et al., *Distinguishing Protein-Coding and Noncoding Genes in the Human Genome*, 104 PNAS 19428, 19428 (2007) ("The twofold challenge is to ensure that the [human gene] catalog includes all valid protein-coding genes and excludes putative entries that are not valid protein-coding genes").

21. *What Is a Gene?*, GENETICS HOME REFERENCE (Nov. 28, 2017), https://ghr.nlm.nih.gov/primer/basics/gene.

involved in the translation of mRNA into proteins and a variety of other regulatory functions.[22]

Three base sequences in the DNA that code for proteins, comprised of amino acids, is called codons.[23] There are 64 possible combinations of the four nucleotide bases into three base sequences.[24] Three of these possible combinations code for stop codons, which terminate translation.[25] The remaining 61 combinations code for the 20 amino acids that normally constitute proteins.[26] Of these amino acids, three have six codons, two have single codons, one has three codons, and the rest have either two or four codons.[27]

Even a slight variation in a gene's coding can change the gene's function by changing the normally coded-for protein.[28]

22. Suzanne Clancy & William Brown, *Translation: DNA to mRNA to Protein*, NATURE, http://www.nature.com/scitable/topicpage/translation-dna-to-mrna-to-protein-393 (last visited Apr. 12, 2018).

23. *Protein Structure*, NATURE, http://www.nature.com/scitable/topicpage/protein-structure-14122136 (last visited Apr. 12, 2018); *see also* Ann P. Smith, *Nucleic Acids to Amino Acids*, NATURE, http://nature.com/scitable/topicpage/nucleic-acids-to-amino-acids-dna-specifies-935 (last visited Apr. 12, 2018).

24. JEREMY M. BERG ET AL., BIOCHEMISTRY 7 (5th ed. 2002).

25. *The Information in DNA Determines Cellular Function via Translation*, NATURE, http://www.nature.com/scitable/topicpage/the-information-in-dna-determines-cellular-function-6523228 (last visited Apr. 12, 2018).

26. *Id.*

27. *See Codon*, ENCYCLOPEDIA BRITANNICA, http://britannica.com/science/codon (last visited April 12, 2018).

28. *Gene Expression*, NATURE, https://www.nature.com/scitable/topicpage/gene-expression-14121669 (last visited Apr. 11, 2018). However, it is important to note that the effect a slight variation has on the gene's function is dependent upon several factors including (1) the type of change; (2) whether it occurs in the coding or in the non-coding components implicated in regulating gene expression; and (3) if the variation occurs in part of the coding component, where the variation occurred. *See DNA Is Constantly Changing Through the Process of Mutation*, NATURE, http://www.nature.com/scitable/topicpage/dna-is-constantly-changing-through-the-process-6524898 (last visited Apr. 11, 2018).

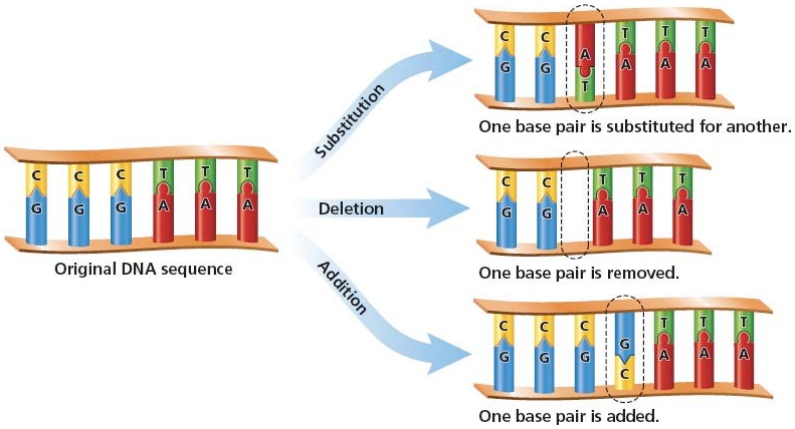

Figure 2. Three Mechanisms of Gene Mutation.

Figure 2 shows the three main ways DNA-copying mechanisms can malfunction and miscopy a gene—by either adding, deleting, or substituting one or more nitrogenous bases.[29] However, it is important to note that not every mutation changes a gene's expression.[30] It is possible for DNA to mutate at a single nucleotide and still code the same amino acid with no effect, which is referred to as a "silent mutation."[31]

B. Gene Editing

Gene editing seeks to use either somatic or germline therapy[32] to silence or correct these "mistakes."[33] Both therapies are currently carried out using one of three main families of engineered nucleases:[34] (1) zinc

29. *DNA Is Constantly Changing Through the Process of Mutation*, *supra* note 28.

30. *Do All Gene Mutations Affect Health and Development?*, GENETICS HOME REFERENCE (Sept. 25, 2018), http://ghr.nlm.nih.gov/primer/mutationsandisorders/neutralmutations.

31. *DNA Is Constantly Changing Through the Process of Mutation*, *supra* note 28.

32. *How Is Genome Editing Used?*, NAT'L HUM. GENOME RES. INST. (Aug. 3, 2017) https://www.genome.gov/27569224/how-is-genome-editing-used. Somatic therapy targets non-reproductive cells, and, therefore, only affects the patient receiving the gene therapy (not potential progeny). *Id.* Germline therapies involve editing in reproductive cells (ex: eggs and sperm), with changes likely to be passed down to subsequent generations. *Id.* This raises more ethical and moral challenges than somatic gene editing. *Id.*

33. *See How Does Genome Editing Work?*, NAT'L HUM. GENOME RES. INST. (Aug. 3, 2017), https://www.genome.gov/27569223/how-does-genome-editing-work/.

34. There is a fourth common family of engineered nucleases, Rapid Trait Development System (RTDS). *See* Noel J. Sauer et al., *Oligonucleotide-Directed*

finger nucleases (ZFNs), (2) transcription activator-like effector-based nucleases (TALENs), and (3) the clustered regularly interspaced short palindromic repeats (CRISPR).[35]

1. Zinc-finger Nucleases (ZFNs)

ZFNs are a type of DNA-binding protein that facilitates gene editing by creating breaks in DNA's double-helix structure at targeted locations.[36] The cell tries to repair a break by either nonhomologous end joining[37] or homology-directed repair.[38] Using ZFN's, scientists are able to insert lab-created DNA fragments into DNA gaps before the homology-directed repair mechanism of the cell provides its own patch of DNA to fill the gap.[39] This will, at least, theoretically alter the gene expression back to "normal."

While ZFNs recently made national headlines for the technology's use in the first U.S.-based in-patient gene editing trial,[40] the use of ZFNs remains limited because they are expensive[41] and difficult to design, engineer, and construct.[42] Furthermore, a new ZFN needs to be engineered for each

Mutagenesis for Precision Gene Editing, 14 PLANT BIOTECHNOLOGY J. 496, 496 (2016). However, this genome editing technology is currently used exclusively in plants and yeast. *Id.* As such, it is not relevant to the hypothetical proposed in this article.

35. Thomas Gaj et al., *ZFN, TALEN, and CRISPR/Cas-Based Methods for Genome Engineering*, 31 TRENDS BIOTECHNOLOGY 397, 398–402 (2013).

36. *How Does Genome Editing Work?*, *supra* note 33.

37. "Nonhomologous end joining" occurs when the cell takes the two ends of the DNA strand that has been broken, and seals them together. Dana Carroll, *Genome Engineering with Targetable Nucleases*, 83 ANN. REV. BIOCHEMISTRY 409, 420–21 (2014). This can cause frame shifts, consequently causing alterations to the DNA code and protein. TERENCE A. BROWN, GENOMES § 14.1.1 (2d ed. 2002), https://www.ncbi.nlm.nih.gov/books/NBK21114/.

38. Homology-directed repair is where a cell tries to repair a DNA break by filling in the gap with a copy of the original sequence. Carroll, *supra* note 37, at 420–21.

39. *Id.* at 412–14; *see also* Cherie L. Ramirez et al., *Engineered Zinc Finger Nickases Induce Homology-Directed Repair with Reduced Mutagenic Effects*, 40 NUCLEIC ACIDS RES. 5560, 5560 (2012).

40. Marilynn Marchione, *2nd Man Undergoes Gene Editing; No Major Side Effects Showing So Far*, N.J. HERALD (Feb. 8, 2018, 12:01 AM), http://www.njherald.com/20180208/2nd-man-undergoes-gene-editing—-no-major-side-effects-showing-so-far.

41. Rozina Sabur, *First Gene-Editing Attempted in Human Body to Cure Disease*, THE TELEGRAPH (Nov. 16, 2017), https://www.telegraph.co.uk/news/2017/11/16/first-gene-editing-attempted-human-body-cure-disease/ ("Zinc finger nucleases are an older and more expensive tool for gene editing than CRISPR genome editing.").

42. NAT'L HUM. GENOME RES. INST., *supra* note 33.

DNA target sequence, decreasing likelihood ZFNs could be scaled up for mass use.[43]

2. Transcription Activator-like Effector Nucleases (TALENs)

TALENs are similar to ZFNs in that both technologies are engineered from naturally occurring proteins capable of binding to specified DNA segments.[44] Specifically, TALENs are nucleases built from arrays of 33-34 amino acid modules that have a strong recognition of specific nucleotides.[45] These modules can be customized to target almost any DNA sequence (and therefore gene mutation).[46] The TALEN cuts the targeted DNA sequence, which induces the cell's repair mechanisms of either non-homologous end joining or homology-directed repair.[47] TALENs have the added benefit of being easier and less expensive to engineer than ZFNs.[48]

3. Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) System

CRISPR-Cas9 ("CRISPR") is the most recently developed high-profile gene-editing technology. CRISPR was adapted from a gene editing system that naturally occurs in bacteria.[49] This system seizes fragments of DNA from invading viruses and uses these fragments to create DNA segments known as "CRISPR arrays."[50] If the original (or similar) virus attacks again, the CRISPR arrays enable the bacteria to recognize the virus and respond by producing RNA segments that use the Cas9 enzyme (or similar)[51] to target

43. Jeffrey M. Perkel, *Genome Editing with CRISPRs, TALENs and ZRNs*, BIOCOMPARE (Aug. 27, 2013), http://www.biocompare.com/Editorial-Articles/144186-Genome-Editing-with-CRISPRs-TALENs-and-ZFNs/.

44. *Id.*

45. *Id.*

46. *Id.*

47. *See supra* notes 37 and 38 and accompanying text; *see also* Carroll, *supra* note 37, at 410–11.

48. Perkel, *supra* note 43.

49. Eric S. Lander, *The Heroes of CRISPR*, 164 CELL 18, 18–22 (2016).

50. *Id.* at 22.

51. A new nuclease has been identified for use with the CRISPR-Cas13 enzyme. Ruth Williams, *RNA Editing Possible with CRISPR-Cas13*, THE SCIENTIST (Oct. 25, 2017), https://www.the-scientist.com/?articles.view/articleNo/50719/title/RNA-Editing-Possible-with-CRISPR-Cas13/.

and cut the virus's DNA (thereby disabling it).[52] In essence, CRISPR acts as the bacteria's immune system, killing the invading virus.[53]

CRISPR-Cas9 works similarly in the lab, where scientists create a short "guide" RNA sequence that binds to a determined DNA target sequence and to the Cas9 enzyme.[54] The resulting RNA is used to recognize the targeted DNA sequence, which the Cas9 enzyme then cuts.[55] After the DNA is cut, researchers utilize the cell's own DNA repair mechanisms to add or delete segments of genetic material. This is done either (1) by utilizing the cell's response of non-homologous end joining to silence problem genes by inserting or deleting genetic material during the repair process,[56] or (2) by using homology-directed repair to insert a lab-created DNA sequence into the void.[57]

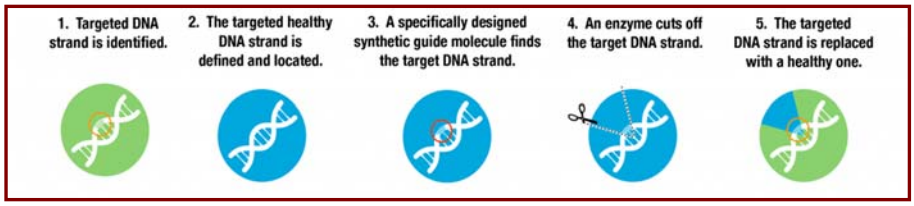

Figure 3. Gene Editing Overview.

CRISPR technology has been praised for being less expensive, more accurate, and more efficient than other gene editing methods.[58] CRISPR's benefits include ease of customization and its abilities to simultaneously target multiple genes and cut DNA strands on its own (whereas other gene editing techniques require separate cleaving enzymes to do this).[59] CRISPR's increased efficiency is evidenced by a study that found CRISPR

52. *Id.*

53. Lander, *supra* note 49, at 18.

54. Carroll, *supra* note 37, at 416.

55. *Id.* While Cas9 is the most commonly used enzyme for this process, other enzymes are also used. *What Are Genome Editing and CRISPR-Cas9?*, *supra* note 1.

56. Carroll, *supra* note 37, at 415-16.

57. *See id.* During this process, the cell typically inserts free-floating genetic material into the void created by the enzyme cut. *Id.*

58. *Questions and Answers About CRISPR*, BROAD INST., https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/questions-and-answers-about-crispr (last visited Nov. 20, 2017).

59. *Id.*

is six times more efficient than TALENs or ZFNs in creating targeted gene mutations.[60]

Legal Principles

With a better technical understanding of how gene editing works, we now turn to the relevant legal principles and considerations. The parents in our Hypothetical may face both criminal and civil liability[61] depending upon (1) whether the child or state has sufficient standing to bring a case against the parents, (2) whether a statute exists that requires gene editing in certain instances, (3) whether a court finds (in the absence of such a statute) the parents had an affirmative duty of care to the child, and (4) if such a duty exists, that the affirmative duty was sufficient to require the parents to acquiesce to gene editing.

This paper will focus on duty and breach, with a brief discussion of causation[62] and damages within a civil context. The following sections that follow focus on current criminal causes of action that the state might bring against parents, and civil causes of action comparable to those a child might try to bring against his or her parents.

A. Does the Child or State Have Standing to Bring Suit?

Before addressing the viability of civil or criminal causes of action, the party bringing suit against the parents—the child or the State—must first

60. Gaurav K. Varshney et al., *High-Throughput Gene Targeting and Phenotyping in Zebrafish Using CRISPR/Cas9*, 25 GENOME RES. 1030, 1030 (2015).

61. While far more cases address parents' criminal liability for breaching an affirmative duty owed to their children, the dearth of civil cases does not mean that currently existing legal principles do not support civil liability. Vincent R. Johnson & Claire G. Hargrove, *The Tort Duty of Parents to Protect Minor Children*, 51 VILL. L. REV. 311, 317–19 (2006).

62. Causation is not covered in depth as the technology implicated in a case like the one proposed in the Hypothetical has yet to be developed. What we know is that the evidence of causation will be heavily scientific in nature, therefore implicating the Daubert Standard. *See generally* Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993) (interpreting Federal Rule of Evidence 702, which states "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."). The test requires the scientific evidence be relevant and reflect good science derived through sound methodology. *Id.* at 596–601.

show they have standing to do so.[63] This is likely to be a hotly contested issue.

Current gene editing techniques are likely to be applied at the embryo stage, as cells at the fetus stage have differentiated too much for current gene editing technologies to be effective. That said, several new gene editing techniques are being developed that hold promise for application at the fetus stage. The time during pregnancy when these treatments are applicable is likely the stage at which the child's legal rights will be decided.

Under current Supreme Court jurisprudence, if standing is analyzed at the time of genetic testing or when gene editing is rejected, the child likely will not have standing, as the Supreme Court in *Roe v. Wade* held "the word 'person' as used in the Fourteenth Amendment, does not include the unborn."[64] However, both *Roe* and its progeny acknowledge a significant state interest in protecting a viable fetus's life, which could lead future courts to expand fetal rights.[65]

B. Potential Causes of Action

1. Parents' Duty of Care to the Child

Generally, U.S. law does not impose an affirmative duty to act upon an individual ("General Rule").[66] This is subject to several exceptions created

63. Joint Anti-Fascist Refugee Comm. v. McGrath, 341 U.S. 123, 151 (1951) ("Limitation on 'the judicial Power of the United States' is expressed by the requirement that a litigant must have 'standing to sue . . . .'").

64. Roe v. Wade, 410 U.S. 113, 157-58 (1973).

65. *Id.* at 160 ("The situation therefore is inherently different from marital intimacy, or bedroom possession of obscene material, or marriage, or procreation, or education . . . . As we have intimated above, it is reasonable and appropriate for a State to decide that at some point in time another interest, that of health of the mother or that of potential human life, becomes significantly involved. The woman's privacy is no longer sole and any right of privacy she possesses must be measured accordingly.").

66. RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM § 37 (AM. LAW INST. 2012) [hereinafter "Third Restatement"] ("An actor whose conduct has not created a risk of physical or emotional harm to another has no duty of care to the other unless a court determines that one of the affirmative duties provided in §§ 38–44 is applicable."); RESTATEMENT (SECOND) OF TORTS § 314(b) (AM. LAW INST. 1965) [hereinafter "Second Restatement"] ("The fact that the actor realizes or should realize that action on his part is necessary for another's aid or protection does not of itself impose upon him a duty to take such action."); RESTATEMENT (SECOND) OF TORTS § 314 illus. 1 (AM. LAW. INST. 1965) ("A sees B, a blind man, about to step into the street in front of an approaching automobile. A could prevent B from so doing by a word or touch without delaying his own progress. A

by common law and legislation.[67] Relevant exceptions are discussed below.

a. Affirmative Duty Created by Statute

Courts may find an affirmative duty where a federal or state statute requires an individual to act for the protection of another in a certain circumstance.[68]

i. Child Abuse

One example of legislatively-created affirmative duties for parents are child abuse laws (and related reporting requirements). These laws, which have been implemented in every state,[69] usually define child abuse as an act (1) by a parent or caregiver who is responsible for a child's (under 18 years of age) welfare, (2) that affects the child, and (3) which results in imminent risk or serious harm to a child's health and welfare.[70] While child abuse is usually proven by affirmative actions, some courts have held omissions can also lead to criminal culpability.[71]

The parents in the Hypothetical could be found criminally culpable for child abuse. The mother's decision not to have gene editing performed would be an omission that resulted in the child being born with severe Huntington's disease, which poses an imminent risk to the child's health

does not do so, and B is run over and hurt. A is under no duty to prevent B from stepping into the street, and is not liable to B.").

67. *See, e.g.*, Phillips v. Deihm, 541 N.W.2d 566, 573 (Mich. Ct. App. 1995) ("A duty can arise by statute, as well as by common law."); State v. Walden, 293 S.E.2d 780, 785 (N.C. 1982) ("Where the common law has imposed affirmative duties upon persons standing in certain personal relationships to others, such as the duty of parents to care for their small children, one may be guilty of criminal conduct by failure to act or, stated otherwise, by an act of omission.").

68. Third Restatement, *supra* note 66, § 38.

69. *Child Abuse Laws State-by-State*, FINDLAW, http://family.findlaw.com/child-abuse/child-abuse-laws-state-by-state.html (last visited Apr. 12, 2018); *see also* Pamela Newell Williams, *A Comparison of Child Advocacy Laws in Abuse and Neglect Cases in England and the United States*, 31 N.C. CENT. L. REV. 33, 39 (2008).

70. *Child Abuse Overview*, FINDLAW, http://criminal.findlaw.com/criminal-charges/child-abuse-overview.html (last visited Nov. 23, 2017).

71. *See e.g.*, *Phillips*, 541 N.W.2d at 573 (finding a grandmother breached her duty of care to a grandchild because the grandmother failed to "act reasonably to prevent the sexual abuse of that child").

and welfare.[72] A child's recovery for child abuse, however, would be much less likely because most child abuse and neglect statutes do not create a private cause of action.[73] Several jurisdictions do, however, have statutes that provide for either express or implied private causes of action.[74]

ii. Child Neglect

Under child neglect laws, many states also vest parents with an affirmative, non-delegable duty to provide adequate medical care to their children.[75] What constitutes adequate medical care differs between states. New York defines adequate medical care as the degree of care provided by a prudent, loving parent who is anxious for the well-being of the child.[76] Whether this standard has been met depends upon the child's condition, the possibility of a cure or prevention (and the risk associated with such treatment), and, if the parents have sought alternative treatment, whether such treatment is recommended by reasonable medical authorities.[77]

72. *See supra* text accompanying note 15. As noted in the Hypothetical, this paper presupposes that the gene editing treatment offered to the mother is safe and does not pose a significant risk to the mother.

73. Marc A. Franklin & Matthew Ploeger, *Of Rescue and Report: Should Tort Law Impose a Duty to Help Endangered Persons and Abused Children?*, 40 SANTA CLARA L. REV. 991, 1022 (2000) ("Most courts . . . have declined to find a civil duty to report child abuse, whether based on the reporting statute or common law."); *see, e.g.*, Marquay v. Eno, 662 A.2d 272, 278 (N.H. 1995) (holding a compulsory child abuse or neglect reporting statute did not create a private cause of action because neither the statute nor legislative history revealed any such intent); *see also* Arbaugh v. Bd. of Educ., 591 S.E.2d 235 (holding a state statute for child abuse reporting did not imply a civil cause of action).

74. Arbaugh, 591 S.E.2d at 239 n.3 (stating there are state statutes for child abuse reporting that "expressly create a private cause of action . . . [in] Arkansas, Colorado, Iowa, Michigan, Montana, New York and Rhode Island."); *see, e.g.*, 40 R.I. GEN. LAWS Ann. § 40-11-6.1 (West 2004) (providing that in addition to criminal prosecution, a guilty defendant can be civilly liable for the damages caused by the failure to report child abuse or neglect).

75. *See, e.g.*, Jensen *ex rel*. Jensen v. Cunningham, 250 P.3d 465, 484–85 (2011) ("The state appropriately takes its parens patriae responsibility seriously. In fact, any person . . . who has reason to believe that a child has been subjected to neglect is required to report the abuse either to law enforcement or DCFS. And the statutory definition of neglect includes a parent's failure to provide proper or necessary medical care or any other care necessary for the child's health. A person required to report who 'willfully fails to do so' is subject to criminal liability."); *see also In re* Hofbauer, 47 N.Y.2d 648, 655 (1979); *cf.* People v. Pierson, 176 N.Y. 201, 205–207 (1903); *In re* Faridah W., 180 A.D.2d 451, 452 (N.Y. App. Div. 1992).

76. *In re* Hofbauer, 47 N.Y.2d at 654–55.

77. *Id.* at 656; *see also In re* Sampson, 37 A.D.2d 668, 668 (1971), aff'd, 29 N.Y.2d 900 (1972); *In re* Faridah, 180 A.D.2d at 452; *In re* Cicero, 101 Misc.2d 699, 702 (1979).

The court in *In re Christine M.* considered whether a father's failure to have his four-year-old daughter vaccinated for measles, when a New York statute required it, made the daughter a "neglected child."[78] The court held that facilitating a child's measles vaccination constitutes sound and necessary medical care, and therefore the father's failure to have his daughter vaccinated for measles during a measles outbreak (without a valid religious exemption) made the daughter a "neglected child" within the legal meaning of the statute.[79]

If in the proposed Hypothetical there were a compulsory gene editing statute, a straight-forward analysis suggests that the parents' choice to deny gene editing treatment for the fetus violated the statute. Less clear is whether the child would be deemed to have been neglected in the absence of such a statute. If *in utero* gene editing is the only way to effectively treat Huntington's, the child (or state) would have a strong argument that the parents neglected the child by failing to provide adequate medical care by refusing gene editing.[80] This argument would likely succeed if the reviewing court utilizes the same analysis as the court in *In re Christine M.*

78. *In re* Christine M., 595 N.Y.S.2d 606, 610-11 (Fam. Ct. 1992); *See* N.Y. FAM. CT. ACT § 1012(f) (McKinney 2017) (defining a "neglected child" as one "whose physical, mental or emotional condition has been impaired or is in imminent danger of becoming impaired as a result of the failure of his parent . . . to exercise a minimum degree of care (A) in supplying the child with adequate . . . medical . . . care, though financially able to do so or offered . . . other reasonable means to do so.").

79. *In re* Christine M., 595 N.Y.S.2d at 618; *but see In re* Hofbauer 47 N.Y.2d at 654–55 (where the New York Court of Appeals addressed the same statute on an appeal of a petition requesting an eight-year-old child suffering from Hodgkin's disease be deemed a neglected child because the parents had failed to acquiesce to the attending doctor's recommendation that the child be treated with radiation and chemotherapy. The court held the child was not a "neglected child" because his parents had undertaken reasonable efforts to ensure the child was provided acceptable medical treatment. In coming to this conclusion, the court considered the justifiable worries of the parents about the harmful effects of radiation and chemotherapy, the parents' securing of qualified doctors to aid in the child's care, that the nutritional treatments being administer by these doctors were controlling the child's condition, and that the child would be administered conventional treatments if his condition warranted such). Despite the finding that the father's failure to get his daughter vaccinated constituted child neglect, the *Christine M.* court nonetheless exercised its discretionary power and did not require the father to facilitate his daughter's vaccination because all evidence indicated the father was a capable and loving parent, there was no other evidence of actual neglect (medical, emotional, or educational), and while the daughter still faced a risk of contracting measles without vaccination, the measles outbreak no longer existed at the time of trial. *In re* Christine M., 595 N.Y.S.2d at 618.

80. The parents may also be liable under child endangerment and/or failure to protect laws, which expose individuals to criminal liability for subjecting children to inappropriate and/or dangerous situations. All states have some form of these laws. *See* CHILD ENDANGERMENT/FAILURE TO PROTECT LAWS, NATIONAL DISTRICT ATTORNEYS ASSOCIATION

While not the subject of this paper, it is worth noting that a more likely alternative to a compulsory gene editing statute might be a state, via the legislature or the judiciary, ordering parents with certain predispositions to harmful genetic diseases not to procreate unless they undergo a preimplantation genetic diagnosis to identify genetic defects within an embryo, utilize available gene editing technologies to "fix" the genetic defects that are present and which are explicitly enumerated in the state statute, and then employ *in vitro* fertilization to impregnate the host mother.

b. Affirmative Duty Created by Parents' Creation of Harm

Another exception to the General Rule occurs when an actor's prior conduct "creates a continuing risk of physical harm of a type characteristic of the conduct," thereby giving rise to a duty for the actor to "exercise reasonable care to prevent or minimize the harm."[81] The child may argue his or her suffering from Huntington's is a continuing risk of physical harm, as Huntington's symptoms have varied onset periods, and present themselves along a spectrum of severity.[82]

Such harm would be "characteristic of the conduct" because the parents intentionally[83] showed wanton disregard for the welfare of the potential child by deciding to procreate, despite knowing that any resulting progeny would have at least one dominant mutant allele, and therefore have Huntington's disease.[84] Even if the parents argue neither one knew they were homozygous dominant, let alone heterozygous dominant, the parents' progeny inheriting Huntington's disease might still have been foreseeable to impose an affirmative duty.[85] This might be the case where both parents have a familial history of Huntington's, and therefore would be remiss in

2-5 (Aug. 2014), https://ndaa.org/wp-content/uploads/Child-Endangerment-2014_-8_25_2014_FINAL.pdf.

81. Third Restatement, *supra* note 66, § 39. The actor's conduct must be sufficiently connected with the potential for future harm to justify the imposition of such an affirmative duty. *Id.*

82. *See supra* text accompanying note 15.

83. Third Restatement, *supra* note 66, § 39. While an actor does not need to know his or her conduct created a risk of harm to raise a duty created by this exception, an objectively foreseeable risk of harm must exist. *Id.* § 39 cmt. a; *see, e.g.*, Grover v. Stechel, 45 P.3d 80 (N.M. Ct. App. 2002) (requiring that the harm be foreseeable before an affirmative duty is imposed under Second Restatement of Torts § 321).

84. Third Restatement, *supra* note 66, § 39 cmt. c ("There must be a similar relationship between the risk-creating conduct and the harm . . . the harm that occurs must be closely enough related to the risks created by the conduct to justify imposition of a duty.").

85. Whether the harm is foreseeable is a question of fact for the jury. *Id.* § 39 cmt. d.

not getting checked for Huntington's before they procreated. However, if both parents carry the trait, they should display symptoms, albeit perhaps not until later in their lives, potentially after the point at which they have procreated in the Hypothetical.

If harm to the child is deemed foreseeable, and *in utero* gene editing is the only cure or treatment for Huntington's, then the parents would have likely breached their duty to "exercise reasonable care to prevent or minimize the harm" by not pursuing gene editing treatment.[86]

However, even if the parents' actios create a harm that raises an affirmative duty of the type described above, the court may nonetheless decide not to impose an affirmative duty, if doing so involves "special problems of principle or policy."[87] Whether a judge exercises this discretion will be determined on a case-by-case basis. That said, parents' religious beliefs, as well as parental rights regarding reproduction and related medical decisions, are likely to be compelling and thus considered "special problems of principle or policy."

c. Affirmative Duty Created By "Special Relationship"

An affirmative duty may also be imposed where an actor is in a "special relationship"[88] with another, and therefore owes that individual a duty of reasonable care "with regard to risks that arise within the scope of the relationship."[89] Parent-child relationships have been deemed "special relationships" in many cases.[90] Whether a "special relationship" exists and

86. *Id.* § 39. Third Restatement notes that "[i]f the injured person is as capable as the actor of taking steps to mitigate further harm, the actor does not breach the duty of reasonable care by failing to take those steps." *Id.* § 39 cmt. e. However, such is not the case in the Hypothetical put forth in this paper, as an embryo cannot take steps to mitigate the harm (such as agreeing to gene editing) caused to the embryo by the parents' decision to get pregnant and reject gene editing.

87. Third Restatement, *supra* note 66, § 39 cmt. b.

88. *See, e.g.*, Regents of the Univ. of Cal. v. Superior Court, 413 P.3d 656, 664 (2018) ("Generally, the [special] relationship has an aspect of dependency in which one party relies to some degree on the other for protection . . . . [and is present] where the plaintiff is particularly vulnerable and dependent upon the defend and, who correspondingly, has some control over the plaintiff's welfare.").

89. Third Restatement, *supra* note 66, § 40(a); *see, e.g.*, Tarasoff v. Regents of the University of California, 17 Cal. 3d 425 (1976). This duty attaches regardless of the source of the risk. Third Restatement, *supra* note 66, § 40 cmt. g.

90. *See generally* Second Restatement, *supra* note 66, §315; *see, e.g.*, State v. Williquette, 129 Wis.2d 239 (1986) ("When a special relationship exists between persons, however, social policy may impose a duty to protect. The relationship between a parent and a child exemplifies a special relationship where the duty to protect is imposed."); *but see* Third Restatement, *supra* note 66, § 40(a)–(b) (excluding the parent-child relationship as a

the scope of duty flowing from any such special relationship are questions of law to be determined by the court.[91]

In answering such questions with regard to the parents, courts will look to the nature of the parties' relationship, and whether the plaintiff in the Hypothetical was within the zone of foreseeable harm.[92]

The best-known case for determining the existence of a "special relationship" is *Tarasoff v. Regents of the University of California*.[93] The court in *Tarasoff* addressed whether a psychologist, who had been told on multiple occasions by a severe paranoid schizophrenic patient that the patient planned to kill a fellow student, had an affirmative duty to the potential victim (or their family) that required the physician to breach doctor-patient confidentiality and warn the potential victim of the likely impending harm.[94]

In doing so, the court noted that when circumstances require an actor to take affirmative action to avoid a foreseeable harm (e.g., warning someone about the likely conduct of another) the actor is usually only liable if they have a "special relationship" with (1) the dangerous individual or (2) the potential victim.[95] The psychologist was found to have a "special relationship" with the dangerous patient,[96] which thereby imposed upon the psychologist an affirmative duty to use reasonable care to protect the student.[97] The psychologist breached this duty by failing to warn the potential victim of the patient's plan (which the patient ended up executing, bringing about this case).[98]

"special relationship"). Other examples of "special relationships" include psychologist-patient and warden-prisoner. *See* Second Restatement § 315.

91. John B. v. Superior Ct., 45 Cal. Rptr. 3d 316, 324 (2006) ("The existence of a legal duty is a question of law for the court."); *see also* State v. Neumann, 348 Wis.2d 455, 506 (2013).

92. Palsgraf v. Long Island R.R. Co., 248 N.Y. 339, 344 (1928) ("The risk reasonably to be perceived defines the duty to be obeyed . . . ."); *see also* Johnson v. Jamaica Hosp., 62 NY2d 523, 527 (1984) ("The damaged plaintiff must be able to point the finger of responsibility at a defendant owing, not a general duty to society, but a specific duty to him.").

93. *See generally Tarasoff*, 17 Cal. 3d 425.

94. *Id.*

95. *Id.* at 434.

96. *Id.* at 435–36.

97. *Id.* at 439 ("[O]nce a therapist does in fact determine, or under applicable professions standards reasonably should have determined, that a patient poses a serious danger of violence to others, he bears a duty to exercise reasonable care to protect the foreseeable victim of that danger. [T]he therapist owes a legal duty not only to his patient, but also to his patient's would-be victim and is subject in both respects to scrutiny by judge and jury.").

98. *Id.*

In deciding *Tarasoff*, the California Supreme Court set out seven factors to determine the existence of a "special relationship," and extent of a resulting affirmative duty. These factors are:

> (1) foreseeability of harm . . ., (2) degree of certainty that the plaintiff suffered injury, (3) closeness of the connection between the defendant's conduct and the injury suffered, (4) moral blame attached to the defendant's conduct, (5) policy of preventing future harm, (6) extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and (7) availability, cost, and prevalence of insurance for the risk involved.[99]

In the Hypothetical the child's injury (Huntington's) was diagnostically certain, and foreseeable as the parents knew, or should have known, any fetus they caused to be conceived would have the disorder. The parents' decision to procreate despite this knowledge, and then to reject gene editing (the one way to mitigate the harm), is directly connected to the child's injury and therefore likely will draw significant moral blame.[100]

Courts have also interpreted criminal laws to characterize a parent-child relationship as "special," and as one that imposes an affirmative duty to protect.[101] Some examples include requiring the parent to: (1) report suspected child neglect or abuse,[102] (2) attempt to remove a child from an abusive living situation,[103] and (3) obtain needed medical care for the

99. *Id.* at 434.

100. Some might argue the mother's decision to reject gene editing does not deserve moral blame, as such a decision is within her rights to bodily autonomy and to make pregnancy-related decisions.

101. *Williquette*, 385 N.W.2d at 150 (Wis. 1986) (the "relationship between a parent and a child exemplifies a special relationship where the duty to protect is imposed").

102. *See* Jessica R. Givelber, *Imposing on Witnesses to Child Sexual Abuse: A Futile Response to Bystander Indifference*, 67 FORDHAM L. REV. 3169, 3181 (1999) (finding all 50 states have enacted mandatory child abuse reporting statutes).

103. One review noted that the courts in these cases "determined that their state's legislature intended to treat a parent's failure to act in the same way that it would punish the affirmative act of abuse . . . . [T]he courts and legislatures have sent a strong message to parents about their responsibility toward their children. If parents do not take action to prevent abuse, they may face criminal liability." Mary Kate Kearney, *Breaking the Silence: Tort Liability for Failing to Protect Children from Abuse*, 42 BUFF. L. REV. 405, 434 (1994); *see, e.g.*, *Williquette*, 385 N.W.2d 145, 261 (holding that mother leaving her children with their abusive father was sufficient to trigger criminal liability for child abuse).

child.[104] Despite the criminal liability that may result from a breach of these duties,[105] most states make available to parents some type of religious exemption regarding medical care.[106] Furthermore, as is the case in the Restatement (Third) of Torts Subsection II(B)(1)(b), a court may decide, based on "special problems of principle or policy" to either impose no duty or only a duty of reasonable care.[107] The same policy reasons in Subsection II(B)(1)(b) are likely to be compelling.

2. State Mandated Medical Care

The state in the Hypothetical might argue that it may constitutionally impose compulsory gene editing, regardless of parental, privacy, or religious rights. The Supreme Court has held parents' traditionally honored right to rear their children according to the parents' personal and religious beliefs is superseded when either the health or safety of the child is threatened, or when the parents' conduct poses a substantial threat to public safety.[108] The government's ability to interfere in such instances is usually based upon the *parens patriae* doctrine[109] or upon each state's general police power to promote public welfare.[110] In supporting its argument for a compulsory gene-editing law, the state may analogize its efforts to compulsory vaccination laws (repeatedly found to be constitutional), and instances where courts have ordered pregnant women to undergo cesarean sections.

104. *See* State v. Cacchiotti, 568 A.2d 1026, 1026-27, 1031 (R.I. 1990) (upholding conviction for involuntary manslaughter of a mother who failed to seek medical attention for her son after he was severely beaten by mother's boyfriend).

105. *See, e.g.*, TEX. FAM. CODE. ANN. §261.109 (Vernon 2015) (defining knowing failure to report child abuse or neglect as class A misdemeanor).

106. *See infra* Subsection II.C.2; *see also* Richard W. Garnett, *Taking* Pierce *Seriously: The Family, Religious Education, and Harm to Children*, 76 NOTRE DAME L. REV. 109, 111 (2000) ("Most states, however, exempt religious parents from prosecution, or limit their exposure to criminal liability, when their failure to seek medical care for their sick or injured children is motivated by religious belief.").

107. Third Restatement, *supra* note 66, § 40 cmt. b.

108. Prince v. Massachusetts, 321 U.S. 158, 166-67 (1944); *see also* Wisconsin v. Yoder, 406 U.S. 205, 220 (1972)*;* Stanley v. Illinois, 405 U.S. 645, 652 (1972); Jehovah's Witnesses v. King County Hospital, 390 U.S. 598 (1968).

109. Under this doctrine, the state may act as a guardian "for those who are unable to care for themselves, such as children or disabled individuals." *Parens Patriae*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/parens_patriae (last visited Nov. 6, 2017).

110. *Prince*, 321 U.S. at 166-69; *see also* Santosky v. Kramer, 455 U.S. 745, 766 (1982).

a. Compulsory Vaccination Laws

All 50 states have passed some form of compulsory vaccination law for children attending public schools.[111] Both times the Supreme Court has addressed these types of laws, they have been found to be a valid exercise of a state's police power, aimed at promoting public health or safety.[112]

In *Jacobson v. Massachusetts*, the Court found the state legislature had the discretion to enact a compulsory smallpox vaccination statute under its police power because the state did so in response to a smallpox outbreak that "imperiled the entire population" and the compulsory vaccination had a "real [and] substantial relation to the protection of the public health and the public safety."[113]

In *Zucht v. King*, the Court upheld a city ordinance[114] providing for compulsory vaccination for all schoolchildren, regardless of whether an immediate threat of an epidemic existed (as was the case in *Jacobson*).[115] The Court rejected plaintiff's due process arguments, holding "the municipality may vest in its official's broad discretion in matters affecting the application and enforcement of a health law."[116]

After *Jacobson* and *Zucht*, several federal[117] and state[118] courts have come to similar conclusions finding compulsory vaccination statutes

111. Kyra R. Wagoner, *Mandating the Gardasil Vaccine: A Constitutional Analysis*, 5 IND. HEALTH L. REV. 403, 415 (2008).

112. Jacobson v. Massachusetts, 197 U.S. 11, 26-27 (1905) (holding it is within a state's power to enact a compulsory vaccination law); *see also* Zucht v. King, 260 U.S. 174 (1922).

113. *Jacobson*, 197 U.S. at 31.

114. The ordinance read "no child or any other person shall attend a public school or other place of education without having first presented a certificate of vaccination." *Zucht*, 260 U.S. at 175.

115. *Id.* Subsequently, the Fourth Circuit in *Workman v. Mingo Cnty. Bd. of Educ.*, 419 F. App'x 348, 353 (4th Cir. 2011) held *Jacobson*'s holding is not limited to diseases that present an immediate danger. This is significant, as the child in the Hypothetical having Huntington's disease would not cause immediate danger to the child, but rather danger when the child reaches age of onset, usually in the 30-40 age range. *See infra* note 15 and accompanying text.

116. *Id.* at 176 (citing Lieberman v. Van de Carr, 199 U.S. 552 (1905)).

117. *See, e.g.*, McCarthy v. Boozman, 212 F. Supp. 2d 945, 948 (W.D. Ark. 2002) ("The constitutional right to freely practice one's religion does not provide an exemption for parents seeking to avoid compulsory immunization for their school-aged children"); *see also* Sherr v. Northport–East Northport Union Free School District, 672 F.Supp. 81, 88 (E.D.N.Y. 1987) ("it has been settled law for many years that claims of religious freedom must give way in the face of the compelling interest of society in fighting the spread of contagious diseases through mandatory inoculation programs").

118. *See, e.g.*, Wright v. DeWitt School District, 385 S.W.2d 644, 646 (Ark. 1965) (it is within the state's police power "to require that school children be vaccinated and that such

constitutional and within the state's police power.[119] If courts continue to follow *Zucht*'s expanded view of what statutes a state may pass to protect the public health under *Jacobson*, a compulsory gene editing statute that addresses circumstances such as those in the Hypothetical, as long as it meets other applicable legal tests,[120] will likely be found constitutional.

b. Court-ordered Cesarean Sections

While less common in recent times, there is a body of case law involving instances where hospitals or physicians have requested court orders to force women to have cesarean sections. For instance, the Georgia Supreme Court in *Jefferson v. Griffin Spalding County Hospital Authority* held a pregnant mother near birth, did not have the right to refuse surgery (or other medical treatment) if the fetus's life was at stake.[121]

However, more recent cases have tended to recognize pregnant women's right to refuse medical treatment. One recent article found that the last time an appellate court upheld a trial court's order for a cesarean section was in 1981.[122] The court in *In re A.C.* held a physician must honor a competent mother's decision of whether to get a cesarean section,[123] and the court in *In Re Baby Boy Doe v. Doe* held a pregnant mother had a right to refuse a physician-suggested cesarean section on religious grounds.[124] The *Doe* court, in coming to its holding, noted no state statute or case law supported the request for a court to mandate the mother undergo a cesarean section.[125] The *Doe* court also rejected the argument that *Roe v. Wade*'s[126]

requirement does not violate the constitutional rights of anyone, on religious grounds or otherwise"); *see also* Cude v. State, 377 S.W.2d 816, 819 (Ark. 1964) ("According to the great weight of authority, it is within the police power of the State to require that school children be vaccinated against smallpox, and that such requirement does not violate the constitutional rights of anyone, on religious grounds or otherwise").

119. One review of cases found that "every court to consider challenges to compulsory vaccination laws has upheld the statutes." Erwin Chemerinsky & Michele Goodwin, *Compulsory Vaccination Laws are Constitutional*, 110 NW. U. L. REV. 589, 603 (2016); *see, e.g.*, *Workman*, 419 F. App'x 348b (the court rejected parents' claim to a religious right not to vaccinate their children, noting "[t]he right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health") (quoting *Prince*, 321 U.S. at 166–67).

120. *See infra* Subsection II.C.2.

121. Jefferson v. Griffin Spalding Cty. Hosp. Auth., 347 Ga. 86 (1981).

122. Farah Diaz-Tello, *When the Invisible Hand Wields a Scalpel: Maternity Care in the Market Economy*, 18 CUNY L. REV. 197, 213 (2015).

123. 573 A.2d 1235 (D.C. 1990).

124. 260 Ill. App. 3d 392 (1994).

125. *Id.* at 397.

emphasis on states' interest in protecting a viable fetus enabled the state in this instance, to mandate the cesarean section.[127]

Despite the strong, more recent trend against requiring cesarean sections, case law nonetheless conveys some courts' willingness to order intrusive medical procedures during pregnancy. Gene editing is arguably less intrusive on a mother's rights than a cesarean section, and therefore may survive the balancing test applied in the cases cited above.

3. Medical Malpractice-like Causes of Action

The child may look to certain types of existing medical malpractice actions for support in bringing a tort claim against his or her parents for failure to use gene editing. All U.S. jurisdictions allow an embryo or fetus injured in the womb, who is later born alive, to recover tort damages.[128] While such actions involve a different combination of involved parties, they nonetheless are similar enough in nature to the hypothetical scenario to be instructive.

a. Harm to Unborn Child

Early decisions denied recovery of tort damages for a child who was injured in the womb but was later born alive,[129] based on the belief (1) no duty was owed to a person who did not yet exist, (2) there was too great a problem with causal proof, and (3) there was too significant a danger of unfounded claims.[130] However, this trend was bucked in *Bonbrest v. Kotz*, where the court held for the first time that a child could recover damages in proper prenatal injury cases, reasoning that the common law protections previously afforded to a viable fetus in the realms of criminal and abortion law should also be extended to viable fetuses with regard to harm to unborn children.[131] Initially, following *Bonbrest*, most courts limited recovery to situations where the fetus was viable at the time of injury.[132] In recent

126. 410 U.S. 113 (1973).

127. Doe, 260 Ill. App. 3d at 404.

128. Second Restatement, *supra* note 66, § 869; *see also* Matthew Browne, *Preconception Tort Law in an Era of Assisted Reproduction: Applying a Nexus Test for Duty*, 69 FORDHAM L. REV. 2555, 2560 (2001).

129. Second Restatement, *supra* note 66, § 869.

130. *Id.*

131. 65 F. Supp. 138 (D.D.C. 1946). The change in *Bonbrest* was driven by significant advancements in our knowledge of embryology and legal commentators' advocacy to recognize the unborn child as a legal entity. *Id.*

132. Browne, *supra* note 128, at 2560.

years, the preponderance of jurisdictions have rejected that requirement, opting instead to allow recovery where the injury occurred any time after conception.[133]

A minority of jurisdictions go as far as to allow recovery of damages when the injury occurred before the child's conception.[134] In such cases, a child can generally only recover where the defendant's conduct causing the harm is a tortious, [135] legal cause of harm.[136] Courts have found conduct to be sufficiently "tortious" to impose liability where the conduct was intended to harm a mother or the fetus, or negligent with regard to either individual.[137] The child in the Hypothetical would likely have a viable argument that the parents intentionally acted (by becoming pregnant and not securing gene editing) in a way they knew, or should have known, would result in significant harm to the fetus once he/she has reached the onset age of Huntington's disease.[138] The child might also be able to successfully argue his or her parents' acts were so unreasonably and recklessly dangerous, in that they knew, or should have known, that their progeny had a 100% likelihood of suffering from severe Huntington's, that strict liability should be imposed.[139]

133. *Id.*; *but see* Andrews v. Keltz, 838 N.Y.S.2d 363 (N.Y. Sup. Ct. 2007) (disallowing recovery of tort damages for injury to a lab-created human embryo pre-implantation, because there was no duty to a pre-implantation human embryo).

134. *See*, *e.g.*, Martin v. St. John Hosp. & Med. Ctr. Corp., 517 N.W.2d 787, 789 (Mich. Ct. App. 1994) (providing the following analogy: "[a]ssume a balcony is negligently constructed. Two years later, a mother and her one-year-old child step onto the balcony and it gives way, causing serious injury to both the mother and the child. It would be ludicrous to suggest that only the mother would have a cause of action against the builder but, because the infant was not conceived at the time of the negligent conduct, no duty of care existed toward the child"); *see also* Renslow v. Mennonite Hosp., 367 N.E.2d 1250, 1255 (Ill. 1977).

135. Second Restatement, *supra* note 66, § 869 cmt. b.

136. *Id.* § 869 cmt. c.

137. *Id.* § 869 cmt. b.

138. The harm would not be suffered immediately, as the symptoms of Huntington's disease do not normally present until after the age of 30. *Huntington's Disease*, *supra* note 15. The exceptions to this onset age range are (1) when an individual inherits two mutant alleles (as opposed to one), Squitieri et al., *supra* note 16, and (2) Juvenile Huntington Disease, which is caused by a mutation called a trinucleotide repeat in the Huntington Disease HTT gene. *Juvenile Huntington Disease*, GENETICS HOME REFERENCE, http://rarediseases.info.nih.gov/diseases/10510/juvenile-huntington-disease (last visited Apr. 11, 2018).

139. Sufficient tortious conduct will also be found where conduct is abnormally dangerous enough to impose strict liability. Second Restatement, *supra* note 66, § 869 cmt. b.

b. Wrongful Life

The child denied gene editing in the Hypothetical may sue his or her parents under a "wrongful life" action. "Wrongful life" actions are usually brought by a child born with a disability (or by his or her *guardian ad litem*)[140] against a doctor or healthcare provider for medical malpractice.[141] Plaintiffs usually argue defendant(s) acted contrary to common medical practice or procedures in not properly diagnosing or disclosing to the parents the fetus's injury or genetic abnormality, thereby foreclosing the parents' right to terminate the pregnancy.[142]

Many states do not allow "wrongful life" suits because of public policy considerations including (1) the life of a disabled child is better than no life at all and (2) the extreme difficulty in calculating damages.[143] However, a minority of states, such as California, have recognized the legal viability of wrongful life suits.[144] If gene editing becomes as safe and inexpensive as expected in the Hypothetical,[145] the child in the Hypothetical would likely be able to argue for a duty to use gene editing by drawing a strong analogy between the existing medical malpractice standards and his or her situation.

140. An individual who can be appointed by a court to protect the interests of an individual involved in a lawsuit, who cannot adequately represent his or her own interests. *Guardian Ad Litem*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/guardian_ad_litem (last visited Nov. 18, 2017).

141. *Wrongful Life Lawsuits*, BIRTH INJ. JUST., https://www.birthinjuryjustice.org/types-of-birth-injuries/wrongful-life-lawsuits/ (last visited Nov. 3, 2017).

142. *Id.*

143. *Id.* Courts have often referred to this idea as the "utter void of non-existence." *Id.*; *see, e.g.*, Gleitman v. Cosgrove, 49 N.J. 22, 28 (1967), *abrogated by* Berman v. Allan, 404 A.2d 8 (N.J. 1979) ("Damages are measured by comparing the condition plaintiff would have been in, had the defendants not been negligent, with plaintiff's impaired condition as a result of the negligence. The infant plaintiff would have us measure the difference between his life with defects against *the utter void of nonexistence*, but it is impossible to make such a determination. This Court cannot weigh the value of life with impairments against the nonexistence of life itself") (emphasis added); *see also* White v. U.S., 510 F.Supp. 146, 148 (1981) ("A cause of action brought by the "wrongfully born" child has been rejected in most jurisdictions as uncompensable because it is impossible to measure the damages for his life against *the utter void of nonexistence*") (emphasis added) (citing Stills v. Gratton, 55 Cal.App.3d 698 (1976); Dumer v. St. Michael's Hospital, 69 Wis.2d 766 (1975); Zepeda v. Zepeda, 41 Ill.App.2d 240 (1963), cert. denied 379 U.S. 945, (1964)).

144. Wendy F. Hensel, *The Disabling Impact of Wrongful Birth and Wrongful Life Actions*, 40 HARV. C.R.-C.L. L. REV. 141, 161 (2005).

145. This is more likely to happen for IVF, PGD screened embryos, than it is for naturally conceived embryos *in utero*. *See* Ian Sample, *IVF Technique that Tests Embryos for Genetic Disorders Has First Success*, GUARDIAN (July 27, 2014, 7:01 PM), http://www.theguardian/com/society/2014/jul/28/ivf-genetic-disorder-check-first-pregnancy-embryo-london.

The parents' decision to refuse gene editing despite knowing their fetus would have severe Huntington's, is likely to constitute action contrary to common parental practices in similar situations.

C. Potential Parental Defenses

While the parents may raise a host of procedural arguments,[146] the following sections focus on substantive defenses commonly raised by parents involved in similar actions to the type discussed above.

1. Parental Immunity Doctrine

The hypothetical parents might argue they are protected by the Parental Immunity Doctrine. This doctrine, created in *Hewlett v. George*, posits that children cannot sue their parents (and vice-versa) in civil suits.[147] Although the court in *Hewlett* does not cite to any authority to support this doctrine, 41 other states subsequently adopted some form of the immunity.[148]

However, the Parental Immunity Doctrine has been significantly limited in recent years. [149] In *Merrick v. Sutterlin*, the court held a child, injured by a parent's negligence in causing a car accident, could sue the parent.[150] Similarly, the court in *Schenk v. Schenk*[151] held that the Parental Immunity Doctrine does not apply where a parent or child willfully, wantonly, or as part of criminal conduct, inflicts injury upon the other.[152]

146. *See* discussion *supra* Section II.A.

147. Hewlett v. George, 68 Miss. 703 (1891). This doctrine is in large part based upon the public policy of trying to maintain the family structure by not undermining parents' authority over their children. Schenk v. Schenk, 100 Ill. App. 2d 199, 202 (1968) ("The public policy involved is the interest of the State in maintaining harmony, avoiding strife, and insuring a proper atmosphere of cooperation, discipline and understanding in the family").

148. Rousey v. Rousey, 528 A.2d 416, 417 (D.C. 1987) (declining to utilize the doctrine of parental immunity).

149. Third Restatement, *supra* note 66, § 40 cmt. o ("family immunities have long been removed as an impediment to [the] development [of case law recognizing affirmative duties among family members"); *see also* RESTATEMENT (SECOND) OF TORTS § 895G(1) (1965) ("A parent or child is not immune from tort liability to the other solely by reason of that relationship").

150. *See* Merrick v. Sutterlin, 93 Wash. 2d 411 (Wash. 1980).

151. Schenk v. Schenk, 100 Ill. App. 2d 199 (1968).

152. *Id.* at 202 ("Any justification for the rule of parental immunity can be found only in a reluctance to create litigation and strife between members of the family unit. While the policy might be such justification to prevent suits for mere negligence within the scope of the parental relationship public policy should not prevent a minor from obtaining redress for willful and wanton misconduct on the part of a parent") (internal quotations omitted).

The significant deterioration of the Parents Immunity Doctrine makes the parents' successful utilization of the doctrine to bar a child's claim based on failure to use gene editing unlikely unless the parents live in one of the few jurisdictions still allowing the doctrine to be employed in limited types of actions.[153]

2. Free Exercise of Religion

The parents might argue they have a right to refuse compulsory gene editing because it unduly infringes upon their First Amendment religious liberty freedoms. The First Amendment reads in part, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof."[154] This encompasses two concepts: freedom to believe[155] and freedom to act.[156] While the freedom to believe is absolute, the Supreme Court has noted an individual's "[c]onduct remains subject to regulation for the protection of society,"[157] as long as the regulatory power is exercised to attain a permissible end, and in doing so, does not unduly infringe the protected freedom.[158]

Parents asserting a free exercise of religion defense may have to deal with the Supreme Court's decision in *Employment Division v. Smith*, which held a religiously neutral and generally applicable law will not be found to

153. *See, e.g.*, Squeglia v. Squeglia, 661 A.2d 1007 (Conn. 1995) (holding the doctrine of parental immunity bars actions based on negligence or strict liability); *see also* Frye v. Frye, 505 A.2d 826, 839 (Md. 1986) (declining to repeal the application of parental immunity in negligence cases); Mitchell v. Davis, 598 So. 2d 801, 805 (Ala. 1992) (endorsing application of parental immunity to negligence claims against defendant foster parents and government agencies (deemed to be acting in *loco parentis*)); Amy L. Nilsen, Comment, *Speaking Out Against Passive Parent Child Abuse: The Time Has Come to Hold Parents Liable for Failing to Protect Their Children*, 37 HOUS. L. REV. 253, 285 (2000) (noting that Texas's doctrine of parental immunity "will continue to bar a child's recovery from a passive parent as long as courts continue to narrowly interpret its exceptions").

154. U.S. Const. amend. I.

155. Preventing US laws from pressuring or coercing any individual to accept a particular form of worship, and thereby providing individuals the freedom to choose whatever religious form they want. Cantwell v. Connecticut, 310 U.S. 296, 303 (1940).

156. Protecting an individual's free exercise of his or her chosen form of religion. *Id.*

157. *Id.*; *see also* Reynolds v. United States, 98 U.S. 145, 166 (1878) ("Laws are made for the government of actions, and while they cannot interfere with mere religious belief and opinions, they may with practices. Suppose one believed that human sacrifices were a necessary part of religious worship, would it be seriously contended that the civil government under which he lived could not interfere to prevent a sacrifice?").

158. *Cantwell*, 310 U.S. at 304 ("the power to regulate must be so exercised as not, in attaining a permissible end, unduly to infringe the protected freedom").

have violated the Free Exercise Clause.[159] The hypothetical gene-editing law is generally applicable[160] (although only triggered by fetal genetic abnormalities) and is religiously neutral in that it does not target, nor benefit, any religion.

Employment Division was seemingly superseded by the subsequent passage of the Religious Freedom Restoration Act of 1993 ("RFRA"),[161] which sought to "provide greater protection for religious exercise than is available under the First Amendment."[162] However, the Supreme Court held in *City of Boerne v. Flores* that the RFRA, which Congress sought to apply to the States and their subdivisions via Section 5 of the Fourteenth Amendment, was unconstitutional as applied to states as it exceeded Congress' powers under that provision.[163] The RFRA does, however, continue to apply to the federal government.[164]

Congress responded to the decision in *Boerne* by enacting The *Religious Land Use and Institutionalized Persons Act* ("RLUIPA"),[165] which applies to the States and their subdivisions and invokes congressional authority under the Spending and Commerce Clauses.[166] The RLUIPA is narrower in scope than the RFRA, concerning two areas of government activity not involved in the proposed hypothetical: land use regulation,[167] and religious exercise by institutionalized persons.[168]

159. 494 U.S. 872 (1990); *see also* Chemerinsky & Goodwin, *supra* note 119, at 609 ("no matter how much a law burdens religious practices, it is constitutional under *Smith* so long as it does not single out religious behavior for punishment and was not motivated by a desire to interfere with religion").

160. Even if the parents successfully argue the law is not "generally applicable," the court in *Zucht* dispelled the belief that a lack of general applicability means the law violates equal protection. *Zucht*, 260 U.S. at 176–77 ("A long line of decisions by this court had also settled that in the exercise of the police power reasonable classification may be freely applied, and that regulation is not violative of the equal protection clause merely because it is not all-embracing").

161. 42 U.S.C. § 2000bb *et seq.*

162. Holt v. Hobbs, 135 S. Ct. 853, 859–60 (2015) (citing Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2760–61 (2014)).

163. 521 U.S. 507, 532–36 (1997).

164. *See, e.g.*, Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 418 (2006) ("Among other things, RFRA prohibits the *Federal Government* from substantially burdening a person's exercise of religion.") (emphasis added); *see also Burwell*, 134 S. Ct. at 2759 (We hold that the regulations that impose this obligation violate RFRA, which prohibits the *Federal Government* from taking any action that substantially burdens the exercise of religion unless that action constitutes the least restrictive means of serving a compelling government interest.") (emphasis added).

165. *See* 42 U.S.C. § 2000cc–1(b).

166. Holt v. Hobbs, 135 S. Ct. 853, 860 (2015).

167. *See* 42 U.S.C. § 2000cc.

168. *See id.* at § 2000cc–1.

Smith also established that neutral and generally applicable laws are analyzed using the highly deferential rational basis test, which requires (1) the challenged statute have a legitimate state interest, and (2) the government be able to show a reasonable, rational connection between the statute's means and its goals.[169] Using gene editing to treat otherwise incurable diseases clearly falls under the recognized legitimate interest of public health,[170] and there is a strong argument that *in utero* gene editing done to fix a genetic abnormality that can only be addressed during the embryonic stage of development, is a reasonable and rational means by which to achieve the public health interest. If courts address compulsory gene-editing in the same way they have addressed compulsory vaccination, the parents' argument will likely fail.[171]

3. *Religious Exemptions*

The parents may also argue compulsory gene-editing intrudes on the right to practice their chosen religion and therefore requires a constitutionally-driven religious exemption to the duty to use gene editing. The viability of this argument likely depends upon whether the hypothetical state legislature created such an exemption, for as the Supreme Court noted in *Smith*, religious exemptions should be created by the legislature, not by the judiciary.[172] Religious exemptions, while constitutional if narrowly tailored, are not required by the Free Exercise Clause, where the statute in question is religiously neutral and generally applicable, such as a law governing drug use.[173] Some courts have even found religious exemptions to be unconstitutional.[174]

169. 494 U.S. 872, 879 (1990); *see also* Miller v. Reed, 176 F.3d 1202, 1206 (9th Cir. 1999) ("In *Employment Division v. Smith*, the Court analyzed a free exercise of religion claim under a rational basis test. Under this test, a rationally based, neutral law of general applicability does not violate the right to free exercise of religion even though the law incidentally burdens a particular religious belief or practice.") (internal citations omitted).

170. *See* discussion *supra* Subsection II.B.2.a.

171. *See* discussion *supra* Subsection II.B.2.a. Both times the Supreme Court has addressed compulsory vaccination laws, it has noted these laws are neutral and generally applicable because they apply to all citizens in a given jurisdiction and are not motivated by a desire to interfere with religious practices. Chemerinsky & Goodwin, *supra* note 119, at 610.

172. Chemerinsky & Goodwin, *supra* note 119, at 609.

173. *Smith*, 494 U.S. 872 (holding that state legislatures may enact narrowly tailored religious exceptions to such affirmative duties without violating the Constitution's establishment clause).

174. *See, e.g.*, Brown v. Stone, 378 So. 2d 218 (Miss. 1979) (finding a religious exemption unconstitutional because it was only available to members of recognized

In the case of criminal laws relating to parents failing to seek medical care for their sick or injured children, many states have enacted full or partial religious exemptions for parents that have failed to do so for religiously motivated reasons.[175]

However, such issues are murkier with regard to civil liability. Once again, it is instructive to examine compulsory vaccination statutes, which are usually accompanied by religious exemptions available to those who (1) hold a religious belief that is against the mandated action, and (2) sincerely hold that religious belief.[176] To meet this, and similar, tests, the opposition of the party requesting the religious exemption must "stem from religious conviction and have not merely been framed in terms of religious belief so as to gain the legal remedy desired."[177] Whether a belief is "sincerely held" is a question of fact for the trial court,[178] aimed at granting

denominations); *see also* Davis v. State, 451 A.2d 107, 113 (Md. 1982) (holding a religious exemption clause to the state's compulsory vaccination statute violated the First Amendment's establishment clause because the exemption was only available to children whose parents were members of a recognized religious denomination). For a more in-depth analysis of similar arguments, see Allan J. Jacobs, *Do Belief Exemptions to Compulsory Vaccination Programs Violate the Fourteenth Amendment?*, 42 U. MEM. L. REV. 73 (2011).

175. Garnett, *supra* note 106 ("Most states, however, exempt religious parents from prosecution, or limit their exposure to criminal liability, when their failure to seek medical care for their sick or injured children is motivated by religious belief").

176. *Sherr*, 672 F. Supp. at 92, 94 (finding that with regard to state-required vaccinations, religious exemptions are usually available to those who (1) hold a religious belief that is against vaccination (opposed to being against vaccinations because of medical or moral reasons), and (2) sincerely hold the religious belief in (1)); *see also* Shaun P. McFall, *Vaccination & Religious Exemptions*, FIRST AMEND. CTR. (Aug. 18, 2008), http://www.firstamendmentcenter.org/vaccination-religious-exemptions/ (noting that states often utilize one of three standards for religious exemptions, including: (1) the requesting parents must be members of a religious organization that is recognized and that opposes vaccination, (2) the requesting parents must show a sincere and genuinely held religious belief opposing one or all of the required vaccinations, (3) the requesting parents must sign a statement confirming they want an exemption because of a religious-based opposition to vaccination).

177. *Sherr*, 672 F. Supp. at 94.

178. U.S. v. Seeger, 380 U.S. 163, 185 (1965); *see, e.g.*, *Sherr*, 672 F. Supp. at 96-97 (finding one pair of plaintiffs' views to be religious but not sincerely held because one of the plaintiffs joined a religious organization for the sole purpose of obtaining a religious exemption, and because the pair had previously requested a vaccination requirement exemption based on science, safety, and conscience justifications. Finding another pair of plaintiffs' views to be religious and sincerely held because the plaintiffs' religiously-driven "conception of human existence and the physical world seems to pervade their whole way of life," and because one of the plaintiff's impressed upon the court "the seriousness with which he ha[d] contemplated the foundations of his religious beliefs and their implications for his family's daily life . . . ."). One court has noted an "adherent's belief would not be 'sincere' if he acts in a manner inconsistent with the belief" or "if there is evidence that the

exemptions only to those whose beliefs' are held as a matter of conscience.[179] Courts typically give significant weight to witnesses' demeanor and apparent candor.[180] Such inquiries are usually difficult for courts, and often teeter on the edge of violating the First Amendment.[181]

Therefore, if the state in the Hypothetical has a religious exemption to compulsory gene editing, the parents' ability to successfully request that exemption would be dependent upon their religious beliefs, and how they testified. However, if the state in the Hypothetical did not have a religious exemption to the compulsory gene editing law, the parents would likely be unsuccessful in arguing they have a constitutional guarantee to an otherwise generally applicable, religiously neutral statute.

4. *Constitutionally-protected Privacy Rights*

The parents might also argue that compulsory gene editing violates the mother's Fourteenth Amendment right to privacy recognized in *Griswold v. Connecticut*,[182] and utilized by the court in *Roe v. Wade* to vest pregnant women with a constitutionally-protected right to abort their pregnancies

adherent materially gains by fraudulently hiding secular interests behind a veil of religious doctrine." Int'l Soc'y for Krishna Consciousness v. Barber, 650 F.2d 430, 441 (1981).

179. *Barber*, 650 F.2d at 441 (noting the goal of the "sincerity analysis"—aimed at determining a requesting party's subjective good faith - is to "protect only those beliefs which are held as a matter of conscience . . . [I]t is frequently difficult to separate this inquiry from a forbidden one involving the verity of the underlying belief . . . an adherent's belief would not be 'sincere' if he acts in a manner inconsistent with the belief . . . or if there is evidence that the adherent materially gains by fraudulently hiding secular interests behind a veil of religious doctrine.").

180. Lewis v. Sobol, 710 F. Supp. 506, 514 (S.D.N.Y. 1989) (finding mother's testimony to be "sincere, direct, and very credible"); *see also Sherr*, 672 F. Supp. at 96-97 (finding one pair of the plaintiffs' manifested "complete sincerity").

181. *Barber*, 650 F.2d at 430. Courts have struggled to define what "religion" and "religious beliefs" mean. The Supreme Court has held "religion" to involve the "ultimate concerns" of individuals, *Seeger*, 380 U.S. at 187, and stated the "test of belief 'in relation to a Supreme Being' is whether a given belief that is sincere and meaningful occupies a place in the life of its possessor parallel to that filled by the orthodox belief in God." *Id.* at 165–66. The Second Circuit has expanded upon this idea and noted one criterion of a religion is that a believer will categorically disregard elementary self-interest rather than transgress the religion's tenets. United States v. Allen, 760 F.2d 447, 450 (2nd Cir.1985).

182. 381 U.S. 479 (1965) (holding that the Bill of Rights has certain penumbras of rights, including the right to privacy. Specifically, the Court held that the right to privacy is "fundamental" when it comes to the actions of married couples because such privacy "'is of the character that it cannot be denied without violating those fundamental principles of liberty and justice which lie at the base of our civil and political institutions'") (quoting Powell v. State of Alabama, 287 U.S. 45, 67 (1932)).

prior to the fetus attaining viability.[183] In doing so, the Court in *Roe* acknowledged a pregnant woman's autonomy over her pregnancy during the first trimester and the right to abortion during the second and third trimesters subject to varying levels of state control.[184]

The mother might argue *Roe*'s first-trimester blanket autonomy makes any compulsory gene-editing statute unconstitutional as applied to her if the mother's genetic testing and the physician's suggestion of gene-editing occurred prior to the end of the first trimester. However, this argument is unlikely to be successful, as most genetic tests are done during the second trimester (with a suggestion of gene-editing likely to follow thereafter if necessary).[185] Even if the mother did get testing during the first trimester, the court in *Roe* stated first-trimester autonomy "is not absolute and is subject to some limitations; and that at some point the state interest as to protection of health, medical standards, and prenatal life, become dominant."[186]

If the mother's genetic testing occurred during the second trimester, *Roe* likely would be of little help to the mother. As the Court noted, "the State . . . [has an] important and legitimate interest in protecting the potentiality of human life"—one which "grows in substantiality as the woman approaches term, and at a point during pregnancy . . . becomes 'compelling.'"[187] The Court noted the state's interest in protecting fetal life after viability is strong enough that a state may proscribe abortion after that point.[188] If the state's interest in protecting fetal life is strong enough to require a mother to go through childbirth and assume the responsibilities associated with motherhood (by not allowing abortion), it is not

183. *Roe*, 410 U.S. 113 ("This right to privacy [(referring in part to the right to privacy found in Griswold)], whether it be founded in the Fourth Amendment's concept of personal liberty and restrictions upon state action . . . or . . . in the Ninth Amendment's reservation of rights to the people, is broad enough to encompass a woman's decision whether or not to terminate her pregnancy.").

184. Nancy K. Rhoden, *Trimesters and Technology: Revamping* Roe v. Wade, 95 YALE L.J. 639, 639–48 (1986).

185. Amniocentesis and chorionic villus sampling (CVS) - the two most common types of *in utero* genetic screening - are done between 15 and 20 weeks, and 10 and 13 weeks of pregnancy, respectively. *Prenatal Genetic Diagnostic Tests*, ACOG (Sept. 2016), https://www.acog.org/Patients/FAQs/Prenatal-Genetic-Diagnostic-Tests.

186. *Roe*, 410 U.S. at 155.

187. *Id.* at 162–63. The Court in *Roe* went on to clarify the "'compelling' point is at viability . . . because the fetus then presumably has the capability of meaningful life outside the mother's womb." *Id.* at 163.

188. *Id.* at 163–64 ("State regulation protective of fetal life after viability thus has both logical and biological justifications. If the State is interested in protecting fetal life after viability, it may go as far as to proscribe abortion during that period, except when it is necessary to preserve the life or health of the mother.").

unreasonable to think the state's interest is also strong enough to impose compulsory gene editing in certain situations starting in the second trimester (when gene editing is most likely to be used).

5. Constitutionally-protected Parental Rights

The parents in the Hypothetical may argue that compulsory gene editing infringes upon their constitutional right to control their child's upbringing.[189] However, these traditionally recognized parental rights are not absolute. While there exists a "private realm of family life which the state cannot enter,"[190] states may pass and enforce a law impinging on these rights if such law is necessary to protect the health and/or well-being of children.[191] An example of this is compulsory vaccination laws, which have been analyzed under the rational basis test,[192] but are believed by many constitutional law experts to meet even the strict scrutiny test.[193] If a compulsory gene-editing law is analyzed the same way as compulsory vaccination laws, it will likely be found constitutional.

Conclusion

Gene editing has a myriad of potentially beneficial uses with wide-ranging implications.[194] It could significantly improve public health by

189. Meyer v. Nebraska 262 U.S. 390 (1923) (holding parents have a substantive due process right to make decisions regarding the upbringing of their children); *see also* Pierce v. Society of Sisters, 268 U.S. 510, 535 (1925) ("The child is not the mere creature of the State; those who nurture him and direct his destiny have the right, coupled with the high duty, to recognize and prepare him for additional obligations."); Troxel v. Granville, 530 U.S. 57, 72–3 (2000) ("The liberty interest at issue in this case—the interest of parents in the care, custody, and control of their children—is perhaps the oldest of the fundamental liberty interests recognized by this Court.").

190. *Prince*, 321 U.S. at 166.

191. *Id.* at 158 ("[T]he family itself is not beyond regulation in the public interest . . . . Acting to guard the general interest in youth's well being, the state as *parens patriae* may restrict the parent's control by requiring school attendance, regulating or prohibiting the child's labor and in many other ways.").

192. *See supra* note 169 and accompanying text.

193. Chemerinsky & Goodwin, *supra* note 119, at 613–14. Strict scrutiny is the highest level of scrutiny applied by courts and requires the government to prove (1) the challenged law has a compelling state interest, and (2) the law is narrowly tailored to achieve its result. *See* Adam Winkler, *Fatal in Theory and Strict in Fact: An Empirical Analysis of Strict Scrutiny in the Federal Courts*, 59 VAND. L. REV. 793, 800 (2006).

194. Potential future uses for CRISPR gene editing include: (1) removing malaria from mosquitos, (2) eliminating cancers like lymphoblastic leukemia, (3) treating muscular dystrophy, (4) making pig organs suitable for transplantation into humans, (5) treating HIV,

eradicating genetically caused disorders, and significantly reduce medical costs by foreclosing the need for the long-term care associated with such disorders. Therefore, in building this framework, it is important to first and foremost have a solid grasp of how the technology being used impacts the implicated legal issues. Specifically, there must be standing. As such, a comprehensive understanding of embryonic and fetal development, as well as what points in time different gene editing technologies can be utilized, will be crucial to understanding what legal issues, rights, and duties may be implicated. However, as with most new technologies, gene editing brings with it risks, as well as moral and ethical considerations. These questions are not of the yes or no sort—they warrant substantial debate and discussion.

Despite the science fiction-like nature of gene editing, the legal framework built to govern its use (and potential misuse) will likely, at least initially, be constructed using established legal principles. It will be instructive to consider the scope of existing parent-child duties; policy reasons for/against a parents' criminal or civil liability for prenatal injury; and the traditionally recognized constitutional rights of privacy, religious liberty, and parental autonomy in raising children. Balancing these interests will be a difficult task, but one that needs to be addressed while gene editing is still in its infancy.

and (6) treating genetic mutation-caused blindness. Jay Bennett, *11 Crazy Gene-Hacking Things We Can Do With CRISPR*, POPULAR MECHANICS (Jan. 26, 2016), http://www.popularmechanics.com/science/a19067/11-crazy-things-we-can-do-with-crispr-cas9/.

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