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Designing Children: Tort Liability for Medical Providers in the Era of CRISPR/CAS-9 Geneticc Editing

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DESIGNING CHILDREN: TORT LIABILITY FOR MEDICAL PROVIDERS IN THE ERA OF CRISPR/CAS-9 GENETIC EDITING

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I. INTRODUCTION

Once only thought possible in the realm of science fiction, today, scientists are able to edit genes in human embryos using a technique that employs a Clustered, Regularly Interspaced, Short Palindromic Repeat (CRISPR) and a CRISPR associated protein (Cas)—typically Cas-9.[1] For

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ease, this comment will refer to the CRISPR system, inclusive of the Cas protein, as CRISPR/Cas-9.

David Cyranoski, a well-respected *Nature* editor,[2] remarked that CRISPR/Cas-9 technologies will trigger a "Sputnik 2.0."[3] Shockingly, China has already used CRISPR/Cas-9 in twin girls to remove part of a gene that is responsible for causing HIV.[4] Similarly, CRISPR/Cas-9 has been used on human cancer cells,[5] and it has the potential to be therapeutic for aggressive forms of lung cancer.[6] CRISPR/Cas-9 also enables researchers to produce specific types of tissues by altering genes in pluripotent stem cells.[7]

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[1] *See* Alberto Cebrian-Serrano & Benjamin Davies, *CRISPR-Cas Orthologues and Variants: Optimizing the Repertoire, Specificity and Delivery of Genome Engineering Tools*, 28 MAMMALIAN GENOME 247, 247 (2017) (noting that Cas-9 is the most commonly used nuclease of the CRISPR-Cas system). Cebrian-Serrano further remarks that the discovery of CRISPR and CRISPR-associated systems have "revolutionized" biomedical research in the genetic modification field. *Id.* Indeed, CRISPR has already completely surpassed the genetic editing tools that preceded it and has shown great potential in diverse fields, including: "functional genomics, genome-wide screening studies, therapeutic gene therapy[,] and agricultural applications." *Id.*

[2] *Nature* is one of the most prestigious scientific journals that only publishes the finest peer-reviewed research. *About the Journal*, NATURE, https://www.nature.com/nature/about [https://perma.cc/4TRG-8DJD].

[3] David Cyranoski, *CRISPR Gene-Editing Tested in a Person for the First Time*, NATURE NEWS (Nov. 15, 2016), http://www.nature.com/news/crispr-gene-editing-tested-in-a-person-for-the-first-time-1.20988 [https://perma.cc/AL3A-5ZDJ].

[4] Marilynn Marchione, *Chinese Researcher Claims First Gene-Edited Babies*, AP NEWS (Nov. 26, 2018), https://www.apnews.com/4997bb7aa36c45449b488e19ac83e86d [https://perma.cc/4T5W-HQ53]. In exchange for free fertility treatment, parents consented to genetic experimentation on their embryos. *Id.* The lead scientist, He Jiankui, was attempting to create embryos that were HIV resistant. *Id.* Although there was no independent confirmation of Jiankui's claim of successful editing, there was a large outcry from many well-known scientists that such experimentation is unconscionable at this time. *Id.* The laws in the United States generally track this thinking, as this type of gene editing is outlawed. *Id.* The general concern is that such experimentation is unsafe and could lead to deleterious effects. *Id.* In particular, the DNA changes imposed by the CRISPR/Cas-9 system could be passed down for many generations—creating a seemingly endless class of people who could be injured. *Id.* Moreover, the CRISPR/Cas-9 system could harm other DNA in a person. *Id.* Currently, China has reported that other comparable experimentation is "on hold" until the safety of the procedure is verified. *Id.*

[5] *See* Marta Martinez-Lage, Pilar Puig-Serra, Pablo Menendez, Raul Torres-Ruiz & Sandra Rodriguez-Perales, *CRISPR/Cas9 for Cancer Therapy: Hopes and Challenges*, 6 BIOMEDICINES 105, 113 (2018) ("In 2016, a team led by oncologist Lu You at Sichuan University, China were the first to inject a patient with aggressive lung cancer with T-cells edited by CRISPR/Cas9 to disable PD-1.").

[6] Cyranoski, *supra* note 3.

[7] David Baltimore, Paul Berg, Michael Botchan, Dana Carroll, R. Alta Charo, George Church, Jacob E. Corn, George Q. Daley, Jennifer A. Doudna, Marsha Fenner, Henry T. Greely, Martin Jinek, G. Steven Martin, Edward Penhoet, Jennifer Puck, Samuel H. Sternberg, Jonathan S. Weissman & Keith R. Yamamoto, *A Prudent Path Forward for Genomic Engineering and Germline Gene Modification*, 348 SCIENCE 36, 36 (2015).

Furthermore, researchers can use CRISPR/Cas-9 to replicate the genetic basis for various human diseases, which will provide unprecedented insight into otherwise enigmatic diseases.[8] Ultimately, at this early stage, the budding uses of CRISPR/Cas-9 extend to sickle cell anemia, cystic fibrosis, muscular dystrophy,[9] cancer, eye diseases,[10] and HIV.[11]

With the rapid strides made in genetic editing, it does not seem far-fetched that parents will eventually use CRISPR/Cas-9 to select genetic characteristics for their child. Indeed, parents can already use preexisting technologies for eugenic selection of embryos with in vitro fertilization (IVF) and preimplantation genetic diagnosis (PGD).[12] Unfortunately, CRISPR/Cas-9 is not a perfectly effective system, and it can introduce mutations at unintended sites in the genome.[13] These unintended mutations are termed "off-target effects," and they can implicate unwanted physical appearance, cell death, or disease.[14]

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[8] *Id.*

[9] Patrick D. Hsu, Eric S. Lander & Feng Zhang, *Development and Applications of CRISPR-Cas9 for Genome Engineering*, 157 CELL 1262, 1274 (2014) ("Although Cas9 has already been widely used as a research tool, a particularly exciting future direction is the development of Cas9 as a therapeutic technology for treating genetic disorders. For a monogenic recessive disorder due to loss-of-function mutations (such as cystic fibrosis, sickle-cell anemia, or Duchenne muscular dystrophy), Cas9 may be used to correct the causative mutation.").

[10] Antonio Regalado, *First Human Test of CRISPR Proposed*, MIT TECH. REV. (June 16, 2016), https://www.technologyreview.com/s/601717/first-human-test-of-crispr-proposed [https://perma.cc/T9U6-DRN4].

[11] Akshat Rathi, *Chinese Researchers Have Genetically Modified Human Embryos—Yet Again*, QUARTZ (Apr. 9, 2016), http://qz.com/658537/chinese-researchers-have-genetically-modified-human-embryos-yet-again/ [https://perma.cc/AS2Y-53J].

[12] *See* Julian Savulescu, *Procreative Beneficence: Why We Should Select the Best Children*, 15 BIOETHICS 413, 413–15 (2001) (discussing that couples should select the child that is likely to have the best life when using in vitro fertilization and preimplantation genetic diagnosis to eugenically select embryos). Savulescu supports past eugenic selection for eradicating disease and argues that children should be selected based off non-disease genes, like intelligence. *Id.* at 413. Savulescu takes a controversial stance, reasoning that this selection of non-disease genes should be maintained even if it increases social inequality. *Id.*

[13] *See generally* Puping Liang, Yanwen Xu, Xiya Zhang, Chenhui Ding, Rui Huang, Zhen Zhang, Jie Lv, Xiaowei Xie, Yuxi Chen, Yujing Li, Ying Sun, Yaofu Bai, Zhou Songyan, Wenbin Ma, Canquan Zhou & Junjiu Huang, *CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes*, 6 PROTEIN & CELL 363 (2015). For example, Liang notes that CRISPR/Cas-9 has "notable off-target effects in human 3PN embryos." *Id.* at 366.

[14] *See* Sharon Begley, *Do CRISPR Enthusiasts Have Their Head in the Sand About the Safety of Gene Editing?*, STAT (July 18, 2016), https://www.statnews.com/2016/07/18/crispr-off-target-effects/ [https://perma.cc/MC2Z-FS54]. Off-target effects have been an issue ever since CRISPR/Cas-9 was first reported. Yu Kang, Chu Chu, Fang Wang & Yuyu Niu, *CRISPR/Cas9-Mediated Genome Editing in Nonhuman Primates*, 12 DISEASE MODELS & MECHANISMS 1, 5 (2019). "A significant number of experiments revealed undesired cleavage by Cas9 at off-target genome sites at which the DNA sequence was partly homologous (with one or more mismatches) to the 20-

More troubling than off-target effects is the thought that a parent may use CRISPR/Cas-9 to purposefully impose a defect on their child. Although seemingly improbable, this has been done in the past.[15] For example, parents have intentionally utilized assisted reproductive technology to have a deaf child.[16] Moreover, some IVF clinics allow parents to select a disabled child before implantation.[17]

Each year, approximately 78,000 infants are born who were conceived using assisted reproductive technology.[18] As parents are already

base sgRNA." *Id.* Avoiding off-target activity is one of the major challenges that scientist face when editing a human genome. *Id.*

[15] *See* Kirsten Rabe Smolensky, *Creating Children with Disabilities: Parental Tort Liability for Preimplantation Genetic Interventions*, 60 HASTINGS L.J. 299, 304 (2008) [hereinafter Smolensky, *Creating Children*] ("[D]espite the general expectation that parents will make beneficial genetic choices for their future children, this may not always be the case. In fact, some evidence suggests that parental preferences for arguably harmful interventions are real."). Although the majority of parents utilize PGD to select embryos without disabilities, there are reported cases of parents using PGD to intentionally select socially disfavored traits. Brigham A. Fordham, *Disability and Designer Babies*, 45 VAL. U. L. REV. 1473, 1480 (2011).

[16] *See, e.g.*, Merle Spriggs, *Lesbian Couple Create a Child Who Is Deaf Like Them*, 28 J. MED. ETHICS 283, 283 (2002). A lesbian couple intentionally sought out a deaf sperm donor to increase the chances of having a deaf child. *Id.* However, when they were turned away from donor clinics because sperm banks disqualify donors who have congenital deafness, they turned to a deaf friend and asked for his donation. *Id.* The women hoped to have a deaf child because both women were born deaf and want to share their culture with their children. *Id.* The women achieved their goal and had a deaf daughter, but their son was born with partial hearing in his right ear. *Id.* Doctors have recommended hearing aids to help the son develop normal speaking skills, but the parents are refusing. *Id.* Although the women's choice has been sharply criticized, others have been sympathetic to their quest. *Id.*; *see generally* Savulescu, *supra* note 12 (discussing whether there are good reasons for honoring such requests for disability selection). It seems that deafness is not the only trait that parents seek to impose, as parents have also attempted to select for other disabilities, like dwarfism. Dov Fox, *Essay: Reproductive Negligence*, 117 COLUM. L. REV. 149, 180 (2017); *see also* Fordham, *supra* note 15, at 1480 (noting that in 1995, a couple utilized PGD to select for a child that had achondroplasia, a form of short-limbed dwarfism). This goes to show that some parents will intentionally seek having a child that is disabled and may even take active measures to ensure that the child is affected by this defect.

[17] Susannah Baruch, David Kaufman, & Kathy L. Hudson, *Genetic Testing of Embryos: Practices and Perspectives of US In Vitro Fertilization Clinics*, 89 FERTILITY & STERILITY 1053, 1054–55 (2008) (describing a 2006 survey of 186 fertility clinics, where 3% of clinics reported that they used PGD to help parents select an embryo that carried a disability). Currently, there are no laws in the United States discussing the legality of a parent's direct genetic intervention to have a child with a particular trait or disability. DENA S. DAVIS, GENETIC DILEMMAS: REPRODUCTIVE TECHNOLOGY, PARENTAL CHOICES, AND CHILDREN'S FUTURES 86–87 (2d ed. 2010). Consequently, so long as the technology exists, parents are free to impose any trait on their embryo—even defects. *See* Fordham, *supra* note 15.

[18] *ART Success Rates*, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 2, 2020), http://www.cdc.gov/art/reports/index.html [https://perma.cc/9PEE-7SE7].

using existing medical technology to select potential children,[19] it seems likely that some parents will try to utilize CRISPR/Cas-9 in the reproductive context. Seventy-eight thousand infants are a remarkable class of potential plaintiffs. Consequently, the American legal system needs to be ready to articulate a plausible claim and method of recovery for children born injured from CRISPR/Cas-9.

In formulating such a claim, this comment will analyze two scenarios: (1) when a doctor performs CRISPR/Cas-9 with the goal of producing a healthy baby, but the child suffers off-target effects; and (2) when a doctor uses CRISPR/Cas-9 to purposefully impose a defect on a child. In an effort to apply preexisting legal frameworks to such novel situations, this comment will explore the aforementioned scenarios through an analysis of tort law.

Tort law has been applied in similar situations—specifically, preconception and prenatal harms.[20] Although these claims were traditionally uncommon, tort law has expanded in recent years to keep pace with medical advances made in areas of reproductive health.[21] When adjudicating a child's tort claim for a prenatal harm, some courts have discussed the child's "right to begin life with a sound mind and body."[22] This

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[19] *See supra* notes 15–16 and accompanying text.

[20] *Compare* Womack v. Buchhorn, 187 N.W.2d 218 (Mich. 1971) (discussing prenatal tort injuries), *with* Martin v. St. John Hosp. & Med. Ctr. Corp., 517 N.W.2d 787, 789 (Mich. Ct. App. 1994) (discussing preconception tort injuries); *see also infra* Section II.C.

[21] *See* Matthew Browne, Note, *Preconception Tort Law in an Era of Assisted Reproduction: Applying a Nexus Test for Duty*, 69 FORDHAM L. REV. 2555, 2556 (2001) (discussing preconception tort claims). There were relatively few preconception tort cases before the 1970s, but the claims have become more common with: (1) the ability to trace the cause of the preconception injury; (2) increasingly common medical procedures that can give rise to preconception tort injuries; (3) nationwide injury of women and their children from faulty pharmaceuticals; and (4) toxic exposure cases that altered parental chromosomes and resulted in deformed children. *Id.* The author takes great care to point out that "[i]ntentional manipulation of human reproductive cells . . . is all but assured in an age of rapidly developing genetic and assisted reproductive technology." *Id.*

[22] In *Smith v. Brennan,* the New Jersey Supreme Court articulated the open future legal right when enumerating why a child should be able to recover for prenatal injuries caused by a third person. 157 A.2d 497, 502–03 (N.J. 1960). In doing so, the court commented: "justice requires that the principle be recognized that a child has a legal right to begin life with a sound mind and body. If the wrongful conduct of another interferes with that right, and it can be established by competent proof that there is a causal connection between the wrongful interference and the harm suffered by the child when born, damages for such harm should be recoverable by the child." *Id.* Some scholars have embraced this reasoning, arguing that if parents selectively edit embryos to have disabled children, those parents are liable to the children if their selection infringes upon the child's right to an open future. *See* Smolensky, *Creating Children*, *supra* note 15, at 309–10. *But see* Fordham, *supra* note 15, at 1512–26 (involving a discussion against recognizing a child's open future as a legally cognizable right). Generally, Fordham argues that "[s]econd-guessing parental decisions about socially disfavored physical traits only disrupts the parent-child relationship and suggests that

lends itself to a moral framework that recognizes a child's right to an "open future" in the context of tort law.[23] Consistent with this "open right," a child with negligent genetic editing will sue for negligence. For purposeful defective genetic editing, the child's cause of action will be battery.

Note that for either scenario, the current judicial stance on wrongful life claims will impede recovery.[24] However, this comment argues that, in the context of CRISPR/Cas-9, the judicial reasoning behind denying wrongful life claims does not apply. To avoid the stigma of wrongful life claims, this comment will refer to the child's claims as *mistaken manipulation*.

Part II of this comment summarizes CRISPR/Cas-9, introduces wrongful life, and highlights current case law on prenatal and preconception torts.[25] Part III analyzes extending the framework gained from tort law to negligent genetic editing and purposeful imposition of defects.[26] Furthermore, Part III explores the elements of negligence and battery and their relation to CRISPR/Cas-9 mistaken manipulation claims.[27] Finally, Part IV will seek to dispel any counterarguments that may attempt to bar recovery.[28]

II. CRISPR/CAS-9 AND WRONGFUL LIFE

Part II will provide the relevant background information on CRISPR/Cas-9, wrongful life claims, and prenatal harms.[29] Section A will describe the general science and history behind CRISPR/Cas-9.[30] Section B will briefly explore wrongful life claims, emphasizing the judicial reasoning

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discriminatory attitudes and practices are natural and acceptable." *Id.* at 1527. Moreover, Fordham is of the opinion that tort law is inappropriate in situations where parents would intentionally impose a defect simply because these situations are uncommon. *Id.* at 1528. Thus, Fordham stipulates it would be better left to the legislature to impose prohibitions. *Id.* at 1527.

[23] Joel Feinberg, *The Child's Right to an Open Future*, *in* WHOSE CHILD? CHILDREN'S RIGHTS, PARENTAL AUTHORITY, AND STATE POWER 124, 126 (William Aiken & Hugh LaFollette eds., 1980).

[24] *See, e.g.*, Gleitman v. Cosgrove, 227 A.2d 689, 692 (N.J. 1967) ("This Court cannot weigh the value of life with impairments against the nonexistence of life itself. By asserting that he should not have been born, the infant plaintiff makes it logically impossible for a court to measure his alleged damages because of the impossibility of making the comparison required by compensatory remedies.").

[25] *See infra* Part II.

[26] *See infra* Part III.

[27] *See id.*

[28] *See infra* Part IV.

[29] *See infra* Part II.

[30] *See infra* Section II.A

behind rejecting these claims.[31] Finally, Section C will provide a framework on prenatal and preconception torts.[32]

A. Scientific Background

This section will seek to simplistically describe the basic concepts that underlie genetic editing and how they relate to CRISPR/Cas-9, beginning with human biology.

1. Human Biology

Fundamentally, the first step to forming life begins when a sperm and an egg unite to form a zygote.[33] The zygote's cell will then divide and start to specialize into various tissues after a few days.[34] After eight weeks, the zygote is termed a fetus,[35] and the genes in the fetus form the basis for hereditary traits.[36] There are approximately 22,000 genes in the human genome that are packed into 23 pairs of chromosomes.[37] Every gene is encoded as DNA,[38] and the fetus's DNA is essentially that individual's blueprint for growth, functionality, and physical traits.[39] With very few exceptions, every cell possesses the same DNA that the zygote had.[40]

DNA is a double-stranded molecule that is arranged in a double-helix.[41] It is essentially composed of four bases, a sugar molecule, and a phosphate molecule.[42] The four bases are chemically connected to the sugar-phosphate backbone, which is the exterior framework of the DNA

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[31] *See infra* Section II.B.
[32] *See infra* Section II.C.
[33] T.W. SADLER, LANGMAN'S MEDICAL EMBRYOLOGY 10 (12th ed. 2012).
[34] *Id.* at 38–39.
[35] *Id.* at 96.
[36] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 580 (2013) (discussing the underlying foundations of genetics). Although this case generally concerns whether naturally occurring subject matter can be patented, the Supreme Court discusses the science behind DNA as well as the creation of proteins from DNA. *See id.*
[37] *Id.*
[38] *Id.*
[39] Like the letters in an alphabet forming words and sentences, the sequence of DNA forms the general structure for an organism's growth and development. *What Is DNA?*, U.S. NAT'L LIBR. OF MED. (Sept. 17, 2020), https://ghr.nlm.nih.gov/primer/basics/dna [https://perma.cc/33XH-JMWL].
[40] *See A Brief Guide to Genomics*, NAT'L HUM. GENOME RES. INST. (Aug. 27, 2015), https://www.genome.gov/18016863/a-brief-guide-to-genomics [https://perma.cc/4N2G-MLJD] ("An organism's complete set of DNA is called its genome. Virtually every single cell in the body contains a complete copy of the approximately 3 billion DNA base pairs, or letters, that make up the human genome.").
[41] ROBERT F. SCHLEIF, GENETICS AND MOLECULAR BIOLOGY 22–23 (2d ed. 1993).
[42] *Id.*

helix.[43] The four possible bases in DNA are adenine, thymine, cytosine, and guanine.[44] These are commonly abbreviated as A, T, C, and G, respectively.[45] Each base pairs with its complementary base when forming the DNA double-strand: A pairs with T, and C pairs with G.[46] Importantly, complementary base pairing allows each strand of the DNA to act as a template to ensure correct replication.[47]

One base pair, one sugar molecule, and one phosphate group form a nucleotide.[48] Three nucleotides are termed a codon.[49] In turn, codons code for amino acids, which form proteins.[50] As there are only four bases and three are needed to form a codon, simple math reveals that there are sixty-four different combinations available for a codon sequence.[51] Of these combinations, even a slight variation can code for a different protein, thereby changing the organism's genetic code.[52] Changes in the genetic code are appropriately termed mutations.[53] The extent of a mutation can vary significantly, but it can lead to disease or increased risks of disease.[54]

2. CRISPR/Cas-9

Targeted genome editing is a process that allows scientists to mutate a gene of interest by deleting segments of the gene, inserting more genetic

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[43] *Ass'n for Molecular Pathology*, 569 U.S. at 581 (noting that the sugar-phosphate backbone forms the outside framework of the DNA helix).

[44] SCHLEIF, *supra* note 41, at 22.

[45] *Id.*

[46] *Ass'n for Molecular Pathology*, 569 U.S. at 581 ("The possible nucleotides are adenine (A), thymine (T), cytosine (C), and guanine (G), each of which binds naturally with another nucleotide: A pairs with T; C pairs with G.").

[47] SCHLEIF, *supra* note 41.

[48] Anne Marie Helmenstine, *What Are the 3 Parts of a Nucleotide? How Are They Connected?*, THOUGHTCO. (Jan. 25, 2020), https://www.thoughtco.com/what-are-the-parts-of-nucleotide-606385 [https://perma.cc/GLW7-4N6L].

[49] *Codon*, NATURE EDUC., https://www.nature.com/scitable/definition/codon-155/ [https://perma.cc/XGA9-YVG5].

[50] *Protein Structure*, NATURE EDUC., http://www.nature.com/scitable/topicpage/protein-structure-14122136 [https://perma.cc/UQZ5-4TEF].

[51] JEREMY M. BERG, JOHN TYMOCZKO & LUBERT STRYER, BIOCHEMISTRY 7 (5th ed. 2002). Simplistically, *4 x 4 x 4 = 64*. The number four is used because there are four possible bases (A,G,T,C), and four is repeated three times over because one codon consists of three bases.

[52] *See Gene Expression*, NATURE EDUC., https://www.nature.com/scitable/topicpage/gene-expression-14121669 [https://perma.cc/W7DX-W8P8]; *see also* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 582 (2013) (noting that changing only one letter in the genetic code can produce entirely different proteins).

[53] *Ass'n for Molecular Pathology*, 569 U.S. at 582.

[54] *Id.* (noting that although some mutations may be harmless, other mutations can cause dire consequences).

sequences, or substituting some genes for other genes.[55] The general aim of genetic editing is to modify a specific characteristic of an organism by changing a small portion of the organism's genetic code.[56] In doing so, there is great potential for curing various genetic diseases.[57] Although there are multiple approaches to targeted genome editing,[58] CRISPR/Cas-9 has revolutionized the field, and over a thousand papers have been published on the method.[59] The immense number of papers published on CRISPR/Cas-9 demonstrates both the popularity of the method and the general outlook in the scientific community that CRISPR/Cas-9 is an efficient and promising method for genetic editing.[60]

Simplistically, CRISPR/Cas-9 technology harnesses a defense mechanism that bacteria use to protect against invading viruses.[61] When

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[55] *See What are Genome Editing and CRISPR-Cas9?*, MEDLINEPLUS, https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting [https://perma.cc/6EJZ-JQ5H]. Types of mutations that can occur in the genome include the following: point mutations or substitutions, insertions, and deletions. Jay Yang, *Genetic Mutation*, SINGER INSTRUMENTS (Mar. 23, 2015), https://www.singerinstruments.com/resource/what-are-genetic-mutation/ [https://perma.cc/9N6R-BY7D]. A point mutation involves substituting a single nucleotide with another nucleotide. *Id.* Insertions occur when nucleotides are added to the gene sequence, while deletions involve deletions of nucleotides from the original gene sequence. *Id.* Regardless of the exact type of mutation, a mutation can lead to vastly different consequences. *Id.* Unfortunately, mutations can lead to deleterious results that affect the organism's fitness. *Id.* Contrastingly, mutations can also be advantageous to the organism or have no effect at all on the organism. *Id.*

[56] Jennifer Walker-Daniels, *CRISPR and Genomic Engineering*, LABOME (Mar. 22, 2013), https://www.labome.com/method/Genomic-Engineering.html#ref29 [https://perma.cc/8FS5-Q73Y].

[57] *See id.* The Supreme Court has recognized the importance in studying genetics, realizing that it can "lead to valuable medical breakthroughs." *Ass'n for Molecular Pathology,* 569 U.S. at 582.

[58] *See* Walker-Daniels, *supra* note 56 (discussing CRISPR and other genetic editing methodologies). Briefly, other common methods include meganucleases, zinc-finger nucleases, and transcription activator-like effector nucleases. *Id.* Although these methods have experienced success in the past, they are both costly and time inefficient. *Id.* CRISPR systems have been deemed superior in part because CRISPR utilizes an already existing immune defense and a guide RNA instead of a new DNA binding protein. *Id.* RNA molecules are typically more cost efficient and easier to synthesize than DNA binding proteins. *Id.*

[59] Samuel H. Sternberg & Jennifer A. Doudna, *Expanding the Biologist's Toolkit with CRISPR-Cas9*, 58 MOLECULAR CELL 568, 568 (2015) ("Beginning in January 2013, a flurry of studies demonstrated that site-specific DNA editing in eukaryotic cells could be achieved through the heterologous expression of Cas9 together with a guide RNA. Two years and >1,000 publications later . . . , the technology has gone viral. The genomes of virtually all model plants and animals have been modified with CRISPR-Cas9, and creative new tools continue to expand the capabilities of this system.") (internal citation omitted)).

[60] *See* Walker-Daniels, *supra* note 56.

[61] Rotem Sorek, Victor Kunin & Philip Hugenholtz, *CRISPR—A Widespread System that Provides Acquired Resistance Against Phages in Bacteria and Archaea*, 6 NATURE REVS. MICROBIOLOGY 181, 186 (2008).

bacteria are first exposed to a virus, CRISPR systems incorporate segments of the virus's genetic code into the bacteria's DNA.[62] As a result, subsequent exposure to the same virus will trigger an enzyme to find the virus and destroy it.[63] The enzyme that targets the virus is known as Cas, and the most commonly used Cas enzyme is Cas-9.[64]

The following three substances are required for a CRISPR system to successfully cleave target DNA: (1) a Cas enzyme that cleaves the DNA; (2) a CRISPR RNA (crRNA) that directs the system to the targeted DNA; and (3) an auxiliary trans-activating RNA (tracrRNA) that recruits the Cas enzyme and hybridizes with the crRNA.[65] The crRNA and tracrRNA fuse together, and the resulting structure is usually called a single-guide RNA (sgRNA).[66] The sequence of the sgRNA is of the utmost importance because this is what guides the CRISPR system to the target DNA.[67] This comment will assume that the Cas enzyme employed is a Cas-9 enzyme, which is why the CRISPR system will be referred to as CRISPR/Cas-9.

Notably, CRISPR/Cas-9 genetic editing is not surefire, and off-target effects are an immense concern.[68] Off-target effects happen when the

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[62] Martin Jinek, Krzysztof Chylinski, Ines Fonfara, Michael Hauer, Jennifer A. Doudna & Emmanuelle Charpentier, *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCIENCE 816, 816–17 (2012).

[63] *Id.*

[64] *See* Cebrian-Serrano, *supra* note 1. Other Cas enzymes include the following: SaCas9, NmeCas9, CjCas9, StCas9, LbCpf1, and AsCrpf1. *See Importance of the PAM Sequence in CRISPR Experiments*, SYNTHEGO tbl.1, https://www.synthego.com/guide/how-to-use-crispr/pam-sequence [https://perma.cc/2VLU-KWUJ]. Notably, the first two letters of every item in the aforementioned list correlate to what organism the nuclease was isolated from. *See id.* Consistent with that naming trend, the reference to Cas-9 in this paper would be identified as SpCas9, as the nuclease was isolated from *Streptococcus pyogenes*. *See id.*

[65] Xiao-Hui Zhang, Louis Y Tee, Xiao-Gang Wang, Qun-Shan Huang & Shi-Hua Yang, *Off-Target Effects in CRISPR/Cas9-Mediated Genome Engineering*, 4 MOLECULAR THERAPY-NUCLEIC ACIDS 1, 1 (2015) (reconstructing the CRISPR/Cas-9 system in mammalian cells using the aforementioned three components).

[66] *See, e.g.*, *id.* ("The crRNA and tracrRNA duplexes can also be fused to generate a chimeric single-guide RNA (sgRNA).").

[67] *See generally* Liang et al., *supra* note 13 (discussing sgRNA). Note that this article refers to sgRNA as gRNA. *See id.* The sgRNA, or gRNA, largely dictates the specificity of the CRISPR/Cas-9 system. *Id.* at 364.

[68] *See* Begley, *supra* note 14. Even scientists that discuss the great potential that CRISPR/Cas-9 usually conclude with remarks that the system is not ready for full-scale implementation. *See* Martinez-Lage et al., *supra* note 5 (concluding that "[t]he great expectations surrounding CRISPR gene editing needs to be coupled with strategic planning, including enabling regulatory processes to ensure the successful development of this advanced gene editing-based modality. What is clear, nevertheless, is that the technology still requires optimization before widespread translation into the clinic, especially with regards to efficacy, safety, and specificity."). Thus, it is critical that the possibility of off-target effects is eliminated before the CRISPR/Cas-9 system is ever used as a therapeutic reagent. Yu Kang et al., *supra* note 14, at 5.

Cas-9 enzyme accidentally cleaves an unintended site in the genome,[69] because the sgRNA possessed sufficient homology with non-target DNA.[70] The exact effect of off-target editing is still unknown, but leading scientist Dr. J. Keith Joung expressed concern that it may lead to an increased risk of cancer.[71] Indeed, any off-target editing could potentially lead to significant cellular toxicity.[72] In a similar vein, it is generally accepted that off-target effects could lead to unwanted physical appearance, cell death, or disease.[73] Due to these concerns, prominent scientists have warned that there needs to be a cautious approach in applying CRISPR/Cas-9 to human genetics.[74]

Although scientists are diligently working to decrease the rates of off-target effects,[75] and to develop off-target predicators,[76] there is no way to "recall" a bad gene.[77] Thus, with the future of genetic editing leaning toward

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[69] Hannah R. Kempton & Lei S. Qi, *When Genome Editing Goes Off-Target*, 364 SCIENCE 234, 234 (2019).

[70] *See* Zhang et al., *supra* note 65, at 2. The sgRNA is typically twenty nucleotides long and up to five nucleotide mismatches between the sgRNA, and the DNA is sufficient for off-target binding. Liang et al., *supra* note 13, at 364. Thus, a DNA sequence that is percent dissimilar to the sgRNA could result in off-target binding and subsequent cleaving of non-target DNA.

[71] *See* Begley, *supra* note 14. Dr. J. Keith Joung is a professor of pathology at Harvard Medical School. *Id.* Dr. Joung holds two advanced degrees: a M.D. from Harvard Medical School and a Ph.D. from Harvard University. *Joung Lab*, CTR. FOR COMPUTATIONAL AND INTEGRATIVE BIOLOGY, https://ccib.mgh.harvard.edu/joung#research [https://perma.cc/J3L9-76HV]. Dr. Joung is a respected, recognized leader in the genetic editing field and has taken the lead on the discussion pertaining to the accuracy in genetic editing. Prashant Nair, *QnAs with Jennifer Doudna*, PROC. OF THE NAT'L ACAD. OF SCI. OF THE U.S. OF AM. (May 3, 2016), https://www.pnas.org/content/113/18/4884 [https://perma.cc/74KN-XCLG].

[72] *See* Walker-Daniels, *supra* note 56.

[73] Begley, *supra* note 14.

[74] *See, e.g.*, Baltimore et al., *supra* note 7, at 37–38. The article calls for a thorough investigation into the general safety and efficacy of CRISPR/Cas-9 before it is used therapeutically. *Id.* at 37. Moving forward, the article puts forth four recommendations: (1) discouraging any attempts to use CRISPR/Cas-9 on humans, (2) creating a forum where scientists and leading bioethicists can communicate and educate others, (3) encouraging transparent research pertaining to the efficacy of CRISPR/Cas-9, and (4) convening a global group of experts to discuss and recommend internationally implemented policies. *Id.* at 37–38.

[75] *See, e.g.*, Liang et al., *supra* note 13.

[76] *See, e.g.*, Daesik Kim, Sangsu Bae, Jeongbin Park, Eunji Kim, Seokjoong Kim, Hye Ryeong Yu, Jinha Hwang, Jong-Il Kim & Jin-Soo Kim, *Digenome-seq: Genome-Wide Profiling of CRISPR-Cas9 Off-Target Effects in Human Cells*, 12 NATURE METHODS 237, 237 (2015). Other notable predicators include Guide-seq, HTGTS, SELEX, BLESS, DISCOVER-Seq, Digenome-seq, High Throughput Profiling by David Liu, and CIRCLE-seq. *See generally* Kempton & Qi, *supra* note 69 (discussing off-target effects).

[77] Eric S. Lander, *Brave New Genome*, 373 NEW ENG. J. MED. 5, 7 (2015). As scientists have no ability to "recall" a bad gene, the best course of action is one of "great caution." *Id.* This caution is reflected in scientific articles that discuss the voluntary applications of CRISPR/Cas-9. *See, e.g.*, Liang et al., *supra* note 13, at 363 ("[O]ur work highlights the

CRISPR/Cas-9, it is necessary that our legal system determine a method for compensating CRISPR/Cas-9 victims.

B. Wrongful Life

The wrongful life claim is essentially a medical malpractice claim a child brings for being born with a disability or disease.[78] Wrongful life claims contrast from wrongful birth claims.[79] Generally, wrongful birth claims involve a parent's claim against a medical provider, alleging that negligent treatment or advice deprived the parent of avoiding the birth of the child.[80] The majority of courts allow parents to sue for wrongful birth claims,[81] but wrongful life claims are generally denied.[82] Briefly, the trend for accepting wrongful birth claims is attributed to: (1) advancements in healthcare that make the detection of defects readily available and (2) a woman's established right of privacy encompassing her choice to terminate

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pressing need to further improve the fidelity and specificity of the CRISPR/Cas9 platform, a prerequisite for any clinical applications of CRISPR/Cas9-mediated editing."); *see also* Baltimore et al.*, supra* notes 7, 74, and accompanying text.

[78] Gami v. Mullikin Med. Ctr., 22 Cal. Rptr. 2d 819, 823 (Cal. Ct. App. 1993).

[79] Turpin v. Sortini, 643 P.2d 954, 957 n.4 (Cal. 1982) ("While courts and commentators have not always been consistent in their terminology, 'wrongful life' has generally referred to actions brought on behalf of children, and 'wrongful birth' to actions brought by parents.").

[80] *See Wrongful Life Action,* BLACK'S LAW DICTIONARY (11th ed. 2019); *see also* Cichewicz v. Salesin, 854 N.W.2d 901, 907 (Mich. Ct. App. 2014) ("A wrongful-birth claim is brought by the parents of a child with a birth defect and generally alleges that the defendant's failure to inform them of the risk of the birth defect deprived them of the opportunity to avoid or terminate the pregnancy.").

[81] *See, e.g.*, Keel v. Banach, 624 So. 2d 1022, 1029 (Ala. 1993) ("[T]he great weight of authority to the contrary forces us to agree with the majority of the courts and the legal commentators and to hold that an action for the wrongful birth of a genetically or congenitally defective child may be maintained by the parents of such a child."). *But see Cichewicz*, 854 N.W.2d. at 907 (noting that both wrongful life and wrongful birth claims are not permitted in Michigan). Notably, Michigan abolished both wrongful life claims and wrongful birth claims in Taylor v. Kurapati, 600 N.W.2d 670, 674–76, 682–84 (Mich. Ct. App. 1999). Michigan later codified this ruling in MICH. COMP. LAWS SERV. § 600.2971 (LexisNexis 2001).

[82] Hester v. Dwivedi, 733 N.E.2d 1161, 1166 (Ohio 2000) (noting that wrongful life claims have been almost universally dismissed by courts in the United States). *But see Gami*, 22 Cal. Rptr. 2d at 825–28 (recognizing that California permits wrongful life claims). In *Gami*, a child sued for wrongful life when a doctor failed to properly conduct alpha fetoprotein (AFP) testing. *Id.* at 821. The AFP testing would have revealed a neural defect in the fetus, and the mother would have then chosen to abort the fetus. *Id.* Because the testing was not done properly, Nandini was born with "congenital hydrocephalus (water on the brain) and spina bifida." *Id.* The court held that Nandini was entitled to legal protection from negligent genetic counseling and testing, which is wrongful life. *Id.* at 827–28.

a pregnancy.[83] Taking it one step further, courts have reasoned that wrongful birth is consistent with the traditional goals of negligence under tort law.[84]

In contrast, courts typically reject wrongful life claims on notions of public policy,[85] and because courts are unable to calculate damages.[86] Regarding public policy, courts have suggested that any life is better than no life, consequently proposing that wrongful life claims should not be adjudicated by courts.[87] One court even explicitly stated that the legal world has "no competence" to answer whether it is better not to be born than to be born with "gross deficiencies."[88] Even courts that accept wrongful life

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[83] Smith v. Cote, 513 A.2d 341, 345–46 (N.H. 1986). Consistent with these two principles, courts have consistently recognized that physicians must adhere to the standards of reasonable professional performance. *Id.* at 346. A failure to meet these standards is recognized in the wrongful birth claim. *See id.* Considering these foundational principles, the Supreme Court of New Jersey held that wrongful birth actions were cognizable. *Id.* at 348 (citing Gleitman v. Cosgrove, 227 A.2d 689, 692 (1967)). However, the Supreme Court of New Hampshire cares to note that recognizing such claim will neither promote nor discourage abortions. *Id.* at 348. Similarly, the judicial recognition of the claim does not somehow impart that the child at issue should never have been born. *Id.*

[84] *See* Plowman v. Fort Madison Cmty. Hosp., 896 N.W.2d 393, 401 (Iowa 2017). In *Plowman*, Iowa joins with the majority of jurisdictions in recognizing a wrongful birth claim. *Id.* The court notes that the wrongful birth claim is essentially a medical malpractice claim that comports well within the elements of negligence. *Id.* at 401–04. *See also* Owens v. Foote, 773 S.W.2d 911, 913 (Tenn. 1989) ("[M]edical malpractice suits of this nature, brought by parents, alleging birth defects of an infant, are not unknown in this State and we see no reason to endeavor to fit them into some specific category beyond a suit for ordinary negligence.").

[85] *See, e.g.*, Becker v. Schwartz, 386 N.E.2d 807, 810 (N.Y. 1978) ("Even as a pure question of law, unencumbered by unresolved issues of fact, the weighing of the validity of a cause of action seeking compensation for the wrongful causation of life itself casts an almost Orwellian shadow . . . Any such resolution, whatever it may be, must invariably be colored by notions of public policy, the validity of which remains, as always, a matter upon which reasonable men may disagree."). The court asserts that it has "no competence" to address the issue of whether it is better to be born injured or never be born at all. *Id.* at 812. Similarly, the court is wary of "drawing of artificial and arbitrary boundaries." *Id.* at 813 (quoting Howard v. Lecher, 366 N.E.2d 64, 66 (N.Y. 1977)).

[86] *See, e.g.*, *Gleitman*, 227 A.2d at 692 ("This Court cannot weigh the value of life with impairments against the nonexistence of life itself. By asserting that he should not have been born, the infant plaintiff makes it logically impossible for a court to measure his alleged damages because of the impossibility of making the comparison required by compensatory remedies.").

[87] *See* Cockrum v. Baumgartner, 447 N.E.2d 385, 388 (Ill. 1983) (affirming the typical "unwillingness to hold that the birth of a normal healthy child can be judged to be an injury to the parents" and reasoning that such a notion "offends fundamental values attached to human life."). Such courts have typically asserted that public policy requires the conclusion that the plaintiff has not suffered any legally cognizable injury. Berman v. Allan, 404 A.2d 8, 12–13 (N.J. 1979). To hold otherwise would seemingly disavow the sanctity of human life in the eyes of most courts. *Id.* Consequently, these courts have held as a matter of law that any life, even life with horrendous impairments, is better than no life. *Id.*

[88] *Becker*, 386 N.E.2d at 812.

claims have referred to the traditional policy that life is *always* preferable to nonlife.[89]

This public policy argument tracks closely with Derek Parfit's Non-Identity Problem,[90] which arises when a child would not have existed but for the negligence of another.[91] For instance, a child born from a faulty tubal ligation would have no tort claim because the child would not have existed but for the mistake.[92] Note that the non-identity problem arises when, in different circumstances (i.e., a proper or faulty tubal ligation), a different number of people would be born.[93] Notwithstanding tubal ligation issues, Parfit himself addresses situations where, in different circumstances, the same number of people will be born.[94] In these circumstances, Parfit suggests that the best choice is to avoid harm and choose the child with the best potential for a good quality of life.[95]

Regarding the quantification of damages, courts often express the inability to weigh the value of nonexistence with existence, which is required for compensatory damages.[96] As damages are typically measured by comparing where the plaintiff would have been to where they are now, some courts have asserted that it is "logically impossible" to calculate damages.[97] Essentially, courts typically find it abhorrent to attempt to measure the

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[89] *See, e.g.*, Turpin v. Sortini, 643 P.2d 954, 961 (Cal. 1982).

[90] *See generally* David Benatar, *The Wrong of Wrongful Life*, 37 AM. PHIL. Q. 175 (2000).

[91] *See generally* DEREK PARFIT, REASONS AND PERSONS 358–59 (Oxford Univ. Press rev. ed. 1987); *see also* Barbara Pfeffer Billauer, *Wrongful Life in the Age of Crispr-Cas: Using the Legal Fiction of "The Conceptual Being" to Redress Wrongful Gamete Manipulation*, 124 PENN ST. L. REV. 435, 479–80 (2020).

[92] Kirsten Rabe Smolensky, *Symposium: Parental Tort Liability for Preimplantation Genetic Interventions: Technological Harms, the Social Model of Disability, and Questions of Identity*, 60 HASTINGS L.J. 411, 411 n.6 (2008) [hereinafter Smolensky, *Symposium*].

[93] PARFIT, *supra* note 91, at 361.

[94] *Id.* at 363–64.

[95] *Id.* (noting that "if the numbers would be the same, it would be worse if those who live have a lower quality of life than those who would have lived.").

[96] Bowman v. Davis, 356 N.E.2d 496, 499 n.3 (Ohio 1976); Rich v. Foye, 976 A.2d 819, 836 (Conn. Super. Ct. 2007). *But see* Curlender v. Bio-Science Labs., 165 Cal. Rptr. 477, 488–90 (Cal. Ct. App. 1990). *Curlender* was a matter of first impression in California, concerning whether a genetically impaired child could sue for preconception negligence. *Id.* at 814. The plaintiff was born with Tay-Sachs after a doctor and medical laboratory failed to properly test her parents' status as carriers for the diseases. *Id.* at 815–16. The court decidedly disagreed with out-of-state courts who held that being born with a disease is not a legally cognizable injury when the alternative is not being born. *Id.* at 828–29. Indeed, the court determined the "real crux" should focus on proximate cause and not a cognizable injury. *Id.* Meaning, the court "need not be concerned with the fact that had defendants not been negligent, the plaintiff might not have come into existence at all." *Id.* at 829. The court then found that the plaintiff's disease was a legally cognizable injury and that damages were measurable. *Id.* at 829, 831.

[97] Gleitman v. Cosgrove, 227 A.2d 689, 692 (N.J. 1967).

difference between nonexistence and the value of life with defects.[98] Less commonly, courts reject wrongful life on the basis of causation.[99] The crux of this reasoning is that a genetic disorder is not caused by a physician but is simply inherited.[100]

Nonetheless, a small number of plaintiffs have been successful in pleading all the elements of negligence in wrongful life claims.[101] Currently, only four states recognize wrongful life claims: California,[102] Washington,[103] Maine,[104] and New Jersey.[105] In these states, the damages are still limited for wrongful life claims.[106] For instance, the California Supreme Court denied general damages to an infant who alleged that, but for a physician's negligence in diagnosing hereditary deafness, she would not have been conceived.[107] The court only permitted recovery for "extraordinary expenses for specialized teaching, training and hearing equipment" associated with her deafness.[108] In doing so, the court explicitly rejected the traditional public policy argument that wrongful life claims renounce the sanctity of life.[109] The court instead put forth the public policy of personal autonomy and "the right of each individual to make his or her own determination as to the relative value of life and death."[110]

Unless the CRISPR/Cas-9 child brings suit in one of the four aforementioned states that recognize wrongful life claims,[111] it is more than likely that the claim will be rejected as a disguised wrongful life claim.[112]

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[98] *See id.* ("By asserting that he should not have been born, the infant plaintiff makes it logically impossible for a court to measure his alleged damages because of the impossibility of making the comparison required by compensatory remedies.").

[99] *See Rich*, 976 A.2d at 837 (discussing causation and wrongful life). *Rich* draws attention to the fact that most diseases are genetic, thus not caused by any doctor. *Id.* Consequently, failing to inform the parents of the child's disease while *in utero* does not actually cause the onset of the disease. *Id.* However, this is not an applicable defense to the CRISPR child's mistaken manipulation claim because the CRISPR/Cas-9 editing does indeed cause the disease. *See infra* Section III.B.4.

[100] Wilson v. Kuenzi, 751 S.W.2d 741, 744–45 (Mo. 1988).

[101] *See, e.g.*, Gami, v. Mullikin Med. Ctr., 22 Cal. Rptr. 2d 819, 827 (Cal. Ct. App. 1993).

[102] *Id.* at 824.

[103] Wuth v. Lab. Corp. of Am., 359 P.3d 841, 853 (Wash. Ct. App. 2005).

[104] ME. REV. STAT. ANN. tit. 24, § 2931 (1985).

[105] Procanik v. Cillo, 478 A.2d 755, 760 (N.J. 1984); Provenzano v. Integrated Genetics, 22 F. Supp. 2d 406, 413 (D.N.J. 1998).

[106] *See, e.g.*, Turpin v. Sortini, 643 P.2d 954, 963 (Cal. 1982).

[107] *Id.* at 956, 963.

[108] *Id.* at 965.

[109] *Id.* at 961–62.

[110] *Id.* at 962.

[111] *See supra* text accompanying notes 102–105.

[112] *See* Sara Weinberger, Sharon Nakar & Dov Greenbaum, *They Chose . . . Poorly: A Novel Cause of Action To Discourage Detrimental Genetic Selection*, 43 AM. J.L. & MED. 107, 110 (2017) (discussing that the only current cause of action for a child born with an intentional, harmful genetic condition is wrongful life).

Therefore, this comment seeks to enumerate why wrongful life reasoning does not apply in the two scenarios put forth.[113] As mentioned previously, this article will term the plaintiff's claim *mistaken manipulation* to avoid any stigmatization of the CRISPR/Cas-9 claim as a wrongful life claim.[114]

C. Injuries in the Prenatal and Preconception Context

A rudimentary history of prenatal and preconception tort claims is necessary for imparting the elements of a *mistaken manipulation* claim. Historically, courts denied prenatal tort claims on the grounds that there is no duty of care to an unborn child.[115] However, in 1946, the court in *Bonbrest v. Kotz* took a radical stance and allowed recovery for prenatal injuries if the child was viable at the time of injury and subsequently born alive.[116] In doing so, the court reasoned that "[t]he law is presumed to keep pace with the sciences."[117] The court further noted that an unborn child is considered a human being under tort law only once it is viable.[118] The reasoning behind the viability mark is that the child could now be considered a separate entity from the mother.[119] Now, all American jurisdictions recognize that a child has a claim when they are injured prenatally and then born alive.[120]

Some jurisdictions even recognize prenatal claims when the injury occurs before the child is viable.[121] For instance, the plaintiff in *Smith v. Brennan* sued a negligent tortfeasor when the tortfeasor hit the plaintiff's mom in an automobile crash.[122] Although the plaintiff was not viable at the time of the injury, the court permitted recovery.[123] Similarly, the court in *Womack v. Buchhorn* allowed the plaintiff to recover under tort law for brain injuries that resulted from trauma suffered while the plaintiff was four months old *in utero*.[124] In doing so, the court reasoned, "justice requires that the principle be recognized that a child has a legal right to begin life with a

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[113] *See infra* Sections III.A, IV.B.
[114] It is common to coin new terms in this field. *See, e.g.*, Weinberger et al., *supra* note 112 (proposing a "wrongful selection" cause of action).
[115] *See* Dietrich v. Northampton, 138 Mass. 14, 15–16 (1884).
[116] 65 F. Supp. 138, 142 (D.D.C. 1946). Because the child was viable, the court recognized him as a separate entity from his mother, which gave him a right of action. *Id.* at 142.
[117] *Id.* at 143.
[118] *Id.* at 141–42.
[119] *Id.*
[120] RESTATEMENT (SECOND) OF TORTS § 869 (AM. L. INST. 1979); G. Edward Powell III, *Embryos as Patients? Medical Provider Duties in the Age of CRISPR/Cas9*, 15 DUKE L. & TECH. REV. 344, 352–53 (2017).
[121] *See, e.g.*, Smith v. Brennan, 157 A.2d 497, 504 (N.J. 1960).
[122] *Id.* at 498.
[123] *Id.* at 504.
[124] Womack v. Buchhorn, 187 N.W.2d 218, 222 (Mich. 1971).

sound mind and body."[125] The court then overruled the standing case law that prevented recovery for prenatal injuries.[126] The court justified its decision to overrule, stating "the present state of science" required a new look at judicial thinking.[127]

Likewise, a minority of jurisdictions have expanded *Bonbrest* to allow recovery when an injury happens before the child is even conceived, a so-called preconception tort.[128] One court famously used the following analogy to demonstrate why preconception injuries should be recognized:

> Assume 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.[129]

In the above case, the time of the negligent act was when the balcony was first constructed, which was before the hypothesized child was even conceived.[130] As the court stated, it would be ludicrous to deny recovery just because the negligent act occurred before conception.[131] Other courts have expressed that "disallowing . . . claims based upon alleged

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[125] *Id.* (quoting Smith, 157 A.2d at 503).

[126] *See* Newman v. Detroit, 281 Mich. 60, 63–64 (Mich. 1937). In *Newman*, a child was injured *in utero* when his mother was harmed during a streetcar accident in Detroit. *Id.* at 62. The accident occurred twenty-two days prior to the child's birth, which occurred at the end of nine months. *Id.* Thus, the child was viable at the time of his injury and subsequently born alive. *See id.* The child was only alive for three months and died from injuries that resulted from the streetcar accident. *Id.* The *Newman* court denied the child's recovery, placing significant emphasis on the fact that the "overwhelming weight of authority is . . . contrary" to allowing recovery for prenatal injuries. *Id.* at 63. Indeed, the child had no recognized claim under either common law or any statute. *Id.* at 64.

[127] *Womack*, 187 N.W.2d at 222. The *Womack* court drew attention to the fact that the great weight of the law in the United States now weighs against the decision in *Newman*. *Id.* at 219–22. When *Newman* was initially decided in 1937, eleven jurisdictions, including Michigan, denied recovery for prenatal injuries. *Id.* at 220. However, by the time *Womack* was decided in 1971, thirty-four years after *Newman*, only one jurisdiction still prevented recovery for prenatal injuries while twenty-seven other jurisdictions permitted recovery. *Id.* at 220–21. The court attributed this trend in favor of recognizing prenatal claims to all the advances made in medical science since *Newman* was decided. *Id.* at 219–20. The court noted that justice demanded the reexamination of the *Newman* rule and its subsequent overruling. *Id.* at 222.

[128] *See, e.g.*, Martin v. St. John Hosp. & Med. Ctr. Corp., 517 N.W.2d 787, 789 (Mich. Ct. App. 1994).

[129] *Id.*

[130] *Id.*

[131] *Id.* at 789–90.

preconception torts is unnecessary, unjust, and contrary to fundamental and traditional principles of . . . tort law."[132]

Some courts employing preconception injury claims have focused on whether the injured party was foreseeable.[133] Notably, children born injured from a doctor's negligence in treating their mother have been interpreted as foreseeable parties—even if the child was not yet conceived.[134] Similarly, courts have reasoned beyond the concept of foreseeable parties and have inquired into whether the child is a third-party beneficiary of a doctor-patient relationship.[135]

In such cases, courts have emphasized that, in doctor-patient relationships, the potential child is a beneficiary of the mother's consensual relationship with the doctor.[136] This resembles the relationship of a third-party beneficiary in a contract.[137] Importantly, the doctor must have some knowledge that the services are for the benefit, at least in part, to the third party.[138] This was illustrated in *Walker v. Rinck*, where the mother was incorrectly diagnosed with Rh-positive blood before conceiving her child and subsequently not given proper treatment, resulting in her child's injury.[139] The knowledge of the third party was satisfied because the administration of the necessary drug for Rh cases was only for the benefit of future children.[140]

Notably, unlike wrongful life, preconception injuries do not correspond to Parfit's Non-Identity Problem because the preconception harm did not lead to the child's birth.[141] It is only when conception and negligence occur at the same time that Parfit's Non-Identity Problem is

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[132] Yeager v. Bloomington Obstetrics & Gynecology, Inc., 585 N.E. 2d 696, 700 (Ind. Ct. App. 1992), *aff'd,* 604 N.E.2d 598 (Ind. 1992).

[133] *See, e.g.*, Renslow v. Mennonite Hosp., 367 N.E.2d 1250, 1258 (Ill. 1977).

[134] *See id.*; *see also Martin*, 517 N.W.2d at 789. The court in *Martin* noted precedence of finding that doctors owe a duty to unborn children and children not yet conceived. *Id.* In finding such duty, the court emphasized that duties owed to preconceived children arise when the doctor's care is aimed to protect subsequently conceived children. *Id.* For example, if a doctor negligently fails to administer a test and subsequent preconception vaccine to a woman before her pregnancy, the doctor will be found liable if a future child is born with Rubella—the syndrome that would have been treated by the immunization at issue. Monusko v. Postle, 437 N.W.2d 367, 369–70 (Mich. Ct. App. 1988).

[135] *Martin*, 517 N.W.2d at 790.

[136] Walker v. Rinck, 604 N.E.2d 591, 594–95 (Ind. 1992) ("[A] duty may be owed to a beneficiary of the consensual relationship, akin to that of a third-party beneficiary of a contract, where the professional has actual knowledge that the services being provided are, in part, for the benefit of such third persons.").

[137] *Id.*

[138] *Id.*

[139] *Id.* at 592–93.

[140] *Id.* at 595.

[141] *See* Billauer, *supra* note 91, at 494.

triggered.[142] Indeed, the courts that have recognized preconception injuries took great measures to distinguish the preconception injury from wrongful life claims.[143] For instance, the court in *Walker v. Rinck* explicitly stated that in a preconception injury case, "no person shall maintain a cause of action . . . based on the claim that but for the negligent conduct of another he would have been aborted," which is a wrongful life claim.[144] The court enumerated this rule when noting that the defendant had misconstrued the terms "wrongful life" and "preconception injury" by essentially commingling them.[145]

Ultimately, if a negligent act occurs before a child's conception, the child's claim will not be barred.[146] Since the harm applies generally to any child born, any child should be able to sue.[147] In turn, if the child's conception and negligent act occur at the same time, the child will suffer from Parfit's Non-Identity problem and the stigma against wrongful life.[148] That child will then not recover even though the damages sought by the child are considerably similar to the damages sought by the child suffering harm from preconception negligence.[149]

The courts' unwillingness to recognize wrongful life claims coupled with their acknowledgment of prenatal and preconception injuries leaves a gap in the law. Strikingly, a CRISPR child's mistaken manipulation claim does not fit neatly within either area of law. Although CRISPR/Cas-9 has its drawbacks, the scientific community credits CRISPR/Cas-9 as a system that will develop into a tool for genetic editing in the clinical context.[150] It is thus pertinent that our legal scheme contemplates and prepares to address the

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[142] PARFIT, *supra* note 91, at 358–59.

[143] *See, e.g.*, *Walker*, 604 N.E.2d at 593.

[144] *Id.*

[145] *Id.*

[146] *See* Billauer, *supra* note 91, at 494–95.

[147] *See id.* at 497. The potential class of plaintiffs is therefore boundless in preconception injuries.

[148] *See* PARFIT, *supra* note 91, at 361. *See also* Andrews v. Keltz, 838 N.Y.S.2d 363, 366 (N.Y. Sup. Ct. 2007), for an example of a court dismissing a child's wrongful life claim after an IVF clinic used the wrong sperm to fertilize an egg. Although the court acknowledged that the child might go through hardships since she is a different race than her parents, the court refused to recognize these injuries as compensable. *Id.* Since the birth of an unhealthy child was not a cognizable injury in New York, by extension neither could be the birth of an otherwise illegitimate child. *Id.* at 368.

[149] *See* Billauer, *supra* note 91, at 495–96.

[150] Katrine S Bosley, Michael Botchan, Annelien L Bredenoord, Dana Carroll, R Alta Charo, Emmanuelle Charpentier, Ron Cohen, Jacob Corn, Jennifer Doudna, Guoping Feng, Henry T Greely, Rosario Isasi, Weihzi Ji, Jin-Soo Kim, Bartha Knoppers, Edward Lanphier, Jinsong Li, Robin Lovell-Badge, G Steven Martin, Jonathan Moreno, Luigi Naldini, Martin Pera, Anthony CF Perry, J Craig Venter, Feng Zhang & Qi Zhou, *CRISPR Germline Engineering—The Community Speaks*, 33 NATURE BIOTECHNOLOGY 478, 479 (2015) (compiling expert opinions on genetic editing).

question of whether a child born injured from CRISPR genetic editing has a cause of action.

III. THE MISTAKEN MANIPULATION CLAIM

This comment seeks to analyze whether a CRISPR child has a cause of action by utilizing preexisting legal frameworks. In doing so, two scenarios will be explored: first, when a doctor performs CRISPR/Cas-9 with the goal of producing a healthy baby, but the child suffers off-target effects, and secondly, when a doctor uses CRISPR/Cas-9 to purposefully impose a defect on a child. The first scenario will be analyzed under negligence law, while the second will be analyzed under intentional tort law, specifically battery.

A. Standing

Before delving into negligent and intentional tort law, it must first be determined whether the CRISPR child has standing.[151] Under *Roe v. Wade*, the Fourteenth Amendment's use of "person" does not encompass those who are not yet born.[152] Consequently, the CRISPR child would not be able to recover under *Roe* if standing were interpreted at the time of the harmful act.[153] However, courts after *Roe* have recognized interests in persons not yet born.[154] Indeed, a frequently cited Tennessee court stated that "preembryos are not, strictly speaking, either 'persons' or 'property,' but occupy an interim category that entitles them to special respect because of their potential for human life."[155] With this rationale, standing could reasonably be interpreted when the child is born alive.[156] Then, the CRISPR

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[151] Joint Anti-Fascist Refugee Comm. v. McGrath, 341 U.S. 123, 150 (1951) (Frankfurter, J., concurring) ("Limitation on the judicial Power of the United States is expressed by the requirement that a litigant must have standing to sue.") (internal quotations omitted).

[152] Roe v. Wade, 410 U.S. 113, 158 (1973) ("[T]he word 'person,' as used in the Fourteenth Amendment, does not include the unborn.").

[153] After all, standing requires that the individual suing be considered a person. Interestingly, property law recognizes that a child is a person as soon as it is conceived while tort law generally requires viability. *See generally* Bonbrest v. Kotz, 65 F. Supp. 138 (D.D.C. 1946). A potential solution to the standing issue would be to apply property law here. Indeed, this idea has been broached before, with some academics suggesting the utilization of property theory in the context of reproductive advancements. *See, e.g.*, Barry Brown, *Reconciling Property Law with Advances in Reproductive Science*, 6 STAN. L. & POL'Y REV. 73, 84 (1995).

[154] *See In re* Marriage of Rooks, 429 P.3d 579, 591 (Colo. 2018) ("[W]e acknowledge that pre-embryos contain the potential for human life . . . . Thus, we agree with courts that have categorized pre-embryos as marital property of a special character.").

[155] Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992).

[156] Philosophers would argue that children have a moral right to an "open future." *See* Feinberg, *supra* note 23. These rights are "anticipatory autonomy rights" and are violated

child's standing would be comparable to a child's standing that sues for preconception or prenatal negligence.[157] Impliedly, the CRISPR child would have to be born alive to sue.[158]

Furthermore, scholars have interpreted Parfit's Non-Identity Problem as a standing argument.[159] In doing so, it has been asserted that a child who is born because of another's negligence—like faulty tubal ligation in a mother leading to a child—has no standing to sue.[160] However, Parfit's Non-Identity Problem does not apply to a CRISPR child's mistaken manipulation claim for two reasons: (1) Parfit himself suggests it is better to avoid harm in such circumstances;[161] and (2) changing a single gene does not necessarily result in the creation of a new person.[162]

First, Parfit suggests it is better to avoid harm.[163] As discussed in Part II,[164] Parfit's Non-Identity Problem primarily concerns a situation that results in life when the alternative would result in no life.[165] For instance, a botched abortion, failed vasectomy, or faulty tubal ligation all lead to a child in Parfit's world.[166] Had these procedures been performed correctly, the child would never have been born.[167] Thus, a child now exists in a situation where there would not have been a child.[168] Moreover, there would not have been a child but for the negligence of another.[169] Importantly, the use of CRISPR/Cas-9 on an embryo does not necessarily result in life where there would have been no life. A child born of CRISPR/Cas-9 genetic editing is more analogous to another circumstance Parfit broached: where, in different circumstances, the same number of people would have been born.[170] In other words, whether or not CRISPR/Cas-9 is used on an embryo, it is likely that someone would be born. This becomes more

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when the child's opportunities are limited. *Id.* Some dicta in prenatal tort cases support this moral right as a legal right. *See, e.g.*, Smith v. Brennan, 157 A.2d 497, 503 (N.J. 1960) ("[J]ustice requires that the principle be recognized that a child has a legal right to begin life with a sound mind and body.").

[157] *See supra* Section II.C., for a discussion of prenatal and preconception injuries.

[158] *See supra* note 156. Note that whether a child could sue while it is in the womb is beyond the scope of this comment.

[159] *See* Billauer, *supra* note 91, at 480.

[160] *Id.*

[161] PARFIT, *supra* note 91, at 363–64.

[162] *See infra* notes 172–86 and accompanying discussion.

[163] PARFIT, *supra* note 91, at 363–64.

[164] *See supra* Section II.B.

[165] PARFIT, *supra* note 91, at 361.

[166] *See id.* at 358–59.

[167] *See* Smolensky, *Symposium*, *supra* note 92, at 411 n.6.

[168] *See* Billauer, *supra* note 91, at 480.

[169] PARFIT, *supra* note 91, at 358–59.

[170] *Id.* at 363–64.

apparent when considering that people would seek out CRISPR/Cas-9 therapy when they are adamantly trying to have a child.

Similarly, altering a few genes in an embryo does not invoke Parfit's Non-Identity Problem.[171] To say that one gene determines a person's identity is placing too much emphasis on genes.[172] Indeed, there is a longstanding debate regarding whether someone's behavior is determined by their genes or by their environment.[173] Appropriately, this debate has been termed "nature versus nurture."[174] Scientists have long considered the nature versus nurture argument,[175] studying combinations of identical twins who were raised together, identical twins who were separated, and fraternal twins.[176] Although behavioral geneticists have correlated traits like aggression to certain genes,[177] scientists usually recognize that nature and nurture are interwoven together.[178] Consequently, a child more prone to aggression can

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[171] *See infra* notes 172–86 and accompanying discussion.

[172] *See* Smolensky, *Creating Children*, *supra* note 15, at 333.

[173] *See* Carl Zimmer, *You Are Shaped by the Genes You Inherit. And Maybe by Those You Don't*, N.Y. TIMES (Jan. 25, 2018), https://www.nytimes.com/2018/01/25/science/children-parents-genes-education.html [https://perma.cc/HG9S-58GL] (noting that the question of whether psychological traits are influenced by heredity or the environment was posed by Francis Galton in the nineteenth century).

[174] *Id.*

[175] *See* Sarah Mae Sincero, *Nature and Nurture Debate*, EXPLORABLE (Sept. 16, 2012), https://explorable.com/nature-vs-nurture-debate [https://perma.cc/S25Q-3JBT] ("One of the hottest issues against nature theory is that there may be an existing 'gay gene', which explains that gays are actually born that way. Another issue is that the criminal acts, tendency to divorce and aggressive behavior causing abuse can be justified by the 'behavioral genes' once the researchers have proven their existence.").

[176] *See* ROBERT PLOMIN, NATURE AND NURTURE: AN INTRODUCTION TO HUMAN BEHAVIORAL GENETICS 47 (1990); *see also* Zimmer, *supra* note 173.

[177] Auke Tellegen, David T. Lykken, Thomas J. Bouchard, Jr., Kimerly J. Wilcox, Nancy L. Segal & Stephen Rich, *Personality Similarity in Twins Reared Apart and Together*, 54 J. PERSONALITY & SOC. PSYCHOL. 1031, 1036 tbl.4 (1988). Based off twin studies, the authors found that the most significant trait variances were attributed to genetic differences instead of environmental differences. *Id.* at 1036. Thus, the authors concluded that "personality differences are more influenced by genetic diversity than they are by environmental diversity." *Id.* This conclusion was contrary to older studies where scientists concluded that traits like aggression are linked more closely to the environment. *See, e.g.*, Albert Bandura, Dorothea Ross & Sheila A. Ross, *Transmission of Aggression Through the Imitation of Aggressive Models*, 63 J. ABNORMAL & SOC. PSYCHOL. 575, 575–82 (1961). In such studies, children in pre-school were exposed to aggressive and non-aggressive adult behavior. *Id.* at 575. Then, the children were observed separately of the adult model to see if they would imitate the adult behavior. *Id.* Ultimately, the children exposed to the aggressive model demonstrated aggression at a markedly higher level than that of the children exposed to the non-aggressive model. *Id.* at 582.

[178] David Rettew, *Nature Versus Nurture: Where We Are in 2017*, PSYCHOL. TODAY (Oct. 6, 2017), https://www.psychologytoday.com/us/blog/abcs-child-psychiatry/201710/nature-versus-nurture-where-we-are-in-2017 [https://perma.cc/6C8E-HR3K]. At the end of the twentieth century, the debate over nature versus nurture largely shifted to a recognition of

treat this disposition through things like psychotherapy, parental guidance, and healthy living—all nurturing factors.[179]

Moreover, the interaction of genes with the environment, termed epigenetics,[180] has shown that genes may manifest differently because of their environment.[181] Thus, both genetic factors and environmental factors play a role in the development of traits.[182] This is observed by noting that infants possess vast genetic possibilities in brain development, but their environment determines what genetic material is incorporated.[183]

"nature and nurture." *Id.* This shift was attributed to both the human genome project and various twin experiments that were being conducted. *Id.* Today, scientists ultimately recognize that "the nature and nurture domains are hopelessly interwoven with one another." *Id.* Thus, while genes can influence one's perception of their environment, their environment can influence the magnitude of what genes are expressed. *Id.*

[179] *Id.*; *but see* ROBERT PLOMIN, BLUEPRINT: HOW DNA MAKES US WHO WE ARE ix, 186 (2018) (finding that genes account for half of the differences between us and the rest is determined by random experiences, but that nonetheless, these systematic experiences are still influenced by one's genetic trajectory).

[180] Michael P. Vandenbergh, David J. Vandenbergh & John G. Vandenbergh, *Lamarck Revisited: The Implications of Epigenetics for Environmental Law*, 7 MICH. J. ENVTL. & ADMIN. L. 1, 1 (2017).

[181] Evan Nesterak, *The End of Nature Versus Nurture*, BEHAV. SCI. (July 10, 2015), https://behavioralscientist.org/the-end-of-nature-versus-nurture/ [https://perma.cc/QKR6-F27P]; *see also* Michael J. Meaney & Moshe Szyf, *Environmental Programming of Stress Responses Through DNA Methylation: Life at the Interface Between a Dynamic Environment and a Fixed Genome*, 7 DIALOGUES CLINICAL NEUROSCIENCE 103, 103 (2005) (observing that rats who were well groomed by their moms in infanthood were less stressed in adulthood than rats who were not well groomed).

[182] DAVID S. MOORE, THE DEVELOPING GENOME: AN INTRODUCTION TO BEHAVIORAL EPIGENETICS 5–6, 11 (2015) ("DNA can't single-handedly cause *any* of our characteristics!").

[183] Jane Rutherford, *Symposium: Juvenile Justice Caught Between the Exorcist and a Clockwork Orange*, 51 DEPAUL L. REV. 715, 732 (2002).

If these arguments are not persuasive, consider that cancer changes a person's DNA.[184] Likewise, pregnancy,[185] and bone marrow transplants,[186] can add to a person's original DNA. If DNA were one hundred percent imperative to one's identity, it would follow that the people exposed to the above circumstances have altered personalities. Most would accept that this is not the circumstance and must therefore accept that DNA is not outcome determinative of a person's identity.

Consequently, Parfit's Non-Identity Problem does not apply to a CRISPR child's mistaken manipulation claim for the two reasons discussed above: (1) Parfit himself suggests in such circumstances it is better to avoid harm;[187] and (2) changing a single gene does not necessarily result in the creation of a new person.[188] Therefore, Parfit's Non-Identity Problem does not defeat a CRISPR child's claim due to a lack of standing. Now that standing has been asserted, the two scenarios of negligent editing and purposeful defective editing can be explored, starting with negligent editing.

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[184] *The Genetics of Cancer*, NAT'L CANCER INST. (Oct. 12, 2017), https://www.cancer.gov/about-cancer/causes-prevention/genetics [https://perma.cc/E7X3-4SF6]; *see also Changes in Genes*, AM. CANCER SOC'Y (June 25, 2014), https://www.cancer.org/cancer/cancer-causes/genetics/genes-and-cancer/gene-changes.html [https://perma.cc/2XYG-GVDG] ("Cells become cancer cells largely because of mutations in their genes. Often many mutations are needed before a cell becomes a cancer cell. The mutations may affect different genes that control cell growth and division. Some of these genes are called tumor suppressor genes. Mutations may also cause some normal genes to become cancer-causing genes known as oncogenes.").

[185] Ten percent of a pregnant mother's free-floating DNA can come from the fetus that she is carrying. Katherine Rowland, *We Are Multitudes*, AEON (Jan. 11, 2018), https://aeon.co/essays/microchimerism-how-pregnancy-changes-the-mothers-very-dna [https://perma.cc/8B44-8PXL]. After pregnancy, this amount of free-floating DNA will decrease, but some cells will remain in the mother's bloodstream. *Id.* Indeed, these cells can even become part of the mother's tissue. Viviane Callier, *Baby's Cells Can Manipulate Mom's Body for Decades*, SMITHSONIAN (Sept. 2, 2015), https://www.smithsonianmag.com/science-nature/babys-cells-can-manipulate-moms-body-decades-180956493/ [https://perma.cc/RJK6-A8SP] ("[F]etal cells cross the placenta and enter the mother's bloodstream. Like stem cells, fetal cells are pluripotent, which means they can grow into many kinds of tissue. Once in the mother's blood, these cells circulate in the body and lodge themselves in tissue. They then use chemical cues from neighboring cells to grow into the same stuff as the surrounding tissue.").

[186] When a person receives a bone marrow transplant, they also receive the donor's stem cells. Roger Schlueter, *Getting a Bone Marrow Transplant Could Give You New DNA, Too*, MED. XPRESS (Jan. 19, 2018), https://medicalxpress.com/news/2018-01-bone-marrow-transplant-dna.html [https://perma.cc/2WJJ-EYBG]. These stem cells retain the donor's DNA, and consequently, the person who receives the bone marrow transplant will also have the donor's DNA in their bloodstream. *Id.* The donor's DNA has also been found in the transplant receiver's nails, urine, and epithelial cells that line a person's mouth, cavities, and organs. *Id.*

[187] PARFIT, *supra* note 91, at 363–64.

[188] *See supra* notes 172–86 and accompanying discussion.

B. Negligence

This section will analyze the first scenario imposed on the hypothetical CRISPR child: when a doctor uses CRISPR/Cas-9 and the subsequent child suffers off-target effects even though the doctor aimed to produce a healthy baby. In line with preconception and prenatal tort cases, such a circumstance fits best within a negligence cause of action. As such, the elements of negligence as they relate to the mistaken manipulation claim must be examined. Therefore, the following sections will survey duty, breach, injury, factual cause, and legal cause, respectively.[189]

1. Duty

Seeing that many preconception,[190] and prenatal claims,[191] turned on the question of duty, this is likely to be the biggest obstacle in the CRISPR child's mistaken manipulation claim. Simplistically, duty can be considered a threshold question that requires the defendant to conform to reasonable standards of conduct.[192] Consistent with wrongful life suits, this comment will explore a doctor's duty to the CRISPR child without getting into the weeds of parental duty.[193]

Although some have proposed a nexus test for duty in the medical malpractice context,[194] duty typically arises from a doctor-patient relationship.[195] At first glance, it may seem that the doctor has no duty to the CRISPR child because the child is not yet in existence.[196] However, courts have seamlessly rejected that argument on the basis that "a duty may be owed to a beneficiary of the consensual relationship, akin to that of a third-party beneficiary of a contract, where the professional has actual knowledge

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[189] David G. Owen, *The Five Elements of Negligence*, 35 HOFSTRA L. REV. 1671, 1672–73 (2007).

[190] *See, e.g.*, Martin v. St. John Hosp. & Med. Ctr. Corp., 517 N.W.2d 787, 790 (Mich. Ct. App. 1994).

[191] *See, e.g.*, Dietrich v. Northampton, 138 Mass. 14, 15–16 (1884), *abrogated by* Angelini v. OMD Corp., 575 N.E.2d 41 (Mass. 1991).

[192] *In re* Thrash, 433 B.R. 585, 596 (Bankr. N.D. Tex. 2010).

[193] Children generally sue their health care providers in wrongful life. Shawna Benston, *Yesterday's Child, Tomorrow's Plaintiff: Why We Should Expect an Uptick in Wrongful-Life Suits Following Embryonic Application of Gene-Editing Technologies*, 19 AM. J. BIOETHICS 41, 41 (2019). However, courts are wary of interpreting whether a child can sue their parents in wrongful life. *See* Tomlinson v. Metro. Pediatrics, LLC, 412 P.3d 133, 152 n.18 (Or. 2018).

[194] *See generally* Browne, *supra* note 21.

[195] Johnson v. Thompson, 650 S.E.2d 322, 323 n.4 (Ga. Ct. App. 2007).

[196] Powell III, *supra* note 120, at 355 ("[E]very physician-patient relationship requires a patient to exist. As a general rule, if a duty does not exist to a person (or class of persons, of whom the injured party is a member) at the time a wrongful act or omission occurred, the person cannot recover for injuries that the wrong caused.").

that the services being provided are, in part, for the benefit of such third persons."[197] Likewise, courts have inferred that it would be ludicrous to deny recovery just because a negligent act occurred before a child was born or conceived.[198] Courts have also reasoned that doctors have a duty to unborn children when the possibility of children is reasonably foreseeable.[199]

In landmark cases where duty was extended to those not yet conceived, courts have determined the duty of the physician to the unborn "by balancing (1) the relationship between the parties, (2) the reasonable foreseeability of harm to the person injured, and (3) the public policy concerns."[200] Importantly, all three prongs and all aforementioned rationale support the extension of finding that a doctor owes a duty of care to the CRISPR child.

Beginning with the first prong—the relationship of the parties—it can be seen that the CRISPR child is a beneficiary of the parent's consensual relationship with the doctor.[201] Importantly, the CRISPR child's doctor would be aware that CRISPR was being performed for the benefit of the child.[202] Like the Rh cases where a mother would only receive the medication RhoGAM to protect future fetuses growing in utero,[203] in this hypothetical, parents would only seek out CRISPR/Cas-9 to hopefully better their child. Thus, the first prong is satisfied based on the analogous relationship between a CRISPR child and a doctor and the comparable relationship of a preconceived child and a doctor.[204]

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[197] Webb v. Jarvis, 575 N.E.2d 992, 996 (Ind. 1991).

[198] *See, e.g.*, Martin v. St. John Hosp. & Med. Ctr. Corp., 517 N.W.2d 787, 789 (Mich. Ct. App. 1994).

[199] *See* Renslow v. Mennonite Hosp., 637 N.E.2d 1250, 1258 (Ill. 1977). This is in accordance with older notions of tort law, as the "duty to exercise ordinary care to avoid injury to another does not depend upon contract, privity of interest or the proximity of relationship between the parties. It extends to remote and unknown persons." Wintersteen v. Nat'l Cooperage & Woodenware Co., 197 N.E.2d 578, 582 (Ill. 1935).

[200] *Martin*, 517 N.W.2d at 790. Using these three prongs, the court in *Martin* held that a doctor owed a duty to a fetus that was conceived after the defendant had performed a cesarean. *Id.* at 493.

[201] Walker v. Rinck, 604 N.E.2d 591, 594–95 (Ind. 1992).

[202] For instance, a parent seeking to treat Duchenne muscular dystrophy (DMD), inherited childhood blindness, or sickle-cell disease would seek out CRISPR/Cas-9 therapy as a "one-time" cure for their child. Shelly Fan, *The Three Frontrunners in the CRISPR Therapy Race*, SINGULARITYHUB (Apr. 7, 2019), https://singularityhub.com/2019/04/07/the-three-frontrunners-in-the-crispr-therapy-race/ [https://perma.cc/J3KD-S9XT]. Since Fan's article, two patients have received CRISPR/Cas-9 treatment for sickle-cell disease and another blood disorder, beta thalassemia. Sharon Begley & Adam Feuerstein, *First CRISPR Treatment for Blood Diseases Shows Early Benefit in Two Patients*, STAT (Nov. 19, 2019), https://www.statnews.com/2019/11/19/first-crispr-treatment-for-blood-diseases-shows-early-benefits/ [https://perma.cc/63JF-KG2F].

[203] *Walker*, 604 N.E.2d at 595.

[204] *See id.*

Likewise, the second prong of reasonable foreseeability is satisfied when focusing both on whether the victim was foreseeable and whether the harm suffered was foreseeable.[205] The victim—a CRISPR child—is foreseeable considering that a doctor specializing in CRISPR/Cas-9 genetic editing would likely hold himself or herself out as a specialist trained to do exactly what was sought out.[206] Moreover, harm is foreseeable even when a child is not yet conceived.[207] In *Albala v. City of New York*, the court recognized it was foreseeable that a mother might birth an injured child after undergoing an abortion that perforated her uterus seven years prior.[208] Like the abortion in *Albala*, CRISPR/Cas-9 has significant risks of injury.[209] Thus, because off-target effects are well-known dangers of CRISPR/Cas-9,[210] it must be accepted that a specialized doctor would be aware of said dangers.[211] Lastly, CRISPR/Cas-9 genetic editing would likely not even be performed without first executing a method that allows doctors to see the probabilities of CRISPR/Cas-9 cleaving at unintended sites in the genome.[212] The probability of off-target effects occurring gives rise to the foreseeability of these effects actually occurring.[213] Consequently, the second prong necessitating both a foreseeable victim and a foreseeable injury is met.[214]

Finally, the third prong for extending a duty to the unborn considers public policy.[215] In *Webb*, the court held that public policy weighed against recognizing such an extension of duty.[216] Importantly, the *Webb* court was

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[205] *See* Webb v. Jarvis, 575 N.E.2d 992, 996–97 (Ind. 1991).

[206] This would be like the doctor in *Martin v. St. John Hosp. & Med. Ctr. Corp.*, who represented that he was a specialist in gynecology and obstetrics. 517 N.W.2d 787, 790 (Mich. Ct. App. 1994). Just as a specialist in reproductive health must be aware that his or her job relates to fetuses and future children, the CRISPR doctor must also be aware that his or her job would relate directly to fetuses.

[207] *See, e.g.*, *Walker*, 604 N.E.2d at 595; Renslow v. Mennonite Hosp., 367 N.E.2d 1250, 1254 (Ill. 1977).

[208] 429 N.E.2d 786, 788, 790 (1981).

[209] *See supra* notes 13–14, 68–77, and accompanying text discussing CRISPR/Cas-9 off-target effects.

[210] *See* Begley, *supra* note 14 ("[G]enome-editing might disable a tumor-suppressor gene or activate a cancer-causing one. It might also allow pieces of two different chromosomes to get together, a phenomenon called translocation, which is the cause of chronic myeloid leukemia, among other problems.").

[211] Like there being well-known risks that a surgery performed on reproductive organs may endanger future pregnancies, the risks of CRISPR/Cas-9 would be well known to a doctor holding themselves out as a specialist in CRISPR/Cas-9 genetic therapy. *See* Martin v. St. John Hosp. & Med. Ctr. Corp., 517 N.W.2d 787, 790 (Mich. Ct. App. 1994).

[212] *See supra* note 76.

[213] Basic assumptions would support that a given probability gives foresight that an event may occur, making that event foreseeable.

[214] *See supra* notes 205–13 and accompanying discussion.

[215] *See Martin*, 517 N.W.2d at 790.

[216] Webb v. Jarvis, 575 N.E.2d 992, 997 (Ind. 1991).

concerned with doctor-patient loyalty.[217] The court thought that doctor-patient loyalty would be eroded if courts held that physicians have a duty to anticipate how a patient will respond to medication.[218] Similarly, the *Albala* court did not recognize a duty because it was afraid this extended duty would incentivize doctors to forego beneficial treatment to a mother in fear of future liability.[219] In the case of CRISPR children, none of the above public policy concerns apply.[220] Indeed, CRISPR parallels more aptly with the Rh cases.[221] Like the Rh cases, the performance of CRISPR/Cas-9 neither harms nor benefits the mother and is ideally only done to better a child's life.[222] Accordingly, public policy supports extending a physician's duty to those who are not yet born.

Finding a physician's duty to CRISPR children is consistent not only with prenatal and preconception tort law, but also with tort law's general aim of compensating victims and deterring would-be tortfeasors.[223] As a duty is already recognized to embryos or fetuses that are in utero,[224] it is not that big of a leap to impose a duty to embryos that are ex utero.[225] After all, the only difference is the embryo's location.[226] Furthermore, therein exists the argument that doctors owe a duty to society not to implant an embryo that will be born injured.[227] The doctor's duty to the CRISPR child would then extend to society as a whole.[228]

Lastly, there is an argument that a doctor owes a duty to the CRISPR child because of his or her acts of misfeasance.[229] In *B.R. v. West*, the court found that healthcare providers have a duty to non-patients when prescribing medication.[230] The court reasoned that the affirmative act of

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[217] *Id.*
[218] *Id.*
[219] *See* Albala v. City of New York, 429 N.E.2d 786, 790 (1981).
[220] *See* Walker v. Rinck, 604 N.E.2d 591, 595 (Ind. 1992).
[221] *See id.*
[222] *See id.*
[223] Powell III, *supra* note 120, at 358–59.
[224] *See* Section II.C for a discussion of prenatal injuries and duties.
[225] Powell III, *supra* note 120, at 357.
[226] Embryos that are in utero are in the mother's uterus. *In Utero*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/in%20utero [https://perma.cc/2AEA-S3YH]; *In Utero*, BLACK'S LAW DICTIONARY (11th ed. 2019). Meanwhile, embryos that are ex utero are outside of the mother's uterus. *Ex Utero*, DICTIONARY OF HUMAN EVOLUTION AND BIOLOGY, http://human-biology.key-spot.ru/search.php?key=ex+utero [https://perma.cc/U98P-46Z2]. Thus, the only difference is where the embryo is located.
[227] Weinberger et al., *supra* note 112, at 133.
[228] *Id.*
[229] *See Misfeasance*, BLACK'S LAW DICTIONARY (11th ed. 2019) (defining misfeasance as "[a] lawful act performed in a wrongful manner").
[230] 275 P.3d 228, 230 (Utah 2012). Briefly, the facts of *B.R. v. West* concern children left parentless after a medical provider negligently prescribed medication to their father that caused him to kill their mother. *Id.*

prescribing medication to a patient creates a risk to the patient's family.[231] The medical provider's acts of misfeasance therefore called for the extension of duty.[232] Along the same lines, it stands to reason that the doctor's act of misfeasance in performing CRISPR/Cas-9 creates a duty owed to the CRISPR child.[233]

In sum, doctors owe a duty to the CRISPR child such that the first element in the mistaken manipulation claim is satisfied. In keeping with tort doctrines, this duty assures that the doctor has reasonable qualifications in the profession and will exercise such attributes in a reasonably skillful, diligent, and caring manner.[234]

2. Breach

Since the issue of whether a duty exists in both preconception and prenatal tort claims has been the most prominent issue, the element of breach has experienced diminished importance.[235] Although this is likely to be the case with the CRISPR child's mistaken manipulation claim,[236] it is still important to discuss. Generally, breach is regarded as tortious conduct that occurs when the tortfeasor does not satisfy his or her duty to another.[237] The *Renslow* court memorably declared that a child has the "right to be born free from prenatal injuries foreseeably caused by a breach of duty to the child's mother."[238] While the *Renslow* court focused on the breach of a physician's duty owed to a mother, the same reasoning supports the inference that a CRISPR child also has the inherent right to be born unhindered by injuries caused when a physician breaches the duty owed to the child.[239]

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[231] *Id.* at 233–34.
[232] *Id.* at 231–33.
[233] This would be analogous to extending parental duties to acts of misfeasance. *See* Smolensky, *Creating Children*, *supra* note 15, at 302.
[234] *See* Worster v. Caylor, 110 N.E.2d 337, 339 (Ind. 1953) ("[T]he physician or surgeon who assumes to treat and care for a patient impliedly contracts that he has the reasonable and ordinary qualifications of his profession and that he will exercise reasonable skill, diligence and care in treating the patient.").
[235] *See* Browne, *supra* note 21, at 2596 ("Of the four elements of negligence (duty, breach, causation and injury), duty has taken center stage in preconception tort law, with causation playing a significant supporting role. Breach is of diminished importance because the issue is not whether the duty breached was the duty owed, but whether there was a duty of care to one not yet in existence.").
[236] Weinberger et al., *supra* note 112, at 133.
[237] *See* Casey v. Colo. Higher Educ. Ins. Benefits All. Tr., 310 P.3d 196, 201 (Colo. App. 2012).
[238] Renslow v. Mennonite Hosp., 367 N.E.2d 1250, 1255 (Ill. 1977).
[239] *See id.*

Notably, a tort case concerning an accident caused when a vessel broke free from a tugboat, *United States v. Carroll Towing Co.*,[240] gives valuable insight into the element of breach in the CRISPR child's mistaken manipulation claim. In *Carroll Towing Co.*, the court held that the owner's duty to prevent harm from a vessel breaking free is determined by "(1) [t]he probability that she will break away; (2) the gravity of the resulting injury, if she does; [and] (3) the burden of adequate precautions."[241] Mathematically, this is expressed as $B < P*L$, where B is the burden of the alternative, P is the probability of injury, and L is the severity of the injury.[242] Using this formula, the court determined that the burden for an employee to be on board the vessel being tugged was less than the probability of the harm multiplied by the severity of the harm.[243] Consequently, the owner of the vessel that broke free was held to have breached his duty because a reasonably prudent person would have foreseen the possibility of harm and then acted to minimize those harms.[244] After all, the cost of an alternative was less than the cost of the harm that occurred.[245]

In the CRISPR/Cas-9 context, the formula of $B < P*L$ can be theoretically applied to ascertain breach using off-target predicators.[246]

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[240] United States v. Carroll Towing Co., 159 F.2d 169 (2d Cir. 1947). In *Carroll Towing Co.*, the Grace Line chartered the Carroll tugboat to pull a barge named Anna C. *Id.* at 170–71. In order to move Anna C to a different dock, the Carroll attempted a difficult maneuver. *Id.* at 171. Unfortunately, this maneuver proved unsuccessful when Anna C was let loose and subsequently floated downstream. *Id.* Both the Grace Line and the Carroll were sued for Anna C's damage, and they defended on the basis that the owner of Anna C was also negligent. *Id.* They argued that Anna C would not have sunk if an employee had been onboard Anna C to alert them of her condition. *Id.*

[241] *Id.* at 173. When developing these three factors, the court drew attention to the fact that every vessel may eventually break loose of her moorings. *Id.* Under this factor analysis, liability attaches to the owner of the vessel when the burden of safety precautions is less than the probability of injury multiplied by the gravity of the injury.

[242] *Id.*

[243] *Id.*

[244] *See id.*; *see also* Doe v. St. Francis Hosp. & Med. Ctr., 72 A.3d 929, 944 (Conn. 2013) ("[A] plaintiff need not prove that the [defendant] actually foresaw . . . the extent of the harm suffered . . . plaintiff must [simply] prove that it is a harm of the same general nature as that which a reasonably prudent person in the [defendant's] position should have anticipated."); Hamilton v. Accu-Tek, 62 F. Supp. 2d 802, 849 (E.D.N.Y. 1999) ("There is negligence if a reasonably prudent manufacturer could foresee injury as a result of its conduct, and acted unreasonably in the light of what could be foreseen."); Morden v. Continental AG, 611 N.W.2d 659, 675 (Wis. 2000) ("A person fails to exercise ordinary care when . . . he does an act or omits a precaution under circumstances in which a person of ordinary intelligence and prudence ought reasonably to foresee that such act or omission will subject the person of another to an unreasonable risk of injury.").

[245] *See Carroll Towing Co.*, 159 F.2d at 173.

[246] *See* Kim et al., *supra* note 76 and accompanying text.

Notably, off-target predicators will give the probability of injury (P).[247] Although one guide will likely have a set of different probabilities because Cas-9 could cleave in many unintended sites, this comment recommends the court impose a rebuttable presumption in favor of the CRISPR child. Under this presumption, the court will value P as the highest probability given by the off-target predictor.

At first glance, the *Carroll Towing Co.* formula might seem like the perfect fit for ascertaining breach in the CRISPR child's mistaken manipulation claim.[248] The formula is compelling because there is a definite value for P.[249] Nonetheless, actually using the *Carroll Towing Co.* formula with set values for B and L creates issues. First, it is not known in the scientific community what every mutation would lead to, as scientists are "still unlock[ing] the secrets of the human genome."[250] Moreover, the potentially vast amount of diseases and defects would likely impose varying levels of harm, which directly affects any attempted damage calculation.[251] Consequently, it would be impossible to impose a value that actually indicates the severity of a potential injury. Any number given to satisfy L would likely just be a random guess. Courts would then be left with assigning an automatic value to L, making it a fixed number. Similarly, the burden of the alternative on the doctor may be unjustifiably small. After all, the doctor could simply not perform the CRISPR/Cas-9 genetic editing. Under this, B also becomes more of a fixed number. So, if B is a relatively small fixed number and L is also a fixed number, the only value that really fluctuates under different circumstances is P. Looking again at the full

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[247] *See, e.g.*, Shengdar Q. Tsai, Nhu T Nguyen, Jose Malagon-Lopez, Ved V Topkar, Martin J Aryee & J Keith Joung, *CIRCLE-seq: A Highly Sensitive In Vitro Screen for Genome-Wide CRISPR–Cas9 Nuclease Off-Targets*, 14 NATURE METHODS 607, 609 fig.2 (2017).

[248] *See supra* notes 240–245 and accompanying discussion of the *Carroll Towing Co.* formula.

[249] *See, e.g.*, Tsai et al., *supra* note 247.

[250] Researchers are currently studying the genetic component of diseases, but not all diseases have been attributed to a specific mutation. *See Genetic Disorders*, NAT'L HUM. GENOME RES. INST. (May 18, 2018), https://www.genome.gov/For-Patients-and-Families/Genetic-Disorders [https://perma.cc/49YD-KC49].

[251] Some diseases may lead to more medical treatment than other diseases. For instance, Parkinson's might be treated with simple dopamine administration. Neil Lava, *Medications for Parkinson's Disease*, WEBMD (Jan. 20, 2019), https://www.webmd.com/parkinsons-disease/guide/drug-treatments [https://perma.cc/5C4J-WH5E]. In contrast, Lou Gehrig's Disease, a neuromuscular disease, necessitates advanced wheelchairs or even speaking assistance once it inevitably leads to paralysis. Steven Dowshen, *Lou Gehrig's Disease (ALS)*, NEMOURS (Nov. 2017), https://kidshealth.org/en/kids/als.html [https://perma.cc/4LKR-H486]. Notably, even the same disease or defect could lead to differing levels of severity and consequently damages. *See* Turpin v. Sortini, 643 P.2d 954, 964 (Cal. 1982). Because the court in Turpin granted damages consistent with the cost of deafness, including specialized teaching and hearing equipment, it can be inferred that these damages would be less if the plaintiff wasn't completely hard of hearing—simplistically, there would be less rigorous teaching expenses, and the hearing equipment might be less sophisticated. *See id.*

Carroll Towing Co. formula, B < P*L,[252] it can be implied that any value of P with the slightest chance of off-target editing would cause a doctor to breach their duty to the CRISPR child.[253]

Notably, the burden of the alternative, B, would be larger if the court considered the CRISPR child's life with whatever defect the doctor is trying to eradicate. Under this, B would vary with the severity of the child's known defect. Doctors would then have more leeway in treatments for objectively bad diseases. The added leeway in the CRISPR/Cas-9 context would translate into using CRISPR/Cas-9 systems with more chances of off-target editing. However, this may be reasonable seeing as there is a sound interest in finding ways to eliminate certain diseases.[254]

Ultimately, the B < P*L formula is a useful tool when analyzing breach in the CRISPR/Cas-9 context, but it cannot be stringently followed by literally plugging in numbers. This comment thus recommends that courts consider the above factors, but also look on an ad hoc basis at what another doctor would do in a similar situation.[255] This is similar to a proposed breach of duty in reproductive-negligence cases.[256] That is, a physician breaches his or her duty of care when his or her conduct falls below "what is 'reasonable to expect of a professional given the state of medical knowledge at the time of the treatment in issue.'"[257] Finally, the court should also consider any legislation Congress passes that clarifies what diseases are "fair-game" to edit and in what circumstances CRISPR/Cas-9 can be used on human embryos.[258]

3. Actual Injury

A claim for negligence usually requires the element of actual injury, which is distinguishable from speculative injury.[259] The rationale behind needing an actual injury is to secure "the rights of individuals by putting within their reach suitable redress whenever their rights have been

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[252] *See* United States v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947).

[253] Rudimentary math reveals that if B is small and L is fixed, any value of P that makes P*L greater than B leads to a breach under the *Carroll Towing Co.* formula.

[254] Various groups are dedicated to raising funds for scientists to find cures to diseases. *See, e.g.*, *About NTSAD*, NAT'L TAY-SACHS AND ALLIED DISEASES, INC. (Aug. 8, 2019), https://www.ntsad.org/index.php/about [https://perma.cc/YN64-PCWZ] ("Leading the Fight to treat and cure Tay-Sachs, Canavan, Sandhoff, GM1 and related diseases.").

[255] Like typical medical malpractice claims, a breach would be observed when a doctor does not take the same care another doctor with a similar background would have taken in the same or similar circumstance. Foster v. Klaumann, 294 P.3d 223, 229 (Kan. 2013).

[256] *See* Fox, *supra* note 16, at 215.

[257] *See id.* (quoting Nowatske v. Osterloh, 543 N.W.2d 265, 272 (Wis. 1996)).

[258] *See* Baltimore et al., *supra* note 7, for an example of a cautious approach to human genetic editing.

[259] *See* Henry v. Dow Chem. Co., 701 N.W.2d 684, 688 (Mich. 2005).

actually violated."[260] Thus, only an actual injury and not a speculative injury will be recognized under negligence theory.[261] Unfortunately, the distinction is not always clear.[262]

Some courts have denied negligence claims where the injury was observed by increases in medical monitoring.[263] Such courts have typically held that increased medical monitoring is simply speculation of future harm.[264] However, the majority of courts have held that increased medical monitoring is a present injury.[265] The policy reasons behind the recognition of medical monitoring as an injury extends to public health interests, deterrence, the interest in early detection of disease, and societal notions of justice and fairness.[266]

In the context of CRISPR/Cas-9, a child may not immediately show physical signs of disease.[267] It is therefore pertinent that the court recognizes increased medical monitoring as an injury suffered by the

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[260] THOMAS M. COOLEY & D. AVERY HAGGARD, A TREATISE ON THE LAW OF TORTS, OR THE WRONGS WHICH ARISE INDEPENDENTLY OF CONTRACT § 32 (4th ed. 1935) (ebook).

[261] Right v. Breen, 890 A.2d 1287, 1293–94 (Conn. 2006).

[262] *See, e.g.*, Sadler v. PacifiCare of Nev., Inc., 340 P.3d 1264, 1272–73 (Nev. 2014). Here, the court discusses whether ongoing medical monitoring is a legal injury when there is no exposure to a specific toxin but simply exposure to unsafe conditions. *Id.*

[263] *See, e.g.*, Hinton ex rel. Hinton v. Monsanto Co., 813 So. 2d 827, 829 (Ala. 2001) (holding that recovery for medical monitoring will not be granted absent an apparent physical injury). Note that a physical injury is required in Alabama even if it is shown that the individual was exposed to toxic substances. The court reasons that to hold otherwise "would result in the courts of this State deciding cases based upon nothing more than speculation and conjecture." *Id.* at 830.

[264] Paz v. Brush Engineered Materials, Inc., 949 So. 2d 1, 5 (Miss. 2007) ("Recognizing a medical monitoring cause of action would be akin to recognizing a cause of action for fear of future illness.").

[265] *See, e.g.*, Friends for All Children, Inc. v. Lockheed Aircraft Corp., 746 F.2d 816, 825–26 (D.C. Cir. 1984); Potter v. Firestone Tire & Rubber Co., 863 P.2d 795, 823–825 (Cal. 1993).

[266] *Potter*, 863 P.2d at 824; Miranda v. Shell Oil Co., 26 Cal. Rptr. 2d 655, 660 (Cal. Ct. App. 1993).

[267] One of the diseases that CRISPR shows promise in treating is Tay-Sachs. *See* Sharon Begley, *New CRISPR Tool Has the Potential to Correct Almost All Disease-Causing DNA Glitches, Scientists Report*, STAT (Oct. 21, 2019), https://www.statnews.com/2019/10/21/new-crispr-tool-has-potential-to-correct-most-disease-causing-dna-glitches [https://perma.cc/TPV5-U75A]. Since CRISPR could potentially cure Tay-Sachs, it follows that the CRISPR/Cas-9 system can edit the four nucleotides in the gene that is attributed with Tay-Sachs, HEXA. *See id.* Now, if the CRISPR/Cas-9 system edited an otherwise "healthy" HEXA gene via an off-target effect, it is possible that the HEXA gene is mutated to now resemble the HEXA gene found in individuals with Tay-Sachs. Thus, the off-target effect of that CRISPR genetic editing is a child born with Tay-Sachs. Unfortunately, Tay-Sachs is not a disease that can be diagnosed immediately and may only manifest between the ages of two and ten. *See Tay-Sachs Disease*, HEALTHLINE, https://www.healthline.com/health/tay-sachs-disease#targetText=People%20with%20the%20juvenile%20form,%2C%20muscle%20cramps%2C%20and%20tremors [https://perma.cc/B7K3-RF4E].

CRISPR child.[268] Note that if the CRISPR child immediately displays signs of an injury, the price of medical monitoring would simply be part of the damages in the actual injury.[269]

Lastly, legal scholars have debated what constitutes a disability in the eyes of the court.[270] In this realm, courts could either follow disability laws and objectively determine what constitutes a disability, or they can use an alternative "market-based methodology."[271] Under a "market-based methodology," courts would recognize a defect that "most honest people would agree render the child's existence an injury."[272] This comment recommends following such a "market-based methodology," which will hopefully allow courts to take an honest look at what society currently considers a disability.[273]

4. Factual Cause

A defendant is typically the factual cause of an injury when they are a but-for cause of the plaintiff's injury.[274] A cause is considered a but-for cause when the event would not have occurred but for the defendant's act.[275] In the medical malpractice context, a plaintiff must prove that he or she would have obtained a more favorable result but for the negligence of the defendant.[276] Thus, if an event would occur regardless of how the defendant acts, the defendant's conduct cannot be considered a but-for cause.[277]

In the case of the CRISPR child, but-for causation will not be a substantial issue.[278] Notably, a doctor will have to sequence the CRISPR

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[268] *See Potter*, 863 P.2d at 824–25.

[269] *See* McLeod v. Cont'l Ins. Co., 591 So. 2d 621, 624 (Fla. 1992) ("[T]he damages recoverable . . . are those damages which are the natural, proximate, probable, or direct consequence of the [act]."); *see also* Fisher v. City of Miami, 172 So. 2d 455, 457 (Fla. 1965) ("[T]he primary basis for an award of damages is compensation [and] the objective is to make the injured party whole.").

[270] *See* Weinberger et al., *supra* note 112, at 130.

[271] *Id.*

[272] *Id.* (quoting Wendy Fritzen Hensel, *The Disabling Impact of Wrongful Birth and Wrongful Life Actions*, 40 HARV. C.R.-C.L. L. REV. 141, 181 (2005)).

[273] *See id.*

[274] *See, e.g.*, Hale v. Ostrow, 166 S.W.3d 713, 718 (Tenn. 2005) ("The defendant's conduct is the cause in fact of the plaintiff's injury if, as a factual matter, it directly contributed to the plaintiff's injury. In a case such as this one, we must ask whether the plaintiff's injury would have happened "but for" the defendants' act.").

[275] Watson v. Meltzer, 270 P.3d 289, 293 (Or. Ct. App. 2011) ("[I]n order to prevail in a negligence action, a plaintiff must establish that *but for* the negligence of the defendant, the plaintiff would not have suffered the harm that is the subject of the claim.").

[276] Jeffries v. Mills, 995 P.2d 1180, 1192 (Or. Ct. App. 2000).

[277] *Hale*, 166 S.W.3d at 718.

[278] *See* Weinberger et al., *supra* note 112, at 133 (discussing proximate cause only briefly).

child's DNA before CRISPR/Cas-9 is performed.[279] Then, after CRISPR/Cas-9 is performed, the doctor will presumably sequence the child's DNA again to see if the CRISPR worked. So, there will be two sets of DNA to compare: (1) DNA before CRISPR and (2) DNA after CRISPR. If there are differences in the DNA sequences, it can be assumed that the CRISPR/Cas-9 editing is what changed the DNA. This assumption is not only reasonable, but it is consistent with the tort law aim of compensating victims.[280] Thus, but for the performance of CRISPR/Cas-9, the genetic alteration would not have occurred.

Nonetheless, the CRISPR child may still not prevail under but-for causation because not all diseases are linked to a specific mutation.[281] However, this comment recommends that the court presume any diseases that manifest after CRISPR/Cas-9 editing are caused by the genetic editing. This presumption would fit well with already established precedence that allows a plaintiff to circumvent the traditional but-for test.[282]

For instance, the court created market share liability to evade but-for causation when a faulty drug, diethylstilbestrol (DES), caused increased risks of cancer.[283] DES was administered as a synthetic hormone with the purpose of preventing miscarriages from 1941 to 1971.[284] During the time drug manufacturers marketed DES, they knew or should have known of the drug's propensity to cause cancerous growths.[285] Nonetheless, drug manufacturers continued to advertise DES as safe, collaborating with other drug manufacturers in marketing, and testing the drug to create industry-wide standards.[286] Because the typical DES plaintiff could not identify the specific drug manufacturer who created the exact pill ingested, the plaintiff

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[279] Sequencing is necessary because of designing gRNAs.

[280] Jarmie v. Troncale, 50 A.3d 802, 814–15 (Conn. 2012) (quoting *Lodge v. Arett Sales Corp.*, 717 A.2d 215, 223 (Conn. 1998)).

[281] *See, e.g.*, *Alzheimer's Disease Genetics Fact Sheet*, NAT'L INST. ON AGING, https://www.nia.nih.gov/health/alzheimers-disease-genetics-fact-sheet [https://perma.cc/PH39-U5MK] (noting that scientists are realizing that genes play a role in Alzheimer's disease but don't know exactly what genes play a role in causing it).

[282] *See infra* notes 283–89.

[283] *See* Sindell v. Abbott Lab'ys., 607 P.2d 924, 936 (Cal. 1980); *see also Diethylstilbestrol (DES) and Cancer*, NAT'L CANCER INST. (Oct. 5, 2011), https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/des-fact-sheet [https://perma.cc/X8HK-FFBY] ("The daughters of women who used DES while pregnant—commonly called DES daughters—have about 40 times the risk of developing clear cell adenocarcinoma of the lower genital tract than unexposed women . . . . DES daughters have an increased risk of developing abnormal cells in the cervix and the vagina that are precursors of cancer . . . . DES daughters may also have a slightly increased risk of breast cancer after age 40.").

[284] *See Sindell*, 607 P.2d at 925.

[285] *Id.*

[286] *Id.* at 926.

would have failed under the traditional but-for test.[287] Due to the traditional notions of fairness in tort law,[288] the court decided to create market share liability—imposing several liability on all market participants.[289]

Similarly, the multiple sufficient factors test in tort law also supports a presumption that the CRISPR child's disease was caused by a DNA mutation.[290] The court in *Summers v. Tice* most famously put this test forth in 1948.[291] In *Summers*, two hunters both independently fired guns in the plaintiff's direction, and although only one bullet hit the plaintiff, both hunters were held liable for the plaintiff's injury.[292] Thus, if but-for fails because there are multiple sufficient causes, each cause is regarded as a factual cause of the injury.[293]

With the aforementioned exceptions to but-for causation and the sound public policy of fairness and compensation, it follows that courts should presume that the CRISPR child's disease was caused by the already established genetic alteration.[294] Under this presumption, a doctor will be presumed to be the but-for cause of the CRISPR child's injury so long as there is a showing that the CRISPR/Cas-9 system effectively altered the child's DNA. Then, the burden can shift to the physician to show that the disease was caused by something under the CRISPR/Cas-9 genetic editing. The presumption will therefore be a rebuttable presumption in favor of the CRISPR child.

5. Legal Cause

Legal cause, or scope of the risk analysis, asks whether the plaintiff's injury falls within a set of injuries that are normally associated with the defendant's act.[295] Simplistically, legal cause will likely not be a problem for the CRISPR child because the risks of genetic alterations are well known.[296] Likewise, some chemical pathways that are used in CRISPR/Cas-

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[287] *See* Gorman v. Abbott Labs., 599 A.2d 1364, 1364 (R.I. 1991) (requiring an identifiable defendant for tort liability).
[288] *See Sindell*, 607 P.2d at 930.
[289] *Id.* at 936–37.
[290] *See* RESTATEMENT (THIRD) OF TORTS § 27 (AM. L. INST. 2012).
[291] *See* Summers v. Tice, 199 P.2d 1, 5 (Cal. 1948).
[292] *See id.*
[293] *See* Landers v. E. Tex. Salt Water Disposal, 248 S.W.2d 731, 735 (Tex. 1952).
[294] *See supra* notes 283–89.
[295] *See* Melchor v. Singh, 935 N.Y.S.2d 106, 110 (N.Y. App. Div. 2011) (noting that a ladder without rubber feet is a proximate cause to falling off the ladder).
[296] *See* Begley, *supra* note 14; *see also* JEAN BRAINARD, CK-12 BIOLOGY (2020) (ebook) ("[A]ny random change in a gene's DNA is likely to result in a protein that does not function normally or may not function at all. Such mutations are likely to be harmful. Harmful mutations may cause genetic disorders or cancer.").

9 genetic editing are readily recognized as error-prone.[297] For instance, the Non-Homologous End Joining (NHEJ) repair mechanism that fixes double-stranded breaks in DNA is known to cause errors by inserting or deleting unintended bases in the target DNA.[298] Finally, the chance of off-target effects occurring is clearly well recognized because otherwise there wouldn't be such a significant need for creating off-target predicators.[299] Consequently, the chance that the CRISPR/Cas-9 system edits an unintended site in the genome and thereafter causes injury to the CRISPR is well within the scope of the risk.

Although some courts have denied medical malpractice actions on scope of the risk grounds, this is usually only an issue with intergenerational harms.[300] In such cases, courts have historically limited recovery to certain generations.[301] However, this comment only addresses the harm suffered by the immediate plaintiff and not any intergenerational harm, as that is beyond the scope of this comment.

Accordingly, a negligence claim brought against a doctor who intended to perform beneficial CRISPR/Cas-9 genetic editing can be satisfied when a child suffers off-target, harmful effects stemming from the genetic editing. The first scenario has thus been analyzed, and the comment will now explore the latter scenario of intentionally imposing defects on a child using CRISPR/Cas-9.

C. Battery

This section will analyze the second scenario imposed on the hypothetical CRISPR child: when a doctor uses CRISPR/Cas-9 to purposefully impose a defect on a child, and that child subsequently suffers harm. In accordance with this comment's theme of utilizing preexisting tort frameworks, the tort claim of battery will be explored since it relates most closely to the CRISPR child's scenario. Notably, an actor is liable for battery if he or she (a) acts "intending to cause harmful or offensive contact with the person of the other or a third person, or an imminent apprehension of such a contact, and (b) a harmful contact with the person of the other directly or

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[297] Tianyuan Su, Fapeng Liu, Pengfei Gu, Haiying Jin, Yizhao Chang, Qian Wang, Quanfeng Liang & Qingsheng Qi, *A CRISPR-Cas9 Assisted Non-Homologous End-Joining Strategy for One-Step Engineering of Bacterial Genome*, SCI. REPS. 1, 1 (2016) ("[T]he NHEJ repair mechanism tends to be prone to insertion and/or deletion (indel) mutations at the junctional site. Thus, with the assistance of the programmable CRISPR-Cas9 DNA cleavage system, NHEJ can generate frameshift mutations that disrupt the targeted gene[.]").

[298] *See* Walker-Daniels, *supra* note 56, at Figure 3.

[299] *See generally* Zhang et al., *supra* note 65.

[300] *See* Grover v. Eli Lilly & Co., 591 N.E.2d 696, 700 (Ohio 1992).

[301] *See* Enright v. Eli Lilly & Co., 570 N.E.2d 198, 203 (N.Y. 1991) (limiting recovery to those who ingested the drug or who were exposed to it in utero).

indirectly results."[302] Both elements of battery will be analyzed separately in conjunction with the CRISPR child's mistaken manipulation claim, beginning with the first element of intention to cause harmful or offensive contact

1. Intention to Cause Harmful or Offensive Contact

An act is done with intent when the actor has purpose or knowledge with substantial certainty that the event will occur.[303] For instance, the court in *Garratt v. Dailey* held that intent could be satisfied when a five-year-old defendant pulled his aunt's chair out from under her.[304] Although the defendant may not have intended to cause harm, intent was satisfied so long as he knew that the plaintiff was going to sit in the chair.[305] In the CRISPR child's case, the doctor would be acting with intent because he or she would have the purpose of imposing such a defect. After all, the doctor would be aware of the parents' goal of selectively having a child with a defect.

Furthermore, the act must be harmful or offensive to a reasonable person's sense of dignity.[306] In this case, the doctor's actions against the CRISPR child would easily be considered harmful. Society generally recognizes that children should be born with "sound mind and body[]" and an imposition of a defect would violate this principle.[307] Consistent with this rationale, intentionally limiting a child's opportunities before he or she even begins life is certainly a harm.[308] If the above is not persuasive, the court could also construe what disabilities or defects are considered injuries, as discussed *supra* in the negligence part of this comment.[309] Then, the court could employ a "market-based methodology" that classifies disabilities or defects as harmful when the average person would think they were indeed harmful.[310]

Finally, note that it is irrelevant in this hypothetical whether the CRISPR child is suing in a single or dual intent jurisdiction. In single intent jurisdictions, an actor can be held liable for battery so long as they intended to make contact—it does not matter if they did not intend to make harmful

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[302] RESTATEMENT (SECOND) OF TORTS § 13 (AM. L. INST. 1965).
[303] *See* Goodin v. Columbia Gas of Ohio, 750 N.E.2d 1222, 1230–34 (Ohio Ct. App. 2000).
[304] Garratt v. Dailey, 279 P.2d 1091, 1094 (Wash. 1955).
[305] *Id.* at 1094–95.
[306] RESTATEMENT (SECOND) OF TORTS § 13 (AM. L. INST. 1965); *see also* Wishnatsky v. Huey, 584 N.W.2d 859, 861 (N.D. Ct. App. 1998).
[307] *See* Smith v. Brennan, 157 A.2d 497, 503 (N.J. 1960).
[308] *See* Feinberg, *supra* note 23.
[309] *See supra* Section III.B.3.
[310] Weinberger et al., *supra* note 112, at 130 (quoting Wendy Fritzen Hensel, *The Disabling Impact of Wrongful Birth and Wrongful Life Actions*, 40 HARV. C.R.-C.L. L. REV. 141, 181 (2005)).

or offensive contact.[311] Conversely, dual intent jurisdictions require that the actor both intended to make contact and intended that the contact would be harmful or offensive.[312] As discussed, *supra*, the doctor must intend to make harmful contact in this hypothetical because the parents are seeking to impose a defect. Thus, the plaintiff would be able to succeed on a mistaken manipulation claim for battery in a dual intent jurisdiction. Since a dual intent jurisdiction is more stringent than a single intent jurisdiction, the plaintiff would therefore be able to succeed in a single intent jurisdiction as well.[313]

Ultimately, an intentional imposition of a defect using CRISPR/Cas-9 will therefore meet the first element of battery: intention to cause harmful or offensive contact. The analysis will now move to the second element of battery.

2. Harmful or Offensive Contact Occurred

The second element of battery requires that the harmful or offensive contact must have actually occurred. [314] In the CRISPR/Cas-9 context, the harmful contact will occur as soon as the doctor edits the embryo—once the doctor uses CRISPR/Cas-9 on the embryo.

Consequently, the elements of battery can easily be satisfied when a defect is purposefully imposed on a child using CRISPR/Cas-9.

IV. DISPELLING COUNTERARGUMENTS

This comment has thus far put forth a CRISPR child's mistaken manipulation claim in the context of (1) negligence and (2) battery. The claim of negligence arises in the CRISPR/Cas-9 context when a child suffers unintended off-target effects from the CRISPR/Cas-9 genetic editing. In contrast, battery applies when a defect is purposefully imposed on the child using CRISPR/Cas-9 technology. The following section will explore potential defenses that may be raised in either scenario. Section A will briefly explore, and then dismiss, parental tort immunity.[315] Then, Section B will enumerate why the mistaken manipulation claim does not suffer the

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[311] *See, e.g.*, White v. Univ. of Idaho, 797 P.2d 108, 109 (Idaho 1990) ("[U]nder Idaho law the intent required for the commission of a battery is simply the intent to cause an unpermitted contact not an intent that the contact be harmful or offensive.").

[312] *See, e.g.*, White v. Muniz, 999 P.2d 814, 815 (Colo. 2000).

[313] A single intent jurisdiction can be considered less stringent than a dual intent jurisdiction simply because the plaintiff only needs to show an intent to cause contact. This is a lesser showing than what is necessary for a plaintiff to prove in a dual intent jurisdiction. *See id.*

[314] RESTATEMENT (SECOND) OF TORTS § 13 (AM. L. INST. 1965); *see also* Sanderson Farms, Inc. v. McCullough, 212 So.3d 69, 76 (Miss. 2017).

[315] *See infra* Section IV.A.

same problem that wrongful life claims do—the inability to calculate damages.[316] Lastly, Section C will explain why the parents' consent to the CRISPR/Cas-9 genetic editing does not bar the CRISPR child's recovery.[317]

A. Parental Tort Immunity

Parental tort immunity was established in *Hewellette v. George*.[318] In *Hewellete*, a mother placed her daughter in an insane asylum in order to gain control of the daughter's assets.[319] The daughter sued her mother, but the court held that the daughter could not recover because parents could not be held liable for torts against their children.[320] The justifications for the newly created parental tort immunity were that it protected: "a) the state's interest in maintaining and preserving family harmony, b) the fear of fraudulent, collusive claims, c) the protection of family finances, d) the protection of parental discretion and authority, and e) the analogy to spousal immunity."[321]

Currently, most courts have withdrawn such broad parental tort immunity.[322] Typically, parental tort immunity no longer applies to wanton or willful misconduct on the part of the parent.[323] Other scholars have discussed parental tort immunity in the context of genetic alterations,[324] but any such parental tort defense would not apply in either mistaken manipulation scenario. Although the CRISPR child may attempt to sue their parent, the scope of this article has focused on whether the *doctor* performing the CRISPR/Cas-9 is liable. Since the doctor is presumably not the CRISPR child's parent, parental tort immunity would not bar the child's claim.[325]

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[316] *See infra* Section IV.B.

[317] *See infra* Section IV.C.

[318] *See* Hewellette v. George, 9 So. 885, 887 (Miss. 1891), *overruled by* Glaskox By & Through Denton v. Glaskox, 614 So. 2d 906 (Miss. 1992).

[319] *Hewellette*, 9 So. at 886.

[320] *Id.* at 887.

[321] Martin J. Rooney & Colleen M. Rooney, *Parental Tort Immunity: Spare the Liability, Spoil the Parent*, 25 NEW ENG. L. REV. 1161, 1163 (1991) (footnotes omitted).

[322] RESTATEMENT (SECOND) OF TORTS § 895G(1) (AM. L. INST. 1965) ("A parent or child is not immune from tort liability to the other solely by reason of that relationship."). *But see* Frye v. Frye, 505 A.2d 826, 838–39 (Md. 1986) (keeping parental tort immunity in negligence cases).

[323] *See* Schenk v. Schenk, 241 N.E.2d 12, 15 (Ill. App. Ct. 1968).

[324] *See* Grant Hayes Frazier, *Defusing a Ticking Time Bomb: The Complicated Considerations Underlying Compulsory Human Genetic Editing*, 10 HASTINGS SCI. & TECH. L.J. 39, 65–66 (2019); *see also* Smolensky, *Creating Children*, *supra* note 15, at 314–17.

[325] *See* Glaskox By & Through Denton v. Glaskox, 614 So. 2d 906, 909 (Miss. 1992) ("The principle of parental immunity bars an unemancipated minor from suing her *parent* for injuries caused by the negligence of the parent.") (emphasis added).

B. Inability to Calculate Damages

As the law stands today, courts may erroneously construe a CRISPR child's claim—a mistaken manipulation claim—as a wrongful life claim. However, this would be improper because the CRISPR child would not be claiming that he or she should never have been born at all. Rather, the child would be claiming that he or she should have never been defectively edited. With traditional wrongful life claims, the alternative to birthing the defective child is abortion. However, with CRISPR, the alternative to birthing the defective child is simply not to impose such defects. The court would therefore be able to avoid the "impossibility" of comparing a defective condition to nonexistence.[326] In assessing damages, the court could compare the defective condition to a healthy, normal child. The more fitting analysis to determine damages would then be injuries that have occurred post conception.[327]

C. Consent as a Defense

The fact that the parent consented to the CRISPR child's genetic editing will not bar the child from succeeding on a mistaken manipulation claim. The reasoning as to why consent does not defeat the claim is different depending on whether the claim is a negligence claim or a battery claim. Due to this difference, both claims will be explored independently.

Beginning with the negligence claim, courts have held that informed consent and medical negligence are two completely separate causes of action.[328] Where informed consent concerns the disclosure of relevant facts so the patient can make an informed decision,[329] medical negligence concerns whether the physician exercised the appropriate degree of skill and care.[330] In medical negligence actions, the argument of consent is irrelevant.[331] Consequently, the parent's consent has no bearing on the CRISPR child's mistaken manipulation claim. Alternatively, CRISPR/Cas-9 is such an advanced scientific concept that therein exists an argument that the parents' general lack of knowledge cannot be addressed by informed consent.[332]

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[326] *See* Gleitman v. Cosgrove, 227 A.2d 689, 692 (N.J. 1967) ("This Court cannot weigh the value of life with impairments against the nonexistence of life itself.").

[327] *See, e.g.*, Saunders By & Through Saunders v. United States, 64 F.3d 482, 486 (9th Cir. 1995).

[328] *See, e.g.*, Gomez v. Sauerwein, 331 P.3d 19, 22–23 (Wash. 2014).

[329] Burnet v. Spokane Ambulance, 772 P.2d 1027, 1030 (Wash. Ct. App. 1989).

[330] *See* Boone v. William W. Backus Hosp., 864 A.2d 1, 14–15 (Conn. 2005).

[331] Mitchell v. Shikora, 209 A.3d 307, 311 (Pa. 2019).

[332] *See* Kendall Lovell, Comment, *CRISPR/Cas-9 Technologies: A Call for a New Form of Tort*, 19 SAN DIEGO INT'L L.J. 407, 417 (2018).

For the battery claim, it would be bad public policy to recognize a defense that the parent consented to a third party causing intentional harm to child. Courts look unfavorably upon child abuse, and to allow a doctor to cause intentional harm would be contrary to protocols—such as mandatory reporting—that place doctors in the "'first line of protection' for abused children."[333]

V. CONCLUSION

Genetic editing is no longer science fiction. Already, CRISPR/Cas-9 has been used to edit human embryos. With the rapid pace of CRISPR/Cas-9 achievements, it is only a matter of time before parents can genetically alter their children. It is therefore imperative that a legal scheme be created to allow recovery for a CRISPR child's mistaken manipulation claim. Courts must first recognize that the mistaken manipulation claim is different from a wrongful life claim. Then, to incorporate preexisting legal frameworks into the mistaken manipulation claim, courts should look to tort law.

If a child suffers unintended off-target effects and subsequently experiences harm, the child's mistaken manipulation claim will mirror a negligence claim. If a child suffers harm from a defect that was purposefully imposed on him or her, the child's mistaken manipulation claim will emulate a battery claim. Without these claims, countless plaintiffs will be left with detrimental genetic editing and no viable means of recovery.

[333] Becker v. Mayo Found., 737 N.W.2d 200, 210 (Minn. 2007).

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