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CRISPR/Cas-9 Technologies: A Call for a New Form of Tort

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ABSTRACT

Once relegated to the domains of science fiction, modern day scientists and researchers are poised on the precipice of making genome editing clinically available. Once introduced into a clinical setting the effects of an off-target mutation or germline edit will remain largely unknown until health issues arise later in life or in the following generation. The novelty of the injuries that will arise require a system that is able to balance the interests of physicians with single and multi-generational plaintiffs, while providing a realistic framework for courts to follow. This comment offers a brand-new context that accounts for these needs and sets expectations for how to handle these injuries in the right way, promulgating the goals of tort law.

I. INTRODUCTION

Imagine you and your spouse have always wanted to have children together. It is important to both of you that your children be genetically related; however, your brother has Hunter's Syndrome making you a carrier of the disease.[1] If the choice is between a genetic child with Hunter's Syndrome and adopting, you would rather adopt. Luckily, you are aware that CRISPR/Cas-9 is now being offered on a clinical basis.[2] This technique enables doctors to edit out certain genes from your child's genetic makeup so that they are born with, or without, certain features including genetic diseases like Hunter's Syndrome. You and your husband go to a nearby clinic and are reassured by the doctor you will have a healthy child, free from genetic defects.[3] Feeling reassured, you pay for the genome editing and undergo the litany of tests, invasive surgeries and steroids[4] in order to conceive your child. Nine months later, your doctor hands the two of you your son, and everything is perfect for two years until you begin noticing developmental

1. Hunter's Syndrome is a rare genetic disorder caused by a missing enzyme. The missing enzyme causes the body to be unable to breakdown certain molecules leading to molecular build up, which impairs development, organ function and physical abilities. Hunter's Syndrome is hereditary and is passed down from the mother's genetic makeup. The disease is quite painful and requires lifelong care. *See Hunter Syndrome - Symptoms and Causes*, MAYO CLINIC (2015), http://www.mayoclinic.org/diseases-conditions/hunter-syndrome/diagnosis-treatment/diagnosis/dxc-20165681 [https://perma.cc/ 329K-N6FZ] (last visited Jan. 21, 2018) .

2. CRISPR/Cas-9 technology is not yet at this stage, but it is only a matter of time, as is discussed later in this comment.

3. This hypothetical is loosely based on the seminal Israeli case CA 518/82 Zeitzov v. Katz 40(2) PD 85 (1986) (Isr.).

4. Steve. P. Calandrillo & Chryssa V. Deliganis, *In Vitro Fertilization and The Law: How Legal and Regulatory Neglect Compromised a Medical Breakthrough*, 57 ARIZ. L. REV. 311, 314–20 (2015).

abnormalities in your child.[5] You and your spouse take your child to his pediatrician's office and are referred to a specialist. After numerous tests you learn that the genome editing you paid for was performed improperly —your child has Hunter's Syndrome. He inherited the disease from you as a result of the doctor's negligence.

In a different scenario, imagine you are the mom of three young boys. Due to developmental delays, the doctor suspects that your eldest son has muscular dystrophy. You consent to the blood test necessary to confirm the diagnosis,[6] and the results come back positive for Duchenne Muscular Dystrophy ("DMD").[7] Boys who suffer from DMD quickly become wheelchair bound,[8] require ventilators,[9] and die before the age of thirty.[10] The doctor informs you that there is a genetic component to DMD;[11] therefore, there is the potential that the mutation exists in your other two sons as well.[12] You have your younger two sons tested and both tests come back positive. You are now faced with the prospect of watching your children die slowly

5. Hunter's Syndrome typically effects males who begin to show symptoms between eighteen-months and two-years of age. Often the initial symptoms are a noticeable regression in motor skills or fine movements. Recognizable symptoms include changes in facial features, the cessation of speech and regression from walking to crawling. *Hunter Syndrome - Symptoms and Causes*, *supra* note 1, at 2.

6. NATIONAL INSTITUTES OF CHILD HEALTH & HUM. DEVELOPMENT, *How is Muscular Dystrophy Diagnosed?*, https://www.nichd.nih.gov/health/topics/musculardys/conditioninfo/pages/diagnosed.aspx [https://perma.cc/GHX4-58FG] (last updated Dec. 1, 2016).

7. DMD is a form of muscular dystrophy that effects one in thirty-six hundred boys and leads to progressive weakening and degeneration of the bodies muscles. DMD effects most muscles within the body by the time the child reaches their late teenage years, including the muscles that control the lungs and heart. *Duchenne Muscular Dystrophy*, N.Y. TIMES, http://www.nytimes.com/health/guides/disease/duchenne-muscular-dystrophy/overview.html (last visited Jan. 15, 2017). *See also* Alan E.H. Emery, *The muscular dystrophies*, 359 LANCET 687, 687–95 (2002).

8. Moser, H., *Duchenne muscular dystrophy: pathogenetic aspects and genetic prevention*, HUM. GENET. 66, 17–40 (1984).

9. *Id.*

10. Hoffman et al., *Dystrophin: the protein product of the Duchenne muscular dystrophy locus*, 51 CELL 919, 919 (1987). In general, patients with DMD tend to become wheelchair bound between the ages of 8 to 10, and usually die around the age of 20. *Id.*

11. DMD is an X-linked recessive disorder that primarily affects boys. They inherit the mutation from their mother who is a carrier of the DMD gene. *Duchenne and Becker Muscular Dystrophy*, U.S. NATIONAL LIBRARY OF MEDICINE, https://ghr.nlm.nih.gov/condition/duchenne-and-becker-muscular-dystrophy#inheritance [http://perma.cc/WV8Q-KZVW] (last visited Jan. 17, 2017).

12. This hypothetical is loosely based on the experiences of Betty Vertin. *See* Betty Vertin, *My Family's Journey with Duchenne Muscular Dystrophy*, E PARENT MAGAZINE, 2016.

and painfully over time. However, CRISPR/Cas-9 offers some relief.[13] In this context, rather than modifying the genome before pregnancy, CRISPR/Cas-9[14] allows doctors to repair the mutation of the dystrophin gene.[15] This is a one-time procedure that is relatively non-invasive.[16] The treatment is not a cure-all and those with DMD will still experience some symptoms, though they are much less severe[17] and make the genetic mutation nonfatal.[18] Regardless, your family decides to proceed with the treatment and is initially thrilled by the results. However, a few years later your middle child begins showing more severe symptoms eventually requiring the use of a wheelchair. When you go back to the doctor, you discover the doctor failed to properly edit the dystrophin gene in the muscle stem cells.[19] As time passed, the therapeutic effects of the CRISPR/Cas-9 treatment faded.[20]

The doctor is unable to tell you whether the progression can be stopped. Regardless, the damage already been done is irreversible. Two possible scenarios position themselves. Either the doctor attempts to remedy his mistake, fails, and your son dies from DMD despite your efforts. Or the doctor remedies his mistake and slows the progress, but your son remains wheelchair bound for the remainder of his life. As for the other two sons, the parents are left hopeless and watch anxiously to see signs that their treatments have also failed.

In one final scenario, imagine parents are aware of a genetic history of hemophilia in their family. Before having their own children, they enlist

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13. Charis L. Himeda et al., *Scalpel or Straitjacket: CRISPR/Cas9 Approaches for Muscular Dystrophies*, 37 TRENDS IN PHARMACOLOGICAL SCIENCES 249, 249 (2016) (There are currently no successful, long-term treatments for DMD though CRISPR/Cas-9 have shown promising results.)

14. In combination with induced pluripotent stem cells. Hongmei Lisa Li et. al., *Precise Correction of the Dystrophin Gene in Duchenne Muscular Dystrophy Patient Induced Pluripotent Stem Cells by TALEN and CRISPR-Cas9*, 4 STEM CELL REPORTS 143–54 (2015).

15. *Id.* at 143.

16. Himeda, *supra* note 13, at 250.

17. *Id.* at 249.

18. *Id.* This hypothetical assumes that these experiments, though currently successful in mice and monkeys, survives the human trial phase of testing. The younger the age of the individual being treated, the milder the form of DMD should be. As a result, in this hypothetical these boys should only manifest a mild form of the disorder. *See also* Antonio Regalado, *Can CRISPR Save Ben Dupree?*, MIT TECH. REV. (Oct. 17, 2016), https://www.technologyreview.com/s/602491/can-crispr-save-ben-dupree/ [https://perma.cc/DS74-PZST].

19. This is necessary for the body to maintain dystrophin production. Jocelyn Kaiser, *CRISPR Helps Heal Mice With Muscular Dystrophy*, SCIENCE (Dec. 31, 2015, 2:00 PM), http://www.sciencemag.org/news/2015/12/crispr-helps-heal-mice-muscular- [https://perma.cc/NX47-N2YU].

20. *Id.*

the help of a physician who will perform CRISPR/Cas-9 on their zygotes[21] prior to implantation of a fertile egg to avoid passing the disorder on to future generations.[22] Nine months later, they have a beautiful girl! As a female, it is unlikely that the X-chromosome linked genetic disorder will exhibit any symptoms,[23] but she might be a carrier[24] and without genome editing, the disorder has a 50% chance of manifesting in any sons she may have.[25] For personal reasons, her parents never disclose to her that she is a CRISPR/Cas-9 baby. She is completely unaware hemophilia was ever once a part of her genetic makeup growing up. Fast forward to adulthood; she gives birth to a baby boy, but before leaving the hospital, the doctors perform a routine circumcision; except her son will not stop bleeding.[26] The doctors use supplementary coagulation therapy,[27] take a small blood sample, and test him for hemophilia.[28] The test results come back positive. The news is devastating; this means an entirely different life other than imagined for the son.[29] The doctors ask the parents if they or their families

21. Merriam Webster defines a zygote as "a cell formed by the union of two gametes." *Zygote*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/zygote [http://perma.cc.K56X-94U8] (last visited Jan. 23, 2018).

22. About 80% of all cases of hemophilia have an identifiable history of the disease. Leon L. Bram & Norma H. Dickey, FUNK & WAGNALLS NEW WORLD ENCYCLOPEDIA (2016).

23. *Id.*

24. Potential carriers are women whose carrier status cannot be clearly defined from the pattern of inheritance but have a maternal hemophilic relative. Additional testing can be performed to ascertain the certainty of the carrier status, but one must be aware that testing is necessary, i.e. that there is a family history of hemophilia. *See generally* Riva Miller, *Counselling about Diagnosis and Inheritance of Genetic Bleeding Disorders: Haemophilia A and B*, 5 HAEMOPHILIA 77, 78 (1999).

25. *See Heredity of Hemophilia*, CAN. HEMOPHILIA SOC'Y, http://www.hemophilia.ca/en/bleeding-disorders/hemophilia-a-and-b/heredity-of-hemophilia/ [https://perma.cc/T39Q-AZRQ] (last visited Jan. 17, 2018).

26. *Diagnosis*, CENT. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/ncbddd/c.

27. *See* Hassan Mansouritorghabeh et. al., *Circumcision in Males with Bleeding Disorders*, 5 MEDITERR. J. HEMATOL. INFECT. DIS. (2013). Supplementary coagulation therapy is designed to cut off the blood supply to a certain area as the patient is unable to stop bleeding when they suffer from hemophilia. *See* Mathews V. et al., *Surgery for hemophilia in developing countries*, 31 SEMINARS IN THROMBBOSIS & HEMOSTASIS. 538, 43 (2005).

28. To test for hemophilia A or B in a child, a physician takes a blood sample and measures the amount of factor VIII and IX in the blood. Miller, *supra* note 24, at 78–79.

29. Prevention of trauma is particularly important for children with hemophilia, this requires children to abstain from or be particularly careful during certain normal childhood activities, such as when on the playground. *See generally* Wagnalls, *supra* note 22.

have a history of hemophilia; it is emphatically denied. Upon hearing this, her parents, wracked with guilt, confess they had their daughter's genome edited before birth in the hope of avoiding this exact situation.[30] Unfortunately, now not only is the daughter dealing with the news and effects of the improper genome editing, but so is your son—and the physician? He died five years ago and will never know how he injured your family. Therefore, in these circumstances, the question turns on who will be held liable for a devastating and pervasive injury.

II. CRISPR/CAS-9 MEDIATED GENOME EDITING

Clustered Regularly Interspaced Short Palindromic Repeat Associated System ("CRISPR/Cas-9") is widely used as a gene editing tool for model systems in animals and humans. The technology is used to modify the genome of animals and humans in a lab setting with the objective of implementing modifications in living species.[31] CRISPR/Cas-9 is appealing to researchers because it is faster, more efficient, and cheaper than prior gene editing techniques[32] and has the potential for a wide range of applications.[33] The technique allows researchers to edit parts of the genome by cleaving or adding in DNA sequences using the Cas-9 enzyme.[34] A piece of ribonucleic acid acts as a guide ("gRNA"), allowing the DNA edit to target the proper sequence and bind to it.[35] The gRNA is designed to target and edit a specific sequence of the genome. However, it is still common for non-target mutations to occur.[36] Mutations can lead the gene to either not function at all or function improperly.[37]

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30. There are currently no cures for hemophilia, only treatments which often have adverse side effects. Miller, *supra* note 24, at 78.

31. The technology has already been used to modify the genomes of live birth monkeys but has not yet resulted in live birth humans. *See generally* Helen Shen, *First Monkeys with Customized Mutations Born*, Nature, https://www.nature.com/news/first-monkeys-with-customized- mutations-born-1.14611 (last visited Jan. 30, 2018, 1:20 PM).

32. Unlike earlier techniques, CRISP/Cas-9 utilizes the Cas-9 protein to guide bacteria and archaea to attack invading, or undesired, DNA. *See* Aparna Vidyasagar, *What is CRISPR?*, LIVE SCIENCE (Apr. 21, 2017, 9:47 PM), http://www.livescience.com/58790-crispr-explained.html (last visited Mar. 21, 2018). This natural defense mechanism allows scientists to more specifically target DNA edits. *Id.*

33. Martina Baumann, *CRISPR/CAS9 Genome Editing—New and Old Ethical Issues Arising From a Revolutionary Technology*, 10 NANOETHICS 139, 139–42 (2016).

34. The Cas-9 enzyme works similarly to a copy and paste tool, in that it allows that portion of the genome to be removed or added to. *See id.* at 139.

35. Liang P. et al., *CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes*, 6 PROTEIN CELL 363, 364–70 (2015). This entire article as a whole provides in depth details and explanation of gRNA participation in CRISPR.

36. *Id.* at 364.

37. Alex Reis & Breton Hornblower, *CRISPR/Cas-9 and Targeted Genome Editing: A New Era in Molecular Biology*, 1 NEB EXPRESSIONS 1, 1–5 (2014).

The pace at which In-Vitro Fertilization ("IVF") techniques have advanced, from being previously controversial to now becoming widely utilized, serves as a counter to critics who argue that widespread clinical application of CRISPR/Cas-9 in the near future is unlikely.[38] IVF faced many of the same criticisms that CRISPR/Cas-9 does in the present: concerns about long-term effects, ethical considerations, and a general governmental ban on funding.[39] Yet after the first IVF birth occurred,[40] private funding began pouring in for IVF treatment research. In following this chain of events, it is likely that once the first live human birth results from a CRISPR/Cas-9 procedure,[41] the desire for a more idealized form of procreation will subsume the current concerns.[42] New CRISPR/Cas-9 techniques may very well also enter the market with few or no pre-market and longitudinal tests performed, much like with IVF.[43]

In absence of certain studies, the continued effects of CRISPR/Cas-9 will be discovered as time unfolds. The effects of an off-target mutation or germline edits will remain largely unknown until health issues arise later in life or in the following generation. Situations similar to the

38. NATIONAL INSTITUTES OF CHILD HEALTH, *supra* note 6. *See also* Powledge TB (2014) *Whole-Genome Sequencing in Your Doctor's Office? A Reality Check, but Sooner than Later*, *http://www.geneticliteracyproject.org/2014/03/25/whole-genome-sequencing-in-your-doctors-office-a-reality-check-but-sooner-than-later/* [https://perma.cc/K4FG-SKFV] (last visited Oct. 4, 2016); Qiantao Zheng et al., *Reconstitution of UCP1 using CRISPR/ Cas9 in the white adipose tissue of pigs decreases fat deposition and improves thermogenic capacity*, 114 PNAS 9474, 9475–79 (2017).

39. NATIONAL INSTITUTES OF CHILD HEALTH, *supra* note 6.

40. Adam Eley, *How Has IVF Developed Since The First 'Test-Tube Baby'?* (July 23, 2015), http://www.bbc.com/news/health-33599353 [https://perma.cc/2NWQ-8E8N].

41. Despite currently low success rates researchers find the technology remains viable. This may not be surprising given that the current success rates of human embryonic CRISPR/Cas-9 testing are reflective of initial success rates found with in vitro fertilization. Daniel Cressey et al., *UK Scientists Apply for License to Edit Genes in Human Embryos*, SCIENTIFIC AMERICAN (Sept. 21, 2015), http://www.scientificamerican.com/article/scientists-apply-for-license-to-edit-genes-in-human-embryos [https://perma.cc/WM4H-YPXR].

Author's Note: the research cited is that of IVF treatments. I use this research to analogize to IVF treatments. CRISPR is new technology and under intense research and experimentation. There is little to no case studies that would apply directly to CRIPR procedures.

42. Live births have already occurred in the cynomolgus monkey tests and have been quite successful, with the resulting infants developing normally. Niu Y. et al., *Generation of Gene-Modified Cynomolgus Monkey via Cas9/RNA-Mediated Gene Targeting in One-Cell Embryos*, 156 CELL 836, 839 (2014).

43. M.De Rycke et al., *Epigenetic Risks Related to Assisted Reproductive Technologies*, 17(10) HUM. REPROD. 2487, 2488 (2002).

hypotheticals raised above in this Comment's introduction will inevitably arise, bringing questions tort law is unprepared to handle.

A plaintiff must prove four elements under the traditional concept of tort law: (1) the defendant owed a duty to the plaintiff, (2) the defendant breached their duty with regard to the plaintiff, (3) the defendant's breach caused injury to the plaintiff, and (4) the plaintiff suffered injury or harm.[44] Additionally, the underlying policy goals of tort law are fairness and deterrence;[45] thus, damages are awarded based on the loss the injured party suffered.[46] However, the traditional concept of tort law takes an all-or-nothing approach, allocating damages only when the injury suffered is both detrimental and physical.[47] Accordingly, this approach is insufficient for torts arising from CRISPR/Cas-9.

The subjective nature of torts arising from CRISPR/Cas-9 pose significant uncertainties that do not exist in other areas of tort law. The elements of the traditional tort law case leave out a few considerations. Such considerations include; (1) when does the cause of action arise?; (2) does it arise when the effects of unsuccessful gene editing manifest or before?; (3) can the injury date back to when the CRISPAR/Cas-9 procedure occurred?; (4) how will damages be assessed?; and (5) what types of remedies will be accessible as a result of a lawsuit? These are just a few questions to consider, some of many, and these questions can only go unanswered for a short period of time before the public requires answers.

CRISPR/Cas-9 techniques in human genome editing will lead to new tortious actions related to the veiled and enduring ramifications of improper editing that will make it difficult to assess harm and the statute of limitations with certainty. Genome editing techniques will inevitably be used in a clinical setting. Thus, it is prudent that society answers these questions sooner rather than later and may do so by applying existing tort frameworks to this context.

Part I of this Comment assesses the application of the loss of chance doctrine. The loss of chance doctrine appears at first glance as the best fit for torts arising from CRISPR/Cas-9; however, the doctrine is overbroad when taken beyond the single generation scope. Part II assesses the application of the fear of harm doctrine. The fear of harm doctrine offers some insight into how a cause of action may arise from CRISPR/Cas-9 but is limited in its assessment of damages. Part III assesses how the conventional award may offer an easy application solution. Finally, Part

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44. *See* RESTATEMENT (SECOND) OF TORTS § 281 (AM. LAW INST. 1965).

45. JOHN G. FLEMING, THE LAW OF TORTS 303–05 (9th ed., 1998); 1 DAN B. DOBBS, ET AL., THE LAW OF TORTS 12–25 (2d ed., 2000).

46. *See id.* at 21.

47. PATRICK ATIYAH, THE DAMAGES LOTTERY 94–95 (1997).

IV proposes a new type of tort and regulatory hybrid as the best way to address torts arising from CRISPR/Cas-9.

III. THE LOSS OF CHANCE DOCTRINE

A. Overview

Unlike traditional tort law, the loss of chance doctrine is not based strictly on the "but for" test.[48] Traditional tort law asks, "but for" the defendant's negligence, would the plaintiff have been injured?[49] If the question is answered in the negative then the test is satisfied, and the defendant is held liable for the injury. If the question is answered in the affirmative, the defendant is not held liable.[50] Courts often hold that if a plaintiff can establish that a defendant's negligence was responsible for more than half of the injury suffered then the plaintiff is entitled to recover damages.[51] If a plaintiff is only able to establish a lesser responsibility on the part of the defendant, the plaintiff is not entitled to recovery. Professor Joseph H. King argues the traditional all or nothing approach both frustrates and undermines the policy goals of tort law itself.[52] Professor King suggests a better approach would be to fully adopt the loss of chance doctrine, thereby allowing a plaintiff to recover a proportional amount of damages.[53]

The loss of chance doctrine is gaining greater recognition in courts around the world.[54] The loss of chance doctrine evaluates damages based on percentile of likelihood of outcome, rather than an all or nothing approach. The idea is to award damages "proportion[al] to the increase in the chance

48. Martin Hogg, *Re-establishing Orthodoxy in the Realm of Causation*, 11(1) EDINBURGH. L. REV. 8, 14–15 (2007).

49. *See* Sidaway v. Bethlehem Royal Hospital [1985] A.C. 871 (appeal taken from Eng. and used to analogize to the issue at hand in this comment).

50. KENNETH S. ABRAHAM, THE FORMS AND FOUNDATIONS OF TORT LAW 116 (5th ed., 2017).

51. This sentence and the next refer to jurisdictions that participate in partial comparative fault. In a pure comparative negligence jurisdiction, the plaintiff may recover any portion of damages to any amount of fault that is attributed to them. For more information, see Joseph H. King Jr., *Causation, Valuation, and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences*, 90 YALE L.J. 1353 (1981).

52. *See* Joseph H. King Jr., *Causation, Valuation, and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences*, 90 YALE L.J. 1353, 1363–73 (1981).

53. *Id.* at 1386–88.

54. *See, e.g.*, Tabet v. Gett (2010) 240 CLR 537 (Austl.); Hotson v. East Berkshire Health Authority [1987] AC 750 (Eng.)

of the adverse outcome."[55] There are two ways that the appropriate percentile of damages may be reached. First, there is the single outcome approach. Second, there is the weighted mean approach.[56] Part B of this comment discusses these approaches in greater detail.

Loss of chance goes to the heart of the doctor-patient relationship[57] wherein a doctor promises implicitly, through the Hippocratic Oath, to give the patient the best possible chance of survival.[58] Patients place themselves under a doctor's care based on the assumption that the doctor will prevent harm to the patient. It is therefore contrary to the underlying policy of fairness in tort law to place the party least capable of preventing harm in the position of bearing the burden of the other party's negligence. Furthermore, placing the patient in such a position undermines the larger policy goal of legal consequences in general: deterrence and compensation.[59] If the law is unable to consistently hold doctors accountable for their negligence so long as the patient does not die, doctors ultimately face no incentives beyond their own moral scruples to take all necessary precautions.[60] The loss of chance doctrine holds the physician liable in situations where their negligence led to a potential harm that may manifest in the future, thereby protecting the doctor-patient relationship and creating incentives for doctors to be diligent in their treatment of patients.[61]

CRISPR/Cas-9 creates a situation where the patient is uniquely vulnerable to the power of the physician. The imposition of liability based on the loss of chance doctrine alleviates some of the concerns raised with regard to CRISPR/Cas-9 torts. By applying this doctrine, physicians are encouraged to take necessary precautions to overcome scientific gaps in establishing the causation element necessary for tortious action.[62] Those seeking to have the genomes of their embryos edited might generally be desperate to have

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55. Gregg v. Scott [2005] 2 AC 176 (HL) 190 (appeal taken from Eng.).

56. The weighted mean approach is also referred to as "expected value." Jeremey Liang Shi Wei & Kee Yang Low, *Recognising Lost Chances in Tort Law*, 2014 SINGAPORE J. OF LEGAL STUD. 98, 119 (2014).

57. Loss of chance is most typically found in medical malpractice cases involving misdiagnosis.

58. This promise is expressed through the words of the Hippocratic oath, which physicians are required to take: "I will apply, for the benefit of the sick, all measures which are required. . . .[,]" however, this 'promise' is not a guarantee and is perhaps better described as a goal doctors strive to achieve. *Physician Oaths*, AAPS, http://aapsonline.org/ethics/oaths.htm [https://perma.cc/RD9S-X4YZ] (last visited on Sept. 28, 2016).

59. FLEMING, *supra* note 45, at 5–11.

60. *See* Margaret T. Mangan, *The Loss of Chance Doctrine: A Small Price to Pay for Human Life*, 42 SAN DIEGO L. REV. 279, 306 (1997).

61. *Id.*

62. *See id.* at 313–14, 320–22.

a genetic child, but are deeply afraid of passing down a genetic illness.[63] The patient likely researched all available treatments and determined CRISPR/Cas-9 as the only viable option for achieving this goal. Thus, the patient likely has only cursory knowledge of CRISPR/Cas-9 and may not fully understand the potential repercussions should something go wrong. This lack of knowledge is not something that would be sufficiently addressed by informed consent,[64] as the doctor is generally the more sophisticated party, and a patient only knows what it has found through precursory research. This leaves the patient to rely almost entirely upon the physician.

The physician is the only party capable of preventing harm in this context. In a CRISPR/Cas-9 setting, it is the physician alone, not the patient, whose negligence could cause the resulting harm from an improperly edited genome within an embryo. The patient would not be aware of the harm until sometime after the birth of their child, in some circumstances perhaps not even until the birth of their grandchild. As a result, it is imperative that the physician be provided with sufficient incentive to take every precaution necessary. This may be easily achieved by imposing liability based on loss of chance, holding the physician accountable not only for realized injuries, but for those with a substantial likelihood of realization.[65]

B. Damages

The proportional awards perpetuated by the loss of chance doctrine would put the courts in the best position to award damages to plaintiffs filing CRISPR/Cas-9 related tortious actions. The damages awarded are capable of integrating the uncertainty presented by the substantial likelihood

63. Joshua Kleinfeld, *Tort Law and In Vitro Fertilization: The Need for Legal Recognition of "Procreative Injury"*, 115 YALE L.J. 237 (2005); Tamar Lewin, *Sperm Banks Accused of Losing Samples and Lying About Donors*, N.Y. TIMES (July 21, 2016), http://www.nytimes.com/2016/07/22/us/sperm-banks-accused-of-losing-samples-and-lying-about-donors.html?rref=collection%2Fbyline%2Ftamar-lewin&action=click&contentCollection=undefined&region=stream&module=stream_unit&version=latest&contentPlacement=2&pgtype=collection&_r=0 [https://perma.cc/S9TK-2YCU].

Author's Note: Both of the articles above use information related to IVF. However, as mentioned, CRISPR technology is new, and thus these articles are used to analogize the issue about CRISPR/Cas-9 this Comment addresses.

64. Sonia M. Suter, *The Politics of Information: Informed Consent in Abortion and End-Of-Life Decision Making*, 39 AM. J. L. MED. 7 (2013).

65. *See generally* Mangan, *supra* note 60.

of harm, which may never be realized.[66] As mentioned above, there are two approaches the court may choose to take when estimating loss of chance damages: the single outcome or the weighted mean approach.

The single outcome approach is simpler, but the damages awarded may not be accurate. This approach involves estimating when the outcome of the injury will occur and then multiply that probability by the loss attributed to the injury.[67] Despite the apparent ease of application, the single outcome approach is insufficient for assessing damages arising from CRISPR/Cas-9 tortious actions.[68] The harm caused by CRISPR/Cas-9 does not lend itself to the "when the outcome will come to pass" single outcome calculations are based on.[69] In a majority of CRISPR/Cas-9 cases, there may be more than one potential outcome.[70] Though the single outcome approach may work if parties became aware of the negligence due to the realization of the injury, it would be more efficient if courts have a blanket method of assessing these damages.

The weighted mean approach may offer a better solution in CRISPR/Cas-9 tort cases. The weighted mean approach considers the likelihood of multiple potential outcomes and awards damages based on the likelihood each will occur.[71] This approach accounts for the likelihood of all possible outcomes, rather than just the most probable, assigns a value to each, multiplies the value by the probability that the outcome will occur, and adds the sums together.[72]

Though critics argue this approach is too complicated[73] and the statistical evidence may confuse juries, proponents such as Professor King argue that such a precise measurement creates a more rational result and prevents overcompensation, a danger inherent in the more traditional loss of chance calculations.[74] Though the calculations involved may appear daunting, it raises a concerning reality: a jury is entrusted regularly with the power to make decisions that will substantially impact a parties' life (i.e. deciding

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66. *See* Gregg v. Scott [2005] 2 AC 176 (HL) 190 (appeal taken from Eng.). This concept refers to the idea that there is exists a more-likely-than-not potential for substantial harm to manifest, but that there remains a chance that the harm may never come to be.

67. Howard Feldman, *Chances as Protected Interests: Recovery for the Loss of a Chance and Increased Risk*, 17 U. BALT. L. REV. 139, 256 (1987).

68. See King, *supra* note 52, at 1383 for a detailed hypothetical applying the single outcome approach.

69. *See* Feldman, *supra* note 67, at 67.

70. *See* Liang, *supra* note 35.

71. Andrew C. Sand, *Standing Uncertainty: An Expected-Value Standard for Fear Based Injury in Clapper v. Amnesty International USA*, 113 MICH. L. REV. 711, 733 (2015).

72. Baumann, *supra* note 33, at 139–43.

73. *See* Todd. S. Aagaard, *Identifying and Valuing the Injury in Lost Chance Cases*, 96 MICH. L. REV. 1358, 1359 (1998).

74. *See* King, *supra* note 52, at 1384–87; *see also* Mangan, *supra* note 60, at 312.

guilt or innocence, approving punishments like the death penalty, and deciding general damages through less complicated means), but is not trusted to conduct math to determine less clear cut damages.[75]

IV. FEAR OF HARM

A. Overview

The injury arising from fear of harm tort actions is the emotional distress experienced as a direct result of the defendant's negligence.[76] In the context of possible future manifestations of disease, emotional distress stems from anticipation of the disease manifesting and possible medical costs. The idea that an individual has the right to be free from harm is deeply rooted within history.[77] Fear of harm often arises in toxic tort actions.[78] Courts focus on two elements: "(1) whether a defendant's conduct has caused the plaintiff to suffer from a physical consequence; and (2) whether the plaintiff demonstrates that she is likely to manifest disease in the future."[79] This Comment focuses on these two elements and how they apply to torts arising from CRISPR/Cas-9. Just as the obstacle posed by latency is prevalent in toxic torts, it also arises from CRISPR/Cas-9, making the two analogous.[80]

Traditionally, however, courts were reluctant to accept the concept of fear of harm, or the fear of future harm, due to judicial economy concerns.[81] To combat this concern, courts developed the physical injury rule. This

75. The jury can be given instructions on how to use the formula and the judge can double-check their calculations.

76. *See* Rachel Bayefsky, *Psychological Harm and Constitutional Standing*, 81 BROOKLYN L. REV. 1555, 1588–89 (2016).

77. *See generally* PETER W. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES (1988) (pointing to the establishment of English tort law recognizing claims for hurt feelings). *See also* Terry Morehead Dworkin, *Fear of Disease and Delayed Manifestation Injuries: A Solution or A Pandora's Box?*, 53 FORDHAM L. REV. 527, 528 (1984) (asserting that fear of harm has roots in 13th century assault actions).

78. Toxic tort actions involve a plaintiff who has been exposed to a toxic chemical agent that may result in a physical injury. *See* Andrew R. Klein, *A Model for Enhanced Risk Recovery in Tort*, 56 WASH. & LEE L. REV. 1173, 1188, n.77 (1999).

79. *See* Andrew R. Klein, *Fear of Disease and the Puzzle of Future Cases in Tort*, 35 U.C. DAVIS L. REV. 965, 970 (2002).

80. *See* Lavelle v. Owens-Corning Fiberglas Corp., 507 N.E.2d 476, 480–81 (1987) (holding that latency is not an obstacle to recovery under this theory so long as there is reasonable apprehension connecting the future possible harm to the injury wherein the injury has manifested as mental distress).

81. *See* Plummer v. Abbott Lab., 568 F. Supp. 920, 925 (D.R.I. 1983).

physical injury rule permits recovery for a physical injury so long as the injury is a directly and causally related to the tortious conduct.[82]

Current law requires a plaintiff show causation by an injury via the physical injury rule;[83] however, the way a plaintiff may show that injury varies.[84] Generally, courts rely on medical evidence to show the substantial likelihood that an injury will manifest.[85] Medical evidence shows that the defendant was in fact the person who placed the plaintiff within the "zone of danger."[86] This may pose a problem for the first generations of negligence claims arising from CRISPR/Cas-9, as the uncertainty of the injury, and our general lack of knowledge of how it will manifest, will result in conjecture from medical professionals.[87] The challenge may be partially overcome by utilizing the fear of harm approach taken by the Sixth Circuit in *Sterling v. Velsicol*, which requires the plaintiff only establish a reasonable causal connection between the emotional distress and the possibility of the injury manifesting in the future.[88] The lower causal connection standard presented by the court in this case would foreseeably allow current knowledge of the genome to suffice. Doctors and researchers currently have enough knowledge to say with reasonable certainty that negligent improper editing of the genome will lead to the potential manifestation of the disease or illness in the future.[89]

Fear of harm may be viable to address torts arising from CRISPR/Cas-9 under the *Sterling* standard; however, such an approach would only work to satisfy current generational injuries, leaving unanswered and un-addressable the potential injury to future generations. It is unacceptable for the current generation to trade potential harm to future generations in order to presently

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82. *See* Klein, *supra* note 79, at 975.

83. Scholars argue that courts should look beyond these two elements and allow recovery wherever it is reasonably established that the injury may arise in the future due to the negligent actions of the defendant. Although these arguments warrant a closer look this is not the current state of the law and the question of whether a modified fear of harm doctrine would better fit torts arising from CRISPR/Cas-9 is beyond the scope of this comment. *See* Debbie E. Lanin, *The Fear of Disease as a Compensable Injury: An Analysis of Claims Based on AIDS Phobia*, 67 ST. JOHN L. REV. 77, 77–78 (2012).

84. *See* Boyd v. Orkin Exterminating Co., 381 S.E.2d 295, 298 (Ga. Ct. App. 1989) (holding that the injury must be proved by medical certainty); Kazatsky v. King David Mem'l Park, Inc., 527 A.2d 988, 996 (1987) (holding that the level of emotional injury must be outrageous).

85. Bayefsky, *supra* note 76, at 1590.

86. The "zone of danger" comes from the doctrine of proximate cause and refers to the area of harm the plaintiff may have been placed into by the defendant. *See* John J. Kircher, *The Four Faces of Tort Law: Liability for Emotional Harm*, 90 MARQ. L. REV. 789, 815–17, 883–905 (2007).

87. *See generally* Baumann, *supra* note 33.

88. Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1196–98 (6th Cir. 1988).

89. Moser, *supra* note 8; Li et al., *supra* note 14; Niu Y. et al., *supra* note 42.

secure a cause of action for themselves. Such an approach would leave numerous potential plaintiffs with a viable means to recover and would allow physicians to sidestep liability so long as their negligence does not manifest in the current generation, thereby undermining the doctor-patient relationship.[90] However, by the very nature of CRISPR/Cas-9, some injuries will not be realized until the next generation.[91] Revisiting the hemophilia hypothetical above, when applying the *Sterling* standard, the physician would not be liable to any potential sons. This is a result that hardly seems fair in the multi-generational context. However, it may be the price that must be paid for securing compensation in the single or current generational context.

B. Damages

Difficulty in calculating damages under the fear of harm doctrine exists as there is no objective standard on which courts may rely.[92] The jury is given broad discretion on what damages to award[93] and is often provided with vague and unenlightening instructions.[94] As a result, juries have returned with greatly differing damage awards amongst seemingly identical cases.[95] The unpredictability of these awards undermines both the deterrence and the fairness goals of tort law. With such a wide variance in awards, physicians may choose to take their chances with the jury and assume that the differing awards will balance over time.[96] Rather than being deterred from the tortious conduct, physician may elect to pay higher insurance

90. Eley, *supra* note 40.
91. Baumann, *supra* note 33, at 149.
92. Richard H. Spector, *Pain and Suffering: Current Concepts,* 34 MED. TRIAL TECH. Q. 202, 203 (1987).
93. *See* Millea v. Metro-North R.R. Co., 2006 Jury Instr. Lexis 2473; Blue v. Bronson & Migliaccio, 2011 Jury Instr. Lexis 82.
94. Florida Pattern Jury Instructions-Civil, Damages § 404.12 (2015)
95. Douglas L. Price, *Hedonic Damages: To Value a Life or Not to Value a Life?*, 95 W. VA. L. REV. 1055, 1065–75 (1993). Hedonic damages are those associated with loss of enjoyment of life cases. *Id.*at 1055. When it comes to personal injury cases, multiple monetary arguments are made in support for a certain return of damages, including opinion evidence and per diem arguments. *Id.* at 1067, 1072. As every living individual is different in day to day life, counsel can make arguments on all activities undertaken at home, work, or elsewhere and those cause the damages to fluxuate. *Id.* at 1066.
96. If one case results in a high damages award while another results in minimal damages, the two will even out to two moderate payouts from the plaintiff. One award of $200,000 and a second award of $20,000 has the same consequences for the physician as two awards of $110,000, well within most physician's insurance coverage.

premiums and risk potential litigation.[97] Additionally, the fact that two seemingly identical cases can result in grossly different damage awards insults the notion of fairness, replacing it instead with a system that fails to award appropriate consistent damages.

In an attempt to address the issue of awarding damages in a fear of harm case, different courts have adopted different approaches. Though no agreement has been reached as to which approach is the best, two predominant approaches have emerged.[98] First, some courts use the per diem method of calculating damages whereby a jury assigns a monetary value to how much the plaintiff suffers as a result of the injury, estimates how many days the plaintiff is likely to suffer the injury, and then multiplies the per-day monetary value by the number of days.[99] But despite giving some guidance on how to calculate the damages, the per diem approach does not address the issues surrounding jury guidance and leaves the daily award entirely to the jury's discretion. Much like the traditional application for damages under the fear of harm doctrine, uniformity is once again at issue.

Second, some courts use the willingness to pay method of calculating damages, whereby a jury calculates the loss of enjoyment in one's life[100] by determining how much one would be willing to pay to be without the injury.[101] There are two primary problems with this approach: loss of pleasure is only one aspect of the injured party's suffering, and using loss of pleasure as a basis provides only the average cost of the injury, ignoring the aspects that may be subjectively unique to the injured party currently before the court.[102]

Neither the per diem nor the willingness to pay approach are capable of sufficiently calculating damages for torts arising from CRISPR/Cas-9. Both approaches lack precision and leave too much to the jury's subjective determinations, which may result in unfair awards. There remain insufficient safeguards to ward against such results, as courts cannot overturn the award unless it is egregious enough to shock the conscience.[103]

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97. Anupam B. Jena, Seth Seabury, Darius Lakdawalla, Amitabh Chandra, *Malpractice Risk According to Physician Specialty*, 365 N. ENG. J. MED. 629, 635 (2011); American Society of Clinical Oncology, *Malpractice Insurance: What You Need to Know*, 3 J. ONCOL. PRACT. 247, 274–77 (2007).

98. James O. Pearson, Jr., *Annotation, Per Diem or Similar Mathematical Basis for Fixing Damages for Pain and Suffering*, 3 A.L.R. 4th 940 (1981).

99. *Id.* at 945.

100. Such damages are often referred to as "hedonic damages." *See* Price, *supra* note 95, at 1055–60.

101. Tina M. Tabbachi, *Hedonic Damages: A New Trend in Compensation?*, 52 OHIO ST. L. J. 331, 331, 341–42 (1991).

102. *Id.*

103. *Id.*

V. THE CONVENTIONAL AWARD

Though only recently introduced as a concept by the House of Lords,[104] the conventional award may serve as a fallback for assessing injury and awarding damages in torts arising from CRISPR/Cas-9. In general, courts are consistently reluctant to view the birth of a child as negative, regardless of the child's health.[105] The conventional award acknowledges the additional costs associated with raising a disabled child, sidestepping the issue of determining whether the actual birth of the disabled child is considered a negative life event.[106] Rather than placing a number on a day's value, or calculating a subjective loss of enjoyment, the court sets a particular sum that plaintiffs are entitled to recover[107] when suing for a particular injury.

Such an approach, however, fails to consider the breadth of injuries that could result from CRISPR/Cas-9. On an instinctive level, not all disabilities are created equal; some are more debilitating than others.[108] The policy of fairness, which drives tort law, is severally undermined by awarding the same monetary damages to all disabilities.[109] As applied to CRISPR-Cas-9 torts, the conventional award would fail to take into consideration the potential long-term ramifications of an improperly edited genome, touching merely on this generation rather than considering the next.

Furthermore, the admittedly paltry sum of the conventional award is unlikely to ensure that physicians take all steps necessary to protect their patient. Not only does the conventional award fail to preserve the sanctity of the doctor-patient relationship, but it fails to promote the goal of deterrence, which is inherit to tort law.[110] Physicians already carry insurance policies due to the risk of medical malpractice and other negligence suits that accompany any practicing physician. The paltry sum from a CRISPR/Cas-9 case that

104. Rees v. Darlington Memorial Hospital N.H.S. Trust [2002] E.W.C.A. Civ. 88; R v. A [2002] 2 All E.R. 177 (C.A.) (Eng.).

105. *See* McFarlane v. Tayside Health Board [2000] 2 A.C. 59 (Eng.).

106. Nicolette M. Priaulx, *A Letter From the U.K.: Tort Law and Damages for the Unwanted Child*, 14 J. OF LEGAL ECON. 53–79 (2008).

107. *See generally* Rees v. Memorial Hospital [2003] UKHL 52 (holding that the conventional award would be set at fifteen thousand pounds, the idea being to set the award so as not to be minimal but also not to be too high).

108. Compare the effects of Hunter's Syndrome discussed in the initial hypothetical, which severally limits a person's life, with the effects of hemophilia which may not affect the current generation, but which may affect the next generation, but whose effects are arguably less debilitating to a person's life than Hunter's Syndrome.

109. DOBBS, *supra* note 45.

110. De Rycke, *supra* note 43.

applies the conventional award approach will hardly raise their rates, nor will it require the physician to pay out of pocket for any portion of the settlement.[111] Thus, the conventional award would serve more as a mere annoyance to physicians than the liability of higher awards would.

Whereas the conventional award leaves unanswered a multitude of problems with torts arising CRISPR/Cas-9, it has the singular advantage of being uniform both in the award of damages and the application. A fund could be created where those injured by improper genome editing may recover a set amount, regardless of the severity of the injury. This would entitle injured parties to some recovery while side stepping ethical concerns. Such ease of use may be more appealing to courts than the nuances of either the loss of chance doctrine or the fear of harm doctrine.

VI. A NEW KIND OF TORT

Each of the existing frameworks discussed above has the potential to address torts arising from CRISPR/Cas-9, but each is flawed in some respect. The loss of chance doctrine furthers tort goals,[112] can be utilized fairly,[113] and provides a way to calculate damages.[114] However, the loss of chance doctrine risks over-deterrence by requiring physicians to pay large sums to future generations effected by improper gene editing that fails to manifest in the first generation.[115] One solution is to only allow recovery for first generation injuries, but this is unfair to future generations who experience very real injuries as a direct result of the physician's negligence.

The fear of harm doctrine allows for ease of recovery by focusing on an emotional rather than physical harm,[116] but it fails to provide a viable way to calculate damages[117] and risks undermining tort goals.[118] In response,

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111. *See* Boyd v. Orkin Exterminating Co., 381 S.E.2d 295, 298 (Ga. Ct. App. 1989) (holding that the injury must be proved by medical certainty.); Kazatsky v. King David Mem'l Park, Inc., 527 A.2d 988, 995 (1987) (holding that the level of emotional injury must be tremendous).

112. FLEMING, *supra* note 45.

113. Feldman, *supra* note 67.

114. Joseph H. King Jr., *"Reduction of Likelihood" Reformulation and Other Retrofitting of the Loss-of-A-Chance Doctrine*, 28 U. MEM. L. REV. 491, 504 (1998). *See also* discussion Part I.B.

115. The risk of over-deterrence manifests itself in the multi-generational context wherein a physician would be liable for potentially large damage awards for an insurmountable amount of time.

116. Bayefsky, *supra* note 76, at 1565, 1586.

117. Spector, *supra* note 92, at 223.

118. DOBBS, *supra* note 45, at 12.

the legislature may enact laws prescribing the proper way to calculate damages, but legislation is unlikely to be uniform in character and application.

Finally, the conventional award is easy to use and can be applied uniformly,[119] but fails to both deter negligent conduct and to provide fair awards to injured parties.[120] One may increase the award amount, but this would have an unfair effect in multi-generational awards and result in over-deterrence.

Given these difficulties, it is prudent to create a new tort structure to address torts arising from CRISPR/Cas-9 and to root this new tort in existing tort law. This tort should focus on furthering the tort goals of deterrence and fairness while addressing the intricacies presented by CRISPR/Cas-9, such as the distinction between single and multi-generational injuries. With these considerations in mind, this Comment proposes a system that borrows heavily from the loss of chance doctrine for single generational injuries and combines the conventional award with governmental regulation for multi-generational injuries.

A. Single Generation Injuries

Single generation injuries present less complexities than multi-generational injuries in a few respects: the plaintiff is alive,[121] the injury is more easily discernable, and the evidence is relatively fresh. As such, single generation injuries are more easily addressed by traditional tort frameworks, such as the fear of harm doctrine and the loss of chance doctrine. Though the fear of harm doctrine can be utilized for torts arising from CRISPR/Cas-9, it is the less desirable of the two doctrines. Despite its ease of applicability, the challenges posed by the calculation of damages for fear of harm would complicate any litigation rooted in this framework and would require either a great deal of regulatory intervention[122] or the intervention of the Supreme Court.[123] In the doctrine's current state, it risks undermining tort policy

119. Spector, *supra* note 92.
120. De Rycke, *supra* note 43.
121. This comment does not specify who the plaintiff is, it may be necessary in the future to be more specific about this but at such an early stage it seems superfluous.
122. Federal law would have to be enacted which would preempt state law and which would have to mandate the precise handling of such cases, such an approach would likely run into heavy state opposition and may stand directly contrary to constitutional guidelines.
123. A Supreme Court decision which set forth the standard for calculating damages in such cases could create the legal unification the approach currently lacks; however, there

goals,[124] which would be an undesirable result in any tort. In particular, as the CRISPR/Cas-9 technique is already likely to face a great deal of uncertainty within a medical context,[125] it would substantially undermine the torts credibility should it fail to further the policy goals of tort law generally.[126] There would simply be too much uncertainty in one tort.

Luckily, the loss of chance doctrine lacks the shortcomings of the fear of harm doctrine and creates a viable option to address single generation injuries arising from CRISPR/Cas-9 techniques. The loss of chance doctrine aims to further tort goals by creating a fair result, provides sound guidelines on how to apply the doctrine, and provides a viable way of calculating damages in the most accurate fashion available: through the weighted means approach.[127] The doctrine's greatest failure is the likelihood of over-deterrence should it be applied in to multi-generational injuries arising from CRISPR/Cas-9.[128] This failure can be sidestepped by applying the doctrine solely to single generation injuries. By limiting loss of chance recovery to single generation injuries in this context, the medical uncertainties of the first generation can be accounted for while acknowledging that harm to future generations may never arise or may be so attenuated from the negligent editing as to not warrant recovery.

B. Multi-Generational Injuries

The inherent risk in CRISPR/Cas-9 gene editing is that any negligence on the part of the physician can affect future generations.[129] On the one hand, it is important that any tort claim proposed to address CRISPR/Cas-9 injuries account for the damage potential for multi-generational injuries, otherwise the very real injuries of future generations may be invalidated. On the other hand, it is unfair to hold physicians or their practices liable for later generations under a traditional tort approach because resulting damages would seemingly have no end. Physicians would end up facing complex litigation and paying large damage awards for their entire lives to injured parties.[130] Further, physicians would be deterred from practicing in a field where they face such liability. Balancing the concerns of compensating

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would likely be many years in which no unifying principles arose and the Supreme Court could ultimately choose not to decide the issue-as is currently the case.

124. *See* Part III.

125. Reis, *supra* note 37.

126. FLEMING, *supra* note 45.

127. King, *supra* note 52.

128. *See* Part I.B.

129. *See* Niu Y. et al., *supra* note 42, at 836 ("But whether [CRISPR] is feasible for primates is unclear."). Currently, scientists are modifying genes in monkeys as monkeys serve as a close comparison to modeling human diseases. *Id.*

130. Feldman, *supra* note 67.

injured parties without over-deterring physicians from practicing in this area will take some finesse.

In order to traverse such a fine line, legislators should model damages after conventional award principles.[131] Legislators should create and manage an award fund, draft regulations making participation mandatory, and make this the only option for multi-generational injury recovery. Physicians who practice genome editing would be required to annually pay a certain percentage of their taxable profits into the fund. Multi-generational injured parties who are able to trace their injury directly to a physician's negligence would then be able to recover a certain amount from the fund. The injured party's recovery would be based on the severity of the injury suffered as not all injuries are equally serious. The amount of damages awarded would be calculated in a manner similar to social security disability benefits; however, unlike social security disability benefits, recovery would be a one time, tax free, payout.

Physicians should not be able to circumvent this payout to multi-generational injured parties through limiting their liability for negligent misconduct by having patients sign a medical waiver. The public interests that override medical waivers in medical malpractice are also prevalent within the CRISPR/Cas-9 context.[132] There is unequal bargaining power between the physician and the patient, because the physician is in a more sophisticated and superior position to determine what is the best treatment for the patient.[133] Furthermore, a vast informational discrepancy exists between the physician and the patient, as the physician more fully understands exactly what the patient is agreeing to. This is particularly true in the context of CRISPR/Cas-9, as the physician has had extensive training and education in genetics. It would be unreasonable to expect a patient to have the same or similar basis of knowledge about the procedure. Rather than focusing exclusively upon the medical emergency situation, courts have instead focused their reasoning on the public policy interests and the discrepancy of bargaining power within that context. Courts should strike

131. Kircher, *supra* note 86, at 341–42, 348–49.

132. *See* Olson v. Molzen, 558 S.W.2d 429, 431–32 (Tenn. 1977); Cudnik v. William Beaumont Hosp., 525 N.W.2d 891, 894–96 (Mich. Ct. App. 1994).

133. Laura Nimmon, Terese Stenfors-Hayes, *The "Handling" of power in the physician-patient encounter: perceptions from experienced physicians*, 16 BMC MED. EDUC. 1, 1–9 (2016). This article shows that a significant number of experienced physicians acknowledge a power discrepancy between the physician and the patient that places the physician in a position of power.

down medical waivers within the context of torts arising from CRISPR/Cas-9 in order to protect the public's interest in deterring physicians' negligence and in compensating injured parties.[134]

A conventional award payout system would not be unduly burdensome to physicians and would still provide sufficient deterrence. In fact, should CRISPR/Cas-9 follow in the footsteps of IVF treatment, as it is currently poised to do,[135] the field should be lucrative for physicians. The tradeoff to practicing in such a lucrative, yet experimental field would be to remain liable under the loss of chance doctrine for single generation injuries while simultaneously paying into the conventional award fund for multi-generational injuries. Legislatures may even be able to draft regulations in such a way as to add the fund payments into already existing medical malpractice premiums. While this approach may seem harsh, no physicians are currently actively using CRISPR/Cas-9 in a clinical setting. Therefore, physicians entering the field would be aware of the cost of practicing in this particular field. Those physicians who feel indignant at the prospect of paying up, when they themselves may never negligently edit genes, are invited to practice in different areas of medicine.

The burden on physicians may be further lessened by the imposition of a statute of limitations upon multi-generational recovery from the fund. Statute of limitations periods vary widely depending on the type of tort at issue. Within the context of medical malpractice,[136] there are three primary approaches. First, there is the termination rule, otherwise known as the continuous treatment rule.[137] Under this rule, the statute of limitations begins to toll when the physician-patient relationship is terminated.[138] Second, there is the discovery rule where the statute of limitations begins to toll when the patient discovers, or through the exercise of reasonable care, should have discovered, the injury.[139] Third, there is the general rule where the statute of limitations begins to toll starting on the date the injury occurred.[140] In

134. *See* Tunkl v. Regents of University of Cal., 383 P.2d 441, 443–47 (Cal. 1963).

135. NATIONAL INSTITUTES OF CHILD HEALTH, *supra* note 6.

136. Medical malpractice statute of limitations appear more analogous to the CRISPR/Cas-9 context than pure personal injury suits such as those arising from a car accident, because in the CRISPR/Cas-9 context medical assistance was sought and the application of the medical assistance has resulted in injury.

137. *See* Dana David Peck, *The Continuous Treatment Doctrine: A Toll on the Statute of Limitations for Medical Malpractice in New York*, 49 ALB. L. REV. 64, 65 (1984).

138. Bowers v. Santee, 124 N.E. 238, 240 (Ohio 1919) (setting forth the underlying rationale for the termination rule). This case has been overruled by Oliver v. Kaiser Community Health.

139. *See* O'Stricker v. Jim Walter Corp., 447 N.E.2d 727, 729–31 (Ohio 1983).

140. Vivian S. Chu, CONG. RESEARCH SERV., R41661, MEDICAL MALPRACTICE LIABILITY REFORM: LEGAL ISSUES AND 50-STATE SURVEYS ON TORT REFORM PROPOSALS 11 (2011).

all three instances, the statute of limitations, once tolled, gives an injured party an average of two to three years to file suit.[141]

Two to three years is an inadequate timeframe for multi-generational injuries arising from CRISPR/Cas-9 because the injury many not be discovered until well after the filing date has passed. Therefore, none of the three primary statute of limitation approaches in medical malpractice work.

However, when tweaked, the termination rule offers a potential framework to lessen the burden on physicians. Although the way the traditional termination rule is laid out focuses on the literal end of the physician-patient relationship,[142] the underlying rationale focuses on the finality of the physician being able to take curative efforts.[143] So long as a physician is practicing, they have the opportunity to take curative efforts; either efforts to remedy the initial problem that made treatment necessary, or to fix the problems arising from their own negligent actions.[144]

It is this rationale that supports a proposed tweak to the termination rule. Rather than allow the physician to remain liable for two to three years after the conclusion of their relationship with the patient, the physician shall remain liable until the time they would be no longer be able to take any curative efforts, or at a minimum, until the termination of their practice. Under this approach, within the CRISPR/Cas-9 context, the physician would be liable so long as they at one time practiced genome editing.

The concept of liability is also tweaked in the sense that the physician does not remain individually liable to each patient they have personally undertaken, rather they are liable to the umbrella group of CRISPR/Cas-9 patients as are covered by the conventional award fund. This would hold the physician liable to contribute to the fund only for so long as they practice genome editing. Such an approach would prevent overburdening the physician because they would be required to make payments to the fund only for the length of time that they themselves are profiting from CRISPR/Cas-9. Though this is an unheard-of length of time for the statute of limitations for medical malpractice,[145] the conventional award does not amount to a lawsuit and should therefore be afforded a different standard when it comes to time limitations. Furthermore, without a broad statute of limitations for the mandatory payments to the fund, physicians would be liable for these

141. *Id.*
142. Peck, *supra* note 137.
143. *Bowers*, 124 N.E. at 239.
144. *Id.*
145. *See* Chu, *supra* note 140, at 11–12.

payments for an indefinite period of time. Should the physician change the area of medicine they wish to practice or should the physician retire, they would risk continuing liability for fund payments. Such an approach would likely over-deter[146] physicians and prevent them from entering the field and practicing CRISPR/Cas-9. By limiting the physician liability to a specified timeframe defined by their own profits within the field, the goals of tort law[147] are allowed to flourish without stifling the medical community.

Under this approach, those who suffer from multi-generational injuries make a sacrifice arguably equal to that which the physicians must make. In order to allow the injured party to recover for a longer period after the physician breached their duty, the damages available are paltry in comparison to those available under the loss of chance. This approach is not meant to invalidate the injury, on the contrary, allowing recovery so long after the fact is meant to validate the injured party's suffering. It is meant to recognize the injury as an actual harm suffered while simultaneously allowing fair treatment of the physician. As stated above, it would simply be unfair to hold a physician liable for their life time and for large damages. The tradeoff between these two goals, fairness to both the injured party and the physician, is the limitation on damages. The damages would be calculated based on those currently used for social security disability benefits.[148] This approach allows regulators to consider the wide variety of resulting injuries, their severity, the harm suffered by the injured party, and how much of an impact the injury is likely to have on the injured party's life. These awards would be larger than those given for social security disability benefits[149] and would more closely mirror the conventional award, because, unlike social security disability benefits, this payout would occur only once. Similar to other personal injury recovery, the award would be tax free.[150] However, this proposal does not provide further guidance as to the award distribution, leaving the determination to the discretion of the legislators.[151]

146. *See* FLEMING, *supra* note 45, at 10.

147. *Id.* at 8–9.

148. *See generally* WAYNE LOU & JULIE M. WHITTAKER, CONG. RESEARCH SERV., RL 32552, SOCIAL SECURITY: CALCULATION AND HISTORY OF TAXING BENEFITS 1–9 (2016) (explaining the calculation of social security disability benefits).

149. Spector, *supra* note 92.

150. 26 U.S.C. § 104 (2015).

151. Regulators would need to decide the actual monetary amounts to be awarded along with the coinciding percentage rates of qualifying injury for each award. Additionally, regulators would need to establish exactly where the limitations for multi-generational recovery should be—whether those experiencing third, fourth, fifth, etc. injuries should be able to recover from the fund or whether there is a cutoff.

VII. APPLICATION

With this new single and multi-generational tort framework in mind, this section returns to the three introductory hypotheticals. Each of these hypotheticals demonstrates a potential injury arising from the use of CRISPR/Cas-9. The first hypothetical is a fairly straight forward single generation injury, the second hypothetical is a more complex single generation injury, and the third hypothetical is a multi-generational injury. These hypotheticals consider application of the weighted means approach to the loss of chance and the multi-generational framework. The goal of these hypotheticals is to demonstrate the straight forward application of the proposed tort system.

This section first considers the Hunter's Syndrome hypothetical and modifies it slightly in order to demonstrate a potential, though not currently manifested, injury. In this version, despite having gone through the gene editing process you decide to have your child genetically tested for Hunter's Syndrome after birth.[152] The results show that your child does have the enzyme deficiency that causes Hunter's Syndrome but the tests are not sophisticated enough to tell you whether your child has an attenuated or severe form of the syndrome.[153] Assume that as a result of the improper gene editing there is a 50% chance of the syndrome manifesting at late childhood, 20% chance at age four, 10% chance at age three, 5% chance at age two, and 15% chance that the syndrome never manifests.[154] Now assume that if the syndrome manifests in late childhood the loss would be $200,000; $300,000 at age four; $350,000 at

152. The Hunter's Syndrome test costs approximately $200. It can be used to confirm a suspected case of Hunter's Syndrome, but since the syndrome is rare the test is not typically implemented without cause. *See e.g.*, GREENWOOD GENETIC CENTER, http://www.ggc.org/diagnostic/tests-costs/test-finder/hunter-syndrome—enzyme-analysis.html (last visited Feb. 12, 2018) [https://perma.cc/A2Z4-9HZS].

153. *See* Barbara K. Burton & Roberto Giugliani, *Diagnosing Hunter syndrome in pediatric practice: practical considerations and common pitfalls*, 171 EUR. J. PEDIATR. 631, 636–37 (2012) (explaining how Hunter's Syndrome comes in two forms: attenuated and severe. Symptoms for the severe version begin manifesting around two to four years of age while symptoms for the attenuated version begin manifesting in late childhood. Though both suffer from debilitating somatic symptoms, those with the severe version also experience severe cognitive impairments. Additionally, though both are associated with early death, those with the severe version typically die before adulthood whereas those with the attenuated version can live into early adulthood. *See* Barbara K. Burton & Roberto Giugliani, *Diagnosing Hunter Syndrome in Pediatric Practice: Practical Considerations and Common Pitfalls*, 171 EUR J. PEDIATR. 631, 635–39 (2012).

154. King, *supra* note 52, at 1384 (showing that the above calculations are based off of Professor King's calculations for the weighted means approach).

age three; and $400,000 at age two. To determine the total value of the chance of injury, the potential loss figures must be added together—$100,000 (50% of $200,000), $60,000 (20% of $300,000), $35,000 (10% of $350,000), $20,000 (5% of $400,000), and $0 (15% of $0)[155]—resulting in a sum of $215,000.[156]

Now, consider the DMD hypothetical in order to more fully explore how the weighted means approach to loss of chance addresses injuries arising from CRISPR/Cas-9. In the DMD hypothetical, the middle son ("MS") already has a tangible injury to be accounted for—he is wheelchair bound, which cannot be reversed—but the full extent of his possible injuries has not yet been realized. The doctor who negligently performed the procedure cannot tell whether or not he can stop the progress of the mutation or whether it will ultimately kill MS. Furthermore, there is a possibility, given the improper edit performed on MS, that either the youngest son ("YS") or the eldest son ("ES") will experience the same problem as MS. However, at this time this injury is purely speculative.

First, in regard to MS, assume the improper CRISPR/Cas-9 editing that caused the injury already suffered by MS is worth $200,000 and there is a 25% chance of further loss of movement (arms, torso, etc.), a 10% chance of having to be on a ventilator, a 20% chance of death, and a 45% chance that the doctor will be able to stop the progress. Now assume that if there was further loss of movement the loss would be $100,000; if a ventilator is required the loss would be $300,000; if death resulted the loss would be $1,000,000; and if the doctor is able to stop the progress the loss would be $0. To find the total value of the chance of injury, the potential loss figures must be added together—$25,000 (25% of $100,000), $30,000 (10% of $300,000), $200,000 (20% of $1,000,000) and $0 (45% of $0)—resulting in a sum of $255,000. Additionally, the worth of the existing injury must be added, which results in a total of $455,000.

Second, in regard to YS and ES, neither YS nor ES have a tangible injury, but they will always be worried about the potential for injury due to the mistake the doctor made with MS. Assume that as a result of the improper CRISPR/Cas-9 editing that has manifested in MS, there is a 15% chance that YS and ES face loss of movement (arms, legs, torso, etc.), 5% chance of having to be on a ventilator, 3% chance of death, and 77% chance that the injury will never manifest. Now assume that if there was loss of movement the loss

155. Although the percentages are derived from Kin's weighted means approach, the actual monetary figures used in this paragraph have been arbitrarily made up by the Author for the purposes of providing an illustration to the calculations of damages.

156. It is important to keep in mind that in all of our single generational injury hypotheticals it is up to the jury to decide whether the injured party is entitled to recover this sum, or a portion of this sum.

would be $150,000 (the mid-point between MS' realized loss of movement and potential further loss of movement); if a ventilator was required, the loss would be $300,000; if death resulted, the loss would be $1,000,000; and if the injury never manifested, the loss would be $0. To find the total value of the chance of injury, the loss figures are added together—$22,500 (15% of $150,000), $15,000 (5% of $300,000), $30,000 (3% of $1,000,000) and $0 (77% of $0)—resulting in a sum of $67,500 per sibling.

Finally, consider the hemophilia hypothetical and apply the multi-generational framework. In the hemophilia hypothetical, the improper genome editing occurred in a generation prior to the actual manifestation of the injury. The grandparents of the injured party paid for genome editing in the mother of the injured party, the genome editing was improperly performed, but because the mother was only a carrier she personally suffered no injury from the negligence. However, when the mother gave birth to a son the injury from the improper genome editing manifested. In this case, not only did the injury occur thirty to forty years from the date of the negligent conduct, but the doctor who improperly performed the genome editing is no longer alive. Though the parties involved are likely to believe they are entitled to a larger damage award than that of single generation injuries, it undermines the notion of fairness to allow this type of recovery.

The injured party still has the right to recover from the conventional award despite the length of time that has lapsed between the conduct and injury. In order to obtain an award, the parents, acting as agents of the child,[157] would file the appropriate paperwork with the agency or board supervising the conventional award. The agency or board would then assess the severity of the injury in order to determine the proper amount of recovery. In this hypothetical, the factors the agency or board would likely want to consider would include: the level of severity of the form of hemophilia, whether doctors foresee the need for ongoing treatment, whether doctors foresee the need for ongoing treatment and how invasive the treatment would be, the effect on quality of life, and whether the injury is likely to result in premature death. The agency or board would then compare the severity of the injury to other injuries arising from CRISPR/Cas-9 and calculate the appropriate amount of recovery based on the totality of these contributing

157. If the multi-generational injury did not become known until the injured party was an adult, then the adult may file for conventional award recovery on their own.

factors. A one-time payment would then be issued to the injured party, which in this hypothetical is the son.[158]

The proposed tort system is easy to apply as it is already rooted in the current tort system and the gross results optimize fairness while minimizing deterrence. Single generation awards require some calculations, but juries are regularly relied upon to calculate the value of injuries with less guidance. Although the multi-generation awards require the establishment of a conventional award fund and a governing body to disperse rewards, this allows an injured party to recover damages when no other legal recourse is available to them. Thus, the system is designed to be the least burdensome on physicians while protecting their patients.

VIII. CONCLUSION

Modern day scientists and researchers are poised on the precipice of making genome editing clinically available. Once the technology is viable it will expand rapidly, much like IVF did, and will initially have little longitudinal data to help guide physicians. As a result, injuries will arise from improper genome editing. Currently our tort system is ill prepared to address these grievances. The novelty of the injuries that will arise require a system that is able to balance the interests of physicians with single and multi-generational plaintiffs, while providing a realistic framework for courts to follow. This comment offers a brand-new context that accounts for these needs and sets expectations for how to handle these injuries in the right way, promulgating the goals of tort law. This approach combines elements of traditional tort law with a proposed governmental regulation that will help compensate victims while not over-deterring physicians to practice in the field of genome editing. By basing this approach on existing doctrine, it should lead to an easier transition for courts and claimants alike.

If society does not preempt the technology with a carefully thought out tort system, the legal framework addressing CRISPR/Cas-9 injuries will become a mix of existing law. Attorneys will have a difficult time trying to wade through the resulting legal miasma and the law will be even more difficult for courts to apply. Therefore, it is important to establish expectations regarding how to handle these injuries now because once the technology is viable, expectations will quickly be set by whatever systems are in place. These expectations will entrench themselves into the legal system and will be difficult to uproot. If society sets the expectations properly on the ground

158. Only the injured party is entitled to recover in the context of multi-generational injuries arising from CRISPR/Cas-9; the grandparents and mother will be unable to recover any damages.

level before people have adjusted to working within a particular system, society can avoid inconsistencies and failures within our legal system.