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THE PRICE TAG ON DESIGNER BABIES: MARKET SHARE LIABILITY

Abstract: The prospect of genetically modifying humans has loomed over the public for decades. Now, science fiction is becoming reality. New technology and expanding research are positioned to make genetic alteration a routine, pre-conception appointment. For several years, China has been experimenting with germline editing on non-viable human embryos. In April 2016, the UK also approved a group of scientists to begin similar research. In the United States, genetic engineering is a multibillion-dollar industry. Although ethical debates over human genetic modification have checked the industry, the potential for clinical trials has become a reality as companies race to dominate the technology. In light of the potential impact of problematic genetic alterations on future generations, the harm inflicted on victims parallels the Diethylstilbestrol cases of the 1980s, signaling a re-emergence of market share liability.

INTRODUCTION

Genetically modified humans have been the source of Hollywood, dystopian science-fiction plot lines, yet such advancements are now the reality of today's headlines.[1] On February 9, 2016, former United States Director of Na-

[1] *See, e.g.*, Stephen S. Hall, *The First Tinkering with Human Heredity May Happen in the Infertility Clinic*, 315 SCIENTIFIC AMERICAN 54, 54–61 (2016); John Harris & Marcy Darnovsky, *Pro and Con: Should Gene Editing Be Performed on Human Embryos?*, NAT'L GEOGRAPHIC (Aug. 2016) https://www.nationalgeographic.com/magazine/2016/08/human-gene-editing-pro-con-opinions/ [https://perma.cc/9KGV-K2Q4]; Heidi Ledford, *Riding the CRISPR Wave*, 531 NATURE 156, 156–59 (2016); Fraser Nelson, *The Return of Eugenics*, SPECTATOR (Apr. 2, 2016) https://www.spectator.co.uk/2016/04/the-return-of-eugenics/ [https://perma.cc/7F2N-53BE]; Alice Park, *A New Technique That Lets Scientists Edit DNA Is Transforming Science—And Raising Difficult Questions*, TIME (Jun. 23, 2016) http://time.com/4379503/crispr-scientists-edit-dna/ [https://perma.cc/B3Q3-7XWJ]; Alice Park et al., *How the Science CRISPR Can Change Your Genes*, TIME (Jun. 23, 2016) http://time.com/4377130/crispr-genome-editing/ [https://perma.cc/FQL8-D9YE]; Jason Pontin, *Editing Human DNA*, MIT TECH. REV. (Apr. 21, 2015), https://www.technologyreview.com/s/536696/editing-human-dna/ [https://perma.cc/7TTE-FNJE]; Sara Reardon, *The CRISPR Zoo*, 531 NATURE 160, 160–63 (2016); Michael Specter, *How the DNA Revolution Is Changing Us*, NAT'L GEOGRAPHIC (Aug. 2016) https://www.nationalgeographic.com/magazine/2016/08/dna-crispr-gene-editing-science-ethics/ [https://perma.cc/GJU7-MTL7]; Michael Specter, *The Gene Hackers*, NEW YORKER (Nov. 16, 2015), https://www.newyorker.com/magazine/2015/11/16/the-gene-hackers [https://perma.cc/CYR2-PAD8]; GATTACA (Columbia Pictures 1997) (portraying a world where humans can be genetically modified pre-birth for physical, mental, and emotional enhancements); *Genome Editing: The Age of the Red Pen*, ECONOMIST (Aug. 22, 2015), https://www.economist.com/news/briefing/21661799-it-now-easy-edit-genomes-plants-animals-and-humans-age-red-pen [https://perma.cc/34NW-4CRE]; *Human Gene Editing: A Timeline of CRISPR Cover Stories*, CTR. FOR GENETICS & SOC'Y (Sept. 20, 2016), https://www.geneticsandsociety.org/internal-content/human-gene-editing-timeline-crispr-cover-stories [https://perma.cc/K8WG-ZNAP] (collecting headlines with CRISPR cover stories).

tional Intelligence, James Clapper, categorized genome editing as a "weapo[n] of mass destruction and proliferation."[2] In the *Worldwide Threat Assessment of the US Intelligence Community* report, Clapper stated that new technology has realized the possibility that flawed heritable human genetic alterations may result from manipulation of the human genome through "deliberate or unintentional misuse."[3] The report added a caveat that the complexity of the human genome still poses a limit on the ability of researchers to manipulate the genome effectively.[4] Nonetheless, the technology is available.[5]

The past few years—2015 in particular—have seen the emergence of simple, precise, and affordable DNA altering techniques.[6] These techniques include the use of clustered regularly interspaced short palindromic repeats ("CRISPR") and the enzyme, protein-9 nuclease ("Cas9").[7] Using CRISPR-Cas9, scientists can effectively and efficiently alter the human germline.[8] "Human germline editing" involves targeting DNA in human sperm, eggs, or embryos that is passed on to future generations through normal reproduction.[9] The potential benefits of germline editing to human society are enormous.[10]

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[2] JAMES R. CLAPPER, SENATE ARMED SERVS. COMM., WORLDWIDE THREAT ASSESSMENT OF THE US INTELLIGENCE COMMUNITY 9 (Feb. 9, 2016), https://www.armed-services.senate.gov/imo/media/doc/Clapper_02-09-16.pdf [https://perma.cc/NH7Q-J42E]; Antonio Regalado, *Top U.S. Intelligence Official Calls Gene Editing a WMD Threat*, MIT TECH. REV. (Feb. 9, 2016), https://www.technologyreview.com/s/600774/top-us-intelligence-official-calls-gene-editing-a-wmd-threat/ [https://perma.cc/KL4D-JEUQ].

[3] CLAPPER, *supra* note 2, at 9 (explaining that gene altering technology is rapidly progressing, and misuse of the technology in humans might lead to spreading heritable diseases or defects).

[4] *See id.* (noting that researchers will "probably" run into problems wielding this technology because of genome complexity, but providing little explanation as to why this is so).

[5] *See id.*; Regalado, *supra* note 2 (explaining how CRISPR is expected to advance gene treatment for diseases).

[6] *See* Fathima Benazir & Gowlikar Abhinayani, *CRISPR/Cas9 Technology: A New Boon in Genome Editing*, 7 INT'L J. PHARMACEUTICAL SCI. & RES. 3336, 3336 (2016) (showcasing other genetic editing technology as compared to CRISPR-Cas9). For instance, zinc finger nucleases ("ZFN") was the first genome altering method to use proteins. *Id.* at 3338. Transcription activator-like effector of nucleases ("TALEN") is a gene editing method that relies on data gathered from repetitive protein repeats and nucleotide sequences. *Id.* at 3341. On the other hand, CRISPR-Cas9 editing technology is more simple and precise than both ZFN and TALEN because rather than using an engineered protein, edits are made using a small sequence of guide RNA. *Id.* at 3336; *see also* Antonio Regalado, *Everything You Need to Know About CRISPR Gene Editing's Monster Year*, MIT TECH. REV. (Dec. 1, 2015), https://www.technologyreview.com/s/543941/everything-you-need-to-know-about-crispr-gene-editings-monster-year/ [https://perma.cc/J3NL-KU8W] (describing the innovative features of CRISPR-Cas9 gene editing technology).

[7] Benazir & Abhinayani, *supra* note 6, at 3338–39 (detailing the use of Cas9 enzymes to alter gene sequences identified as threats on the CRISPR locus by guide RNA).

[8] *See* Regalado, *supra* note 6 (describing the widespread availability of CRISPR-Cas9 and use of CRISPR-Cas9 to make beagles more muscular and mosquitoes malaria resistant).

[9] *Id.*

[10] *See* Heidi Ledford, *CRISPR Fixes Disease Gene in Viable Human Embryos*, 548 NATURE 13, 13–14 (2017) (describing an international research team's success using CRISPR to reverse a mutation in a human embryo that is the primary cause of death in young athletes–hypertrophic cardiomyo-

Researchers are hopeful that they can reduce—or eliminate—the risk of heritable diseases such as Huntington's disease.[11] Likewise, researchers want to introduce beneficial genes to strengthen one's body and prolong good health.[12]

Nonetheless, CRISPR-Cas9 is not a magic bullet.[13] According to Dr. Keith Joung, a renowned pathologist at the Massachusetts General Hospital and Harvard Medical School, more research is needed to reduce off-target gene editing before CRISPR-Cas9 can be used in clinical applications.[14] "Off-targets" occur when the splicing enzyme matches the designated sequence to the wrong gene causing potentially disastrous side-effects.[15] For instance, an off-target impact may result in creating a higher likelihood of a future cancer diagnosis.[16] While scientists remain hopeful that they will be able to more accurately assess the risk of unintended editing through advancing technology, the effects remain unclear for now.[17] Off-target gene altering may create unintended and uncertain changes in a gene pool that could last for *generations*.[18]

One major difficulty with off-target editing is creating a legal scheme that will compensate victims whose symptoms may not appear for generations.[19]

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pathy); David Warmflash, *How Will We Use Gene Editing to Treat Human Disease?*, GENETIC LITERACY PROJECT (Sept. 12, 2016), https://www.geneticliteracyproject.org/2016/09/12/will-use-gene-editing-treat-human-disease/ [https://perma.cc/U8SL-L593] (explaining the potential for genetic engineering to fix a person's inherited abnormal gene pair so that a disease never manifests itself).

[11] Warmflash, *supra* note 10 (explaining how Huntington's disease could be erased from a child's embryo by replacing the abnormal allele sequence).

[12] Eric S. Lander, *Brave New Genome*, 373 NEW ENG. J. MED. 5, 7 (2015) (researching the possibility of adding a gene to increase one's oxygen count for endurance).

[13] *See generally* Yanfang Fu et al., *High-Frequency Off-Target Mutagenesis Induced by CRISPR-Cas Nucleases in Human Cells*, 31 NATURE BIOTECHNOLOGY 822 (2013) (studying the unpredictable nature of CRISPR-Cas9 on human cells that are not targeted for gene modification).

[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/9YG5-EB46] (questioning the safety and clinical readiness of CRISPR-Cas9 in light of research showing that scientists underestimate the frequency of off-target genetic impacts); Fu et al., *supra* note 13, at 1 (providing Dr. Joung's credentials at Harvard Medical School and Massachusetts General Hospital).

[15] Begley, *supra* note 14.

[16] *See id.* (quoting Dr. Joung, from the Massachusetts General Hospital, that off-target impacts "var[y] by ethnic group" and that the unpredictable nature of the off-targets is a problem scientists are ignoring).

[17] *See id.* (describing scientist Dr. Bill Lundberg, from the large genome-editing company CRISPR Therapeutics, as confident that algorithms will display the risk of inaccuracies and improve single-guide RNA to reduce those risks).

[18] *See* Lander, *supra* note 12, at 7 (expressing the inability to "recall" a defective gene from the human gene pool); Jim Kozubek, *How Gene Editing Could Ruin Human Evolution*, TIME (Jan. 9, 2017), http://time.com/4626571/crispr-gene-modification-evolution/ [https://perma.cc/2CRK-KRZ6] (warning that genetic manipulation of the human germline may simultaneously strip humans of genes with harmful mutations but that are also essential for human environmental adaptation).

[19] *See* Sarah Ashley Barnett, *Regulating Human Germline Modification in Light of CIRSPR*, 51 U. RICH. L. REV. 553, 568–69 (2017) (explaining that scientists are unlikely to fully understand how

The Diethylstilbestrol ("DES") drug from the 1980s was a drug prescribed to pregnant women who, years later, suffered from cervical cancer and passed on this genetic predisposition and other health issues to their daughters.[20] DES cases provide a useful framework for addressing generational products liability.[21] They also demonstrate the need to establish a streamlined theory of recovery before cases arise.[22] The potential for market share liability incentivizes genetic manufacturers to anticipate and limit their liability before entering the market.[23]

Part I of this Note explores the expanding germline editing field and the potential risks inherent in human genetic modifications.[24] It also assesses the DES cases to provide insight on how courts have implemented generational tort products liability in the past.[25] Part II analyzes the development of market share liability across the DES cases and how it is analogous to germline engineering liability.[26] Part III draws from the successes and failures of the DES cases to propose a market share liability regime for generational germline editing cases.[27]

I. HUMAN GERMLINE EDITING AND TORT PRODUCTS LIABILITY

Human germline editing is a 2018 reality.[28] In addition to the fierce ethical debate about whether germline editing is moral or beneficial, society needs

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off-target effects will present themselves in humans until clinical trials take place, which poses huge problems since CRISPR-Cas9 can lead to generations of unintended genetic changes).

[20] *DES History*, CTRS. FOR DISEASE CONTROL, https://www.cdc.gov/des/consumers/about/history.html [https://perma.cc/RN6D-A4FN] (recounting the history and legacy of DES).

[21] Naomi Sheiner, Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 FORDHAM L. REV. 963, 995–96 (1978) (recommending a new theory of tort liability based on market share so that DES victims could recover despite not knowing which specific defendant caused the harm). In fact, the California Supreme Court adapted this student's Comment recommendation to extend liability to DES manufacturers on a proportional scheme for recovery. *See* Sindell v. Abbott Labs., 607 P.2d 924, 937 (Cal. 1980).

[22] *See* Sheiner, *supra* note 21, at 1007 (cautioning future courts of the problems modern technology may create when a gap in tort law precludes recovery for harmed consumers).

[23] *See id.* at 1005 (stating that increased liability by virtue of market share liability should result in 1) companies maintaining better records in order to demonstrate their innocence from an accusation of wrongdoing, and 2) companies retaining insurance for cases in which innocence cannot be proven).

[24] *See infra* notes 28–87 and accompanying text.

[25] *See infra* notes 88–122 and accompanying text.

[26] *See infra* notes 123–179 and accompanying text.

[27] *See infra* notes 180–242 and accompanying text.

[28] *See* Lydia Ramsey, *A Revolutionary Gene-Editing Technology Is on Track to Be a $10 Billion Market by 2025*, BUS. INSIDER (Nov. 2, 2017), http://www.businessinsider.com/crispr-set-to-be-a-10-billion-market-by-2025-citi-2017-11 [https://perma.cc/8MDB-N5JW] (citing *Disruptive Innovations V: Ten More Things to Stop and Think About*, CITI, (Nov. 2017), https://ir.citi.com/uims9KeGQBxXr2JWqUOQjpNwL9HlVE9xT6rG0XYhQI%2BlmtfIYoLJ16k%2BJB%2FT48WZqbCUF2pDgc0%3D [https://perma.cc/G5T5-H53D] (predicting that CRISPR-Cas9 will grow to a $10 billion dollar industry, and that CRISPR-based medicine will enter the market in about six years); *Human Gene Editing: A Timeline of CRISPR Cover Stories*, *supra* note 1 (illustrating the nearing possibility and technological breakthroughs of human germline editing through recent cover stories and articles).

a liability scheme for unintended gene editing effects.[29] Courts have dealt with a similar issue of unpredictable generational liability through tort litigation.[30] For instance, germline editing's impact on successive generations resembles the DES cases involving birth defects from the 1940s and 1970s that are still being litigated today.[31] The DES cases impart important lessons for allocating tort liability moving forward.[32]

This Part describes the history and recent breakthrough behind the new gene editing technology—CRISPR-Cas9—and how market share liability emerged in response to DES victims.[33] Section A explains how CRISPR-Cas9 technology is used and regulated, and discusses potential mishaps with the technology.[34] Section B analyzes the history of DES and the rise of market share liability in response to harms that do not manifest for decades but last for generations.[35]

A. Human Germline Editing

1. Recent Technology Developments Involving CRISPR-Cas9

Praised as *Science's* "2015 Breakthrough of the Year," CRISPR-Cas9 gives researchers the tools to edit genes in the human germline with remarkable precision.[36] This breakthrough was the result of scientists studying the in-

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[29] *See* Sarah Karlin, *Gene Editing: The Next Frontier in America's Abortion Wars*, POLITICO (Feb. 16, 2016), http://www.politico.com/story/2016/02/gene-editing-abortion-wars-219230 [https://perma.cc/8BAL-M683] (explaining how the contentious debate on whether to modify genes may unite both pro-life and pro-choice advocates but for varying policy reasons, and that the technology is susceptible to "catastrophic errors").

[30] *See* Sindell v. Abbott Labs., 607 P.2d 924, 937 (Cal. 1980) (applying market share liability for recovery from DES injuries); Bichler v. Eli Lilly & Co., 436 N.Y.S.2d 625, 625 (App. Div. 1981) (using market share liability to award future compensation damages for cancer arising from DES ingestion).

[31] *See Settlement Reached in Eli Lilly Pregnancy Drug Linked to Breast Cancer Case*, CBS NEWS (Jan. 9, 2013), http://www.cbsnews.com/news/settlement-reached-in-eli-lilly-pregnancy-drug-linked-to-breast-cancer-case/ [https://perma.cc/U2KG-XNGH] (stating there are over fifty-one women with pending DES cases in the U.S. District Court for the District of Massachusetts). Negative health effects from both germline genetic modification and DES exposure can be passed on to generations of children. *Compare Sindell*, 607 P.2d at 936 (bringing suit for DES injuries in children), *with* Karlin, *supra* note 29 (describing the potential for scientists to edit the human germline and "tinker with the human race").

[32] *See* Sheiner, *supra* note 21, at 1003 (arguing for courts to consider, for the first time, the application of enterprise liability as a means of recovery for DES victims because the latency period of the drug effectively precluded normal tort recovery); *Settlement Reached in Eli Lilly Pregnancy Drug Linked to Breast Cancer Case*, *supra* note 31 (finding that the numerous pending DES cases and that proof of DES injury by a specific defendant serve as some of the greatest legal barriers).

[33] *See infra* notes 36–122 and accompanying text.

[34] *See infra* notes 36–87 and accompanying text.

[35] *See infra* notes 88–122 and accompanying text.

[36] Marcia McNutt, Editorial, *Breakthrough to Genome Editing*, 350 SCI. 1445, 1445 (2015) (declaring CRISPR gene editing technology to be the scientific breakthrough of the year "poised to revo-

teractions between bacteria and viruses and using their same natural defenses to target specific genes.[37] Bacteria and viruses differ in that bacteria are more complex and can live on their own, whereas, viruses are much smaller and require a host cell in order to survive.[38] Viruses invade bacteria cells by attaching and inserting its genetic DNA or RNA into it.[39] If the bacteria does not recognize it as foreign DNA, it will begin reproducing the viral DNA or RNA until it explodes, thereby, creating more viruses.[40] "CRISPR" describes sections of DNA that serve as part of the bacteria's immune system to protect itself against viruses that it has previously encountered.[41] But, if a bacterium is re-infected with a virus, the CRISPR memory sequences will trigger the bacterium to release a cutting enzyme that fastens itself to the genes of the virus and removes the genes from the bacteria's genome.[42]

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lutionize research"). *Science* articles and journals are sponsored by the American Association for the Advancement of Science ("AAAS"), which is comprised of over 262 scientific societies and is the oldest general science organization. *About Science & AAAS*, SCI. (Nov. 17, 2017), http://www.sciencemag.org/about/about-science-aaas [https://perma.cc/V9BL-V95Z]. As opposed to "gene therapy", which also uses CRISPR-Cas9 and other gene editing technology, germline engineering is heritable, thus it passes on the modified genes. Antonio Regalado, *Engineering the Perfect Baby*, MIT TECH. REV. (Mar. 5, 2015), https://www.technologyreview.com/s/535661/engineering-the-perfect-baby/ [https://perma.cc/NA2P-A4QR]. In contrast, gene therapy allows scientists to target defective cells for repair but the repair is not heritable. *See id.*; *see also* Kenneth W. Krause, *CRISPR-Cas9 Not Just Another Scientific Revolution (Special Report),* DOTING SKEPTIC (Feb. 2016), https://thedotingskeptic.wordpress.com/2016/02/06/crispr-cas9-not-just-another-scientific-revolution/ [https://perma.cc/W4YY-U78V] (expressing the pros and cons of the rapidly advancing germline editing technology). Currently, there is a patent debate on who owns the rights to the recent innovations in CRISPR. *See generally* Kristin Beale, *The CRISPR Patent Battle: Who Will Be "Cut" Out of Patent Rights to One of the Greatest Scientific Discoveries of Our Generation?*, 2016 B.C. INTELL. PROP. & TECH. F. 1, http://bciptf.org/wp-content/uploads/2016/02/KBeale-CRISPR.pdf [https://perma.cc/TK99-Y63Y] (analyzing the patent debate over CRISPR-Cas9). The debate is between Jennifer Doudna of the University of California, Berkeley, and Dr. Feng Zhang of the Broad Institute and MIT, who each claim they developed CRISPR first. *See id.* at 2.

[37] *See* Krause, *supra* note 36 (explaining how CRISPR-Cas9 functions by utilizing the cell's natural functions and merely engineers them to cut specific strands identified by the researcher).

[38] *Bacteria vs. Virus*, DIFFEN (Nov. 18, 2017), http://www.diffen.com/difference/Bacteria_vs_Virus [https://perma.cc/MX2Z-4BQA].

[39] *Id.* (explaining that a virus attaches to a cell using its legs and thereafter injects its genetic material into the cell to either produce proteins immediately, or to be stored in the RNA or DNA and triggered at a later time).

[40] *Id.*

[41] Krause, *supra* note 36. Scientists observed that bacteria retain small segments of virus DNA it has previously encountered and separates them to form a repetition of "clustered regularly interspaced short palindromic repeats". *Id.*

[42] 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/W69C-H6CP]. Sometimes a protein will incorporate an invading virus's DNA into its genetic makeup in the form of non-coding RNA in order to identify and stop viruses attempting to invade the bacteria. Alex B. Berezow, *Bacteria Have Immune Systems, Too*, REALCLEAR SCI. (Sept. 6, 2012), http://www.realclearscience.com/blog/2012/09/bacteria-have-immune-systems-too.html [https://perma.cc/RU4B-JLGP]. Non-coding RNA allows the bacteria to function as usual without performing the detrimental instructions the

As opposed to other gene editing methods, like zinc finger nucleases ("ZFN") and transcription activator-like effector of nucleases ("TALEN"), CRISPR-Cas9 is more precise, simple, and affordable.[43] Both ZFN and TALEN require more complicated processes using a customized protein rather than a short RNA sequence.[44] By contrast, scientists using CRISPR can encode a single guide RNA with the proper gene sequence for editing.[45] The Cas9 enzyme will read the RNA and make the genetic cuts.[46] Unlike traditional gene editing methods, CRISPR-Cas9 increases efficiency by allowing scientists to alter multiple genome sites at once.[47] This technology is both readily available and simple; a scientist can edit a DNA strand for a mere sixty-five dollars.[48]

2. Current Uses and Regulations of Human Germline Editing

In an outpouring of recent experiments, the CRISPR-Cas9 methodology has enabled scientists to treat muscular dystrophy in mice, counteract drug-resistance in insects, increase physical strength in dogs, generate virus-resistant pigs, and modify crops for greater protection.[49] In April 2015, Chinese re-

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virus inserted. *Id.* If the same viral DNA is inserted into the bacteria, the non-coding RNA serves as an alarm system to notify the bacteria that a foreign invader has entered and that it must rid itself of the material immediately. *Id.* Specifically, the Cas-9 protein is the enzyme from the bacterium Streptococcus pyogenes used to initiate the cutting technique that scientists have discovered makes the gene editing process much easier. Benazir & Abhinayani, *supra* note 6, at 3338.

[43] *See* Josiah Zayner, *DIY CRISPR Kits, Learn Modern Science by Doing*, INDIEGOGO (Nov. 18, 2017), https://www.indiegogo.com/projects/diy-crispr-kits-learn-modern-science-by-doing#/ [https://perma.cc/4A3Y-KHAF] (selling CRISPR kits online for a mere seventy-five dollars, and advertising that "everyone" can follow the instructions and genetically engineer bacteria). Other gene editing methods include zinc finger nucleases and transcription activator-like effector of nucleases. Krause, *supra* note 36. The CRISPR-Cas9 methods only require three components: the CRISPR RNA and a trans-activating RNA which signal the Cas9 enzyme to cut the specific sequence. *Id.*

[44] Benazir & Abhinayani, *supra* note 6.

[45] Krause, *supra* note 36. Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) both hold genetic information, but DNA is double stranded while RNA is single stranded, and they have different roles in the body. Anne Marie Helmenstine, *The Differences Between DNA and RNA*, THOUGHTCO. (Aug. 3, 2017), https://www.thoughtco.com/dna-versus-rna-608191 [https://perma.cc/DNL8-G4TG]. DNA carry and transfer genetic information throughout the body. *Id.* RNA codes directly for amino acids and transfers protein-making information from DNA to ribosomes. *Id.*

[46] Regalado, *supra* note 42.

[47] Krause, *supra* note 36 (explaining the simplicity of CRISPR-Cas9 in that it only requires three components which can alter multiple sites on the genome from one application).

[48] *See* Krause, *supra* note 36 (explaining how a scientist can create a single guide RNA with the sequence of DNA it wants to splice, order it from a manufacturer for sixty-five dollars, and wait for mail delivery).

[49] John Travis, *Making the Cut*, 350 SCI. 1456, 1456–57 (2015) (describing another experiment where scientists wiped out populations of mosquitos by making them infertile and created malaria-resistant mosquitos); Fiona MacDonald, *10 Things You Need to Know About the UK Allowing Genetic Modification of Human Embryos*, SCI. ALERT (Feb. 2, 2016), http://www.sciencealert.com/10-things-you-need-to-know-about-the-uk-s-decision-to-allow-genetic-modification-of-human-embryos [https://perma.cc/7PWB-R5DW] (describing a recent regulation by the UK Human Fertilisation and Embryology Authority sanctioning an experiment on germline-editing of human embryos); Regalado, *supra*

searchers shocked the world by becoming the first to use CRISPR-Cas9 to edit human embryos.[50] In 2017, researchers in the United States also edited human embryos using CRISPR-Cas9.[51] The moral dilemma surrounding human genetic editing has remained a heated issue.[52] About five hundred scientists gathered in Washington D.C. in 2015 for the International Summit on Human Gene Editing.[53] The Summit established a worldwide consensus to prohibit human germline clinical trials using this technology.[54] While the Summit agreed that research was "clearly needed and should proceed," it also concluded that it would be "irresponsible" to create a genetically engineered human at such an early stage of research, citing safety and moral concerns.[55] In contrast to this 2015 worldwide consensus, the National Academy of Sciences, Engineering, and Medicine, in February 2017, expressed its support for editing a child's germline under a strict regulatory framework: the circumstances require the

note 6 (highlighting the important nature of genetically edited crops compared to classically genetically modified crops, like corn, in that Federal Drug Administration ("FDA") regulations may not apply since genes from bacteria are not introduced and instead the plant's genes are spliced themselves).

[50] *See* Puping Liang et al., *CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes*, 6 PROTEIN & CELL 363, 363 (2015) (detailing a study that replaced the gene for a blood disorder (β-thalassaemia) in twenty-eight out of seventy-one non-viable human embryos); Sara Reardon, *Ethics of Embryo Editing Paper Divides Scientists*, NATURE (Apr. 24, 2015) http://www.nature.com/news/ethics-of-embryo-editing-paper-divides-scientists-1.17410 [https://perma.cc/8VWE-QDPE] (commenting on the intense ethical debate surrounding genetically modifying human embryos).

[51] *See* Hona Ma et al., *Correction of a Pathogenic Gene Mutation in Human Embryos*, 548 NATURE 413, 414–15 (2017) (editing *MYBPC3* mutations from human embryos using CRISPR-Cas9 in order to eliminate the gene for myocardial disease, HCM); Steve Connor, *First Human Embryos Edited in U.S.*, MIT TECH. REV. (July 26, 2017), https://www.technologyreview.com/s/608350/first-human-embryos-edited-in-us/ [https://perma.cc/4XLW-HMDY] (proclaiming that scientists in Portland, Oregon used CRISPR-Cas9 to edit a gene mutation in human embryos that causes a harmful heart disease).

[52] *See generally* Michael Gross, *Bacterial Scissors to Edit Human Embryos?*, 25 CURRENT BIOLOGY MAG. R439 (2015) (reviewing the negative public response to recent developments in germline editing technology). On March 19, the International Society for Stem Cell Research called for "a moratorium on attempts" to edit the genome in clinical applications. *Id.* at R441. They reasoned that the technology was too insecure and that current research "lack[s] an adequate understanding of the safety and potential long-term risks of germline genome modification." *Id.* Also, the International Bioethics Committee of UNESCO has recently amended their report on the Human Genome asking for a moratorium on human germline engineering. *See About Human Germline Gene Editing*, CTR. FOR GENETICS & SOC'Y (July 9, 2015) http://www.geneticsandsociety.org/article.php?id=8711 [https://perma.cc/W99Y-HJ4Q].

[53] Rob Stein, *Scientists Debate How Far to Go in Editing Human Genes*, NPR (Dec. 3, 2015), http://www.npr.org/sections/health-shots/2015/12/03/458212497/scientists-debate-how-far-to-go-in-editing-human-genes [https://perma.cc/A675-RF6E].

[54] *See id.*

[55] *Id. see also Open Letter Calls for Prohibition on Reproductive Human Germline Modification*, CTR. FOR GENETICS & SOC'Y (Nov. 2015), http://www.geneticsandsociety.org/article.php?id=8999 [https://perma.cc/YM6B-PGXZ] (publishing an open letter signed by over 100 scientists calling for a prohibition on human germline modification because "the creation of 'genetically modified humans' or 'designer babies'" has the potential to "irrevocably alter the nature of the human species and society").

procedure to be reviewed and the child to be monitored periodically for generations.[56]

As scientists continue to debate the ethical questions of human genetic modification, some countries maintain loose regulations on the practice while at least twenty-five countries have prohibited human germline engineering entirely.[57] China has created "guidelines"—but not laws—regulating the industry, and Japan, Mexico, and South Africa, have ambiguous policies about whether or not human germline editing research is allowed.[58] In contrast, Canada, Brazil, Germany, and Australia do not allow human germline genetic experimentation at all.[59] In 2016, the British Human Fertilization and Embryology Authority ("HFEA") granted the first license by a national regulator for scientists to edit the human germline using human embryos for research.[60]

In the United States, there is no federal ban on germline engineering and the government only places restrictions on the practice.[61] In 2015, Congress passed the United States Federal Omnibus Bill, which prohibits any Federal Drug Administration ("FDA") funding to be given to research on human germline genetic engineering.[62] The National Institutes of Health ("NIH") manages funding of gene transfer research through the Recombinant DNA Advisory Committee ("RAC").[63] The RAC's current stance is that it is too soon for companies to perform germline gene edits on human embryos.[64] The FDA regulates the industry for all gene modifications performed in clinical trials.[65]

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[56] Harald König, *The Illusion of Control in Germline-Engineering Policy*, 35 NATURE BIOTECHNOLOGY 502, 503 (describing the National Academy of Sciences, Engineering, and Medicine's contingent support for germline engineering); Amy Harmon, *Human Gene Editing Receives Science Panel's Support*, N.Y. TIMES (Feb. 14, 2017), https://www.nytimes.com/2017/02/14/health/human-gene-editing-panel.html [https://perma.cc/S9HD-YJ36] (describing the National Academy of Sciences, Engineering, and Medicine's decision to support, in extenuating circumstances, the need to edit a child's germline).

[57] Melanie Senior, *UK Funding Agencies Weigh in on Human Germline Editing*, 33 NATURE BIOTECHNOLOGY 1118, 1119 (2015) (analyzing the procedures and regulations that countries have imposed on human germline engineering).

[58] *See* König, *supra* note 56, at 504 (charting the different national and international policies on germline engineering research and clinical trials).

[59] *Id.*

[60] MacDonald, *supra* note 49.

[61] König, *supra* note 56, at 504; *see also* Heidi Ledford, *Where in the World Could the First CRISPR Baby Be Born?*, NATURE (Oct. 13, 2015), http://www.nature.com/news/where-in-the-world-could-the-first-crispr-baby-be-born-1.18542 [https://perma.cc/9VGL-AMB2] (describing United States policies towards germline engineering).

[62] *About Human Germline Gene Editing*, *supra* note 52.

[63] Barnett, *supra* note 19, at 577.

[64] *Id.* at 579. The director of the NIH issued a statement that the safety and ethical consequences of genetically editing human embryos is too uncertain to approve any current clinical trials. Francis S. Collins, *Statement on NIH Funding of Research Using Gene-editing Technologies in Human Embryos*, NAT'L INSTS. HEALTH (Apr. 28, 2015), https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos.

[65] Barnett, *supra* note 19, at 578.

Although the FDA would most likely regulate genetically modifying humans in the U.S., it does not officially ban potential clinical application.[66]

The biotechnology industry for genome editing is expanding rapidly because of revolutionary technology like CRISPR-Cas9.[67] In May 2015, MarketsandMarkets published a report predicting that the genome editing market will be worth $3.5 billion in just four years.[68] In Boston, three start-up companies have partnered with pharmaceutical companies such as Bayer and Novartis and raised an aggregated $1 billion.[69] In fact, the pharmaceutical giant Novartis has funded and contracted with the biotechnology start-up Intellia to develop CRISPR techniques to treat cancer and to research "limited in vivo" applications of the technology.[70]

A large concern with gene editing is that companies will exploit CRISPR-Cas9 to perform risky experiments since it is cheap, simple, and yields high rewards.[71] Sir Venki Ramakrishnan, the 2009 Nobel prize winner in chemistry, echoes the fears of many in the scientific community that "once a technology is feasible, we may well regulate it, but someone somewhere may start using it in ways we consider unethical."[72] With such technology at their fingertips,

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[66] Ledford, *supra* note 61 (explaining that the FDA does not directly state whether or not clinical applications are banned).

[67] *Genome Editing Market Worth $3,514.08 Million by 2019*, PR NEWSWIRE (May 7, 2015), http://www.prnewswire.com/news-releases/genome-editing-market-worth-351408-million-by-2019-502930301.html [https://perma.cc/TCS2-N9Q2]. Already, start-up company Editas has made an announcement that it hoped to use CRISPR technology to edit human DNA to treat blindness in 2017. Antonio Regalado, *CRISPR Gene Editing to Be Tested on People by 2017, Says Editas*, MIT TECH. REV. (Nov. 5, 2015), https://www.technologyreview.com/s/543181/crispr-gene-editing-to-be-tested-on-people-by-2017-says-editas/ [https://perma.cc/N75R-GPSB]. While the plans are to perform clinical trials in gene therapy and not germline, they still discuss the rapid development of the industry in applying CRISPR to modify human DNA. *See id.*

[68] *Genome Editing Market Worth $3,514.08 Million by 2019*, *supra* note 67 (projecting the market growth of the genome editing market and listing the following companies as industry leaders: GenScript USA Inc. (U.S.), Horizon Discovery Group plc (U.K.), Integrated DNA Technologies, Inc. (U.S.), Lonza Group Ltd. (Switzerland), New England Biolabs, Inc. (U.S.), OriGene Technologies, Inc. (U.S.), Sangamo Biosciences, Inc. (U.S.), Sigma-Aldrich Corporation (U.S.), Thermo Fisher Scientific, Inc. (U.S.), and Transposagen Biopharmaceuticals, Inc. (U.S.)).

[69] Regalado, *supra* note 42.

[70] *7 Gene Editing Companies Investors Should Watch*, NANALYZE (Apr. 25, 2015), http://www.nanalyze.com/2015/04/7-gene-editing-companies-investors-should-watch/ [https://perma.cc/8JH2-2VCQ].

[71] *See* Amy Dockser Marcus & Joe Palazzolo, *Breakthrough Gene Technology Attracts Investors Amid Patent Dispute*, WALL STREET J. (Sept. 22, 2016), https://www.wsj.com/articles/breakthrough-gene-technology-attracts-investors-amid-patent-dispute-1474567512?mod=briefly_more_on [https://perma.cc/2PNW-BKBB] (explaining the "messy" nature of CRISPR-Cas9's patent dispute and how companies are responding by licensing from both sides, or using the gene editing technology without a license until the issue is resolved).

[72] Ian Sample, *Genetic Engineering of Humans Has Great Potential, Says Nobel Winner*, THE GUARDIAN (May 23, 2016), https://www.theguardian.com/science/2016/may/24/genetic-engineering-humans-great-potential-nobel-winner [https://perma.cc/799L-LT69] (quoting British scientist, Sir

companies may strive to remain ahead of competitors by racing to patent lucrative applications of CRISPR-Cas9 to the human germline and clinically apply the technology before it is thoroughly tested.[73]

3. Potential Consequences and Risks of Human Germline Editing

As CRISPR-Cas9 techniques advance, off-target consequences for individuals and subsequent generations are of immense concern.[74] In a 2013 study on Duchenne muscular dystrophy ("DMD"), which results from a genetic mutation on the X chromosome and causes muscle deterioration, Dr. Eric Olson successfully treated DMD afflicted mice by editing their genome using CRISPR-Cas9.[75] Although off-target consequences were rare in that specific experiment, Dr. Olson acknowledged that CRISPR genome editing can unintentionally cause lifelong changes to an organism's DNA.[76] Many scientists worry that treating a human with DMD using CRISPR-Cas9 technology may lead to generations of unforeseen and possibly irreparable harm—such as removing someone's protective gene for cancer.[77] Thus, scientists worry that human manipulation of the genome may lead to long-term negative impacts on the gene pool itself.[78]

Venki Ramakrishnan, in an interview about his thoughts on the application of human germline genetic engineering).

[73] *See Genome Editing Market Worth $3,514.08 Million by 2019*, *supra* note 67 (showing the popularity of the industry by listing the numerous genetic companies trying to take advantage of the growing market). According to an investment report by MarketsandMarkets, the genome editing industry is estimated to reach $3,514.08 million by 2019, and expand at a compound annual growth rate of 13.75%. *See id.* With such strong incentives to invest in genome editing research, it is only a matter of time before Pandora's box is opened and clinical trials are performed around the world resulting in a race to dominate the market. *See id.* Already, the following companies have invested heavily in CRISPR-Cas9 therapies without regard to who wins the patent dispute: Bayer invested $335 million into CRISPR Therapeutics; Regeneron Pharmaceuticals invested $125 million into Intellia Therapeutics; Vertex invested $105 million into CRISPR Therapeutics; Fulcrum Therapeutics invested $55 million into Horizon Discovery Group; Juno Therapeutics invested $47 million into Editas Medicine. Amy Dockser Marcus & Joe Palazzolo, *Crispr-Cas9 and the Companies Getting on Board*, WALL STREET J. (Sept. 22, 2016), http://blogs.wsj.com/briefly/2016/09/22/crispr-cas9/ [https://perma.cc/6465-L69T].

[74] *See* Patrick Skerrett, *Experts Debate: Are We Playing with Fire When We Edit Human Genes?*, STAT (Nov. 17, 2015), https://www.statnews.com/2015/11/17/gene-editing-embryo-crispr/ [https://perma.cc/R4LC-KBW8] (compiling comments from renowned scholars on the ethical and safety concerns of genetically modifying human embryos).

[75] Chengzu Long et al., *Prevention of Muscular Dystrophy in Mice by CRISPR/Cas9-Mediated Editing of Germline DNA*, 345 SCI. 1184, 1184 (2014) (analyzing the impact of using CRISPR-Cas9 to edit out harmful DMD genes on the germline of DMD afflicted mice).

[76] Regalado, *supra* note 42 (describing the DMD study and Dr. Olson's thoughts on its success).

[77] *See* Kozubek, *supra* note 18 (explaining the potential evolutionary consequences of diluting the gene pool with mutations); Skerrett, *supra* note 74 (noting that the secondary effects of removing a harmful gene may be removal of a protective gene for cancer).

[78] *See* Kozubek, *supra* note 18; Skerrett, *supra* note 74 (noting that excision of a particular gene may result in removal of both harmful and beneficial genetic characteristics). Nevertheless, Cornell scientist, Philipp Messer, predicts that natural mutations will disrupt the ability of target genes to cut the

In the first reported human germline genetic modification, Chinese researchers replaced the gene for a blood disorder called β-thalassaemia in twenty-eight out of seventy-one non-viable embryos.[79] In the process, they caused unwanted alterations in other parts of the genome.[80] In subsequent research, Chinese researchers attempted to insert a mutated gene into the germline to create HIV resistance and were successful in a mere four out of twenty-six non-viable embryos and again, caused unwanted mutations.[81]

Notably, even if scientists can precisely edit the targeted gene, unintended *causal reactions* may still ensue.[82] This is because genes that increase the risk for some diseases may actually decrease the risk for others.[83] For instance, if a genetic company targets someone's CCR5 gene, which increases the risk for contracting West Nile, removal of the gene will also rid her of an important protection from HIV.[84] Likewise, altering someone's MC1R gene in order to produce vibrant red hair can also increase her risk of melanoma.[85] In one study, geneticists who modified a mouse's gene in order to protect against tumors

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DNA, and thus create a limitation to spreading modified genes. *See* Tina Hesman Saey, *Seeing the Upside in Gene Drives' Fatal Flaw*, ACCESS SCI. (July 15, 2016), https://www.accessscience.com/content/seeing-the-upside-in-gene-drives-fatal-flaw/SN1607261 [https://perma.cc/3NHZ-VTGA]. If predicted correctly, the mutations would be slowly passed with a fifty percent acceptance rate meaning after one hundred generations, the mutation would be present in fifty percent of the population. *See id.*

[79] *See* Liang et al., *supra* note 50, at 363 (noting the unwanted changes in gene sequencing and increased genetic mutations).

[80] *See id.*; Akshat Rathi, *Chinese Researches 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/AH2X-MM7S] (describing the Chinese research using CRISPR-Cas9 and the unsuccessful trials that produced unplanned and unwanted genetic mutations).

[81] Rathi, *supra* note 80 (assessing the impact of trying to alter the germline to create HIV resistance). Notably, recent developments in CRISPR germline editing technology, called "base editing," allow for a single edit to change a letter in a DNA strand, as opposed to CRISPR-Cas9 which works to deactivate an entire gene or allow gene insertion. *See* James Gallagher, *DNA Surgery on Embryos Removes Disease*, BBC NEWS (Sept. 28, 2017), http://www.bbc.com/news/health-41386849 [https://perma.cc/PAB8-XQF9] (describing the new advancements to CRISPR technology using "base editing"). Because base editing is so narrow, it may decrease off-target impacts for diseases caused by a single mutation. *See id.* A team of researchers in China has recently demonstrated that base editing leads to less off-target impacts than CRISPR-Cas9 when they cured the genetic defect of a blood disorder by changing the genetic code from a G to an A. *See id.*

[82] *See* Emily Mullin, *CRISPR 2.0 Is Here, and It's Way More Precise*, MIT TECH. REV. (Oct. 25, 2017), https://www.technologyreview.com/s/609203/crispr-20-is-here-and-its-way-more-precise/ [https://perma.cc/VRJ8-CY62] (describing the recent advancements in CRISPR to use "base editing," which results in increased targeted genetic changes with less risk of unwanted mutations). *But see* Lander, *supra* note 12, at 6 (commenting on the significant genetic advancements CRISPR has to offer and cautioning that the technology is still not ready for human germline trials).

[83] Lander, *supra* note 12, at 6.

[84] *See id.* at 6–7 (explaining how these "protective variants" that increase the risk for one disease and protect against another are also present for type 1 diabetes and Crohn's disease). Another disease that looks especially appealing to the germline editing community is Alzheimer's; however, the targeted gene has also been known to improve working memory in young adults. *See id.*

[85] *Id.* at 7.

also had the unintended effect of causing the mouse to age prematurely, complete with osteoporosis, decreased life-span, and organ deterioration.[86] Even if perfectly executed, human disruption of genes may have unintended and poorly—if at all—traceable consequences for generations.[87]

B. Product Liability Issues and DES Cases for Comparison

1. DES's Generational Impacts

Diethylstilbestrol, commonly known as "DES," was hailed as a miracle drug that shielded pregnant women from miscarriages, premature labor, and other pregnancy complications.[88] DES was manufactured in 1938 by researchers who synthesized estrogen into pill-form so that it could be taken orally.[89] In 1939, Chicago physiologists discovered that giving DES to pregnant rats and mice caused damage to a developing fetus and produced miscarriages.[90] Despite these findings, pharmaceutical companies successfully persuaded the FDA to allow them to continue to prescribe DES to pregnant women.[91]

The drug was routinely prescribed from 1940 to 1971, until researchers detected a strong correlation between DES and cervical and vaginal cancer.[92] At this point, the damage could not be undone since about 5–10 million children were exposed while in utero.[93] As revealed in later studies, young daughters of women who took DES while pregnant had cancer risks *forty times* higher than non-exposed daughters.[94] These risks increased as the daughters aged.[95] Research on

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[86] Stuart D. Tyner et al., *P53 Mutant Mice That Display Early Ageing-Associated Phenotypes*, 415 NATURE 45, 45 (2002) (researching the impact of inserting a gene into a mouse to protect against tumors).

[87] *See* Lander, *supra* note 12, at 7 (cautioning that even a flawless gene alteration to protect against cancer may have unexpected negative impacts like early aging).

[88] *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/T87J-22DA] (analyzing the compiled data on women who took DES and their children from a variety of studies).

[89] *DES History*, *supra* note 20 (describing the history and negative health impacts of DES on pregnant women). Doctors and researchers believed that the added estrogen would prevent miscarriages. *Id.* DES proved to be profitable in that it could be synthesized from coal tar and was more than twice as powerful as naturally occurring estrogen and could be taken orally. Bichler v. Eli Lilly & Co., 436 N.Y.S.2d 625, 628 (App. Div. 1981).

[90] *Bichler*, 436 N.Y.S.2d at 629.

[91] *See id.* at 628–29.

[92] *See Diethylstilbestrol (DES) and Cancer*, *supra* note 88 (outlining the history of DES and noting that doctors in Europe continued to prescribe the drug for seven years after the FDA issued warnings to physicians about the devastating effects).

[93] *See DES History*, *supra* note 20.

[94] *Diethylstilbestrol (DES) and Cancer*, *supra* note 88.

[95] *Id.* (finding that the risks of cancer for women who took DES and their daughters increase once in their forties). *See generally* Janneke Verloop et al., *Cancer Risk in DES Daughters*, 21 CANCER CAUSES & CONTROL 999 (2010) (studying how the risk of certain cancers, like vaginal and melanoma, increase with age in a study of 12,091 DES exposed Dutch women). Exposed daughters experi-

potential DES side effects has continued as scientists and doctors strive to identify and treat DES exposed victims from diseases that escalate or appear with age.[96] With generations of negative health effects and increased risks for diseases over time, plaintiffs have struggled to find a legal remedy for their harm.[97]

2. Tort Liability Challenges and Innovations

Because of the extraordinary circumstances surrounding the DES disaster, including latent health effects and the vast number of unidentifiable defendants, DES victims argued for a novel theory of tort liability.[98] As the Supreme Court of California, in *Sindell v. Abbott Laboratories* in 1980 explained, one of the greatest predicaments was whom to hold responsible since finding the specific DES manufacturer for a prescription taken decades earlier was nearly impossible.[99] Drug manufacturers often did not have direct interaction with consumers, so most plaintiffs could not retrace or remember what a specific pill, taken years ago, looked like.[100] The *Sindell* court noted that consumer harm from DES exposure often did not show up for at least a generation, and manufacturers did not prescribe its drugs, let alone maintain records of who received its drug.[101] Therefore, under traditional tort law, a DES plaintiff could not re-

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enced a 1.7% greater risk for breast cancer at ages forty or older, and a 35.4% greater risk for preterm delivery. Robert N. Hoover et al., *Adverse Health Outcomes in Women Exposed in Utero to Diethylstilbestrol*, 365 NEW ENG. J. MED. 1304, 1306 (2011) (assessing future DES impacts on women exposed in utero).

[96] *See Role of DES Cohort Studies*, CTRS. FOR DISEASE CONTROL, https://www.cdc.gov/des/consumers/research/understanding_cohort.html [https://perma.cc/5X7U-7A2C] (explaining that DES daughters typically do not need to worry about infertility, ectopic pregnancy, or other endocrinal difficulties until after their thirties). In fact, Cohort studies compiled by the Center for Disease Control, still monitor about 15,000 exposed individuals since many cancers are not visible until later in life. *See id.* (listing the following ongoing Cohort Studies: Diethylstilbestrol Adenosis Project; DES Mothers Study; Mayo Clinic Sons Study; Connecticut Mothers Study; Dieckmann Cohort; British Research Medical Council Study; British Randomized Trial; Registry for Research on Hormonal Transplacental Carcinogenesis).

[97] *See* Zafft v. Eli Lilly & Co., 676 S.W.2d 241, 242, 247 (Mo. 1984) (dismissing plaintiff's suit when they could not identify the specific manufacturer who supplied the DES); Victor E. Schwartz & Liberty Mahshigian, *Failure to Identify the Defendant in Tort Law: Towards a Legislative Solution*, 73 CALIF. L. REV. 941, 942–43 (1985) (analyzing potential tort and legislative solutions to the problem of assigning liability for harm caused by a generic drug when the defendant is unidentifiable).

[98] *See* Sindell v. Abbott Labs., 607 P.2d 924, 937–38 (Cal. 1980) (applying a novel concept of market share liability in order to compensate women and children suffering from the disastrous health effects of DES exposure); Sheiner, *supra* note 21, at 966–67 (declaring that by 1977, hundreds of DES plaintiffs sought recovery from DES manufacturers).

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

[100] *See id*. at 930.

[101] *See id*.

cover unless she could identify the specific manufacturer of the pill she ingested years ago.[102]

In response to these DES cases, tort law evolved to allow plaintiffs to recover despite a pill's generic formula and the inability to find specific defendants.[103] Without a change or compromise in tort law, recovery proved "insurmountable" to plaintiffs whose cancer arrived years later.[104] This new tort theory assigned liability via a company's DES *market share*.[105] The *Sindell* court was the first to adopt the market share liability theory and held that plaintiffs could recover against pharmaceutical companies according to their participation in the market.[106] The principle emanated from the "alternative liability" theory as expressed in the 1948 Supreme Court of California case, *Summers v. Tice*.[107] *Summers* held that a plaintiff, whose eye was injured by one of two negligent hunters, could hold them jointly and severally liable despite not knowing which one was ultimately responsible.[108] This theory relied on a fairness rationale: both hunters were wrongdoers, so the burden should shift from the plaintiff to the defendants to prove otherwise.[109]

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[102] *See* Gorman v. Abbott Labs., 599 A.2d 1364, 1364 (R.I. 1991) (holding that tort liability requires an identifiable defendant who caused the injury); Schwartz & Mahshigian, *supra* note 97 (explaining the identification problem in tort law for harm caused by a generic drug).

[103] *See* Sheiner, *supra* note 21, at 994, 996 (responding to the problem of defendant identification in DES cases with a new concept of tort liability based on market share). This novel theory of tort liability was proposed in a student comment and adopted for the first time in *Sindell*. *See Sindell*, 607 P.2d at 924–43.

[104] *See Bichler*, 436 N.Y.S.2d at 632 (reasoning that courts must adapt the law as fairness demands when "traditional evidentiary requirements of tort law may be insurmountable"); Abel v. Eli Lilly & Co., 343 N.W.2d 164, 173 (Mich. 1984) (applying a modified version of alternative liability theory tailored specifically to DES plaintiffs given the unique hurdles surrounding proof of causation). The court clarified that the policy of alternative liability is not just being applied, but that it is forming a "new DES-unique version of alternative liability." *Abel*, 343 N.W.2d at 173. Several courts have adopted their own version of market share liability and expanded upon the doctrine as they believed justice required. *See generally* Andrew B. Nace, Note, *Market Share Liability: A Current Assessment of a Decade-Old Doctrine*, 44 VAND. L. REV. 395 (1991) (comparing and contrasting various courts' applications of market share liability).

[105] *See Sindell*, 607 P.2d at 938 (applying market share liability for the first time); *Bichler*, 436 N.Y.S.2d at 625 (applying market share liability and awarding future damages for children's increased risks of cancer).

[106] *Sindell*, 607 P.2d at 937; Nace, *supra* note 104, at 396 (noting that the Supreme Court of California "created" the theory of market share liability).

[107] *See Sindell*, 607 P.2d at 928, 936 (building on notions of tort law that allow for recovery because fairness and common acts of negligence and justice permit it); Summers v. Tice, 199 P.2d 1, 4 (Cal. 1948) (finding that when two defendants are culpable for causing the plaintiff's injury, the burden shifts to the defendants to prove they were not the party responsible).

[108] *See Summers*, 199 P.2d at 1, 5.

[109] *See id*. at 4.

3. Successes and Failures in Providing Remedies to DES Victims

One of the problems with compensating DES victims is the inability to predict with certainty what damages are sufficient to cover present and future health complications.[110] The effects of DES correlate with a victim's age in that breast and vaginal cancer risks increase dramatically as the victim gets older.[111] Accounting for such risks when filing a lawsuit can be difficult.[112] Particularly, once a plaintiff is on notice, she risks losing her claim through the statute of limitations unless a state has instituted revival statutes which allow DES claims to be brought once effects are experienced, and not just once she knows she was exposed to DES.[113] On the other hand, with little information except health impacts, a court may find it necessary to restrict standing to a specific generation.[114] In *Enright v. Eli Lilly and Company* in 1988, the Court of Appeals of New York did not recognize a handicapped grandchild's claim against DES manufacturers since the evidence was too obscure and attenuated to have a jury trial.[115]

Courts have been sympathetic to plaintiffs' concerns about developing cancer and have awarded damages for future harm.[116] In 1995, the New York state trial court in *In re New York County DES Litigation* affirmed a jury verdict awarding damages ranging from $2,500–$58,000 for future health complications for multiple DES plaintiffs.[117] Notably, the court recognized that future damages served as valid compensation for the plaintiffs' "unique, far-ranging and severe physical and psychological injuries."[118]

As DES exposed children begin to experience latent health effects, there remain numerous pending DES cases across the country.[119] Nonetheless, many

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[110] *See supra* notes 92–96 (explaining the increased risks of diseases associated with DES as one ages).

[111] *See* Hoover et al., *supra* note 95, at 1306 (identifying DES health risks).

[112] *See* Enright v. Eli Lilly & Co., 570 N.E.2d 198, 228–30 (N.Y. 1991), *rev'g*, 553 N.Y.S.2d 494 (App. Div. 1990) (explaining the difficulty of connecting negative health impacts from cancer and other diseases to DES exposure).

[113] *See id.* at 229–30 (recognizing the constitutionality of New York's revival statute that allows DES claims stemming from latent effects or injuries that appear years later, but limiting recovery to three generations of victims).

[114] *See id.* at 228 (insisting that after three generations of victims, the connection between the alleged harm and DES becomes too attenuated).

[115] *See* Enright v. Eli Lilly & Co., 533 N.Y.S.2d 224, 228 (Sup. Ct. 1988) (explaining that the "passage of time and generations obscure such evidence to the extent that a third generation lawsuit" could only stand on "sympathy and conjecture").

[116] *See In re* New York County DES Litig., 211 A.D.2d 500, 500 (N.Y. App. Div. 1995) (affirming the jury verdict awarding damages for likelihood of disease).

[117] *See id.*

[118] *See id.*

[119] *Settlement Reached in Eli Lilly Pregnancy Drug Linked to Breast Cancer Case*, *supra* note 31 (discussing the current litigation of DES injuries in Massachusetts federal court and acknowledging there are thousands of similar lawsuits that have been filed across the nation, but many have settled).

of these cases are beginning to settle without much information released to the public.[120] Recently, four sisters diagnosed with breast cancer, allegedly caused by their mother's use of DES while pregnant, settled with the pharmaceutical company Eli Lilly and Company.[121] Although market share liability may be inadequate to fully compensate individuals who fear suffering from painful diseases or who actually suffer from said diseases, this recent settlement indicates that recovery is possible and ongoing.[122]

II. COMPANY LIABILITY FOR GENERATIONS OF PRODUCTS LIABILITY CLAIMS

Beyond the lucrative profits and health benefits resulting from gene altercation lies the potential for generations of health defects.[123] In turn, multigenerational health defects raise serious liability questions.[124] Market share liability acts as an alternative theory of tort law appropriate for situations in which the harm from a defective product does not appear for decades or even generations.[125] Under traditional tort law, plaintiffs suffering from a genera-

[120] *See id.* One of the problems with settling, as opposed to receiving a verdict at trial, is that the public does not know the extent of recovery by a victim. *See Lilly in a DES Settlement*, N.Y. TIMES (May 19, 1992), http://www.nytimes.com/1992/05/19/business/lilly-in-a-des-settlement.html [https://perma.cc/DV35-NEMG] (discussing the 1992 DES settlements outside of the courtroom and noting that they were sealed). For instance, Eli Lilly and Company, one of the largest DES manufacturers, has settled repeatedly with DES victims after they file suit. *See id.* In 1992, Eli Lilly and Company settled 250 cases in just seventeen months. Settlement offers were sealed, but one claimant reportedly received $1 million from the company. *See id.*

[121] *See Settlement Reached in Eli Lilly Pregnancy Drug Linked to Breast Cancer Case*, *supra* note 31 (describing how four sisters brought suit against Eli Lilly after suffering from miscarriages, fertility problems, and breast cancer, and later reached a private settlement with Eli Lilly).

[122] *See id.* (explaining that similar claims have been instigated in Boston specifically, and around the country, with fifty-one women having lawsuits currently pending in U.S. District Court in Massachusetts).

[123] *See* James Gallagher, *"Designer Babies" Debate Should Start, Scientists Say*, BBC NEWS (Jan. 19, 2015), http://www.bbc.com/news/health-30742774 [https://perma.cc/W2CA-QTL9] (quoting various scientists, ethicists, and regulators that the time for public debate on human germline engineering has arrived).

[124] *See generally* Alicia R. Ouellette, *Insult to Injury: A Disability-Sensitive Response to Smolensky's Call for Parental Tort Liability for Preimplantation Genetic Interventions*, 60 HASTINGS L.J. 397 (2008) (analyzing various legal avenues harmed genetically modified children may pursue, such as for moral harm and physical disability, and whether parents who consent to the modification can serve as defendants).

[125] *See* DAN B. DOBBS ET AL., DOBBS' LAW OF TORTS § 194 (2d ed. 2017) (explaining that alternative tort liability allows courts to use statistical causation when justice requires and to impose responsibility for harm when a specific defendant is undeterminable). Market share liability imposes damages on manufacturers based on their percentage of market share with the understanding that their product harmed approximately the same percentage of plaintiffs. *See id.* For the averaging to maintain the appearance of fairness, the potential number of plaintiffs should be a substantial number so that there is a likelihood a manufacturer on trial contributed to the specific harm. *See id.* This is usually the case when thousands of people are impacted and the repercussions are passed down to offspring. *See id.*

tional harm are unlikely to recover since they must prove that the defendant's product—such as DES, asbestos, a vaccine, or genetic alteration—caused their individual harm.[126]

Courts are often split on whether or not to recognize the doctrine of market share liability, thus making its application beyond a narrow category of "fungible products" uncertain.[127] If a harmful product is interchangeable, then a court is more comfortable allowing proportional recovery among plaintiffs since the manufacturers are, in theory, equally culpable for its distribution.[128] *Sindell* narrowed the scope of the new market share liability theory by suggesting that any future claims must involve products that are 1) interchangeable, 2) have equivalent risks across company lines, and 3) are controlled in the market through concerted efforts on behalf of the industry.[129] Thus, courts have largely restricted use of this doctrine to classic DES-type cases and treated its use as an *exception* to normal tort doctrine.[130]

This Part analyzes the limitations of extending market share liability beyond the DES context.[131] Section A discusses one of the biggest barriers to market share liability, fungibility of the product.[132] Section B considers difficulties in tracing a product's harm when the harm is passed down from generation to generation.[133] Finally, Section C examines the problem of compensating

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[126] *See* Gorman v. Abbott Labs., 599 A.2d 1364, 1364 (R.I. 1991) (dismissing the DES plaintiffs' cause of action by holding that tort liability requires the "identification of the specific defendant responsible for the injury"); Bostic v. Georgia-Pacific Corp. 439 S.W.3d 332, 346 (Tex. 2014) (requiring the plaintiff to show that his asbestos exposure was a "substantial factor" in developing mesothelioma).

[127] *See* Sindell v. Abbott Labs., 607 P.2d 924, 932–33 (Cal. 1980) (declaring DES to be "fungible," meaning various manufacturers sold an interchangeable drug). Compare *Sindell*, 607 P.2d at 937 (incorporating market share liability into the state's tort law), Conley v. Boyle Drug Co., 570 So. 2d 275, 287 (Fla. 1990) (same), Smith v. Cutter Biological, Inc., 823 P.2d 717, 729 (Haw. 1991) (same), Hymowitz v. Eli Lilly & Co., 539 N.E.2d 1069, 1078 (N.Y. 1989) (same), Martin v. Abbott Labs., 689 P.2d 368, 382 (Wash. 1984) (same), *and* Collins v. Eli Lilly & Co., 342 N.W.2d 37, 50 (Wis. 1984) (same), *with* Smith v. Eli Lilly & Co., 560 N.E.2d 324, 345 (Ill. 1990) (refusing to recognize market share liability), Mulcahy v. Eli Lilly & Co., 386 N.W.2d 67, 75 (Iowa 1986) (same), Zafft v. Eli Lilly & Co., 676 S.W.2d 241, 246 (Mo. 1984) (same), Sutowski v. Eli Lilly & Co., 696 N.E.2d 187, 193 (Ohio 1998) (same), *and Gorman*, 599 A.2d at 1364 (same).

[128] *See* Allen Rostron, *Beyond Market Share Liability*: *A Theory of Proportional Share Liability for Nonfungible Products*, 52 UCLA L. REV. 151, 165 (2004) (explaining the policy reasons for holding defendants liable who introduce harmful products into the public).

[129] *See Sindell*, 607 P.2d at 931–37; Rostron, *supra* note 128, at 163–68 (synthesizing the three factors laid out in *Sindell* for a court to analyze before applying market share liability).

[130] *See* Rostron, *supra* note 128, at 163–73 (noting that courts have restricted the "fungibility" requirement since the term itself is vague and ambiguous, and therefore exercise considerable control over the application of market share liability).

[131] *See infra* notes 135–179 and accompanying text.

[132] *See infra* notes 135–153 and accompanying text.

[133] *See infra* notes 154–163 and accompanying text.

victims when injuries are not present for decades and are passed on to subsequent generations.[134]

A. Fungible Product by Design

In order for liability to be spread among companies based on market participation, the distributed product must be interchangeable between companies.[135] In 1980, the California Supreme Court, in *Sindell v. Abbott Laboratories*, first applied market share liability when hundreds of manufacturers produced DES using the same generic formula and then marketed their product to pregnant women.[136] The court found that each manufacturer contributed roughly the same percentage of harm to plaintiffs based on market contribution.[137]

The relevant inquiry, in determining whether market share liability is appropriate, is whether a company's product presents a similar enough risk of harm to consumers or the public such that their liability can be based on the percentage of their market involvement.[138] For instance, in a 2005 consolidated multi-district lawsuit, the United States District Court for the Southern District of New York in *In re Methyl Tertiary Butyl Ether ("MTBE") Products Liability Litigation* extended the use of market share liability to allow "innocent water users" to recover from petroleum distributors that delivered gasoline contain-

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[134] *See infra* notes 164–179 and accompanying text.

[135] *See* DOBBS, *supra* note 125, § 194. For market share liability to be fairly administered, a company must be connected to the harm alleged by the plaintiff. *See id.* Even if not directly connected, a company can still be culpable for distributing a product that resulted in harm to consumers. *See id.* In the DES cases, the pills were manufactured using the same generic formula, which promoted a fairness rationale for holding each of the manufacturers culpable for how many drugs they had on the market. *See id.* In addition to the DES context, the court in *Wheeler v. Raybestos-Manhattan* found asbestos concentrations in brake pads to be uniform enough across the industry to hold manufacturers liable based on market contribution. *See* Wheeler v. Raybestos-Manhattan, 8 Cal. App. 4th 1152, 1156 (1992). Before holding genetic companies uniformly responsible for future injuries based on market participation, courts will need to find that genetic companies use the same process for performing the germline modification to target the same genetic disease. *See id.*

[136] *See Sindell*, 607 P.2d at 935–36 (justifying market share liability as the means for compensating plaintiffs by a culpable industry rather than allowing manufacturers to escape liability merely because they could not be directly identified). The court in *Sindell* measured market share liability based on the "likelihood that any of the defendants supplied the product which allegedly injured the plaintiff by the percentage which the DES sold by each of them for the purpose of preventing miscarriage bears to the entire production of the drug sold by all for that purpose." *See id.* at 937. The court noted that plaintiffs could not single out one particular defendant from hundreds of DES manufacturers because they created and sold DES using an "identical formula." *See id.* at 936.

[137] *See id.* at 937. Specifically, the court noted that if the defendants, Eli Lilly and Company and five or six other companies, contributed 90% of the DES that was on the market, then there would be a 10% chance that the responsible defendant would not be held accountable. *See id.*

[138] *See* DOBBS, *supra* note 125, § 194 (describing that for an industry to be accountable, the harm of each manufacturer's product must be equivalent in order to assign liability based on production).

ing the carcinogenic chemical MTBE.[139] The court was compelled by evidence that defendants understood the risks of immense groundwater contamination from mixing gasoline with MTBE and that any contamination could not be traced to a single source.[140] As a result of active concealment by the defendants and MTBE being fungible, the court allowed plaintiffs to recover damages under the theory of market share liability.[141]

Nonetheless, market share liability has been reserved almost exclusively to the DES context because most products are not generic across an industry.[142] For example, in 1995 in *Bly v. Tri-Continental Industries, Inc.*, the United States Court of Appeals for the D.C. Circuit referred to market share liability as a "last resort" largely limited to DES cases where each manufacturer's product is "identical."[143] As a result, the plaintiff could not show fungibility since the product at issue, benzene gasoline, was manufactured using different formulas across the industry.[144] Thus, the harm that each manufacturer contributed could not be considered equal per product on the market because the varying concentrations of harmful benzene changed the severity of harm of the product, making some companies more or less culpable than others.[145] Similarly, allergy-causing latex gloves and harmful lead paint are not recognized as fungible products since manufacturers assemble them with different quantities of the harmful products.[146] Courts are hesitant to expand market share liability when manufacturers use different quantities of a harmful substance in their products, and/or the injury could be attributed to another product altogether.[147]

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[139] *See In re* Methyl Tertiary Butyl Ether Prods. Liab. Litig., 379 F. Supp. 2d 348, 376–77 (S.D.N.Y. 2005) (applying market share liability to manufacturers of carcinogenic gasoline).

[140] *See id.* at 365.

[141] *See id.* at 376–77.

[142] *See* Bly v. Tri-Continental Indus., 663 A.2d 1232, 1244 (D.C. Cir. 1995) (finding that gasoline produced with different formulas was not fungible since the harmful product, benzene, varied in quantities across the industry); City of St. Louis v. Benjamin Moore & Co., 226 S.W.3d 110, 116 (Mo. 2007) (refusing to apply market share liability to lead paint manufacturers when the plaintiff could not identify the specific offender); Goldman v. Johns-Manville Sales Corp., 514 N.E.2d 691, 697 (Ohio 1987) (holding that market share liability was inapplicable to asbestos-ridden duct tape since the duct tape varied by 15% to 100% asbestos based on weight).

[143] *See Bly*, 663 A.2d at 1243–44 (finding that plaintiffs did not demonstrate that there were similar enough products such that gasoline exposure constituted one of the "extraordinary circumstances" market share liability covered).

[144] *See id.* at 1244.

[145] *See id.*

[146] Kennedy v. Baxter Healthcare Corp., 50 Cal. Rptr. 2d 736, 739–40, 744 (Ct. App. 1996) (finding that plaintiffs could not recover under market share liability theory for harm resulting from latex gloves containing allergy-causing proteins because manufacturers vary their protein concentrations); Skipworth v. Lead Indus. Ass'n, 690 A.2d 169, 173 (Pa. 1997) (refusing to extend market share liability to the paint industry since paint containing lead varied in concentration among manufacturers).

[147] *See Goldman*, 514 N.E.2d at 697 (finding market share liability inapplicable to asbestos-ridden duct tape since the harmful asbestos concentrations varied significantly by brand type); Case v.

In the 1987 Supreme Court of Oklahoma's ruling in *Case v. Fibreboard Corporation*, the court found that asbestos would rarely—if at all—be a fungible product like DES.[148] It found that "asbestos" generally referred to products with varying concentrations of harmful minerals and the risk of exposure often correlated with the type of asbestos product.[149]

Moreover, courts' applications of market share liability have important distinctions.[150] For instance, in *Sindell*, the court applied market share liability with an important caveat: if a manufacturer proved it could not have sold the DES to the specific plaintiff, then it was excused from liability.[151] Alternatively, in 1989 the New York Court of Appeals, in *Hymowitz v. Eli Lilly and Company*, ruled that it would apply a national market share liability theory based on the "overall-risk produced" to the *public* and not specific causation to an individual plaintiff.[152] Therefore, under that approach, even companies who could prove they definitely did not cause the plaintiff's injury were still liable based on their national market share so long as they were culpable for the overall harm.[153]

Fibreboard Corp., 743 P.2d 1062, 1066 (Okla. 1987) (emphasizing the diverse risk factors associated with asbestos products based on type and composition).

[148] *See Case*, 743 P.2d at 1065–66 (contrasting asbestos products and the varying risks in composition and types of products with DES pills, which were generically administered to pregnant women). Of note to the court, "asbestos" is the name of a family of minerals and can be a combination of more than thirty different minerals. *See id.* at 1065.

[149] *See id.* at 1065; Nace, *supra* note 104, at 414–15 (explaining that most courts have not applied market share liability in the asbestos context because of the difficulty in attributing the specific harm to a product). People are exposed to countless asbestos products in the workplace or at home resulting in a product identification problem similar, yet different, than DES in that it is not merely one harmful product. *See id.*

[150] *See* Nace, *supra* note 104, at 396. States have adopted varying market share liability doctrines depending on important notions of fairness and how liability should be determined. *See id.* at 406. In *Sindell*, the court allowed companies to escape liability if they could prove they did not injure the specific plaintiff with their product so that only manufacturers with some probability of contributing to the specific injury and a substantial share in the sales could be held accountable. *See Sindell*, 607 P.2d at 937. Ambiguity in whether market share would be a percentage of the plaintiff's harm or a percentage of the national market share resulting in less than a full recovery led to some varying interpretations of *Sindell*. *See* Note, *Market Share Liability: An Answer to the DES Causation Problem*, 94 HARV. L. REV. 668, 672–73 (1981) (analyzing court applications and interpretations of market share liability). In *Martin v. Abbott Laboratories*, the court applied a theory of market share recovery that the California Supreme Court later adopted in *Brown v. Superior Court* that assessed liability based on a manufacturer's harm to a particular plaintiff. *See* Brown v. Superior Court, 751 P.2d 470, 485 (Cal. 1988); *Martin*, 689 P.2d at 382. By contrast, the court in *Hymowitz v. Eli Lilly & Co.* departed from this structure by focusing on the culpability of each defendant to the public and assigning liability based on the risk of harm each contributed. *See* 539 N.E.2d at 1078.

[151] *See Sindell*, 607 P.2d at 937 (refusing to extend market share liability to a defendant if she proved her product could not have caused the plaintiff's injuries).

[152] *Hymowitz*, 539 N.E.2d at 1078.

[153] *See id.* ("Nevertheless, because liability here is based on the over-all risk produced, and not causation in a single case, there should be no exculpation of a defendant who, although a member of the market producing DES for pregnancy use, appears not to have caused a particular plaintiff's injury.").

B. Tracing Causation Across Broken Family Lines

While market share liability helps plaintiffs recover when a specific manufacturer of the DES itself cannot be identified, proving that the product actually caused the injury is one of the greatest hurdles to compensation.[154] In reviewing studies on DES's impact on mothers' and their children's increased risk of cancer, some courts have found in favor of the plaintiffs so long as they prove DES exposure.[155] Unfortunately, many plaintiffs impacted by DES cannot recover because the causal connection is often too speculative to prove that DES itself led to the negative health effects generations later as opposed to other genetic risks, exposures, or activities.[156]

Products that increase someone's risk for contracting a common disease or cancer in and of themselves are extremely difficult to associate with a particular defendant since the defendant can easily cast doubt on whether their product was a "substantial factor" in causing the mainstream disease.[157] For instance, a woman's risk of breast cancer doubles from 2% to 4% if her mother consumed DES while pregnant; however, countless other factors also increase a woman's probability of getting breast cancer.[158] In fact, the Center for Disease Control ("CDC") has listed over fifteen risk factors that make a woman more likely to develop breast cancer such as drinking alcohol and aging.[159] In 2008, in *Borg-Warner Corporation v. Flores*, the Supreme Court of Texas

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The court sought to avoid a "windfall" scenario where manufacturers could escape liability because they stayed in a local market or made their product "more identifiable," yet remained equally culpable to the public as a whole. *See id.*

[154] *See* Clayton v. Eli Lilly & Co., 421 F. Supp. 2d 77, 81 (D.D.C. 2006) (explaining how the jury must weigh the credibility of a witness's memory for whether she can accurately remember the color and markings of a DES pill she took decades ago while pregnant); Enright v. Eli Lilly & Co., 533 N.Y.S.2d 224, 228 (Sup. Ct. 1988) (stating that the "passage of time and generations obscure such evidence to the extent that a third-generation lawsuit" could only stand on "sympathy and conjecture").

[155] *See e.g. Sindell*, 607 P.2d at 937; *Hymowitz*, 539 N.E.2d at 1072, 1078.

[156] *See Enright*, 533 N.Y.S.2d at 228 (commenting on the serious hurdles, namely time and generational harm, that plaintiffs face in obtaining recovery).

[157] *See* Borg-Warner Corp. v. Flores, 232 S.W.3d 765, 765 (Tex. 2007) (holding that the jury legally could not have found a defendant's asbestos product was a "substantial factor" in contributing to the plaintiff's injury). *See generally* Brent M. Rosenthal, *Toxic Torts and Mass Torts*, 62 SMU L. REV. 1483 (analyzing the evidentiary hurdles to toxic and mass tort litigation in Texas).

[158] *See* Bonnie Rochman, *DES Daughters: Banned Pregnancy Drug Linked to Infertility, Prematurity, and Cancer*, TIME (Oct. 6, 2011), http://healthland.time.com/2011/10/06/des-daughters-now-banned-drug-linked-to-infertility-prematurity-and-cancer/ [https://perma.cc/3K5H-62Q9] (describing the increased risks for many mainstream health issues faced by daughters whose mothers consumed DES while pregnant); *What Are the Risk Factors for Breast Cancer?*, CTRS. FOR DISEASE CONTROL (Sept. 27, 2017), https://www.cdc.gov/cancer/breast/basic_info/risk_factors.htm [https://perma.cc/V4N8-3J3F] (describing sixteen factors that can increase a woman's chance of getting breast cancer).

[159] *What Are the Risk Factors for Breast Cancer?*, *supra* note 158 (listing the following factors: taking birth control, drinking alcohol, having a family history of breast cancer, getting older, genetic mutations).

found that as a matter of law the jury did not have sufficient evidence to find that a plaintiff's lung cancer was caused by inhaling asbestos dust at work when grinding asbestos-ridden brakes for more than three decades.[160] The court highlighted that the plaintiff smoked, there existed over one hundred different causes for lung disease, and there was little evidence showing how much asbestos the plaintiff had been exposed to when grinding brake pads.[161] Similarly, in *Case v. Fibreboard Corporation*, the plaintiff also could not prove a specific asbestos product caused the injuries.[162] The court noted that the asbestos-injuries could have come from any one of the three thousand asbestos products a typical person encounters at work or at home.[163]

C. Compensating a Broken Family Line: Collection and Liquidity Problems

Compensating victims who suffer detrimental effects from a product that increases the risk of developing a severe, latent health problem proves challenging, especially when the risk of harm continues to be passed down from generation to generation.[164] Courts will have to estimate not only the claimant's present harm and future medical bills, but also that of potential children who may suffer from the harm.[165] DES exposure increases cancer risks, which are passed on through daughters, leading to a litany of negative health repercussions still in existence today.[166]

Due to varying court interpretations of market share liability, many victims could not recover if the manufacturer went out of business or proved it

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[160] *Borg-Warner*, 232 S.W.3d at 773–74 (concluding that the plaintiff's lung disease could have been caused by many factors and it is not sufficient proof of causation to just state that plaintiff dealt with asbestos at work).

[161] *Id.* at 766, 768, 774.

[162] *See Case*, 743 P.2d at 1065–66 (refusing to apply market share liability for alleged asbestos injuries when the plaintiff could not identify the particular wrongdoer).

[163] *Id.* at 1065.

[164] *See* Wood v. Eli Lilly & Co., 38 F.3d 510, 513–14 (10th Cir. 1994) (denying a grandchild damages for a premature birth allegedly caused by their grandmother consuming DES while pregnant); Victor E. Schwartz & Cary Silverman, *The Rise of "Empty Suit" Litigation*, 80 BROOK. L. REV. 599, 602 (2015) (describing the recent increase in litigants seeking to recover for "no injury" claims in which the product's harm has not yet manifested itself, but there are emotional and medical check-up claims).

[165] *See In re* New York County DES Litig., 211 A.D.2d 500, 500 (N.Y. App. Div. 1995) (affirming the jury verdict for likelihood of disease damages). The court in *In re New York County DES Litigation* held that "reasonable compensation" could include future damages for an increased risk of disease and medical appointments. *See id.* In *Bichler v. Eli Lilly & Co.*, the Supreme Court of New York affirmed a $492,842.39 jury award to a DES plaintiff, which included damages for her children's future cancer costs. *See* 436 N.Y.S.2d 625, 625 (App. Div. 1981).

[166] *See* Rochman, *supra* note 158 (listing the various negative health effects from DES on subsequent generations and recapping a study that was published in the *New England Journal of Medicine*).

could not have sold DES to that particular plaintiff.[167] In *Brown v. Superior Court*, the California Supreme Court in 1988 noted that it would not assign liability to DES manufacturers that proved they did not and could not have caused the injuries of the claimant.[168] By comparison, another interpretation of market share liability was used in *Hymowitz*.[169] There, the court reasoned that manufacturers were culpable to the *public* as a whole.[170] Thus, under that interpretation, even if a manufacturer definitively proved it was not responsible in a specific case, victims could still recover based on its contribution to the national market.[171]

Although allowing for recovery is the first step, a critical concern is how manufacturers will compensate generations of victims for harm.[172] Companies, like people, can become judgment-proof.[173] Many manufacturers subject to latent tort liability will run out of money before not only the symptoms manifest, but before the victims in subsequent generations receive compensation.[174] As illustrated through asbestos reorganizations in the 1980s, companies attempted to use Chapter 11 of the Bankruptcy Reform Act of 1978 to shed overhanging tort liability.[175]

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[167] *See* Nace, *supra* note 104, at 396 (outlining the various market share liability theories across states). In California, courts assess manufacturer market share liability based on their stake in the relevant market but offer a complete defense if they can show there was no possible way they supplied DES to the specific plaintiff in the case. *See id.* at 403–05; *Brown*, 751 P.2d at 485–87 (resolving an ambiguity in the application of market share liability by determining that defendant manufacturers will only be held severally liable).

[168] *See Brown*, 751 P.2d at 485.

[169] *See Hymowitz*, 539 N.E.2d at 1078 (assigning liability based on the risk of harm each manufacturer defendant contributed to the public).

[170] *See id.* This is because each manufacturer was at fault for having released a dangerous product into the public although the exact ramifications were unknown. *See id.*

[171] *See id.* Because each manufacturer released a harmful product into the public, each was culpable based on their percentage of the market and should be held accountable on an industry-scale. *See id.*

[172] *See Collins*, 342 N.W.2d at 48 (explaining that many DES companies have left the market, while others have entered, and there were uncertain records concerning the overall national production of DES).

[173] *See* MARK J. ROE & FREDERICK TUNG, BANKRUPTCY AND CORPORATE REORGANIZATION 336 (4th ed. 2016) (describing the institutional problem with mass tort compensation when companies declare bankruptcy and future tort victims are unable to collect damages).

[174] *See id.* (analyzing the problem of compensation in mass tort cases for victims who incur medical expenses at a later time after all possible distributions have already happened).

[175] *See* 11 U.S.C. § 1102 (2012). Chapter 11 essentially lets companies write down their tort debt and, perhaps more importantly, fix it at a known quantity. *See id.* One of Chapter 11's unforeseen consequences is the attempt by companies to use Chapter 11 bankruptcy to skirt massive tort liability by reorganizing. *See* Note, *The Manville Bankruptcy: Treating Mass Tort Claims in Chapter 11 Proceedings*, 96 HARV. L. REV. 1121, 1122 (1983) (predicting the future of Chapter 11 proceedings in mass tort claims). Because there were many potential debtors, since the effects of asbestos exposure had yet to materialize, asbestos companies, like Manville, tried to limit their future liabilities by having experts and not juries determine the scope of each tort claimant's recovery. *See id.* at 1132.

In order to maintain company liability for DES, to allow for more directly harmed plaintiffs to recover, and to meet evidentiary concerns, New York courts applied a policy compromise in favor of limiting liability to the third generation at the expense of other victims.[176] The Court of Appeals of New York in 1991, in *Enright v. Eli Lilly and Company*, reduced the liability of DES defendants to "manageable limits."[177] Thus, it limited recovery only to first generation DES victims and not to daughters and granddaughters despite suffering from "malformations or immaturity of the uterus, cervical abnormalities, misshapen Fallopian tubes, and abnormal cell and tissue growth."[178] Evidently, even if liability is established, court awarded recovery may not be enough in light of courts' self-designated restrictions on limiting pay outs.[179]

III. Preparing for the Worst and Planning for the Future with Market Share Liability

Genetic modification may feel like it is part of the scientific future, but tests are already being done on non-viable human embryos and the industry is heavily invested in the new CRISPR technology.[180] Market share liability offers a solution for victims to recover when tortfeasors cannot be readily identified because of time or drug uniformity.[181] As genetic editing becomes the new generic vaccine or commonly prescribed medication, states should adopt a

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[176] *See* Enright v. Eli Lilly & Co., 570 N.E.2d 198, 203–04 (N.Y. 1991) (finding that the passage of time and uncertain impact of DES exposure on subsequent generations requires a stopping point in litigation). The court wanted to avoid measures of "over deterrence" and instead recognize a manufacturer's breach of duty towards those directly impacted by the defective drugs. *See id.* at 204.

[177] *See id.* at 203 (predicting that "manageable limits" requires limiting litigation to the third generation). Although the court in *Enright* did not list the factors for why it believed manageable limits should be in place, it cited to the New York Court of Appeals case, *Tobin v. Grossman*, which listed the following factors to be considered when limiting a defendant's liability: "foreseeability of the injury, proliferation of claims, fraudulent claims, inconsistency of the zone of danger rule, unlimited liability, unduly burdensome liability, and the difficulty of circumscribing the area of liability." *Id.* (citing *Tobin v. Grossman*, 249 N.E.2d 419, 422 (N.Y. 1969)).

[178] *See Enright*, 570 N.E.2d at 200.

[179] *See id.*

[180] *See* Ewen Callaway, *Embryo-Editing Research Gather Momentum*, 532 NATURE 289, 289–90 (2016) (explaining that germline engineering is expected to become more commonplace, especially in countries like Sweden, China, and the United Kingdom which already approve such research); Ledford, *supra* note 10 (commenting on the 2017 germline engineering performed in the United States to rid an embryo of a heart-disease causing mutation); Marcus & Palazzolo, *supra* note 73 (explaining that millions of dollars are being invested in CRISPR-Cas9 without regard to who wins the patent debate on the technology).

[181] *See* DOBBS, *supra* note 125, § 194 (explaining market share liability as an alternative form of tort liability for when the defendant cannot be found). Additionally, companies will be incentivized to maintain better records and retain adequate insurance for such claims. *See* Sheiner, *supra* note 21. As a result, specific defendants should be more identifiable, resulting in regular awarding of tort damages. *See id.*

form of market share liability so that genetic companies can predict their long-term legal and liability costs before entering the market.[182]

This Part argues that market share liability should be adopted in the genetic modification context.[183] Section A discusses the likelihood of being able to identify a specific genetic company as the source of harm, and argues that as the process becomes streamlined, similar DES defendant identification problems will occur.[184] Section B examines germline engineering using CRISPR-Cas9 as a fungible product comparable to DES pills and vaccines.[185] Section C assesses the complications of company identification when a defective germline procedure may not show itself for decades or generations down the line.[186] Finally, Section D advocates for market share liability as a means of compensating generations of victims and serving as a pre-market cost for companies entering this risky industry.[187]

A. Courts Should Adopt Market Share Liability for Harm Arising from Genetic Alteration

Unlike DES manufacturers selling pharmaceutical drugs, one of the biggest differences in human genetic alteration is that businesses are in never-before-chartered territory.[188] Any germline engineering transactions for the first decade or so are likely to be highly contentious and heavily monitored by journals, medical records and news reports.[189] Evidently, market share liability

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[182] *See* Emily H. Damron, Comment, *Reviving the Market for Liability Theories: The "Commingled Product" Theory of Market Share Liability Enters the Judicial Lexicon*, 111 PENN. ST. L. REV. 505, 520 (2006) (listing the reasons why defendant manufacturers are in the best position to sustain the costs of consumer injuries). A corporation that can predict its litigation costs can prepare by maintaining adequate insurance, aggregating profits and resources, increasing the price for products to spread costs, and investing in safety. *See id.*

[183] *See infra* notes 188–242 and accompanying text.

[184] *See infra* notes 188–199 and accompanying text.

[185] *See infra* notes 200–211 and accompanying text.

[186] *See infra* notes 212–222 and accompanying text.

[187] *See infra* notes 223–242 and accompanying text.

[188] *Compare* König, *supra* note 56, at 504 (displaying a chart showing that currently no country, not even China, publicly permits germline engineering for clinical trials—in other words, to allow germline editing in viable human embryos with the intention of bringing them to term), *and* Skerrett, *supra* note 74 (describing scientific, ethical, and health concerns from genetic research experts in this new and expanding field), *with Medicine and Pregnancy*, FOOD & DRUG ADMIN (May 19, 2017), https://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118567.htm [https://perma.cc/LB58-HDPJ] (recommending online sources and tips for women who want to take medication during their pregnancy).

[189] *See* König, *supra* note 56, at 504 (describing one of the National Academies of Sciences, Engineering, and Medicine's conditions for supporting a clinical trial of a genetically engineered human embryo as requiring "multigenerational follow-up" to understand the long-term impacts); Liang et al., *supra* note 50, at 363 (researching CRISPR germline modification on non-viable human embryos for the first time by Chinese researchers in 2015); Adam Pasick & Akshat Rathi, *Chinese Researchers Have Genetically Modified a Human Embryo—And Many Scientists Think They've Gone Too Far*,

may deviate in genetic engineering cases from generic pharmaceutical or asbestos cases because of the likelihood that plaintiffs will be able to identify the proper defendants.[190] If defendants are readily identifiable, then market share liability—as it is currently understood—would not apply.[191] The very reason for establishing market share liability was to address the problem of an unidentifiable defendant, and assign a percentage of liability to a market participant because of its tortious market involvement.[192]

On the other hand, if human germline engineering becomes a routine procedure for families, as predicted, then defendants may not be readily identifiable.[193] Market share liability would be invaluable to victims of a defective genetic procedure whose harm manifests decades later in their children or children's children.[194] Presently, prenatal genetic screening is offered to parents who would like an assessment of their child's genetic condition.[195] For little to no cost with insurance coverage, parents can learn of potential chromosomal malformations

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QUARTZ (Apr. 23, 2015), https://qz.com/389494/chinese-researchers-are-the-first-to-genetically-modify-a-human-embryo-and-many-scientists-think-theyve-gone-too-far/ [https://perma.cc/53JC-GR46] (describing the "bombshell" that Chinese researchers dropped by genetically modifying human embryos for the first time in 2015).

[190] *See* Celotex Corp. v. Copeland, 471 So. 2d 533, 533 (Fla. 1985) (refusing to apply market share liability in an asbestos case where the plaintiff could readily identify the manufacturers of the asbestos products he encountered); Hymowitz v. Eli Lilly & Co., 539 N.E.2d 1069, 1072 (N.Y. 1989) (holding that the court will apply market share liability expressly because identifying the DES manufacturer who sold the plaintiff's drug was "generally impossible"). Also, the pool of genetically altered victims must be large enough for the averaging of market share liability to be fair across companies. *See* DOBBS, *supra* note 125, § 194 (identifying the potential unfairness for assigning liability to a few potential plaintiffs based on market share liability since averaging over a larger number of consumers increases a manufacturer's likelihood of directly contributing to the harm).

[191] *See* DOBBS, *supra* note 125, § 194 (describing how market share liability arose because plaintiffs could not know for certain who caused their injuries, but defendant companies were equally culpable for contributing the harmful product to the public to be held accountable).

[192] *See id.*

[193] *See* Begley, *supra* note 14 (commenting on the enthusiasm of over 150 scientists at the American Society of Hematology conference at the implications of using CRISPR-Cas9 to eradicate blood disorders such as HIV/AIDS and leukemia); Harmon, *supra* note 56 ("This opens the door to advertisements from fertility clinics of giving your child the best start in life with a gene-editing packet…." quoting Marcy Darnovsky, the executive director of the Center for Genetics and Society, about her thoughts on germline editing); Ramsey, *supra* note 28 (quoting CITI biotech analyst, Yigal Nochomovitz's prediction that "the first CRISPR-based medicine could reach the market in ~6 years or less"). DES manufacturers often did not have direct contact with consumers nor maintain records about who received their drugs from prescribers. *See* Sindell v. Abbott Labs., 607 P.2d 924, 930 (Cal. 1980).

[194] *See Hymowitz*, 539 N.E.2d at 1072 (recognizing the predicament of DES victims when the destruction of pharmaceutical records made finding the specific defendant who manufactured the DES pill they consumed decades earlier unlikely).

[195] *See* Cari Nierneberg, *Prenatal Genetic Screening Tests: Benefits & Risks*, LIVE SCI. (Dec. 18, 2014), http://www.livescience.com/45949-prenatal-genetic-testing.html [https://perma.cc/J45Z-K28H] (explaining that genetic testing can determine or predict a child's risk for a genetic disorder and can be conducted after the first ten weeks of pregnancy).

such as sickle cell anemia or Down syndrome.[196] Presently, the worldwide prenatal testing market is expected to increase, between 2016 and 2022, at a rate of 28.85%.[197] With an expected $7.2 billion dollar market by 2022, the temptation to use genetic scissors to eradicate chromosomal deformities prior to conception are likely to mainstream germline modification at a rapid rate.[198] As a result of widespread popularity and high demand, germline modifications are likely to become so streamlined and generic that they may be used with such frequency analogous to the prescription of drugs like DES.[199]

B. Genetic Modification as a Fungible Product

To function like a fungible product, genetic companies would need to target the same genetic disease using the same modification process.[200] This proves a more complicated inquiry than the DES cases since CRISPR-Cas9 is a process, not a product like DES pills, and the altered gene may have repercussions distinct to an individual's genetic make-up.[201] Nonetheless, a court

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[196] *Id.*; *see also What Is the Cost of Genetic Testing, and How Long Does It Take to Get the Results?*, GENETICS HOME REFERENCE (Nov. 14, 2017), https://ghr.nlm.nih.gov/primer/testing/cost results [https://perma.cc/T68C-Z363] (stating that genetic testing can cost between $100 to greater than $2000 depending on the test, and that newborn screening usually ranges from $15 to $60 depending on the state and insurance coverage).

[197] *Global $7.2 Billion Prenatal Testing Market Analysis & Forecast Report 2016–2022*, NASDAQ GLOBE NEWSWIRE (Oct. 20, 2016), https://globenewswire.com/news-release/2016/10/20/881253/0/en/Global-7-2-Billion-Prenatal-Testing-Market-Analysis-Forecast-Report-2016-2022.html [https://perma.cc/5XVS-GW6H] (citing Research and Markets' recent report on the prenatal genetic testing industry). This growth in prenatal testing is due to a combination of factors such as affordable testing, more known treatments for genetic disorders, and increasing cases of genetic disorders in the U.S., U.K, Japan, and India. *See id.*

[198] *See id.* Many countries like the United States and Japan do not have enforceable regulations on germline modifications. *See* Ledford, *supra* note 61. With little to no regulations and the popularity of *in vitro* fertilization and genetic testing, the potential for human germline clinical trials does not appear far away. *See id.* (predicting that Japan will be the first to apply human germline modification because of the popularity of *in vitro* fertilization).

[199] *See* Carolyn Gregoire, *How New Genetic Technologies Are Reshaping Pregnancy and Parenting*, HUFFINGTON POST (Feb. 20, 2017), http://www.huffingtonpost.com/entry/genetic-testing-babies_us_58a5c4bae4b037d17d25664d [https://perma.cc/2ZRA-GF4V] (describing the significant impact genetic testing has on parents and commenting that although "designer babies may not be here yet" the field of genetics is expanding rapidly). In the United States, one out of every thirty-three babies is born with a genetic defect. *Facts About Birth Defects*, CTRS. FOR DISEASE CONTROL (Oct. 11, 2016), https://www.cdc.gov/ncbddd/birthdefects/facts.html [https://perma.cc/Q6SE-EK6T].

[200] *See* Rostron, *supra* note 128, at 163–68 (explaining that fungible products are those that are "interchangeable" and create a similar risk of harm). For example, if a product from Company B is considered "fungible" to a harmful product from Company A, then Company B's product will also be considered harmful and pose that same risk to consumers. *See id.*

[201] *See* Begley, *supra* note 14 (quoting Dr. Joung, from Massachusetts General Hospital, that off-target impacts "var[y] by ethnic group" and are unpredictable with today's technology); *see also Celotex*, 471 So. 2d at 537–38 (refusing to apply market share liability to an asbestos-related harm in part because of the different methods for manufacturing asbestos products, unlike DES, which was produced "pursuant to one formula").

may analogize the same formula used to manufacture DES, to companies using the same gene modification process—CRISPR-Cas9—to insert or remove a specific gene.[202] Moreover, prescribed DES pills often varied by concentration, which shows that courts allowed for some variance.[203]

Unlike asbestos products, where market share liability has not been accepted, germline modification differs in that CRISPR-Cas9 is likely to be streamlined among the industries.[204] Instead of thousands of products containing different variations of a drug or chemical, germline modification is likely to be the same for individuals who have a specific genetic abnormality that is fixed using CRISPR-Cas9.[205] For instance, renowned Harvard scientist, David Sinclair, exclaimed that scientists can use CRISPR to excise a defective gene that causes Huntington's disease—a fatal brain disease—from the germline "before we generate your child."[206] Thus, the fungible product would be a defective Huntington's disease germline modification.[207]

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[202] *See Hymowitz*, 539 N.E.2d at 1072 (discussing the similar formula and use of DES pills prescribed to pregnant women); Beale, *supra* note 36, at 4 (identifying CRISPR-Cas9 technology as the "most widely used gene-editing technology" to date).

[203] *See* Rostron, *supra* note 128, at 166 (describing how market share liability still applied to DES manufacturers even though the concentrations of some pills were greater than others). In *George v. Parke-Davis*, the Supreme Court of Washington grappled with how to spread liability among DES manufacturers when the plaintiff's DES dosage was a set quantity. *See* 733 P.2d 507, 512–13 (Wash. 1987). The court reasoned that it should only hold manufacturers liable that could have caused the harm. *See id.* at 513.

[204] *See* Case v. Fibreboard Corp., 743 P.2d 1062, 1065–66 (Okla. 1987) (refusing to apply market share liability in an asbestos case because the lung disease could have come from any one of the 3000 asbestos products a typical person encounters); McNutt, *supra* note 36, at 1445 (praising CRISPR gene editing technology as the 2015 breakthrough of the year that will lead to unprecedented advancements); Antonio Regalado, *U.S. Panel Endorses Designer Babies to Avoid Serious Disease*, MIT TECH. REV. (Feb. 14, 2017), https://www.technologyreview.com/s/603633/us-panel-endorses-designer-babies-to-avoid-serious-disease/ [https://perma.cc/M426-RSTN] (comparing CRISPR editing technology's future application to that of vaccines and how inserting a protective gene like ApoE can protect people from developing Alzheimer's).

[205] *Compare Case*, 743 P.2d at 1065–66 (declaring that there are too many products with varying concentrations of asbestos that could be the cause for lung disease decades later), *with* Regalado, *supra* note 36 (explaining that CRISPR-Cas9 allows scientists to fix a heritable disease, like Huntington's disease, by altering the gene defect in the germline). In addition to CRISPR-Cas9, a recent CRISPR advancement called "base editing" allows for even more specific editing that changes only a single letter. *See* Gallagher, *supra* note 81. Scientists predict this will decrease the likelihood of unintentional edits in the germline since this base edit will prevent diseases caused by a single mutation. *See id.*

[206] Regalado, *supra* note 36 (quoting David Sinclair, a scientist and age specialist, that gene editing can eradicate diseases before symptoms develop).

[207] *See id.*; Rostron, *supra* note 128, at 163–68 (summarizing what generally constitutes a "fungible product" as interchangeable, having equivalent risks across the industry, and controlled by the industry).

Market share liability requires that the harm be attributable to any one of the products provided by the industry.[208] For this reason, California courts have extended market share liability to defective vaccine formulas, but not to negligent *administration* of vaccines.[209] A CRISPR-Cas9 germline modification procedure to treat a specific disease may be similar enough to a defective vaccine for courts to apply market share liability.[210] Whether or not harm will result from flawed CRISPR-Cas9 applications and/or faulty genetic testing, or from the disease alteration procedure itself, will ultimately determine if CRISPR-Cas9 is a fungible product.[211]

C. Tracing the Cause of Genetic Defects Across Generations

Off-target impacts of a specific genetic alteration may be obvious and consistent across victims, similar in nature to defective vaccines.[212] In fact, proving that a genetic alteration caused cancer or a physical deformity may be easier than connecting a DES pill to cancer.[213] Because an individual's altered genetic make-up is passed on to subsequent generations, a victim generations

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[208] *See Hymowitz*, 539 N.E.2d at 1072 (emphasizing the identical nature of the DES products produced by hundreds of manufacturers).

[209] *Compare* Sheffield v. Eli Lilly & Co., 144 Cal.App.3d 583, 594 (1983) (refusing to extend market share liability to vaccine products that are not the result of a uniformly defective product, but a "deviant defective vaccine"), *with* Morris v. Parke, Davis & Co., 667 F. Supp. 1332, 1342 (C.D. Cal. 1987) (extending market share liability to a vaccine after the plaintiff proved the vaccine itself was defective).

[210] *See Morris*, 667 F. Supp. at 1342–43 (allowing market share liability for production of a defective vaccine); Regalado, *supra* note 36 (predicting germline engineering using CRISPR-Cas9 will be "as important to this century as vaccines were to the last"); Regalado, *supra* note 204 (analogizing the future application of gene editing to prevent diseases like Alzheimer's to the present understanding and application of vaccines).

[211] *See* Begley, *supra* note 14 (noting that although many scientists are worried about the unpredictable effect of gene modification on diverse populations, others are optimistic that advancing gene technology will allow for more accurate risk assessment of off-target impacts). Given the unpredictable nature of genetic modification, the consequences for mass-consumers of these services are unknown and difficult to predict. *See id.*

[212] *See* 42 U.S.C. §§ 300aa-1 to 34 (2012) (creating a system to deal with the negative health impacts from known defective vaccines in order to streamline victim recovery). Congress passed the National Childhood Vaccine Injury Act in 1986 to facilitate victim remedies from vaccine injury claims because specific vaccine injuries manifested themselves similarly in the victims. *See The National Childhood Vaccine Injury Act of 1986*, NAT'L VACCINE INFO. CTR. (Nov. 18, 2017), http://www.nvic.org/injury-compensation/origihanlaw.aspx [https://perma.cc/A7QQ-KABF]. Victims only need to prove by a preponderance of the evidence that they (1) took the vaccine listed on the Vaccine Injury Table and (2) suffered one of the injuries listed on the table known to have been caused by that particular vaccine. *See* 42 U.S.C. § 300aa-14.

[213] *See* David Baltimore et al., *A Prudent Path Forward for Genomic Engineering and Germline Gene Modification*, 348 SCI. 36, 36 (2015) (detailing the groundbreaking combination of DNA sequencing and genome engineering, hailed as "precision medicine"); Gallagher, *supra* note 81 (hailing the advancements in CRISPR technology which allow scientists to edit a single gene's letter).

down the line would have a copy of the manipulated gene.[214] Expert testimony could probably point to the manipulated gene and statistical harm across similarly altered people to prove causation.[215] Whereas DES plaintiffs are often forced to rely on circumstantial evidence that a woman in their family took DES while pregnant, which resulted in a mutated gene passed on to subsequent generations that increased the risk for certain diseases, here the genetic alteration can serve as proof of heritability.[216] For instance, children who underwent genetic engineering to rid their germline of a defective gene that caused sickle-cell anemia would continue to pass on that modified gene to subsequent generations.[217]

Still, echoing the concerns of scientists everywhere, some off-target impacts from germline modification may be unique to each individual's genome making it hard for plaintiffs to connect the side effects to a defective procedure.[218] Additionally, an individual's specific genome may interact differently with the modified gene than in the majority of other users resulting in negative health effects despite a perfectly executed modification process.[219] Genetic companies are likely to argue, like DES manufacturers, that their connection to a negative health defect is too attenuated to prove liability.[220] Without statisti-

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[214] *See* Barnett, *supra* note 19, at 555–56 (noting that changing a human germline is in fact changing someone's genetic makeup, thus affecting "every cell in the body").

[215] *See Role of DES Cohort Studies*, *supra* note 96 (showing the role of DES studies in identifying and tracking health repercussions from DES over generations and calculating a woman's risk for developing certain cancers).

[216] *See* Enright v. Eli Lilly & Co., 533 N.Y.S.2d 224, 228 (Sup. Ct. 1988) (noting the weak testimony of women who are asked to identify a drug from decades past and show it was the cause of their daughter's premature birth); *Genetic Testing for Hereditary Cancer Syndromes*, NAT'L CANCER INST. (Apr. 11, 2013), https://www.cancer.gov/about-cancer/causes-prevention/genetics/genetic-testing-fact-sheet [https://perma.cc/7NX5-QCT5] (explaining that genetic testing enables scientists to assess someone's genetic makeup for abnormalities and identify specific cancer-causing genes).

[217] *See* Regalado, *supra* note 36 (contrasting germline engineering where the modified gene is heritable since it is altered in the egg cell, with that of gene therapy, which helps relieve the symptoms of a person already suffering from the disease, but the benefits are not passed on to future generations).

[218] *See* Begley, *supra* note 14 (explaining the unpredictable nature of off-target impacts from germline modification depending on an array of factors like ethnicity); Fu et al., *supra* note 13, at 822 (noting the high frequency of off-target mutations using CRISPR-Cas9 on human cells); Lander, *supra* note 12, at 7 (cautioning that a gene alteration to protect against cancer might interact with other genes and result in unpredictable consequences like early aging). Algorithms that were created to estimate the risk of off-target effects from CRISPR-Cas9 gene editing have proven to be inaccurate in practice. *See* Begley, *supra* note 14. Dr. Joung, a gene editing researcher at Massachusetts General Hospital, commented that these algorithms "miss a fair number" of off-target impacts and "they really aren't very good at predicting where there will be off-target effects." *See id.*

[219] *See* Lander, *supra* note 12, at 7 (cautioning that genetic modifications may have unintended negative health effects when interacting with other protective genes).

[220] *See* Skerrett, *supra* note 74 (expressing the uncertainty and inability of scientists to predict the consequences of germline editing on the human genome); *Settlement Reached in Eli Lilly Pregnancy Drug Linked to Breast Cancer Case*, *supra* note 31 (reporting that the defendant told the jury there was no proof that DES caused breast cancer in the daughters of women who took it, but the plaintiff

cal support of similarly altered people experiencing similarly harmful side-effects, a plaintiff is unlikely to prove causation.[221] Hopefully, algorithms that predict off-target effects and gene modification impact will become more precise, but consumers are probably willing to risk negative side-effects to avoid passing on a deadly disease, such as Huntington's disease or sickle cell anemia, to their children.[222]

D. Market Compensation for Genetic Defects

Compensating victims for a defective gene alteration proves challenging because of the potential harm to generations of plaintiffs who inherit the defective gene sequence.[223] Courts will have to estimate not only the claimant's present harms and future medical bills, but also that of potential children suffering from the genetic harm.[224] Until genetic modification of the germline undergoes clinical trials, the scale of possible harm remains speculative.[225]

Given the unique field of genetic alteration, gene companies are in the best position to sustain liability without compromising consumer compensation for defective products.[226] CRISPR-Cas9 is hailed as a multi-million dollar industry in which companies are investing and expanding rapidly.[227] National

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pointed to a 2011 study by the National Cancer Institute that found an increased risk for breast cancer).

[221] *See* E.E. Hatch et al., *Prenatal Diethylstilbestrol Exposure and Risk of Obesity in Adult Women*, 6 J. DEVELOPMENTAL ORIGINS HEALTH AND DISEASE 201, 201–07 (2015) (describing that in addition to dysfunctional reproductive organs, cancer, dangerous pregnancies, infertility, and early menopause, taking DES while pregnant may also contribute to one's increased risk of obesity).

[222] *See* Fu et al., *supra* note 13, at 826 (studying the ability to predict off-target mutations, and offering suggestions for increasing accurate predictions); Regalado, *supra* note 67 (explaining how there are thousands of genetic diseases like Huntington's disease without cures that CRISPR has the potential to fix).

[223] *See* Barnett, *supra* note 19, at 568–69 (cautioning researchers from prematurely engaging in clinical trials because editing the human germline means those genes will be passed on to subsequent generations); Begley, *supra* note 14 (emphasizing the potential devastating health effects from a genetic alteration that goes wrong such as triggering a cancer-causing gene).

[224] *See In re* New York County DES Litig., 211 A.D.2d 500, 500 (N.Y. App. Div. 1995) (affirming the jury verdict allowing damages for likelihood of disease). The court in *In re New York County DES Litigation* found that jury damages awarded for severe and long-lasting diseases, as well as the increased risk for new diseases, will be accepted if they do not "materially deviate" from a "reasonable compensation." *See id.*

[225] *See Open Letter Calls for Prohibition on Reproductive Human Germline Modification*, *supra* note 55 (calling for a moratorium on any clinical applications of germline genetic engineering until further research clarifies its impact on the human gene pool); *see also* Skerrett, *supra* note 74 (suggesting that the unintended effects of human genetic manipulation will be little different than when people choose sex partners or encounter radiation or chemicals).

[226] *See* Damron, *supra* note 182, at 520 (explaining why defendant manufacturers are in the best position to compensate plaintiffs for their injuries: insurance, profit and resource aggregation, increased product price to spread costs, and investment in safety).

[227] *See Genome Editing Market Worth $3,514.08 Million by 2019*, *supra* note 67 (finding the following companies to be leading the market: GenScript USA Inc. (U.S.), Horizon Discovery Group

market share liability based on the culpability of the company to the public ensures that newer companies will continue to compensate victims for harm caused by older companies that eventually go out of business.[228] Under market share liability, a company, as a market participant, will effectively assume the bankrupt company's tort debts regardless of whether it did so as a formal or legal matter.[229] Simply by virtue of competing in the same market, new and growing companies will keep tort collection alive.[230] In such a risk-intensive and ethically charged industry, older genetic engineering companies will serve to grow the market and create demand for new companies to enter.[231]

Accordingly, successive companies paying for generational liability stemming from older companies may be a necessary pre-market cost to enter the genetic engineering business.[232] Without an entrance cost, subsequent companies would be free-riding off companies who spearheaded a new industry and generated public trust in a hotly debated and ethically disputed field.[233]

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plc (U.K.), Integrated DNA Technologies, Inc. (U.S.), Lonza Group Ltd. (Switzerland), New England Biolabs, Inc. (U.S.), OriGene Technologies, Inc. (U.S.), Sangamo Biosciences, Inc. (U.S.), Sigma-Aldrich Corporation (U.S.), Thermo Fisher Scientific, Inc. (U.S.), and Transposagen Biopharmaceuticals, Inc. (U.S.)). A 2015 in depth report predicted the genome editing market will be worth $3.5 billion in four years. *See id.*

[228] *See Hymowitz*, 539 N.E.2d at 1078 (requiring compensation from company defendants based on the risk of harm each manufacturer defendant contributed to the public); ROE & TUNG, *supra* note 173, at 336 (describing the potential insolvency of companies in mass tort compensation cases that results in future tort victims not being compensated).

[229] *See Hymowitz*, 539 N.E.2d at 1078; DOBBS, *supra* note 125, at § 194 (describing market share liability as expressed in *Hymowitz* to mean that entrants who contributed to the tortious conduct even if definitively not the particular offenders to the plaintiff individually, are still liable based on their percent share in the national market).

[230] *See* DOBBS, *supra* note 125, § 194 (requiring the market industry as a whole, including new applicants, to be liable because they all have contributed to the public harm, should lead to more consistent recoveries by future tort victims whose latent health effects occur after a company who contributed to the harm has gone bankrupt).

[231] *See* Barnett, *supra* note 19, at 569 (recounting the charged ethical debates about whether genetically modified humans will result in disastrous gene pool complications or will provide unbelievable opportunities for genetic cures); Dorothy J. Glancy, *Autonomous and Automated and Connected Cars—Oh My! First Generation Cars in the Legal Ecosystem*, 16 MINN. J.L. SCI. & TECH. 619, 657–58 (2015) (analyzing potentially novel civil claims that "first generation" self-driving car manufacturers must account for when creating this new market for consumers and other companies to enter).

[232] *See* Collins v. Eli Lilly & Co., 342 N.W.2d 37, 48 (Wis. 1984) (explaining that the DES market was "fluid" in that companies entered and exited frequently). Before entering a market, business owners must understand the start-up costs both concrete, like capital expenditures for purchasing products, and estimations, like expenses for advertising, training, and insurance. *See* Caron Beesley, *How to Estimate the Cost of Starting a Business from Scratch*, SMALL BUS. ASS'N (Sept. 27, 2016), https://www.sba.gov/blogs/how-estimate-cost-starting-business-scratch [https://perma.cc/23SN-Y534] (providing advice to entrepreneurs about how to estimate the costs of starting a business). Importantly, these costs should be calculated based on the industry and requires a fact-intensive analysis. *See id.*

[233] *See* Rathi, *supra* note 80 (noting the distinct change in public reaction between the first and second Chinese research experiments on the human germline from that which "shocked" the public, to that of an "annoyed shrug").

Moreover, rather than allow a bankrupt genetic company to discharge its debts to the detriment of a family who continues to suffer generations of health defects, tort law can ensure that subsequent participants pay for that harm.[234] The growing pains of this high-risk, high-reward industry will last for generations, so pre-market costs ensure fairness to those who paved the way for others to enter.[235]

As noted earlier, the harm from a defective germline modification may be consistent across victims leading to streamlined recovery or the off-target impacts may be uniquely assessed according to each individual.[236] Regardless of the impact, the repercussions of a faulty procedure can be passed to subsequent generations resulting in massive medical costs.[237] Unlike the Court of Appeals of New York's 1991 decision in *Enright v. Eli Lilly and Company*, which justified limiting the liability of DES defendants to the third generation so that companies could stay in business, genetic companies are likely to stay in the lucrative business and be able compensate for multiple generations of recovery.[238]

Lastly, gene companies should actively embrace market share liability.[239] First, embracing a broad concept of alternative liability, such as market share

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[234] *See* ROE & TUNG, *supra* note 173, at 336 (explaining the problem with mass tort compensation in that future tort victims are poorly compensated, if at all, when companies declare bankruptcy).

[235] *See* Barnett, *supra* note 19, at 568, 571 (noting that even if CRISPR-Cas9 is performed flawlessly, there may still be off-target effects in other parts of the genome, so researchers may not know the impact of a genetic alteration until after human testing).

[236] *See supra* notes 212–222 and accompanying text (acknowledging the current uncertainty in the long-term effects on humans from germline editing technology).

[237] *See supra* notes 90–96 and accompanying text (describing the increased risks of cancer for subsequent generations of DES daughters); Skerrett, *supra* note 74 (explaining that removing or editing a gene may have unintended effects like also removing a protective gene for cancer); Arlene Weintraub, *Even Insured Patients Are Overwhelmed By the Cost of Care*, FORBES (Aug. 10, 2017), https://www.forbes.com/sites/arleneweintraub/2017/08/10/even-insured-patients-are-overwhelmed-by-the-cost-of-cancer-care/#1544f2f351c4 [https://perma.cc/KL7L-WUT3] (commenting on the rising costs of cancer treatments in the U.S. and estimating that a new treatment for leukemia provided by Novartis will cost $200,000 or more per patient).

[238] *See Enright*, 570 N.E.2d at 204 (seeking to prevent companies from leaving the industry and not creating beneficial products because of incurring too much liability, and instead recognizing a manufacturer's breach of duty towards those more directly impacted by the defective drugs); *Genome Editing Market Worth $3,514.08 Million by 2019*, *supra* note 67 (estimating the genome market to be worth $3.5 billion by 2019). In the August 2017 study in the United States, researchers successfully repaired a mutation in a human embryo that if brought to term, would result in a child with none of the unwanted mutations. *See* Pam Belluck, *In Breakthrough, Scientists Edit a Dangerous Mutation from Genes in Human Embryos*, N.Y. TIMES (Aug. 2, 2017), https://www.nytimes.com/2017/08/02/science/gene-editing-human-embryos.html [https://perma.cc/3YD8-V5PK] (analyzing the recent research advancements in decreasing off-target impacts and how this will affect future applications). Moreover, the disease would not be passed on to any descendants. *See id.* This technology provides huge benefits to families with one of the 10,000 specified heritable mutations, who can then make the choice to eliminate this disease from their family line by electing to undergo the procedure. *See id.*

[239] *See* Jim Gorzelany, *Volvo Will Accept Liability for Its Self-Driving Cars*, FORBES (Oct. 9, 2015), http://www.forbes.com/sites/jimgorzelany/2015/10/09/volvo-will-accept-liability-for-its-self-driving-cars/#3c4e06973d80 [https://perma.cc/M9NY-8KVL] (describing the recent announcement by

liability, may alleviate public policy concerns that fuel the regulatory roadblocks preventing the commercialization of gene-editing technology.[240] By assuring injured consumers that future recovery is possible, genetic companies can pre-empt many concerns about liability and fears of leaving potential victims empty-handed.[241] Second, even catastrophic exposure to liability can be priced into the technology as a cost of doing business—so long as the risk is accurately known in advance.[242]

CONCLUSION

When the stories of science fiction touch today's reality, the legal and health ramifications call for preparation. The exceptional implications of genetically engineering children to be born without predispositions to genetic diseases prove too beneficial not to be questioned. As companies—and nations—begin to tap into these new markets and sell germline engineering like they would a prescription drug or vaccine, tort liability must adapt to the unusual circumstances. Entire family lines are at stake from a defective germline procedure. In order to ensure continued compensation and to incentivize conservative entrance into the field, courts and legislatures should adopt the DES-created market share liability in the context of genetic alteration. Market share liability is an incomparable method to spread costs for the generational harm an invaluable industry may inflict onto the public.

Volvo to be held strictly liable for any accidents with their self-driving vehicles). Genetic companies can learn from another industry entering the unchartered territory of widespread tort liability: manufacturers of self-driving cars. *See id.* Companies that want to commercialize self-driving cars face hurdles from regulators worried about liability to the public. *See id.* As a result, they have taken matters into their own hands and pressured regulators into licensing their cars by taking responsibility for accidents. *See id.* Currently the U.S. does not have federal laws or regulations on researchers modifying the human germline. *See* Barnett, *supra* note 19, at 577–78. In fact, while the FDA has the authority to regulate "human subjects," gametes and embryos involved in human germline modification do not meet that identification. *See id.* at 578. Once the embryos are inserted into a human, then the FDA can regulate and prevent clinical trials. *Id.* By taking responsibility for defective procedures in an industry based on market share liability, genetic companies may be able to further federal support for clinical trials. Gorzelany, *supra*.

[240] *See* Barnett, *supra* note 19, at 580 (stating that regulators and legislatures will most likely leap into action before any clinical tests of human germline editing are actually performed in the U.S.).

[241] *See id.* at 569, 580 (recounting the fiery ethical dilemmas facing society in whether genetically modified humans will have consequences for the genome that humanity will regret forever or will provide unbelievable opportunity for genetic cures).

[242] *See* Jonathan Salem Baskin, *What Will Self-Driving Cars Mean for Insurance?*, FORBES (Apr. 18, 2016), http://www.forbes.com/sites/jonathansalembaskin/2016/04/18/what-will-self-driving-cars-mean-for-insurance/#5b152b7db7a5 [https://perma.cc/89RY-A6LN] (answering the question of how self-driving cars will impact insurance carriers). As one insurance director stated, "the purpose of insurance is to let people go on with their lives, knowing that they'll get help if something catastrophic happens." *See id.* A genetically defective family line from a faulty procedure would certainly qualify as a catastrophic event, and company insurance to cover off-target injuries, just as most states require minimum auto insurance for drivers, can lead to greater assurance of victim compensation. *See id.*