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CRISPR Has the Potential to Change the World, but First We Have to Give It a Chance

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CRISPR HAS THE POTENTIAL TO CHANGE THE WORLD, BUT FIRST WE HAVE TO GIVE IT A CHANCE

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I. INTRODUCTION

CRISPR is potentially science and medicine's greatest invention of our generation—it could redefine life as we know it today.[1] CRISPR could be our *secret weapon* for curing and preventing genetically inherited diseases such as cancer, Alzheimer's disease, sickle cell anemia, Amyotrophic Lateral Sclerosis ("ALS"), and many others.[2] While CRISPR has the potential to eliminate these diseases, it also might have the potential to cause harm.[3]

CRISPR stands for "Clustered Regularly Interspaced Short Palindromic Repeats of genetic information."[4] CRISPR Therapeutics created a powerful gene-editing tool—known as CRISPR—that can be harnessed to accurately "modify, delete, [and even] correct disease-causing abnormalities at their genetic [foundation]."[5] Human "DNA is [basically] a series of instructions" that controls, for example, our height, eye color, and hair color.[6] These "instructions are written as a series of chemical letters in our DNA," and just like letters that make up a textual sentence, there can be errors or mistakes.[7] An error in the DNA chain can have no effect at all in one person, but in another, the error of just a single letter can cause a horrific disease.[8] Specifically, CRISPR embodies the Cas9 enzyme, which acts as a pair of *molecular scissors*.[9] The Cas9 enzyme is guided by ribonucleic acid ("RNA") which leads the Cas9 enzyme to a specific location where the enzyme will then slice the DNA.[10] Once a cut has been made in the DNA, the body's own natural repair mechanism will trigger the repair of the cut.[11]

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1. Charles Crutchfield III, *CRISPR: Life-Changing, World-Changing Science that Will Revolutionize Medicine*, MINN. SPOKESMAN-RECORDER (June 1, 2018), http://www.spokesman-recorder.com/2018/06/01/crispr-life-changing-world-changing-science-that-will-revolutionize-medicine/.

2. *Id.*

3. *Id.*

4. *CRISPR/Cas9*, CRISPR THERAPEUTICS: GENE EDITING, http://www.crisprtx.com/gene-editing/crispr-cas9 (last visited May 1, 2019).

5. Hamza Abdullah, *Is CRISPR Dead? A Breakthrough in Genetic Engineering*, MEDIUM (Jan. 9, 2018), http://www.medium.com/search/is-crispr-dead-a-breakthrough-in-genetic-engineering-51574d6e6c0d. "Dr. Emmanuelle Charpentier, one of [CRISPR Therapeutics'] scientific founders, co-invented [the application of] CRISPR/Cas9 [in] gene editing." *CRISPR/cas9*, *supra* note 4.

6. Crutchfield III, *supra* note 1.

7. *Id.*

8. *Id.*

9. *CRISPR/Cas9*, *supra* note 4.

10. *Id.*; *Therapeutic Approach*, CRISPR THERAPEUTICS: GENE EDITING, http://www.crisprtx.com/gene-editing/therapeutic-approach (last visited May 1, 2019).

11. *CRISPR/Cas9*, *supra* note 4.

By utilizing the CRISPR-Cas9 technology, it will be possible to delete and correct hereditary diseases.[12]

CRISPR Therapeutics sought approval from the United States Food and Drug Administration ("FDA") to begin human genomic editing trials.[13] However, in May of 2018, the FDA denied CRISPR Therapeutics' request to move forward with these human trials.[14] The FDA has stated their reasoning for denying the company's request involves "*certain questions* it wants [to resolve] before it gives the go-ahead for the human CRISPR study."[15]

CRISPR has gone through numerous lab testing experiments involving non-human trials.[16] These lab results have been promising enough to suggest that CRISPR is ready to be tested on humans.[17] But until CRISPR gets the green light to move forward with human trials, "we [cannot] know for sure whether [CRISPR] will work as expected."[18] It is important to realize that these trials would not be the first human trials to ever take place.[19] In 2016, China was the first country to test CRISPR's effect on humans.[20] While it is true that we are *exploring uncharted territory* and should certainly proceed with caution, millions of people in the United States suffer from—and will continue to suffer from—these terrible diseases every day.[21] The sad truth is that many of those people have exhausted their options for treatment and CRISPR could be their last hope for survival.[22]

Accordingly, this Comment will first examine how the CRISPR-Cas9 technology works and how it differs from the technology that already exists.[23] Following this, the many benefits and few legitimate concerns involving CRISPR will be discussed.[24] In Part III, the analysis will address

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12. *Id.*; Crutchfield III, *supra* note 1.

13. Kristin Houser, *The FDA Puts the Brakes on a Major CRISPR Trial in Humans*, FUTURISM: HEALTH & MED. (May 31, 2018), http://www.futurism.com/human-crispr-trial-fda-stops/.

14. *Id.*

15. *Id.*; *see also CRISPR Therapeutics and Vertex Provide Update on FDA Review of Investigational New Drug Application for CTX001 for the Treatment of Sickle Cell Disease*, CRISPR THERAPEUTICS (May 30, 2018), http://ir.crisprtx.com/news-releases/news-release-details/crispr-therapeutics-and-vertex-provide-update-fda-review#.

16. *See* Houser, *supra* note 13.

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. Houser, *supra* note 13; *see also* Crutchfield III, *supra* note 1.

22. *See* Randi Nord, *China Breaks Ground with World's First CRISPR Clinical Trials*, SOC. UNDERGROUND, http://www.socialunderground.com/2018/04/china-crispr-gene-editing-cancer/ (last visited May 1, 2019).

23. *See* discussion *infra* Part II.A, II.B.

24. *See* discussion *infra* Part II.C, II.D.

the central questions of why the current FDA ban was placed on CRISPR human trials and why CRISPR should get the green light.[25] This section embarks on a journey into the regulatory framework of the FDA and why other drugs and devices that have proven to be harmful to consumers—like tobacco products and chemotherapy—are allowed.[26] Are they regulated by the FDA?[27] If so, why are we continuing to allow those dangerous and destructive products on the market, but not CRISPR?[28] Lastly, this Comment introduces the concept of Big Pharma and addresses the question: Is Big Pharma involved here?[29]

In considering each of these moving parts, one thing stays the same—CRISPR might offer life-changing cures that could change the future of mankind.[30] "The catch is we [will not] know for sure until we try."[31]

II. HOW DOES CRISPR WORK?

In order to understand why the FDA has halted CRISPR human trials in the United States, we first have to understand how the technology works and how it affects the human body.[32] After all, the purpose of the FDA is to protect the general health of the public "by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices."[33]

A. *Explanation of Genome Editing*

Genome editing is a process by which scientists can genetically engineer or alter the DNA of an organism—including bacteria, plants, animals, and even humans.[34] Starting small, the first question becomes:

25. *See* discussion *infra* Part III.B.

26. *See* discussion *infra* Part III.B.2.

27. *See* Action on Smoking & Health v. Harris, 655 F.2d 236, 237 (D.C. Cir. 1980); Christian Nordqvist, *What You Need to Know About Chemotherapy*, MED. NEWS TODAY, http://www.medicalnewstoday.com/articles/158401.php (last updated Dec. 14, 2017); *What We Do*, FDA, http://www.fda.gov/about-fda/what-we-do (last updated Mar. 28, 2018).

28. *See Effects of Tobacco*, TOBACCO FREE FLA., http://www.tobaccofreeflorida.com/why-should-i-quit/effects-of-tobacco/ (last visited May 1, 2019); Houser, *supra* note 13; Nordqvist, *supra* note 27.

29. *See* discussion *infra* Part III.C.

30. Houser, *supra* note 13.

31. *Id.*

32. *See id.*; Crutchfield III, *supra* note 1.

33. *What We Do*, *supra* note 27.

34. *Genome Editing: What Is Genome Editing?*, NAT'L HUM. GENOME RES. INST. (Aug. 3, 2017), http://www.genome.gov/27569222/genome-editing/.

What is DNA?[35] DNA stands for *deoxyribonucleic acid* and consists of four different bases: Adenine ("A"), Cytosine ("C"), Guanine ("G"), and Thymine ("T").[36] DNA exists in the body as a double helix where A must always pair with T, and, similarly, C must always pair with G.[37] This chemical pattern is what makes up our hereditary material.[38] Moving up to the next molecule is the gene.[39] One single gene is made up of DNA.[40] One gene is responsible for one characteristic; for instance, one gene carries the hereditary information that dictates our eye color.[41] The gene responsible for our eye color sits on the same part of the DNA chain in every person, but contains a different make-up of genetic bases.[42] The genome is made up of all of our genes put together.[43]

Just like everything in this world, the human body can make mistakes.[44] Sometimes a DNA mutation occurs where the nucleotide sequence that makes up our DNA becomes altered.[45] For example, during the replication process, "the DNA polymerase could read an A instead of a C and hence add a G instead of a T."[46]

The idea behind genome editing is to locate the DNA mutation or broken gene, cut out the defect, and repair the DNA chain.[47] Ultimately, by correcting a harmful mutation, scientists could change the activity of targeted genes.[48]

B. *How is CRISPR Technology Different?*

"Scientists have had the knowledge and ability to edit genomes for many years, but CRISPR technology has brought major improvements to the

35. *DNA (Deoxyribonucleic Acid)*, MYVMC (July 23, 2008), http://www.myvmc.com/anatomy/dna-deoxyribonucleic-acid/.
36. *Id.*
37. *Id.*
38. *Id.*
39. *Id.*
40. *DNA (Deoxyribonucleic Acid)*, *supra* note 35.
41. *Id.*
42. *Id.*
43. *Id.*
44. *Id.*
45. *DNA (Deoxyribonucleic Acid)*, *supra* note 35.
46. *Id.*
47. Ian Sample, *Gene Editing — and What It Really Means to Rewrite the Code of Life*, GUARDIAN, Jan. 15, 2018 at 10. "Scientists liken it to the find and replace feature used to correct misspellings in documents written on a computer. Instead of fixing words, gene editing rewrites DNA, the biological code that makes up the instruction manuals of living organisms." *Id.*
48. *Id.*

speed, cost, accuracy, and efficiency of genome editing."[49] The history of the different methods utilized to perform genome editing shows the *remarkable progress* scientists have been able to make in the field of genetic engineering.[50]

The earliest technique used for gene editing was a process called homologous recombination.[51] This method involves "generat[ing] and isolat[ing] DNA fragments bearing genome sequences similar to the portion of the genome that is to be edited."[52] Once these fragments are inside the cell—typically, by injection—"these DNA fragments can then recombine with the cell's DNA to replace the targeted portion of the genome."[53] However, this type of editing is severely limited in that it is not efficient in most cell types.[54] Because of this, the success rate of homologous recombination is extremely poor—it "can have as low as a one-in-a-million probability of successful editing."[55] Further, this type of editing is known to have a *high rate of error*, as the injection of DNA fragments can be inserted into "unintended part[s] of the genome."[56]

During the 1990s, scientists created zinc-finger nucleases ("ZFNs"), which are engineered proteins that are programmed to bind to DNA sequences.[57] Once binding of the protein to the targeted portion of the DNA sequence occurs, the ZFNs cut the DNA.[58] This process allowed for two new possibilities: To delete the faulty DNA or replace the faulty DNA with a new sequence through homologous recombination.[59]

More recently, in 2009, scientists created "a new class of proteins called Transcription Activator-Like Effector Nucleases ("TALENs")."[60] TALENs are similar to ZFNs in that they bind to specific sequences of DNA.[61] The only difference between the two is that TALENs are easier to engineer than ZFNs.[62]

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49. *Genome Editing: How Does Genome Editing Work?*, NAT'L HUM. GENOME RES. INST. (Aug. 3, 2017), http://www.genome.gov/27569223/how-does-genome-editing-work/.
50. *Id.*
51. *Id.*
52. *Id.*
53. *Id.*
54. *Genome Editing: How Does Genome Editing Work?*, *supra* note 49.
55. *Id.*
56. *Id.*
57. *Id.*
58. *Id.*
59. *Genome Editing: How Does Genome Editing Work?*, *supra* note 49.
60. *Id.*
61. *Id.*
62. *Id.*

Now, scientists present the groundbreaking technology we call CRISPR or more specifically, the CRISPR-Cas9 system.[63] So, how does it work?[64]

> With CRISPR, researchers create a short RNA template that matches a target DNA sequence in the genome. Creating synthetic RNA sequences is much easier than engineering proteins . . . required for ZFNs and TALENs. Strands of RNA and DNA can bind to each other when they have matching sequences. The RNA portion of the CRISPR, called a guide RNA, directs Cas9 enzyme to the targeted DNA sequence. Cas9 cuts the genome at this location to make the edit. CRISPR can make deletions in the genome and/or be engineered to insert new DNA sequences.[65]

C. *Benefits of CRISPR*

CRISPR, unlike its predecessors, offers a vast array of improvements to the genome editing world.[66] "One group of scientists found that CRISPR is six times more efficient than ZFNs or TALENs in creating targeted mutations to the genome."[67] Of CRISPR's many benefits, a few of the most noteworthy include the elimination of genetic diseases, cutting down on major health care costs, high rate of precision and accuracy, and an infinite supply of organ donors.[68]

1. Elimination of Genetic Diseases

It is no secret that perhaps the most obvious benefit of CRISPR would be the fact that it has the ability to literally wipe out deadly genetic diseases.[69] "There are over 600 diseases—like cancer, sickle cell, Alzheimer's, Huntington's, ALS, hemophilia, and many others—that are the

63. *Id.*; Sample, *supra* note 47.

64. Sample, *supra* note 47; *Genome Editing: How Genome Editing Work?*, *supra* note 49.

65. *Genome Editing: How Does Genome Editing Work?*, *supra* note 49.

66. *Id.*; *see also* Crutchfield III, *supra* note 1.

67. *Genome Editing: How Does Genome Editing Work?*, *supra* note 49.

68. *See* Pam Belluck, Designer Babies *Still Seem Unlikely*, N.Y. TIMES, Aug. 5, 2017, at A14; Crutchfield III, *supra* note 1; Cara MacDonald, *CRISPR Could Cure Genetic Diseases*, DAILY UTAH CHRON. (Apr. 10, 2018), http://www.dailyutahchronicle.com/2018/04/10/crispr-could-cure-genetic-disease/; Thom Patterson, *Unproven Medical Technique Could Save Countless Lives, Billions of Dollars*, CNN: HEALTH (Oct. 30, 2015, 7:28 PM), http://www.cnn.com/2015/10/30/health/pioneers-crispr-dna-genome-editing/index.html.

69. *See* Sample, *supra* note 47.

result of defective DNA [and] CRISPR has the potential to prevent and/or cure them all."[70] For example, "5.7 million Americans are living with Alzheimer's. [And] [b]y 2050, this number is projected to rise to nearly 14 million."[71] Stated another way, someone is diagnosed with Alzheimer's disease in the United States every sixty-five seconds.[72] That is just one of the diseases that could be eliminated through the use of CRISPR.[73] Imagine how many United States citizens could benefit from this ground-breaking technology—the number could easily be in the millions.[74]

Not only would CRISPR wipe out the disease from the suffering individual, but it would also have the ability to stop the disease from being inherited by future generations.[75] In addition to being able to modify somatic cells—non-reproductive cells in the body—it would also be possible to alter germline cells—egg/sperm cells—producing permanent changes which will be passed down to all future generations.[76] For instance, "sickle-cell anemia is an autosomal recessive disease, which means that an affected individual has inherited a defective hemoglobin gene from both parents, so every one of his or her sets of chromosomes carries [the] defective gene."[77] It is with scientific certainty then that all offspring of the two parents will be plagued with the disease.[78] Repair of the germline would rid that family's DNA of sickle-cell anemia for good.[79]

It is of the utmost importance that scientists use precaution with germline editing, "but if we [do not] take the first small step—learning how to modify embryos precisely and reproducibly and implanting them—[we will] never reach the goal of ridding families of hideous genetic diseases."[80]

2. Cutting Down on Health Care Expenses

Not only can CRISPR have an effect on individuals and their families, but the entire nation—meaning even those not suffering from a

70. Crutchfield III, *supra* note 1.

71. *Alzheimer's and Dementia Facts and Figures*, ALZHEIMER'S ASS'N: FACTS & FIGURES, http://www.alz.org/alzheimers-dementia/facts-figures (last visited May 1, 2019).

72. *Id.*

73. Crutchfield III, *supra* note 1.

74. *See id.*

75. Sample, *supra* note 47.

76. *Types of Gene Therapy*, GENE THERAPY NET, http://www.genetherapynet.com/types-of-gene-therapy (last visited May 1, 2019).

77. Henry I. Miller, *Modification of Embryos Will Someday Treat Hideous Diseases*, NAT'L REV.: CULTURE (Feb. 2, 2016, 7:34 PM), http://www.nationalreview.com/2016/02/embryo-gene-modification-disease-treatment/.

78. *Id.*

79. *See id.*

80. *Id.*

genetic disease—could reap the benefits CRISPR has to offer.[81] It is not surprising that the United States has become famous for its outrageous *over-spending on health care*.[82] Once again, using Alzheimer's disease as an example, "[i]n 2018, Alzheimer's and other dementias . . . cost the nation $277 billion [and] by 2050, these costs could rise as high as $1.1 trillion."[83] The math here is simple—if we eliminate the disease, we eliminate the costs associated with that disease.[84]

3. High Rate of Precision and Accuracy

One of the obvious concerns with using new technology on humans is whether the technology is going to be safe and actually function the way it was intended to function.[85] CRISPR has been said to be the Microsoft Word of the genetic editing world.[86]

"'Genome editing is a little bit like text editing' . . . . 'You place a cursor where you want it and make local changes in the text [you have] written. We can go in and place our cursor and make a break at one site in the DNA—exactly where we want it.'"[87]

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81. Sample, *supra* note 47.

82. Yoni Blumberg, *Here's the Real Reason Health Care Costs So Much More in the U.S.*, CNBC (Mar. 22, 2018, 11:37 AM), http://www.cnbc.com/2018/03/22/the-real-reason-medical-care-costs-so-much-more-in-the-us.html.

> The [United States] spent 17.8 percent of its GDP on health care in 2016. Meanwhile, the average spending of [eleven] high-income countries assessed in a new report published in the Journal of the American Medical Association—Canada, Germany, Australia, the [United Kingdom], Japan, Sweden, France, the Netherlands, Switzerland, Denmark, and the [United States]—was only 11.5 percent.
>
> Per capita, the [United States] spent $9,403. [That is] nearly double what the others spent.
>
> This finding offers a new explanation as to why America's spending is so excessive. According to researchers at the Harvard Chan School, what sets the [United States] apart may be inflated prices across the board.
>
> In the [United States], they point out, drugs are more expensive. Doctors get paid more. Hospital services and diagnostic tests cost more. And a lot more money goes to planning, regulating, and managing medical services at the administrative level.

Id.

83. *Alzheimer's and Dementia Facts and Figures*, *supra* note 71.

84. *See id.*; Crutchfield III, *supra* note 1.

85. *See* Nord, *supra* note 22.

86. MacDonald, *supra* note 68. "It would hypothetically scan the document, highlight errors, and then correct them." *Id.*

87. *Id.*

> CRISPR uses a natural mechanism in bacteria that functions like a primitive immune system. It allows scientists to break parts of DNA on predetermined points so that they can cut areas of DNA with mutations or viruses

As with any new scientific technology, CRISPR has been tested on mice and other animals before human testing and the results were nothing short of astounding.[88] Scientists have treated mosquitos to disable them from transmitting diseases, such as malaria, and have even treated mice and monkeys who were once blind, but through CRISPR, are now able to see.[89] Further "[i]n 2017, testing was done to see if the CRISPR-Cas9 gene-editing method could be used to eliminate [human immunodeficiency virus ("HIV")] in infected rodents."[90] After just one treatment, "all traces of infection [disappeared] from the mouse's organs and tissue."[91]

Of course, even though CRISPR is praised for its huge improvements in accuracy and precision, it is not completely error free.[92] One of the main worries is that CRISPR may mutate or edit "unintended parts of the genome."[93] However, Dr. Gaetan Burgio noted that "these unintended mutation[s] are likely to have preexisted prior to the injection of [the] CRISPR system."[94]

4. Forget the Shortage of Organ Donors

"Currently in the [United States], an average of [twenty-two] people die each day waiting for organ transplants because of donor shortages . . . ."[95] But with CRISPR, this is yet another statistic that could change drastically.[96] Instead of twenty-two people dying per day while awaiting an organ for transplant, imagine if that number were zero.[97]

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and then edit it. When CRISPR senses a virus invading, it can attack and cut up its DNA.

Id.

88. *See* Crutchfield III, *supra* note 1.

89. *Id.*

90. Alexandra Perry, *The Billion-Dollar Industry I Found on YouTube*, ENERGY & CAP. (Jan. 25, 2018, 7:00 PM), http://www.energyandcapital.com/articles/the-billion-dollar-industry-i-found-on-youtube.

91. *Id.*

92. Teodora Zareva, *CRISPR May Cause Hundreds of Unintended Mutations into the Genome, New Study Finds*, BIG THINK (June 4, 2017), http://www.bigthink.com/design-for-good/new-study-finds-that-crispr-may-cause-hundreds-of-unintended-mutations-into-the-genome.

93. *Id.*

94. *Id.* (quoting Paul Knoepfler, *Journal Club Review of New CRISPR "Lots of Off-Target Activity" Mouse Paper*, NICHE (May 31, 2017), http://www.ipscell.com/2017/05/journal-club-review-of-new-crispr-lots-of-off-target-activity-mouse-paper/).

95. Patterson, *supra* note 68.

96. *Id.*

97. *See id.*

Researchers are now looking to pigs as the newest type of organ donor.[98] They may not look like us but "their organs and ours are very much alike."[99] Specifically, the heart, liver, and kidneys have proven to function similarly to that of humans and are roughly the same size.[100] A doctor in Massachusetts has opined that pig organs are a real potential replacement for almost all human internal organs.[101] "Theoretically, CRISPR-Cas9 could manipulate the pig genes so human bodies [would not] reject them [ultimately resulting in] no shortage of available donor organs."[102]

D. *Legitimate Concerns*

With such advanced technology, there are inevitably going to be concerns.[103] While there are legitimate concerns and risks associated with CRISPR, there are logical ways to address them.[104] After all, sometimes "[t]he biggest risk is not taking any risk [at all]."[105] The key is to take intelligent risks.[106]

1. Freewheeling Biohackers

One of the concerns being voiced is that because CRISPR is easier and cheaper to use than ZFNs or TALENs, it creates room for *biohackers*.[107] Biohackers are those who are not trained or educated in the field of science, but who believe, nonetheless, that they can use highly advanced

98. *Pigs May Be Future Organ Donors*, ABC NEWS (Aug. 23, 2001), http://www.abcnews.go.com/WNT/story?id=130708&page=1.

99. *Id.*

100. *Id.*; Patterson, *supra* note 68.

101. *Pigs May Be Future Organ Donors*, *supra* note 98. "'The heart is very similar, the kidneys are very similar, their function is very similar,' says Dr. David Sachs of Massachusetts General Hospital in Boston. 'So it really is a potential donor for almost all of the internal organs.'" *Id.*

102. Patterson, *supra* note 68.

103. *See* MacDonald, *supra* note 68.

104. *Id.*

105. Salim Ismail, *3 Ways Companies Can Encourage Smart Risk Taking*, ENTREPRENEUR: GROWTH STRATEGIES (Oct. 16, 2014), http://www.entrepreneur.com/article/238543.

106. *Id.* Overall, "we need to figure out how to balance the risks and potential rewards of gene editing . . . a meticulous, professional scientist with freewheeling biohackers . . . practical applications with wild theories; best case scenarios like ending malaria with catastrophic prophesies of thirty-foot wolves." *Last Week Tonight with John Oliver: Gene Editing* (HBO television broadcast July 1, 2018).

107. *See* Carmen Russo, *John Oliver Thinks We Need to Stop Freaking Out About Gene Editing*, SLATE: CULTURE (July 2, 2018, 1:44 PM), http://slate.com/culture/2018/07/last-week-tonights-john-oliver-on-gene-editing.html.

technology.[108] CRISPR is so affordable that biohackers could begin collecting the supplies needed to operate the CRISPR gene editing technology and start selling these kits for large-scale public access.[109] In fact, it is already happening.[110] One of these *freewheeling biohackers*, Josiah Zayner, sells do-it-yourself CRISPR kits out of his garage in the state of California.[111] Mr. Zayner has compared the use of this gene editing technology to downloading an app.[112] Mr. Zayner then asks the following hypothetical question: "Why [cannot] people use this technology without necessarily completely knowing how it works?"[113] While most can easily see the obvious problem with this convoluted line of thinking, there will always be those who are metaphorically blind to the magnitude of the effects that can come from reckless self-experimentation.[114]

2. Designer Babies

Another popular concern is that more and more people will begin to use this technology to create designer babies.[115] "But there are good reasons to think that these fears are closer to science fiction than they are to science."[116] Although it is possible to alter simple traits with CRISPR, parents have had "the ability to select their child's sex, eye color, hair color, and skin complexion with preimplantation genetic diagnosis" for years; this is nothing new.[117]

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108. *Id.*; *see also Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

109. Russo, *supra* note 107; *see also Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

110. Russo, *supra* note 107; *see also Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

111. Russo, *supra* note 107; *see also Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

112. Russo, *supra* note 107; *see also Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

113. *Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106. Mr. Zayner went on to further say, "I want to live in a world where people get drunk and instead of giving themselves tattoos, they're like 'I'm drunk, I'm going to CRISPR myself.'" *Id.* Although a ludicrous and quite frankly scary statement, this should not inhibit us from moving forward with technology that could save the lives of so many. *See id.*

114. *See id.*

115. Bailey Kirkpatrick, *Cut Out the Hype: Gene Editing with CRISPR and the Truth About Superhuman* Designer Babies, WHATISEPIGENETICS.COM (Feb. 28, 2017), http://www.whatisepigenetics.com/gene-editing-crispr-cas9-designer-babies/; *see also* Russo, *supra* note 107; *Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

116. Belluck, *supra* note 68.

117. Kirkpatrick, *supra* note 115.

The main fear then becomes whether we can control more "complex traits such as intelligence, personality, or temperament."[118] For example, could parents custom-order a baby with *Usain Bolt's speed* or *Beyonce's vocal range*?[119] The answer is simply *no* because the diseases which CRISPR was made to cure are defects appearing on a single gene or sometimes "an easily identifiable number of genes."[120] Conversely, a person's intelligence, personality, or other special skill arises from an incalculable number of genes.[121] Not only are traits such as personality and temperament controlled by a myriad of genes, but in addition, these traits are molded by our environments and by personal experiences.[122] Thus, scientists are nowhere near being able to alter and predetermine such complex traits.[123]

3. What Constitutes a Genetic Problem That Needs Fixing?

Lastly, there is another more complicated issue that is causing growing concern.[124] CRISPR's whole platform centers around the fact that, with this new technology, we can fix and even eliminate genetic problems that cause diseases.[125] But "who decides what constitutes a genetic problem that needs to be fixed?"[126] For example, is deafness considered a disease?[127] Or dwarfism?[128] There are some people who might think so, but many with

118. *Id.*

119. Belluck, *supra* note 68.

120. *Id.*

> Here is what researchers did: [R]epair a single gene mutation on a single gene, a defect known to cause—by its lonesome—a serious, sometimes fatal, heart disease.
>
> Here is what science is highly unlikely to be able to do: [G]enetically predestine a child's Ivy League acceptance letter, front-load a kid with Stephen Colbert's one-liners, or bake Beyonce's vocal range into a baby.

Id.

121. *See id.* "Even with an apparently straightforward physical characteristic like height, genetic manipulation would be a tall order. Some scientists estimate height is influenced by as many as 93,000 genetic variations." *Id.*

122. Kirkpatrick, *supra* note 115.

123. *See* Belluck, *supra* note 68.

124. *See* Russo, *supra* note 107; *Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

125. *See CRISPR/Cas9*, *supra* note 4.

126. *Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

127. Russo, *supra* note 107; *see also Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

128. Russo, *supra* note 107; *see also Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

such conditions do not.[129] This is a subjective concept which creates a vast gray area.[130]

Consider the following factual scenario: A young boy named Martin is an albino, meaning "his genes do not give the right instructions for his body's production of pigment, the dye that colors the skin, eyes, and hair."[131] As a result, Martin was born with extremely pale skin and "is at high risk of sunburn and skin cancer" when exposed to sunlight.[132] In addition, his light eyes cause poor vision and harsh light can hurt his eyes.[133] Consider also the fact that Martin's mother is worried about him because he is bullied at school by other children in his class for his skin color and hair color.[134] If genetic treatment is made readily available to Martin to produce the average amount of pigmentation in his skin, should he have the treatment?[135] "In other words [is] . . . being albino . . . a medical problem that needs fixing? Or . . . is [it] more along the lines of a nose job or face-lift—something nice, but not necessary?"[136] And what about the choice Martin's mother may have to make?[137] "If she loves Martin the way he is, how does she explain a decision to have him treated? But if *he* is unhappy with the way he is, how does she explain a decision *not* to treat him?"[138] These are difficult questions because there is technically no correct answer as everyone may have a different opinion on the issue.[139]

III. THE CURRENT FDA BAN ON CRISPR HUMAN TRIALS IN THE UNITED STATES

In December 2017, CRISPR Therapeutics officially announced their merger with a biotech company called Vertex.[140] Through their partnership, the two companies produced the CTX001—a special version of CRISPR—to treat sickle-cell patients.[141] As with all forms of genetic treatment, CRISPR

129. *See* Russo, *supra* note 107; *Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

130. *See* Russo, *supra* note 107; *Last Week Tonight with John Oliver: Gene Editing*, *supra* note 106.

131. CATHERINE BAKER, YOUR GENES, YOUR CHOICES: EXPLORING THE ISSUES RAISED BY GENETIC RESEARCH 12 (1999).

132. *Id.*

133. *Id.*

134. *Id.* at 9.

135. *See id.* at 12.

136. BAKER, *supra* note 131, at 12.

137. *Id.*

138. *Id.*

139. *See id.* at 13.

140. Houser, *supra* note 13.

141. *Id.*

and Vertex collectively sought approval from the FDA to move forward with human trials with consenting adult volunteers.[142] However, after review, the FDA denied the request, "placing a *clinical hold* on the application."[143] According to a recent press release held by CRISPR Therapeutics, the FDA has expressed certain questions with regard to CRISPR technology and will not permit the company to proceed with testing on humans.[144]

A. *Has CRISPR Been Tested in Other Countries?*

China has been conducting human trials for several years now—making China the first country in the world to conduct human trials with CRISPR technology.[145] Dr. Shixiu Wu, head of the Hangzhou Cancer Hospital located in China, is perhaps one of the doctors most heavily associated with the use of CRISPR.[146] Dr. Wu treats many patients with advanced esophageal cancer—one of the most common forms of cancer in China.[147] Typically, Dr. Wu treats his patients in the ways that most of us are probably familiar with, such as chemotherapy and radiation treatments.[148] In one case, Dr. Wu treated a fifty-three year old man suffering from advanced esophageal cancer through many rounds of chemotherapy and radiation, but the cancer just kept spreading.[149] Upon the suggestion of CRISPR, Dr. Wu's patient expressed interest in this form of experimental treatment.[150] Dr. Wu then explained that the process—called *T-cell infusion*—would involve "using cells from [the patient's] own immune system, known as T-cells, after they ha[d] been taken out of his body and genetically altered in a lab by the gene-editing tool called CRISPR."[151] The cells are modified "so that they zero in on and attack the cancer cells once [they are] infused back into each patient"—basically instructing the immune

142. *Id.*; *What Is Gene Therapy?*, FDA: VACCINES, BLOOD & BIOLOGICS (July 25, 2018), http://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy.

143. Houser, *supra* note 13.

144. *Id.*

145. Kristen V. Brown, *China Has Already Gene-Edited 86 People with CRISPR*, GIZMODO: GENETICS (Jan. 22, 2018, 1:00 PM), http://www.gizmodo.com/china-has-already-gene-edited-86-people-with-crispr-1822297524; Nord, *supra* note 22.

146. *See* Rob Stein, *Doctors in China Lead Race to Treat Cancer by Editing Genes*, NPR (Feb. 21, 2018, 5:00 AM), http://www.npr.org/sections/health-shots/2018/02/21/585336506/doctors-in-china-lead-race-to-treat-cancer-by-editing-genes.

147. *Id.*; Nord, *supra* note 22.

148. Nord, *supra* note 22.

149. Stein, *supra* note 146.

150. *See id.*

151. *Id.*

system to attack the malignant cancerous cells.[152] After preparation of the T-cells was complete, the patient was intravenously infused with "millions of genetically modified immune system cells" which flowed into his veins for about an hour.[153] After his very first infusion, the patient reported feeling a bit weak initially, but feeling better and feeling very stable soon after.[154] Although Dr. Wu is still treating this patient, Dr. Wu remarked that another one of his patients has been doing well after almost a full year of CRISPR treatments.[155] Although one of Dr. Wu's patients decided to discontinue with CRISPR treatments after experiencing a high fever, "[t]he rest appear to be stable or in *partial remission* [after] . . . undergoing monthly treatments."[156] Dr. Wu reports that a total of nine patients have died in the study, "but Wu says that was from their cancer, not the [CRISPR] treatment."[157]

"So far, [twenty-one] patients have participated in the trials [and] [t]he efficiency was about [forty] percent."[158] At first glance, forty percent does not seem like a very high success rate, but the fact is that forty percent is significantly better than zero percent.[159]

B. *Why the FDA Should Allow Human Trials in the United States*

Although it is important to have a *cautious gatekeeper* in place, "[t]he FDA is commonly viewed as a roadblock."[160] "Patients are looking for answers. Biotech is looking for big bucks. Both oppose regulation."[161] While it is no doubt imperative to ensure medical technology is not harming individuals, the question boils down to whether competent and informed adults should be able to subject themselves to risk.[162]

152. *Id.*
153. *Id.*
154. Stein, *supra* note 146.
155. *Id.*
156. *Id.*
157. *Id.*
158. Nord, *supra* note 22.
159. *See id.*
160. Megan Molteni, *China Used CRISPR to Fight Cancer in a Real, Live Human*, WIRED: SCI. (Nov. 18, 2016, 2:00 PM), http://www.wired.com/2016/11/china-used-crispr-fight-cancer-real-live-human/.
161. *Id.*
162. *Id.*

1. Many of Those with Genetic Diseases Are Out of Options

"Clinical research attempts to address a relatively straightforward, and extremely important challenge: [H]ow do we determine whether one medical invention is better than another, whether it offers greater clinical benefit and/or poses fewer risks?"[163] CRISPR is now at the stage where it requires testing with real, live humans.[164] Human testing of any kind poses some kind of risk to the patient "no matter how many laboratory and animal tests have preceded them."[165] Herein lies the ethical dilemma: When does it become permissible to expose living, breathing human beings to a risk of harm to further medical research?[166]

With medical devices like CRISPR, scientists and medical providers "should be permitted to conduct research and expose subjects to risks provided they obtain [the] subjects' 'free, voluntary, and undeceived consent and participation.'"[167] Yet, the FDA does not regard the notion of informed consent as a sufficient basis for human testing.[168] Are the FDA's limitations "justified, or are they inappropriate infringements on the free actions of competent individuals" who have otherwise run out of options?[169]

Looking at the twenty-one patients who have undergone CRISPR treatments in China, it is easy to see why the country allowed such treatment and why patients were voluntarily subjecting themselves to serve as guinea pigs of the new technology.[170] Every single one of those patients was suffering from an advanced stage of cancer and had already tried surgery, chemotherapy, and radiation to no avail.[171] After exhausting all other methods of killing the cancer cells, these patients would ultimately be told there is nothing further doctors can do.[172] If not for CRISPR, these patients would be out of options and would live each day knowing it could be their last.[173]

The bottom line is that most of the ethical concerns that arise from exposure of humans to CRISPR are shattered when the patient, if of age and

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163. David Wendler, *The Ethics of Clinical Research*, STAN. ENCYCLOPEDIA PHIL. (Feb. 27, 2017), http://plato.stanford.edu/entries/clinical-research/.

164. *See* Houser, *supra* note 13.

165. Wendler, *supra* note 163.

166. *Id.*

167. *Id.* (quoting JOHN STUART MILL, ON LIBERTY 16 (Currin V. Shields ed., The Bobbs-Merrill Co. 1956) (1859)).

168. *See id.*; *What We Do*, *supra* note 27.

169. Wendler, *supra* note 163; *What We Do*, *supra* note 27.

170. *See* Nord, *supra* note 22.

171. *Id.*

172. *Id.*

173. *See id.*

standard mental competence, cannot be helped by any other form of treatment.[174]

2. But What About These Products?

a. *Big Tobacco*

Imagine if every product with harmful qualities were regulated in the same way as CRISPR.[175] The United States is proceeding with the utmost caution in allowing CRISPR human trials, yet we allow products like cigarettes to be sold to the general public every day.[176] "Causing more than 480,000 deaths each year in the United States, smoking is the leading preventable cause of death in the United States."[177] Smoking damages almost every organ in the human body and contributes to serious health issues such as stroke, heart disease, and, of course, lung cancer.[178] Not only is smoking responsible for causing lung cancer, but it can cause just about any type of cancer imaginable.[179] "If nobody smoked, one in every three cancer deaths in the United States would not occur."[180]

Perhaps even more troubling is the lengthy and frightening list of chemicals found in cigarettes.[181] "[O]f the [ninety-three] known harmful . . . chemicals [found] in cigarettes," a few particularly troublesome chemicals include: Nicotine, cadmium, lead, acetaldehyde, benzene, ammonia, and carbon monoxide.[182] These chemicals—many of which are known to be deadly—are contained in each and every cigarette.[183] This is what our governmental regulatory agencies are allowing to be ingested by United States citizens every day.[184]

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174. *See id.*

175. *See* Nord, *supra* note 22.

176. *See* Houser, *supra* note 13; *Effects of Tobacco*, *supra* note 28.

177. *Effects of Tobacco*, *supra* note 28.

178. *Id.*

179. *Id.* "Such areas include (but are not limited to): [T]he bladder, bloodstream, cervix, colon, rectum, esophagus, kidney, ureter, larynx, liver, oropharynx, pancreas, stomach, trachea, bronchus, and lung." *Id.*

180. *Id.*

181. *Chemicals in Cigarettes: From Plant to Product to Puff*, FDA, http://www.fda.gov/tobacco-products/products-ingredients-components/chemicals-cigarettes-plant-product-puff (last visited May 1, 2019).

182. *Id.*

183. USFoodandDrugAdmin, *Chemicals in Every Puff of Cigarette Smoke — Combustion Stage*, YOUTUBE (Feb. 13, 2017), http://www.youtube.com/watch?v=EXdxl0yH904.

184. *See What We Do*, *supra* note 27.

One of the common reservations with regard to tobacco litigation is: Why should individuals be suing tobacco companies when they are knowingly and willfully smoking cigarettes that have proven to be directly linked to causing lung cancer—that was their choice, right?[185] In this day and age, when all of this data has been made available to the public, that is certainly a valid question.[186] And it is this very same logic that should be used when we evaluate tools like CRISPR.[187] With genetic counseling, and all that is known thus far about CRISPR, individuals can make informed decisions about whether they wish to proceed with the new form of treatment or keep exploring other options.[188]

One of the reasons tobacco companies are able to continuously market and sell their deadly product is because of how the FDA's regulatory framework is structured.[189] Interestingly, the intent of the manufacturer determines whether the FDA will have jurisdiction over a given product.[190] Where a manufacturer intends for a product to affect the human body in structure or function, it will be labeled a drug or device that is subject to FDA regulation.[191] For example, CRISPR Therapeutics claims their product can eliminate genetic diseases through the mutation or alteration of genes—making it subject to FDA authority.[192] The FDA proclaims that their goal is to protect the health and safety of the public by guaranteeing that drugs and devices are safe and effective for their intended use.[193] While it is true that tobacco companies generally do not make therapeutic claims regarding their products, cigarettes certainly have an effect on the structure and function of the human body—a largely negative one at that.[194] Nicotine should certainly

185. Robert L. Rabin, *A Sociolegal History of the Tobacco Tort Litigation*, 44 STAN. L. REV. 853, 871 (1992); *Effects of Tobacco*, *supra* note 28.

186. *See Effects of Tobacco*, *supra* note 28. However, that is not a valid question for plaintiffs who qualify for class certification and have standing in regard to the *Engle* progeny cases. Engle v. Liggett Grp., 945 So. 2d 1246, 1267 (Fla. 2006).

187. *See Genome Editing: What Is Genome Editing?*, *supra* note 34.

188. *See id.*; Crutchfield III, *supra* note 1; Houser, *supra* note 13.

189. *See* Action on Smoking & Health v. Harris, 655 F.2d 236, 238–39 (D.C. Cir. 1980); Daniel F. Hardin, *Blowing Electronic Smoke: Electronic Cigarettes, Regulation, and Protecting the Public Health*, 2011 U. ILL. J.L. TECH. & POL'Y 433, 439.

190. Hardin, *supra* note 189, at 439; *see also* 21 U.S.C. § 321 (2012).

191. Hardin, *supra* note 189, at 439; *see also* 21 U.S.C. § 321.

192. *CRISPR/Cas9*, *supra* note 4; *see also* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (2000), *superseded by statute*, Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (quoting 21 U.S.C. § 321(g)–(h)).

193. *What We Do*, *supra* note 27.

194. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 155; *Effects of Tobacco*, *supra* note 28.

qualify as a drug since it has been proven time and time again to have potent, addictive qualities.[195]

In 1996, however, the FDA did attempt to regulate cigarettes on the grounds that cigarettes are both a drug and a device because they deliver exact and controlled amounts of nicotine to the body to sustain addiction.[196] In the famous case, *FDA v. Brown and Williamson Tobacco Corp.*,[197] the Supreme Court of the United States found that the FDA was precluded from regulating tobacco products.[198] The Supreme Court held that if the FDA were to have jurisdiction over tobacco products, they would be banned from the market as "no measures the agency could take would make tobacco products safe for human use."[199] "The Court reasoned Congress favored informing consumers about adverse health risks of tobacco use over harming the nation's economy through an outright ban of tobacco."[200]

In applying this to CRISPR, there is no doubt that CRISPR makes a therapeutic claim and, thus, constitutes a medical device subject to FDA jurisdiction.[201] But what kind of message does it send to allow billions of cigarettes to be sold every day with the knowledge that the FDA would ban them in a heartbeat if they were in the driver's seat of tobacco's marketability?[202] Perhaps the answer is that the blood of the United States runs green with greed.[203] If there were as big a desire to help one another as

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195. *The Top 5 Most Addictive Drugs in the World*, RECOVERY FIRST, http://www.recoveryfirst.org/drug-abuse/most-addictive-drugs/ (last updated June 6, 2016). Ranking in at number three, "[n]icotine is considered one of the most addictive substances in the world." *Id.*

> Part of the reason nicotine is so addictive is that this stimulant decreases appetite, boosts mood, and increases heart rate, blood pressure, and alertness. However, it has a very short life span in the bloodstream, with users typically feeling cravings for nicotine after [two to three] hours. This craving often includes psychological symptoms like anxiety [or] depression, along with headaches or restlessness.

Id.

196. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 127.

197. 529 U.S. 120 (2000).

198. *Id.* at 133.

199. Hardin, *supra* note 189, at 440 (citing *Brown & Williamson Tobacco Corp.*, 529 U.S. at 135–36) (discussing the FDA's failed attempt to regulate traditional tobacco).

200. *Id.* at 440–41; *see also Brown & Williamson Tobacco Corp.*, 529 U.S. at 138–39.

201. *See* 21 U.S.C. § 321(g)–(h); Crutchfield III, *supra* note 1; *What We Do*, *supra* note 27.

202. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 135–36; Hardin, *supra* note 189, at 440–41.

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Id.

196. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 127.

197. 529 U.S. 120 (2000).

198. *Id.* at 133.

199. Hardin, *supra* note 189, at 440 (citing *Brown & Williamson Tobacco Corp.*, 529 U.S. at 135–36) (discussing the FDA's failed attempt to regulate traditional tobacco).

200. *Id.* at 440–41; *see also Brown & Williamson Tobacco Corp.*, 529 U.S. at 138–39.

201. *See* 21 U.S.C. § 321(g)–(h); Crutchfield III, *supra* note 1; *What We Do*, *supra* note 27.

202. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 135–36; Hardin, *supra* note 189, at 440–41.

203. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 138–39; Hardin, *supra* note 189, at 440–41.

there is to make a profit, maybe CRISPR would already be doing away with genetic diseases.[204]

b. *Even the Widely Used Chemotherapy*

Another harmful product used on a daily basis is chemotherapy—conceivably the most commonly used and well-known cancer treatment available.[205] "[C]hemotherapy refers to the drugs that prevent cancer cells from dividing and growing. It does this by killing the dividing cells."[206] In essence, the combination of drugs used in chemotherapy will:

> [I]mpair mitosis, or prevent cell division . . . ;
>
> [T]arget the cancer cells' food source, which consists of the enzymes and hormones they need to grow;
>
> [T]rigger the suicide of cancer cells, known medically as apoptosis; [and]
>
> [S]top the growth of new blood vessels that supply a tumor in order to starve it.[207]

Given this wide array of functions, it is not surprising that chemotherapy comes with a long list of side effects and reaching the remission stage is not always guaranteed.[208] Most are aware of the common and almost inevitable side effects of chemotherapy—nausea, vomiting, alopecia (hair loss), fatigue, and anemia.[209]

But what about the effects of chemotherapy that are not so common?[210] "Back in September 2004, the Centers for Disease Control and Prevention ("CDC") and the National Institute for Occupational Safety & Health ("NIOSH") . . . warned that working with chemotherapy drugs and other common pharmaceuticals can be a serious danger to your health."[211] Ironically, "one of the effects of chemotherapy is that it actually [causes]

204. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 139; Crutchfield III, *supra* note 1.

205. *See* Nordqvist, *supra* note 27.

206. *Id.*

207. *Id.*

208. *See id.*

209. *Id.*

210. *See* Ty Bollinger, *The Truth About Chemotherapy — Toxic Poison or Cancer Cure?*, TRUTH ABOUT CANCER (May 5, 2015), http://www.thetruthaboutcancer.com/truth-about-chemotherapy/.

211. *Id.*

cancer!"[212] Further, numerous chemical specialists are of the opinion that in reality, chemotherapy does much more harm than it does good.[213] "The truth is that chemo is toxic, carcinogenic (causes cancer), destroys erythrocytes (red blood cells), devastates the immune system, and destroys vital organs."[214]

Chemotherapy, as we know, can have catastrophic side effects; in comparison, CRISPR's are minimal.[215] Looking at the human trials performed in China, Dr. Wu has said "the only side effects have been mostly minor—an occasional fever or rash."[216] Just like chemotherapy has proven, the mere fact that a drug produces side effects does not automatically bar it from FDA approval.[217] "[E]very new therapy has some potential [for] side effects—[the key is], we need to be aware of what they are."[218]

C. *Is This Big Pharma at Play?*

Imagine if you had the power to change the world—to rid it of disease, to save millions, to ease someone else's pain and suffering—all while earning a profit.[219] If you were to start up a pharmaceutical conglomerate, this is likely what your end goal would look like.[220] Initially, you plan to use your company for good and you truly desire to help the

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212. *Id.*

213. *Id.* "Dr. Alan C. Nixon, past president of the American Chemical Society writes, 'As a chemist trained to interpret data, it is incomprehensible to me that physicians can ignore the clear evidence that chemotherapy does much, much more harm than good.'" *Id.*

214. Bollinger, *supra* note 210. "The serious toxic effects of chemotherapy have long been ignored by virtually everyone in medicine and the federal government. Chemotherapy drugs have always been assumed to be safe just because [they are] used to treat cancer. This is an outright lie." *Id.*

215. *See id.*; Nord, *supra* note 22. Dr. Wu stated that "although [he has] only used the technology on a small number of people, it appears much safer than traditional chemotherapy." Nord, *supra* note 22.

216. Stein, *supra* note 146.

217. *See* Bollinger, *supra* note 210; Nordqvist, *supra* note 27.

218. Zareva, *supra* note 92.

> Chemotherapy is an invasive treatment that can have severe adverse effects. This is because the drugs often target not only cancerous cells but also healthy cells. The adverse effects can be worrying, but given early, chemotherapy can in some cases achieve a complete cure, making the side effects bearable for many patients. It is important that patients know what to expect before starting treatment.

Nordqvist, *supra* note 27. Sound familiar?* This is the exact premise that should be used when discussing the administration of CRISPR to human patients. *See id.*

219. BIG PHARMA, http://www.bigpharmagame.com (last visited May 1, 2019). Video game inventors even made an online game called *Big Pharma* with the slogan, "Marketing and Malpractice is the brand new expansion for Big Pharma. . . . [You have] created your wonder drug, now it is time to sell, sell, sell." *Id.*

220. *See id.*

human race.[221] But the *uncomfortable truth* is that "illness is good for business."[222] This is the world of Big Pharma.[223]

Big Pharma is often used to describe "massive pharmaceutical companies that make literally billions of dollars every year to keep Americans regularly supplied with a medicine cabinet's worth of pills."[224] So how do these pharmaceutical companies have an influence on CRISPR?[225]

Due to their extremely high profit margins, Big Pharma has some pretty deep pockets and "[w]ith those pockets comes a strong hand of political and legislative influence."[226] Even though the FDA has been instituting massive fines, Big Pharma companies are significant contributors to the FDA's budget, thus "leading to concerns of conflicts of interest and outright bribery."[227] For these reasons, the pharmaceutical industry is now being referred to as *America's new mafia*.[228]

> Big Pharma has raised a lot of eyebrows for the money it can throw at doctors and legislators, but perhaps the most serious effect it has had on American healthcare is the epidemic of the overprescription of powerfully addictive drugs . . . The United States makes up only [five] percent of the world's population but consumes [eighty] percent of the painkillers in the world.[229]

Pharmaceutical companies, theoretically, are "meant to write themselves out of the equation. True success—a world without disease—would also mean a world without drugs and a world without pharmaceuticals."[230] But when pharmaceutical companies are successful in

221. *See id.*
222. *Id.*
223. BIG PHARMA, *supra* note 219.
224. *Who Are the Players in the Pharmaceutical Industry (Big Pharma)?*, DESERT HOPE, http://www.deserthopetreatment.com/big-pharma/ (last updated Nov. 28, 2016).
225. *See id.*
226. *Id.*
227. *Id.*
228. *Id.*
229. *Who Are the Players in the Pharmaceutical Industry (Big Pharma)?*, *supra* note 223. "A 2011 survey conducted by the Kaiser Family Foundation revealed that Americans aged [nineteen through sixty-four] were prescribed an average of 11.9 prescriptions, and Americans [sixty-five] and up received an average of [twenty-eight] prescriptions." *Id.*
230. Elizabeth Balboa, *Curing Disease Is Bad for Business: How Do Big Pharma Companies Continue Their Growth?*, BENZINGA (Feb. 14, 2017, 8:55 AM), http://www.benzinga.com/general/biotech/17/02/9017199/curing-disease-is-bad-for-business-how-do-big-pharma-companies-continu.

actually curing patients, they no longer have a purpose, "and the market responds to that lost purpose by withdrawing investments."[231] Adam Feuerstein, a national biotech columnist, made a Twitter post stating: "Perhaps the awful, brutally honest lesson here is: Curing disease is great for patients but sucks for business."[232] This is the premise behind Big Pharma—"[s]uccess is not always profitable in the pharmaceutical industry, and [it is] this perspective [that has] fueled numerous conspiracy theories . . . about drug companies intentionally missing their marks."[233]

Although CRISPR does not have the ability to cure every disease, it could potentially cure some of health care's most expensive treatments—HIV, cancers, and Alzheimer's.[234] As mentioned previously, Alzheimer's disease—along with other forms of dementia—"will cost the nation $277 billion [and] by 2050, these costs could rise as high as $1.1 trillion."[235] "[That is] why *Bloomberg* is calling CRISPR-Cas9 'the discovery of the century' and *Science* magazine is calling it 'the breakthrough of the year.'"[236]

On the one hand, CRISPR could shatter the conspiracy theory behind Big Pharma.[237] Pharmaceutical companies may not be the biggest advocates of CRISPR since CRISPR could have the potential to disrupt their trillion-dollar industry; curing so many diseases might just be bad for business.[238]

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231. *Id.*

232. Adam Feuerstein (@adamfeuerstein), TWITTER (Feb. 7, 2017, 6:18 PM), http://twitter.com/adamfeuerstein/status/829152296764395520; *Adam Feuerstein*, STAT, http://statnews.com/staff/adam-feuerstein/ (last visited May 1, 2019). One stock market trader, Dennis Dick, said "[t]he bottom line here is: [D]on't make your drugs so effective . . . . [That is] a sad world we live in when capitalism is going to punish a stock because their drugs are too effective." Balboa, *supra* note 230.

233. *Id.* "Some wonder if pharmaceuticals announce just enough progress to draw in funds while maintaining a safe distance from cure-driven obsolescence." *Id.*

234. Perry, *supra* note 90.

235. *Alzheimer's and Dementia Facts and Figures*, *supra* note 71.

> In the United States, an average of $173 billion is spent every year on cancer research. Heart disease treatment costs another $200 million annually. Then there is diabetes, which is on the rise and costs Americans $245 billion annually. Those are some big numbers, and they [are not] even the worst. Alzheimer's, one of the scariest diseases to any aging human—which is all of us—costs Americans $259 billion a year! When you do the math, that means just four diseases are raking up a $1 trillion medical bill. And [that is] just the big boys. Imagine the costs that come with genetic diseases that appear at birth—diseases that parents will pay for throughout their child's adolescence. Then when that child becomes an adult, they will inherit the costs of a disease they never wanted and [could not] fight. But with CRISPR-Cas9, that could end. In our current war against disease, [it is] Big Pharma that rakes in the dough.

Perry, *supra* note 90.

236. *Id.*

237. *See id.*; Balboa, *supra* note 230.

238. *See* Perry, *supra* note 90.

On the other hand, CRISPR might open up a brand new realm of income that Big Pharma might want in on.[239] The still young industry surrounding the CRISPR-Cas9 system "could form the foundation of a billion-dollar gene-editing industry."[240]

IV. CONCLUSION

As demonstrated throughout this Comment, CRISPR has massive medicinal potential.[241] CRISPR has the ability to rid the world of deadly genetic diseases, make real changes in the cost of healthcare in the United States, make stellar improvements to the accuracy and precision of genetic editing, and even eliminate the growing need for organ donors.[242] Although the legitimate concerns expressed should not be taken lightly, many of those concerns "are closer to science fiction than they are to science."[243]

Further, there is a lot to learn from the country that has been testing CRISPR on humans for years now.[244] This is not to say that the FDA should not keep doing its job; however, when looking at the drugs and devices that are allowed on the market today, the fact that CRISPR is not allowed leaves room for serious questions.[245] Is the FDA really the ethical gatekeeper it presents itself to be?[246] Or is it actually persuaded by profit?[247] With tobacco products and chemotherapy in heavy use in this country, and Big Pharma's influence, the latter seems to be the winning answer.[248]

"Hopefully, CRISPR Therapeutics and Vertex are able to answer the FDA's questions in a way that promotes confidence in the treatment."[249] While it is important to keep in mind that we are *exploring uncharted territory* and certainly should *proceed with caution*, the truth is that millions of people throughout the United States, as well as the rest of the world, suffer from diseases that could be cured by CRISPR technology.[250]

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239. *See id.*
240. *Id.*
241. Crutchfield III, *supra* note 1.
242. *Id.*; MacDonald, *supra* note 68; Patterson, *supra* note 68.
243. Belluck, *supra* note 68.
244. *See* Molteni, *supra* note 160; Stein, *supra* note 146.
245. *See* Hardin, *supra* note 189, at 439, 449; Molteni, *supra* note 160; Stein, *supra* note 146.
246. *See* Molteni, *supra* note 160.
247. *See Who Are the Players in the Pharmaceutical Industry (Big Pharma)?*, *supra* note 224.
248. *See id.*; Balboa, *supra* note 230; Bollinger, *supra* note 210; *Effects of Tobacco*, *supra* note 28.
249. Houser, *supra* note 13.
250. *Id.*; *see also* Crutchfield III, *supra* note 1.

One thing is clear—CRISPR could change the world.[251] The only question that remains is: When will the United States give it the chance?[252]

251. Crutchfield III, *supra* note 1; *see also* Houser, *supra* note 13.

252. *See* Houser, *supra* note 13. Just one month after the submission of this Comment, the United States made the decision to sponsor the first CRISPR human trial. Catherine Offord, *US Companies Launch CRISPR Clinical Trial*, THESCIENTIST (Sept. 3, 2018), http://www.the-scientist.com/news-opinion/us-companies-launch-crispr-clinical-trial-64746. "Although the study itself is to be carried out in a hospital in Germany, it marks the first clinical trial of CRISPR genome-editing technology to be sponsored by [United States] companies, Boston based Vertex Pharmaceuticals and CRISPR Therapeutics, a Swiss biopharmaceutical [company] with labs in Cambridge, Massachusetts." *Id.* These companies will "jointly launch[] a trial of an experimental CRISPR-Cas9 therapy for the blood disorder ß-thalassemia, according to [an] announcement posted Friday, August 31, [2018]." *Id.* CRISPR Therapeutics [Chief Executive Officer], Samantha Kulkarni, stated, "Just three years ago we were talking about CRISPR-based treatment as a sci-fi fantasy . . . But here we are." *Id.*