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Opening a Can of Genetically-Modified Worms: Funding and Regulating CRISPR Technology

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OPENING A CAN OF GENETICALLY-MODIFIED WORMS: FUNDING AND REGULATING CRISPR TECHNOLOGY

I. INTRODUCTION

Recent advances in biotechnology have led to a revolutionary process in which scientists are able to edit the genes of an organism with unprecedented accuracy, speed, and affordability.[1] This technological process can come from different gene-editing technologies such as CRISPR/Cas9 or CRISPR, which stands for Clustered Regularly Interspaced Short Palindromic Repeats.[2] The potential benefits of CRISPR are expansive and could redirect how we treat genetic diseases.[3] Of course, a powerful technology like CRISPR raises serious ethical questions about how it should and should not be used.[4] While many agree that our society would benefit immeasurably from CRISPR, we must first ask ourselves how far we are willing to go to achieve such desired results.[5]

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1 *See CRISPR Timeline*, BROAD INSTITUTE https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-timeline [https://perma.cc/ZAE2-ZESZ] (providing the timeline leading up through the advent of CRISPR). The natural process of CRISPR was discovered in the early 1990s, but was not realized as a technological tool for scientists until 2012. *Id.* Currently, CRISPR aims to cure a rare eye disease called Leber congenital amaurosis. *Id.* Antonio Regaledo, *CRISPR Gene Editing to be Tested on People by 2017*, 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/LS5E-PN29]. Scientists are striving to cure a large variety of genetic diseases in the coming years and believe that a cure for cancer is not out of reach in the near future. *Id.*

2 *See* Martin Jinek et al., *A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 SCIENCE MAG. 816–21, http://science.sciencemag.org/content/337/6096/816.full.pdf+html [https://perma.cc/THZ4-5LZX] (discussing the discovery of the CRISPR/Cas system discovery). CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats. *Id.* The process is an evolved adaptation in bacteria used to fight off viruses. *Id.* A deeper discussion on what CRISPR is and how it works will be discussed below. *See also infra* Part II.B (discussing the process of gene editing through the use of CRISPR technology).

3 *See* Thom Patterson, *Unproven Medical Technique Could Save Countless Lives, Billions of Dollars,* CNN (Oct. 30, 2015), http://www.cnn.com/2015/10/30/health/pioneers-crispr-dna-genome-editing/ [http://perma.cc/Q7XC-3JWL] (describing the health and financial benefits CRISPR could bring to our society).

4 *See, e.g.*, Edward Lanphier et al., *Don't Edit the Human Germline*, NATURE http://www.nature.com/news/don-t-edit-the-human-germ-line-1.17111 (Mar. 12, 2015), [htttp://perma.cc/MRW2-MHVW] (exemplifying one of many ethical concerns involving CRISPR). The article discusses the most serious concerns involving permanent changes to human DNA. *Id.*

5 *See* Staff Reporter, GENOMEWEB https://www.genomeweb.com/gene-silencinggene-editing/scientists-call-caution-use-crisprcas9-technology [http://perma.cc/5X6R-V3RX] (reporting the weighing tests scientists consider when acknowledging the benefits and consequences associated with CRISPR). Scientists have called for transparency and standardized benchmarking in an attempt to curb concerns of human germline modification.

This Note aims to answer some of these questions by proposing new legislation that could be passed by Congress to help facilitate further research involving CRISPR, while also addressing many of the ethical concerns that have many fearful for the future direction of biosciences.[6]

Part II of this Note outlines the background behind CRISPR by first briefly discussing the inception of CRISPR and how it is truly revolutionary in comparison to the technologies that came before it.[7] Part II.B continues by explaining what CRISPR is, how it works, and the potential benefits of CRISPR as well as the relevant ethical considerations.[8] Part III analyzes the current law and balances the law with the current scientific and ethical discussions going on regarding CRISPR.[9] Part III also explains why new legislation is not only necessary to address these problems, but also why legislation is the most effective and efficient way of doing so as opposed to alternative proposals.[10] Part IV provides ethical boundaries and funding considerations that should be met with this legislation.[11]

Id. Human germline modification is the editing of genes of future generations of humans. *About Human Germline Editing*, CTR. FOR GENETICS AND SOC. (July 9, 2015), http://www.geneticsandsociety.org/article.php?id=8711 [http://perma.cc/BM5K-64HX].

> "Human germline gene editing" or "human germline modification" means deliberately changing the genes passed on to children and future generations–in other words, creating genetically modified people. Human germline modification has for many years been widely considered off-limits, for both safety and social reasons. It is formally prohibited in more than 40 countries.

Id.

6 *See infra* Part IV.A (proposing a piece of legislation to address multiple ethical and legal concerns associated with CRISPR, while also attempting to facilitate further research).

7 *See infra* Part II.A (chronicling the advances in research that led to the discovery of CRISPR in bacteria and developing it into a tool).

8 *See infra* Part II.B (discussing the revolutionary power of CRISPR and why it raises such urgent ethical and legal issues).

9 *See infra* Part III (advocating for changes in the law, partially by repealing the Dickey-Wicker Amendment that no longer accurately serves its original purpose).

10 *See infra* Part III.B (explaining the unique advantages that naturally come with solving legal issues through new legislation).

11 *See infra* Part IV (proposing a model act with narrowly tailored guidelines for directing federal funding toward CRISPR research). This act aims to fund certain types of studies on CRISPR with the goal of being an investment in public health. *Id.* This proposed act proposes a repeal of the Dickey-Wicker Amendment, as discussed in Parts II and III. *Id*. Next, the proposed act establishes a series of guidelines that specifically detail the types of studies that are funded by this act. *Id.* Additionally, the proposal specifies the types of research that are wholly prohibited, and what types of repercussions could follow if such a guideline is violated. *Id.* After the proposal is fully laid out, Part IV will continue by addressing a few anticipated reactions and arguments against this proposal. *Id.* These counter-arguments provided will involve the scope of the proposal and differentiating between the proposed act laid out below and recent developments in the law. *Id.*

II. BACKGROUND

Gene editing is a practice that has been developing and has been theorized over the past few decades.[12] "What used to be science fiction" has suddenly become a real part of modern science and medicine.[13] Part II.A briefly traces the history of gene editing and its development up to this point.[14] Next, Part II.B discusses what CRISPR/Cas9 is, how it works, and why it has changed the way we look at science and medicine.[15] Part II.C touches on the ethical issues CRISPR raises and why these concerns should be immediately addressed by scientists, ethicists, and lawmakers.[16] Part II.D brings attention to the current legal issues that CRISPR is encountering as the full potential of CRISPR technology is being realized.[17] A background on each of these subjects is necessary to consider the legal and ethical landscape ahead of us, and how lawmakers can most efficiently address these numerous issues.[18]

A. Gene Editing and the Development of CRISPR

Gene editing can be traced back to studies in the 1980s that looked to modify specific genes in mice.[19] Shortly after that, gene-editing technologies, such as TALENs, were developed as efficient ways to modify an organism's genes.[20] The development of these technologies quickly accelerated after scientists successfully mapped the human

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12 *See CRISPR Timeline*, *supra* note 1 (tracing the theoretical discovery of a CRISPR system back to 1993 or earlier).

13 *See* Jennifer Doudna, *How CRISPR Lets Us Edit Our DNA,* TED, at 11:55, https://www.ted.com/talks/jennifer_doudna_we_can_now_edit_our_dna_but_let_s_do_it_wisely?language=en [https://perma.cc/ZGN2-2C4Z] (suggesting that this subject could easily be seen as ridiculous because of its impossibility only a few years ago).

14 *See infra* Part II.A (setting up the revolutionary nature of CRISPR).

15 *See infra* Part II.B (explaining CRISPR in further detail to highlight why the technology is so controversial).

16 *See infra* Part II.C (turning to the specific concerns scientists, ethicists, and lawmakers alike have regarding proceeding with further research involving CRISPR).

17 *See infra* Part II.D (delving into issues raised by the Dickey-Wicker Amendment and *Sherley v. Sebelius* in the United States District Court of Washington D.C.).

18 *See infra* Part IV (advocating for a remedy to these problems through new legislation).

19 *See* Jon Chestnut, *Analyzing TALEN v. CRISPR*, GENETIC ENG'G & BIOTECHNOLOGY NEWS (Oct. 13, 2016), http://www.genengnews.com/gen-exclusives/analyzing-talen-vs-crispr/77900759 [https://perma.cc/P83U-LYVX] (mentioning a brief description of early gene-editing research in the 1980s conducted on mice).

20 *See id.* (explaining TALENs as an alternative gene-editing method that is highly accurate, but lacks the "simplicity and versatility of CRISPR"). TALENs stands for Transcription Activator-Like Effector Nucleases. *Id.* One clear advantage is that TALENs is licensed for commercial use. *Id.* CRISPR is still in a bitter patent dispute, which maintains a level of uncertainty with its availability for commercial use in the very-near future. *Id.*

genome in 2003.[21] But, it wasn't until 2012 when Professor Jennifer Doudna and her colleagues at the University of California, Berkeley discovered a breakthrough technology now known as CRISPR/Cas9 (or CRISPR) in bacteria.[22]

Before the development of CRISPR, the process of editing genes was an arduous process that would cost thousands of dollars for each use and could have taken weeks or months to achieve a desired result.[23] Even then, the results lacked accuracy—which is a great concern in the business of changing an organism's genes.[24] Now CRISPR has provided an exponentially faster method of altering DNA.[25] Additionally, the cost of a single use of the technology has been reduced to about $75 per use.[26] On top of the increased affordability and speed of the gene-editing technology, CRISPR has improved accuracy of the desired result tremendously.[27]

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[21] *See Human Genome Project,* NAT. INST. OF HEALTH, https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=45 [https://perma.cc/M7MG-86LF] (chronicling the human genome project and what has resulted from the project's completion). Notably, over "1,800 disease genes" have been discovered. *Id.*

[22] *See* Jinek et al., *supra* note 2, at 816–21 (presenting the discovery of the CRISPR system in bacteria). The naturally occurring CRISPR system was discovered as a result of evolution in bacteria. *Id.* It is the process by which bacteria fights off viruses, similarly to the way a vaccine works in patients. *Id.* A bacteria cell is able to record or "take a snapshot" of the virus DNA so that the next time the bacteria encounters a virus with that DNA, it will be able to efficiently attack that virus through its recognition recorded by CRISPR. *Id.* This Note references Jennifer Doudna as the discovering part of the CRISPR technology (as she has been represented in the media), but this could be disputed. Broad Inst., Junior Party v. The Regents of The University of Cal., Patent Interference No. 106,048 (P.T.A.B., Feb. 15, 2017). Doudna and her team lost the first stage of the CRISPR patent dispute in early 2017, which will likely continue through several rounds of appeals. *Id.*

[23] *See generally* Jim Yeadon, *Pros and Cons of ZNFs, TALENs, and CRISPR/Cas*, JACKSON LAB. (Mar. 4, 2016), https://www.jax.org/news-and-insights/jax-blog/2014/march/pros-and-cons-of-znfs-talens-and-crispr-cas# [https://perma.cc/QK63-UB4D] (discussing Zinc Finger Nucleases (ZFN or ZNF) and TALENs as alternatives to earlier gene-editing technologies). While both technologies are still used and have their advantages, both have been overshadowed by CRISPR's abilities. *Id.*

[24] *See generally id.* (describing how CRISPR is far more economically feasible and far more accurate).

[25] *See id.* (listing differences between CRISPR, TALENs, and ZNFs). *See, e.g.*, *Overview*, INTELLIA THERAPEUTICS (last visited Sept. 3, 2017), http://www.intelliatx.com/about-us/overview/ [https://perma.cc/MV9G-6RH7] (describing the company as a "leading genome editing company"). Intellia was founded by co-inventor of CRISPR, Jennifer Doudna. *Id. See also, Company Overview*, EDITAS MEDICINE (last visited Sept. 3, 2017), http://www.editasmedicine.com/company-overview [https://perma.cc/6HJF-5NWJ] (presenting itself as another "leading genome editing company").

[26] *See generally* Yeadon, *supra* note 23 (noting how previous gene-editing techniques could take "2-3 years to complete and could cost up to $100,000").

[27] *See generally* Yeadon, *supra* note 23 (explaining CRISPR's ability to target specific genes to change or delete).

B. How CRISPR Works and Why it is a Game-Changer

CRISPR's revolutionary ability is derived from a naturally occurring process in human immune systems, whereby proteins can recognize foreign organisms such as viruses.[28] The proteins then work with the DNA to take a "snapshot" of this potentially harmful organism so that the cell may recognize it again at a later time and know how to attack it, thereby eliminating the virus from the body.[29] Scientists have learned to influence this process by using the Cas9 protein to first locate a specific sequence in an organism's DNA.[30] After the desired sequence is identified, the protein is then able to "cut out" the selected sequence and replace it with an entirely new DNA sequence.[31] As a result, this changes one of the organism's natural traits.[32]

In the naturally occurring version of this process, DNA is altered to build immunity to foreign and possibly harmful organisms like viruses.[33] With CRISPR, the intentional alteration of DNA may come with a wide range of goals.[34] Some of these goals are more practical, while others are

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[28] *See* Jinek et al., *supra* note 2, at 816–21 (recounting the discovery which first occurred in bacteria cells, where the bacteria cells use RNA to record a genetic "snapshot" of the virus in order for the cell to better protect itself against future viral attacks).

[29] *See* Doudna, *supra* note 13, at 00:33 (analogizing the CRISPR process to a human immune system).

[30] *See* Jinek et al., *supra* note 2, at 820 (explaining how scientists may harness this process and manipulate it to target specific genes).

[31] *See* Jinek et al., *supra* note 2, at 816 (illustrating how RNA strands are guided by the Cas9 protein to read and identify specific genes).

[32] *See Genes,* MERRIAM-WEBSTER (last visited Sept. 3, 2017), http://www.merriam-webster.com/dictionary/gene [https://perma.cc/VZV4-HQTM] (providing a definition of "gene" as a part of a cell that controls or influences the appearance, growth, etc. of a living thing). A more specific definition provides:

> A specific sequence of nucleotides in DNA or RNA that is located usually on a chromosome and that is the functional unit of inheritance controlling the transmission and expression of one or more traits by specifying the structure of a particular polypeptide and especially a protein or controlling the function of other genetic material.

Id. See also Traits, MERRIAM-WEBSTER (last visited Sept. 3, 2017), http://www.merriam-webster.com/dictionary/trait [https://perma.cc/DPX7-V5MR] (describing a trait as "a quality that makes one person or thing different from another").

[33] *See* Jinek et al., *supra* note 2, at 820 (providing the conclusions reached by the study).

[34] *See* 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/YLA7-SCYX] (providing the wide-ranging potential of CRISPR). Purposes range from medical to cosmetic. *Id.* Some scientists aspire to bring back extinct species, while others aim to cure diseases or solve world hunger. *Id.* While other uses may have an impact on public health, such as using CRISPR on crops to combat world hunger or to increase the health benefits of certain foods, those issues are outside the scope of this discussion. *Id.* The use of CRISPR to combat diseases spread by animals is also outside the scope of this Note. *Id.* Using CRISPR on viable human embryos that will eventually develop

more theoretical for the time being (even though the technology's ability already exists).[35] Of the more immediately practical uses, some scientists see value in using CRISPR to alter crops in a variety of ways, such as combatting world hunger, or climate change by developing food that can grow in a changing climate, as well as herbicide resistant crops.[36] Using CRISPR on animals also has potential value in a more narrow sense.[37] Altering the DNA of mosquitoes so that they are incapable of carrying the West Nile or Zika viruses is an example that provides humans with advantages in eradicating diseases.[38] However, the most popular proposed use of CRISPR involves human application to treat and cure various human ailments.[39] The medical application of CRISPR is likely

into a person will not be permitted with this act. *Id.* The concerns involving cost of CRISPR treatments are too skeptical at this point in time and the relevant problems are still not entirely tangible. *Id.* Finally, theoretical uses including resurrecting extinct species will not be discussed. *Id.* These exclusions are not intended to rule on the merits of those scientific goals, but to restrict this act to aid the issues most immediately of concern to the American public. *Id.* It is not out of the question for these excluded issues to still be addressed in this act, but for the purpose of having a narrowly tailored goal, they will be regarded as outside the scope of consideration. *Id.*

35 *See generally* Abumrad & Krulwich, http://www.radiolab.org/story/antibodies-part-1-crispr/ [https://perma.cc/3JQA-EPJ2] (recounting an earlier conversation between one of the hosts and an anonymous scientist familiar with CRISPR). While the scientific value of changing a Golden Retriever into a Great Dane likely does not exist, scientists claim to already have the power to do so with CRISPR. *Id.* Using DNA found from Wooly Mammoth hair could be inserted into an elephant embryo and it could develop into a fully grown, living Wooly Mammoth. *Id.*

36 *See* Maywa Montenegro, *CRISPR is Coming to Agriculture–With Big Implications for Food, Farmers, Consumers, and Nature*, ENSIA (Jan. 28, 2016), http://ensia.com/voices/crispr-is-coming-to-agriculture-with-big-implications-for-food-farmers-consumers-and-nature/ [https://perma.cc/SD59-BSAR] (stating the intended uses of CRISPR in agriculture range from "crop resistance to pests to livestock disease"). *See also* Alison Peck, *The Failure of Federal Biotechnology Regulation*, 51 VAL. U. L. REV. 483, 510 (2017) (describing the use of CRISPR in crops).

37 *See generally id.* (discussing various attempts made to address problems related to livestock diseases and production).

38 *See id*. (explaining the highly controversial idea of using CRISPR to sterilize the roughly thirty species of mosquitoes that carry malaria, effectively driving them to extinction). This can be done by using CRISPR on viable mosquito embryos. *Id.* This type of change (as opposed to a change to an adult mosquito) would be naturally passed down to that mosquito's offspring, thereby permanently changing the mosquito's genome. *Id.* Issues involving altering the DNA of viable human embryos and altering the human germline are the primary ethical issues linked to CRISPR, both of which will be discussed later. *See also infra* Part II.C (providing information on germline editing); *infra* Part III (discussing aspects of the law and their effect on CRISPR).

39 *See generally* Patterson, *supra* note 3 (noting the specific plans to go after genes linked to obesity and Alzheimer's).

the most immediate potential use of CRISPR, as scientists are already beginning human trials on a small scale.[40]

Scientists and medical experts alike are thrilled with the prospect of treating or even curing diseases such as Alzheimer's, to other genetic diseases from muscular dystrophy to rare forms of blindness.[41] The first studies that research the human application of CRISPR are underway in other countries, while the first clinical trial here in the United States was approved by a federal ethics panel in June of 2016.[42] However, the ethical concerns involved with CRISPR are many in number and are the primary reason why research has slowed for the time being.[43]

C. Ethical Considerations Linked to CRISPR

Despite the possible benefits of curing many of the diseases that have plagued humanity for centuries, many scientists, ethicists, and lawmakers believe that we should seriously consider how far we are willing to go in order to achieve such results.[44] If humans have the power to alter the

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[40] *See generally* Patterson, *supra* note 3 (implying that CRISPR will not be raising extinct species in the near-future). *See also* Emily Mullin, *Gene Editing Study in Human Embryos Points Toward Clinical Trials*, MIT TECH. REV. (Aug. 2, 2017), https://www.technologyreview.com/s/608482/gene-editing-study-in-human-embryos-points-toward-clinical-trials/ [https://perma.cc/TSU3-768T] (discussing one of the most recent studies using CRISPR).

[41] *See* Megan Thielking, *Using CRISPR to Edit Out Blindness*, STAT (Jan. 27, 2016), https://www.statnews.com/2016/01/27/crispr-gene-editing-blindness/ [https://perma.cc/682T-6JR9] (reporting on the ability to create retinal cells using CRISPR and to transplant them into a patient experiencing blindness due to a genetic mutation).

[42] *See* Sharon Begley, *Federal Panel Approves First Use of CRISPR in Humans*, STAT (June 21, 2016), https://www.statnews.com/2016/06/21/crispr-human-trials/ [https://perma.cc/QW9Y-Q9KC] (discussing a proposed study that would use CRISPR to "alter immune cells to attack three kinds of cancer"). The National Institutes of Health's Recombinant DNA Advisory Committee (RAC) approved the study unanimously. *Id.* The study will be the first clinical trial in the United States and will test the safety of the human application of CRISPR. *Id.* Studies such as this are precisely the type this proposed legislation aims to encourage and make more common. *See also* Mullin, *supra* note 40 (discussing a groundbreaking study involving human embryos); *infra* Part III.D (reflecting CRISPR's progress through current and proposed studies).

[43] *See generally* Abumrad & Krulwich, *supra* note 35 (saying that the term moratorium is perhaps too severe in light of remaining goals to continue CRISPR research). *See also* Doudna, *supra* note 13 (asking for a temporary "moratorium" on the use of CRISPR in embryos). Doudna cites to "recent precedent" for such a temporary moratorium, as molecular cloning became possible in the late 1970s. *Id.*

[44] *See Genetically Engineered Human DNA: Hearing before the Subcomm. on Research and Technology of the H. Comm. on Science, Space, and Technology*, 114th Cong. (2015) (statement of Jeffrey P. Kahn) http://congressional.proquest.com.ezproxy.valpo.edu/congressional/result/congressional/pqpdocumentview?accountid=14811&groupid=95261&pgId=68781576-d0a2-4cc3-90e2-5799ae98f525&rsId=1577698A153 [https://perma.cc/P6GR-V8PD] (testifying to the importance of establishing an ethical framework for how to approach CRISPR).

DNA of their own species, what would keep them from using that ability frivolously or to disadvantage certain classes of people?[45] This does not exclude Jennifer Doudna, CRISPR's co-creator.[46] She believes that permanently altering the human germline is an irresponsible and dangerous step to take at this point in time.[47]

This ethical concern largely involves the use of CRISPR on viable human embryos.[48] If changes are made to the DNA of a human embryo that will eventually grow into a living person, those alterations are not only permanent, but will be passed on to the individual's offspring.[49] This is what scientists call "editing the human germline."[50] Editing the human germline irreversibly changes the natural path of human evolution and essentially puts humans in control of their own future, taking it out of nature's hands.[51]

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45 *See generally* Anna Louise Sussman, *Burden of Healthcare Costs Shifting to the Middle Class*, THE WALL STREET JOURNAL (Aug. 25, 2016), http://www.wsj.com/articles/burden-of-health-care-costs-moves-to-the-middle-class-1472166246 [https://perma.cc/KK94-H65H] (discussing the general burdens of health care costs and how they are disproportionately harming the middle class).

46 *See* Abumrad & Krulwich, *supra* note 35 (calling for a temporary moratorium on using CRISPR). Jennifer Doudna states that CRISPR is not yet ready for human application, primarily because of a lack of success in a Chinese study done on unviable human embryos. *Id.*

47 *See* Abumrad & Krulwich, *supra* note 35 (noting specifically the permanent effect of editing the human germline).

48 *See generally* Ewen Callaway, *Second Chinese Team Reports Gene Editing in Human Embryos*, NATURE (Apr. 8, 2016), http://www.nature.com/news/second-chinese-team-reports-gene-editing-in-human-embryos-1.19718 [https://perma.cc/CQ3Y-9PQB] (reporting on a Chinese study which used unviable human embryos). While the article notes remaining controversy; in using unviable embryos, it clarifies that no viable embryos were used, emphasizing what a wholly unethical step it could have been. *Id.*

49 *See* Patrick Skerrett, *A Debate: Should We Edit the Human Germline?*, STAT (Nov. 30, 2015), https://www.statnews.com/2015/11/30/gene-editing-crispr-germline/ [https://perma.cc/T7YH-U2VT] (discussing the risks associated with editing the human germline). *See also* Jeff Delviscio, *NIH Director Francis Collins to Stay on, At Least for Now, Under Trump*, STAT (Jan. 19, 2017), https://www.statnews.com/2017/01/19/francis-collins-nih-donald-trump/ [https://perma.cc/Y5BG-5NMH]. President Trump has retained Collins for now, but the director may not be kept on for a full term. *Id.*

50 *See id.* (describing germline editing). Francis Collins states that "medical research should always seek to balance benefits and risks." *Id.*

51 *See* Skerrett, *supra* note 49 (explaining the nature of germline editing). George Church asks what we should consider improvements in the human germline. *Id.* This work can be done through the use of gene drives. *See also* Brooke Borel, *When Evolution Fights Back Against Genetic Engineering*, THE ATLANTIC (Sept. 12, 2016), https://www.theatlantic.com/science/archive/2016/09/gene-drives/499574/ [https://perma.cc/DA8C-AU87]. The use of gene drives is a process that is essentially a "forced succession" of a trait. *Id.* This process has already been successfully executed on fruit flies in a lab setting. *Id.* However, scientists disagree as to how a gene drive would play out in the wild, should it ever occur. *Id.* They may be just as likely to destroy a species as they are to save or alter one. *Id.*

Since the inception of *in vitro* fertilization (IVF), people have had the ability to choose the sex of their child, as well as their eye or hair color.[52] However, CRISPR raises new issues in this respect.[53] The accuracy, ease of use, and affordability of CRISPR leads many to wonder what would prevent parents from increasing the intelligence of their child or making them more physically gifted.[54] Using CRISPR with the goals of changing the appearance, strength, or intelligence of future generations is a major concern of many.[55] The idea of genetically engineered humans to this degree still sounds like science fiction, but the issue caught the attention of the *MIT Technology Review* enough to warrant a cover story in 2015 on exactly this issue.[56] While arguably speculative, the next logical concern is the potentially increased costs of these types of procedures, which would lead to only the higher economic classes having access, disadvantaging the majority of Americans.[57]

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[52] *See* Emily Singer, *Choosing Babies*, MIT TECH. REV. (Mar. 1, 2007), https://www.technologyreview.com/s/407398/choosing-babies/ [https://perma.cc/76LY-JCGN] (reporting how parents frequently use *in vitro* fertilization to choose the sex of their child).

[53] *See id.* (speculating that parents may someday be choosing the IQ of their child). *See also* Regalado, *supra* note 34 (discussing the present concern of CRISPR's future ability to control an embryo's genes that control intelligence).

[54] *See* Regalado, *supra* note 34 (explaining the numerous types of genetic alterations that could be made to a child during the prenatal stages of development).

[55] *See id.* (discussing the more theoretical, but scientifically possible future uses of CRISPR which concern many scientists). These concerns include permanent changes to the human genome. *Id.* There are also slippery slope arguments pertaining to somatic gene therapy. *See also* Tony McGleenan, *Human Gene Therapy and Slippery Slope Arguments*, 21 J. OF MEDICAL ETHICS, 350–55 (1995). Somatic gene therapy includes gene therapy where DNA changes are not passed down to further generations. *Id.* These arguments could potentially be carried over to germline editing discussions. *Id.* These arguments can be classified as logical slippery slope arguments and rhetorical slippery slope arguments. *Id.* However, "with unambiguous legislation logical slippery slope arguments have little or no force." *Id.* These arguments mostly become relevant when regulation is on the table. *Id.* When it comes to rhetorical slippery slope arguments, the flaws can often be resolved with close analysis. *Id.* This is because the rhetorical slippery slope arguments often present larger leaps in logic. *Id.*

[56] *See* Regalado, *supra* note 34 (noting CRISPR's capabilities rather than its current uses). *See also generally* McGleenan, *supra* note 55 (inferring that this concern falls in line with a logical slippery slope argument that the legalization of germ line editing could lead to designer babies).

[57] *See generally* David Warmflash, *Gene Therapy 2.0: Will CRISPR Make Expensive Treatment Accessible to All?*, GENETIC LITERACY PROJECT (Aug. 16, 2016), https://www.geneticliteracyproject.org/2016/08/16/gene-therapy-2-0-will-crispr-make-expensive-treatment-accessible/ [https://perma.cc/HBE2-ZCTD] (noting current gene therapy treatments to cost around $1,000,000).

D. Legal Implications

The problems CRISPR is encountering in regards to federal funding begin with The Dickey-Wicker Amendment, and therefore, this discussion must logically begin there.[58] Discussing what The Dickey-Wicker Amendment was intended for, and how it has been interpreted, is critical to understanding the problem and the appropriate remedy for CRISPR to attain federal funding.[59] Part II.D.1 discusses the ethical scope of the Dickey-Wicker Amendment and its implications related to CRISPR.[60] Next, Part II.D.2 discusses how *Sherley v. Sebelius* could affect CRISPR going forward.[61] Together, this legal and ethical background and analysis will provide a sufficient basis for the introduction of new legislation.[62] The ultimate goal of this section is to examine the original purposes of the Dickey-Wicker Amendment and analyze the interpretations of the Dickey-Wicker Amendment.[63] The effects of the Dickey-Wicker Amendment on the National Institutes of Health (NIH) have prevented them from funding promising advances in science such as CRISPR.[64]

1. The Dickey-Wicker Amendment

In 1996 a bill that would become the "The Balanced Budget Down Payment Act of 1996" was introduced in the U.S. House of Representatives.[65] The text of Section 128 of this bill would become known

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58 *See infra* Part II.D.1 (discussing the Dickey-Wicker Amendment).

59 *See infra* Part II.D.2 (analyzing the *Sherley v. Sebelius* case).

60 *See infra* Part II.D.1 (examining the shifting ethical considerations associated with the Dickey-Wicker Amendment). *See also* Part III.B (analyzing various proposals).

61 *See infra* Part II.D.2 (discussing the effect of *Sherley v. Sebelius* on CRISPR).

62 *See infra* Part III (proposing new legislation).

63 *See infra* Part II (discussing, generally, the implications of the Dickey-Wicker Amendment).

64 *See* Francis S. Collins, *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, NATIONAL INSTITUTES OF HEALTH (Apr. 29, 2015), https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos [https://perma.cc/93FU-P8AJ] (exemplifying the impact of the Dickey-Wicker Amendment in 2015). "Practically, there are multiple existing legislative and regulatory prohibitions against this kind of work." *Id.* "The Dickey-Wicker amendment prohibits the use of appropriated funds for the creation of human embryos for research purposes or for research in which human embryos are destroyed." *Id.*

65 *See* The Balanced Budget Downpayment Act, Pub. L. No. 104–99, § 128, 110 Stat. 34 (1996) [hereinafter The Balanced Budget Downpayment Act] (providing original text of the bill). The name of the amendment comes from the sponsors of the amendment, Representative Jay Dickey of Arkansas' 4th District and now-Senator Roger Wicker of Mississippi's 1st District. *Id.* This was one section of a larger appropriations bill pertaining to the Departments of Interior, Labor, Health and Human Services, and Education. *Id.*

as the Dickey-Wicker Amendment in subsequent budget acts.[66] The amendment states:

> None of the funds made available by Public Law 104–91 may be used for—
> (1) the creation of a human embryo or embryos for research purposes; or
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and 42 U.S.C. 289g(b).[67]

At the time, Congressional opposition described the amendment as pro-life opposition to IVF.[68] What is certain is that the Dickey-Wicker Amendment arose out of concern over IVF.[69] The language of the law explicitly prohibits federal funding to be applied to research on human embryos.[70] This broad language does not discern between viable and unviable embryos; it appears more as a blanket prohibition.[71]

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[66] *See id.* (giving the language of The Dickey-Wicker Amendment as it appears in subsequent budget acts). The amendment provides that:

> (a) None of the funds made available in this act may be used for—(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CF.R. 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). (b) For purposes of this section, the term "human embryo or embryos" include any organism, not protected as a human subject under 45 CF.R. 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or diploid cells.

Id.

[67] *See id.* (providing the original language of the Dickey-Wicker Amendment).

[68] *See* 142 Cong. Rec. 16,866 (1996) (debating the merits of conflicting amendments). Whether the amendment was pro-life is debatable and irrelevant to this Note. *Id.*

[69] *See generally* Ann A. Kiessling, *The History of the Dickey-Wicker Amendment*, BEDFORD RESEARCH FOUNDATION (Aug. 24, 2010), http://archive.is/vjHtK [https://perma.cc/2B67-3V5G] (discussing the introduction of the Dickey-Wicker Amendment in light of the in vitro fertilization and "test tube baby" debates).

[70] *See* The Balanced Budget Downpayment Act, *supra* notes 65–66 (citing to the language of the bill).

[71] *See id.* (citing to the language of the bill).

Of course, a bill restricting research in the field of biotechnology was sure to become outdated relatively quickly.[72] The amendment has had unintended consequences as science has progressed over the past two decades.[73] The National Institutes of Health—the primary government agency that awards research grants to medical studies across the country—has identified this problem as one of the main reasons why they will not fund gene-editing research.[74] Attempts have been made to eliminate or overturn the Dickey-Wicker Amendment, but those attempts have been unsuccessful as they lack legislative action.[75] An Executive Order from President Obama in 2009 gave the NIH permission to fund embryonic stem cell research.[76] This order required the NIH to establish new guidelines for how the organization approaches stem cell research.[77] Dickey-Wicker's continuing impact can be felt to this day, as the amendment has been included in every omnibus spending bill since the Dickey-Wicker Amendment was enacted.[78] Additionally, the United States Court of Appeals weighed in on how the NIH should interpret the Dickey-Wicker Amendment in *Sherley v. Sebelius*.[79]

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72 *See* Sherley v. Sebelius, 689 F.3d 776, 779 (D.C. Cir. 2012) (describing the rapid advance of stem cell research capabilities shortly after the initial enactment of the Dickey-Wicker Amendment). At the time the Dickey-Wicker Amendment was drafted, germ line editing was not scientifically feasible. *See also* McGleenan, *supra* note 55 (reflecting the progress of gene editing in the 1990s). *Cf.* Sharon Begley, *Scientists Solve CRISPR's 'Energizer Bunny' Problem*, STAT (Apr. 27, 2016), https://www.statnews.com/2016/04/27/crispr-energizer-bunny-problem/ [https://perma.cc/L8A6-EE84] (exemplifying the rapid advances of biotechnology, especially with CRISPR).

73 *See* Collins, *supra* note 64 (exemplifying the impact of the Dickey-Wicker Amendment in 2015).

74 *See* Collins, *supra* note 64 (stating the National Institutes of Health stance on awarding grants to gene-editing research with the Dickey-Wicker Amendment still in place).

75 *See, e.g.*, Proclamation No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009) (allowing the NIH to conduct and fund research on human embryos to the extent of the law, but the extent of the law is where the Dickey-Wicker Amendment begins).

76 *See id.* (addressing the issue of embryonic research as it pertains to the stem cell research controversy).

77 *See* 74 Fed. Reg. 32,170 (July 7, 2009) (describing the guidelines). *See also* Sherley, 689 F.3d at 780 (discussing the new NIH guidelines as they apply to the Dickey-Wicker Amendment in the facts of the case).

78 *See, e.g.*, The Balanced Budget Downpayment Act, *supra* notes 65–66 (exemplifying the continued presence of the amendment the 2015 budget).

79 *See Sherley*, 644 F.3d at 390 (discussing President Obama's Executive Order and its effect on the interpretation of the Dickey-Wicker Amendment). The Supreme Court discusses the history of the Dickey-Wicker Amendment in more detail:

> In 1996, when the Congress first passed Dickey–Wicker, scientists had taken steps to isolate ESCs but had not yet been able to stabilize them for research in the laboratory. The historical record suggests the Congress passed the Amendment chiefly to preclude President Clinton from acting upon an NIH report recommending federal funding for

2. *Sherley v. Sebelius* & The National Institutes of Health

Sherley v. Sebelius arose out of dispute about NIH guidelines that were mandated by an executive order from President Obama in 2009.[80] Prior to this proclamation, President Bush had also issued an executive order permitting stem cell research in a very restricted manner.[81] Scientific advances in the years following the creation of the Dickey-Wicker Amendment led to President Obama's proclamation allowing the NIH to support stem cell research "to the extent permitted by law."[82] It is this executive order that led to the dispute in *Sherley*.[83] The guidelines required in President Obama's executive order provided stem cell researchers with fewer restrictions in their work.[84] Accordingly, the appellant brought the action after its concerns went unaddressed during the comment period.[85]

In the *Sherley* court's analysis the interpretation of the term "research" in the Dickey-Wicker Amendment was deemed ambiguous, which sided

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> research using embryos that had been created for the purpose of in vitro fertilization. Dickey–Wicker became directly relevant to ESCs only in 1998, when researchers at the University of Wisconsin succeeded in generating a stable line of ESCs, which they made available to investigators who might apply for NIH funding.
>
> For that reason, on January 15, 1999, the General Counsel of the Department of Health and Human Services issued a memorandum addressing whether Dickey–Wicker permits federal funding of research using ESCs that had been derived before the funded project began; she concluded such funding is permissible because ESCs are not "embryos." After notice and comment, the NIH issued funding guidelines consistent with this opinion, but the NIH did not fund any ESC research project while President Clinton was in office.

Id.

80 *See id.* at 779–80 (discussing executive orders issued by President George W. Bush and President Obama). *See also* Proclamation No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009) (providing the original language of the executive order).

81 *See Sherley*, 644 F.3d at 779–80 (giving a brief background that led to the case at bar). *See also* Proclamation No. 13,435, 72 Fed. Reg. 34,591 (June 27, 2007) (showing the scope of President Bush's executive order).

82 *See* Proclamation No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009) (quoting the language of the 2009 executive order).

83 *See Sherley*, 644 F.3d at 779–80 (discussing the background of the case).

84 *See id.* at 780 (citing to the executive order). The guidelines state the following:

> Embryonic stem cell research project may receive NIH funding as long as it utilizes cells from lines (1) created by *in vitro* fertilization for reproductive purposes, (2) no longer needed for that purpose, and (3) voluntarily donated by the individuals who owned them—even if that line was derived after 2001).

Id.

85 *See id.* (discussing the original cause of action in the case).

with the NIH's interpretation.[86] By applying *Chevron* deference to the NIH's interpretation of the Dickey-Wicker Amendment, the court held that it was reasonable to interpret the "term 'research' as a discrete project rather than an extended process."[87] As a result of this decision, the destruction of embryos as part of the embryonic stem cell derivation process was not a part of the funded research project, and therefore no violation of the Dickey-Wicker Amendment existed.[88] Additionally, the court saw these enacted guidelines allowing for the funding of stem cell research as following the triggering executive order.[89] However, this funding of stem cell research would not have been possible without the two executive orders mentioned above, which specifically endorse stem cell research to different extents.[90]

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[86] *See id.* at 783 (applying the *Chevron* deference). The appellants in this case were scientists objecting to the funding of any kind of stem cell research. *Id.* Specifically, the group was opposed to the guidelines set out in President Obama's executive order allowing stem cell research to the extent allowed by law. *Id.* The appellants sought an injunction against the NIH to halt the funding of any embryonic stem cell research despite President Bush's executive order allowing such funding for ten years. *Id.* The appellants' argument raised three main issues. *Id.* First, that the guidelines being implemented violated the language of the Dickey-Wicker Amendment prohibiting funding for "research in which a human embryo or embryos are destroyed." *Id.* Second, that in the alternative, the guidelines violate the language prohibiting research where human embryos are "subjected to risk of injury or death greater than that allowed for research on fetuses in utero." *Id.* Finally, appellants argued that the failure to respond to objecting comments during the regulation's comment period. *Id.* The Court discounted all three arguments by applying *Chevron* deference to the NIH's interpretation of the executive order, and that the NIH has no duty to respond to objections before the regulation is enacted. *Id.*

[87] *See Sherley*, 689 F.3d at 783 (explaining how the NIH made a reasonable interpretation of the term "research" as ambiguous); Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 865 (1984). Further, Justice Stevens states:

> An agency to which Congress has delegated policy-making responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of government to make such policy choices—resolving the competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency.

Id. See Sherley, 689 F.3d at 785–87 (plurality opinion) (discussing how the concurring opinion disagrees with the applicability of *Chevron* deference to executive orders). Judge Henderson believes that it only applies to legislative material coming from Congress. *Id. Chevron* deference provides administrative agencies the ability to resolve ambiguity in the language of a law. *Id.*

[88] *See Sherley*, 689 F.3d at 783–84 (explaining how the funded research projects did not destroy human embryos or subject them to risk).

[89] *See id.* at 785 (addressing the failure to reply to comments during the set time period while the proposed change is made public).

[90] *See generally* Consolidated Appropriations Act of 1996, Pub. L. No. 104-99, 110 Stat. 26, 34 (providing the language of the Dickey-Wicker Amendment preventing this type of

3. Applicability to CRISPR

At this time, there is no such executive order or legislation that specifically allows for the federal funding of research related to CRISPR.[91] As a result, the Dickey-Wicker Amendment still bars the NIH from becoming involved with CRISPR.[92] In *Sherley*, executive orders react to the progress of science.[93] What is also evident is that these executive orders were necessary to bypass the Dickey-Wicker Amendment.[94] Since the discovery of the CRISPR technology in 2012, no such executive orders or legislation have been enacted relating to CRISPR.[95] However, some pieces of proposed legislation have come forward in 2017.[96]

Twenty years ago, long before the conception of CRISPR, lawmakers recognized the problems involved with banning federal funding of stem cell research.[97] In 1996, there was support for the "Lowey Amendment," which would have overturned the Dickey-Wicker Amendment and restored the federal government's ability to fund embryonic stem cell research.[98] This amendment would have served as an appropriations bill "rider," rather than an independent bill.[99] Ultimately, the arguments in

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research). The court's application of *Chevron* and the two executive orders gave the NIH freedom to fund stem cell research. *See also Sherley*, 644 F.3d at 390. CRISPR lacks such an executive order or legislation permitting federal funds to go towards CRISPR research specifically. *Cf. id.* But The Dickey-Wicker Amendment is still good law. *Id.*

91 *See* Chestnut, *supra* note 19 (discussing the Dickey-Wicker Amendment's bar on federal funds going toward germ line editing).

92 *See id.* (implying the need for a new law allowing for the allocation of federal funds for CRISPR research).

93 *See Sherley*, 644 F.3d at 390 (discussing the purpose of the two executive orders).

94 *See* Proclamation No. 13,435, *supra* note 82 (addressing recent advances in stem cell research that had occurred shortly after the Dickey-Wicker Amendment was first enacted). *See also* Proclamation No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009) (reacting to further progress in stem cell research).

95 *See generally* Collins, *supra* note 64 (illustrating the need for changes in the law).

96 *See e.g.*, H.R. 2921, 114th Cong. (2015) (exemplifying proposed legislation that intended to intensify stem cell research in the interest of possible clinical benefits). This bill exemplifies recent attempts to facilitate genetic research. *Id. But see* H.R. 5269, 114th Cong. (2016) (exemplifying the intensity of opposition to genetic research). This bill would intend to nationally criminalize the destruction of a human embryos through in vitro fertilization or other purposes. *Id.*

97 *See* 142 Cong. Rec. 16,864, 16,869 (1996) (stating the potential scientific benefits from IVF and stem cell research known at the time). Representative Lowey mentions the potential for finding treatments or cures for various types of cancer and other diseases. *Id.* Speakers arguing for the adoption of the amendment also discuss their general intent to repeal the Dickey-Wicker Amendment. *Id.*

98 *See id.* (debating whether the federal government should fund research on human embryos).

99 *See id.* (describing the Lowey Amendment as a replacement for the Dickey-Wicker Amendment, which did not come to fruition).

opposition to the Lowey Amendment won out, especially the repeated argument that taxpayer dollars should not go to the destruction of human embryos.[100]

E. Current Landscape: Developing Legal and Ethical Issues

To paint a picture of where we stand with CRISPR now and what the road looks like going forward, three primary issues should be addressed.[101] First, what type of funds are coming to CRISPR, and who controls that money?[102] Second, with the Dickey-Wicker Amendment still in place, what are the ethical ramifications of that law today?[103] Finally, with the recent amendments to NIH guidelines, how does it affect CRISPR moving forward?[104]

Companies working with CRISPR have arisen in recent years that either receive private funding, are publicly traded, or both.[105] This may lead some to believe that the issue of funding is resolved and that private funding is all that is necessary.[106] However, institutions receiving only private funding rather than government grants have fewer restrictions and regulations to abide by.[107] This is especially problematic with a highly

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[100] *See id.* (stating the argument from then-Representative Coburn that life at such an early stage should not be destroyed). The arguments in support continually reiterate that the nature of the research to be funded would not destroy any embryos. *Id.*

[101] *See infra* Part II.E (providing information on the current outlook for CRISPR relating to sources of funding, ethical concerns related to the Dickey-Wicker Amendment, and recent updates to the National Institutes of Health guidelines).

[102] *See infra* Part II.E (discussing the relevance of public and private funding in relation to research on CRISPR).

[103] *See infra* Part II.E (explaining current concerns about the Dickey-Wicker Amendment).

[104] *See infra* Part II.E (reporting recent changes to the NIH guidelines which open the door for CRISPR research).

[105] *See The Intellia Therapeutics IPO – Editas vs. Intellia*, NANALYZE (Apr. 18, 2016), http://www.nanalyze.com/2016/04/the-intellia-therapeutics-ipo-editas-vs-intellia/ [https://perma.cc/5SS9-UKBT] (discussing the initial public offerings (IPO) of Editas Medicine and Intellia Therapeutics). These two companies debuted their IPOs during the Spring of 2016 and recognize themselves as the future of gene-editing research. *Id.* After initially taking in nearly $150 million combined for their IPOs, the stocks have halted in growth. *Id.* This is likely due to the current patent litigation for CRISPR. *Cf. id.*

[106] *See generally id.* (inferring that government funding could be seen as unnecessary in light of the hundreds of millions of dollars that companies have been raising and receiving from investors).

[107] *See* Anna Zaret, *Editing Embryos: Considering Restrictions on Genetically Engineered Humans*, 67 HASTINGS L.J. 1805, 1828–29 (2016) (proposing regulations on gene editing). The author similarly proposes that laws such as the Dickey-Wicker Amendment prevent proper regulation of gene-editing technologies. *Id.* However, the author stresses the need for a committee to consider the ethical issues relating to different pieces of proposed legislation as well as a commissioned federal entity that would perform similar functions in facilitating gene-editing research. *Id.* Zaret's proposal is similar in purpose to this Note, but focuses far

controversial technology like CRISPR, which many claim needs government oversight.[108] With the Dickey-Wicker Amendment still in place, proper oversight and regulation cannot be implemented.[109] Ethical guidelines on how research funds may be used are likely to be less stringent, because federal funding is not being provided.[110]

At the peak of its relevancy, the Dickey-Wicker Amendment attempted to halt the cutting-edge, but ethically debatable, science of stem cell research.[111] At this time in the mid 1990s, IVF was still controversial, and little was known about stem cell research, and the potential benefits of curing diseases were quite speculative.[112] Twenty years later, these prospects are much more tangible.[113] Not only are these benefits being realized in lab settings, but the ethical discussions have shifted due to a greater understanding of the science.[114] The primary ethical concerns associated with CRISPR are no longer the destruction of embryos, but instead what changes could eventually be made to human embryos.[115] This shift not only signals that new issues must be addressed in the coming years, but also that the concerns addressed in the Dickey-Wicker Amendment are becoming increasingly irrelevant.[116] Yet the law still exists and still bars federal funding for research that has advanced

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less on what institutions or government bodies may be required to address specific legislation, but rather a specific ethical framework itself that will be discussed below. *Id.*

108 *See Genetically Engineered Human DNA: Hearing before the Subcomm. on Research and Technology of the H. Comm. on Science, Space, and Technology*, 114th Cong. (2015) (statement of Jeffrey P. Kahn, Professor of Bioethics and Public Policy; Deputy Director for Policy and Administration, Berman Institute of Bioethics, Johns Hopkins University) (discussing current ethical frameworks in place, current ethical issues, and policy involving CRISPR and gene editing research).

109 *See* Zaret, *supra* note 107 (discussing regulation and the Dickey-Wicker Amendment).

110 *See* Collins, *supra* note 64 (explaining the negative implications of the Dickey-Wicker Amendment on CRISPR research).

111 *See* 142 Cong. Rec. 16,864 (1996) (arguing the merits of the Dickey-Wicker Amendment against the alternative Lowey Amendment).

112 *See generally Sherley*, 689 F.3d at 779 (noting the state of stem cell research in the mid 1990s). "At the time of the adoption of the first Dickey-Wicker rider, scientists had not yet isolated embryonic stem cells (ESC), and the original enactment was apparently directed at another type of research performed on human embryos in the field of in vitro fertilization." *Id.*

113 *See* Susan Noakes, *CRISPR Gene Editing Heads to Human Trial as Cancer Treatment*, CBC NEWS (June 24, 2016), http://www.cbc.ca/news/health/human-trial-crispr-1.3651755 [https://perma.cc/UXB9-Z2RT] (discussing approval by an NIH review board). Even though the clinical trial was approved, the study is privately funded by billionaire Sean Parker's cancer foundation. *Id.*

114 *See id.* (expressing the promise of CRISPR to treat or cure diseases in the near future).

115 *See* Regaledo, *supra* note 34 (acknowledging the power and capabilities of CRISPR).

116 *See generally* Consolidated Appropriations Act of 2015, Pub. L. No. 114-113, 129 Stat. 2242, 2283 (citing to the provisions of the Dickey-Wicker Amendment).

dramatically in recent years.[117] The Dickey-Wicker Amendment's likely unintended consequences are still ringing more than two decades later, and its language is outdated to a point of concern for the medical and scientific communities.[118]

Rapidly-developing science may lead to rapidly-developing policy, and the NIH is no exception to this.[119] In 2016, the NIH updated their guidelines to accommodate advancing research for CRISPR.[120] In the same year, the NIH's ethics panel approved a study involving the use of CRISPR in an attempt to cure a rare form of blindness.[121] As of summer 2016, no research institution has come forward to offer a home to this study and no start date had been announced.[122] But new studies involving CRISPR are reported on at an increasingly higher rate.[123] The NIH's willingness to adapt to CRISPR is an encouraging sign, and a bump in investment of CRISPR may be on the horizon.[124]

The House and Senate passed the 21st Century Cures Act, in late November and early December of 2016.[125] This Act is a major bipartisan effort to fund and overhaul different aspects of the healthcare industry.[126] Parts of this bill encourage the investment in cancer research generally, and also provide enormous funding to the NIH.[127] Some of these funds may theoretically find their way to CRISPR research, but it may be some

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117 *See generally* Collins, *supra* note 64 (acknowledging the problems still in place caused by the Dickey-Wicker Amendment).

118 *See id.* (reiterating the concerns from the NIH director).

119 *See, e.g.*, *id.* (providing the NIH's original stance on CRISPR).

120 *See Emerging Biotechnologies and the Role of the NIH RAC*, NATIONAL INSTITUTES OF HEALTH (June 16, 2016), http://osp.od.nih.gov/under-the-poliscope/2016/06/emerging-biotechnologies-and-role-nih-rac [https://perma.cc/NWF7-UXXF] (stating that the NIH would alter its grant guidelines in light of CRISPR developments).

121 *See* Begley, *supra* note 42 (outlining the basic plan of the study).

122 *See* Doudna, *supra* note 13, at 11:17 (calling for a temporary moratorium on embryonic CRISPR research). *See also* Begley, *supra* note 42 (reporting the proposal put forward by researchers at the University of Pennsylvania). *Cf.* Jacob Sherkow, *Is CRISPR Patent Dispute Hurting Scientific Progress?*, GENETIC LITERACY PROJECT (Apr. 19, 2016), https://www.geneticliteracyproject.org/2016/04/19/crispr-patent-dispute-hurting-scientific-progress/ [https://perma.cc/5BWA-W66U] (discussing the CRISPR patent battle). Research proposals have slowed and less research could take place before the conclusion of CRISPR's patent dispute. *Id.*

123 *Cf.* Begley, *supra* note 42 (approving research aiming to cure genetic diseases).

124 *See generally id.* (reporting on the NIH's approval of a study using CRISPR). *Cf.* Sherkow, *supra* note 122 (discussing the competing gene-editing companies).

125 *See* Sherkow, *supra* note 122 (stating the bill's history). After three years of debate, both houses passed the bill with overwhelming support. *Id.*

126 *See id.* (discussing the act's bipartisan support).

127 *See id.* (stating the act's inclusion of Vice President Biden's "Moonshot"—an ambitious aim to cure cancer).

time before the direction of these new funds are realized.[128] President Obama signed this act into law in December 2016.[129] As explained below, new legislation should be introduced to address these numerous issues.[130] However, the more pertinent question is what approach is most appropriate to exploit the CRISPR technology and with what level of caution should our society approach it?[131]

III. ANALYSIS

The co-inventor of CRISPR, Jennifer Doudna, has called for a worldwide "conversation" on how we should address the relevant ethical issues.[132] Knowing what we do about CRISPR and its potential, as well as the law and policy surrounding gene editing, how our society addresses the relevant issues becomes the pressing question.[133] Part III will attempt to accomplish two goals.[134] First, Part III.A synthesizes the present issue that CRISPR raises in the United States.[135] Second, Part III.B advocates for the best method to address these issues.[136] The best way to remedy these issues is new legislation that will not only repeal past law that inhibits genetic research, but will also direct where federal funding for CRISPR research will go.[137]

The Dickey-Wicker Amendment, which continues to be included in each year's consolidated appropriations act, has led to some unintended consequences due to advances in genetics over the past two decades.[138] After some scientific advances with stem cell research, an executive order

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128 *See id.* (discussing how the act will take years to implement because the bill includes few deadlines and because it is over 1,000 pages long, among other reasons).

129 *See* Associated Press, *Obama Signs 21st Century Cures Act into Law*, (Dec. 13, 2016), https://www.statnews.com/2016/12/13/21st-century-cures-obama-signs/ [https://perma.cc/C53E-2SGJ] (reflecting the quick passage of the act and subsequently being signed into law by President Obama).

130 *See infra* Part III (calling for the introduction of a new federal legislation).

131 *See infra* Part III (discussing various approaches to handling CRISPR's ethical concerns through legislative and administrative means).

132 *See generally* Doudna, *supra* note 13, at 11:17 (citing Jennifer Doudna on her position on a temporary halt to CRISPR's use on embryos). *See also* Abumrad & Krulwich, *supra* note 35 (reiterating her stance on careful thought before proceeding with the editing of embryos).

133 *See infra* Part III (balancing concerns with the benefits to our society of attempting to cure various genetic diseases).

134 *See infra* Part III (addressing the ethical problems we face with CRISPR and how we may overcome such problems).

135 *See infra* Part III.A (discussing the problem presented).

136 *See infra* Part III.B (advocating for a particular solution).

137 *See infra* Part III.B (detailing a solution through new legislation that can repeal old law while also directing research funds through ethical concerns).

138 *See* Consolidated Appropriations Act, *supra* note 78 (citing to the Consolidated Appropriations Act of 2015, which includes the Dickey-Wicker Amendment).

from President Bush adapted the law to the science.[139] Two years later, an executive order from President Obama similarly expanded the NIH's ability to fund stem cell research to the extent of the law.[140] On top of these two executive orders, the *Sherley v. Sebelius* court found that some language of the Dickey-Wicker Amendment was ambiguous.[141] With a shift on the Supreme Court in 2017, it is unclear how such an interpretation might change, if at all.[142] Only a few cases exist that could indicate Justice Gorsuch's stance on a CRISPR issue relating to NIH

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139 *See Sherley*, 689 F.3d at 780 (citing to President George W. Bush's 2007 executive order allowing for limited stem cell research).

140 *See id.* (providing the language of President Obama's 2009 executive order).

141 *See* 689 F.3d at 780 (finding the word "research" to be ambiguous). Currently, no case law exists on the issues of ethics, regulation, or funding for CRISPR. *Id.* The only case law relating to CRISPR at this early stage of development has been related to the CRISPR patent dispute. *See also Junior Party*, No. 106,048 (referring to the case between the University of California and the Broad Institute). This case covered the first patent dispute involving CRISPR. *Id.* Jennifer Doudna's team at the University of California at Berkeley published their now-famous CRISPR study in 2012, which described the use of CRISPR in bacteria and the *potential* use of it in multicellular organisms. *Id.* Subsequently, the Broad Institute in Massachusetts published a study confirming CRISPR's capabilities in multicellular organisms. *Id.* The California team submitted a non-expedited patent request before the Broad Institute; however, The Broad Institute's patent request was expedited and approved. *Id.* As a result, the California team's patent was reviewed later and caused a patent interference, despite its earlier submission. *Id.* The court ruled that the California patent partially infringed the Broad Institute's patent and that the California patent was restricted to technology relating only to CRISPR's use in bacteria. *Id.* The ruling is thought by many to be a major blow to the California team in what is likely an emerging multi-billion-dollar industry. *Id.* Deborah Netburn, *UC Berkeley Suffers Big Loss in CRISPR Patent Fight: What's Next for the Powerful Gene-Editing Technology?*, LOS ANGELES TIMES (Feb. 15, 2017), http://www.latimes.com/science/sciencenow/la-sci-sn-crispr-patent-decision-20170215-story.html [https://perma.cc/BGG4-KPLL] (showing the likelihood of this case to go through multiple appeals before the dispute is completely resolved, which could likely take years).

142 *See* Harry Enten & Oliver Roeder, *Trump Picks Neil Gorsuch, A Scalia Clone, For The Supreme Court*, FIVETHIRTYEIGHT (Jan 31, 2017), http://fivethirtyeight.com/features/neil-gorsuch-supreme-court-trump/ [https://perma.cc/L72F-U5RA] (stating Judge Gorsuch's "likelihood to invoke originalism in his opinions"). *See also* Pino v. United States, 507 F.3d 1233, 1238 (10th Cir. 2007) (certifying the question as to whether the Oklahoma Supreme Court should hear an appeal on wrongful death of an unviable fetus). Judge Neil Gorsuch wrote the opinion certifying the question for the state court. *Id.* This case presented the question of whether a physician could be sued for wrongful death of a fetus that was unviable before medical treatment had been administered to the carrying mother. *Id.* Gorsuch stated that the question was "precisely the sort that calls for us to seek authoritative guidance of the state supreme court." *Id.* While this case only certified a question and did not decide the issue at hand, this case may loosely indicate where Gorsuch stands in similar cases that involve unviable embryos. *See generally id.* (providing the most relevant opinion written by Gorsuch).

guidelines.[143] This would indicate that a solution may be necessary that does not rely on whatever the current makeup of the Supreme Court is.[144] Former Chief Justice Burger once said the following: "[t]he law does not search out as do science and medicine; it reacts to social needs and demands."[145] The law has reacted to the science on this issue before, now it must be done again in a more conclusive manner.[146]

Ethicists and scientists alike agree that the possibility of permanently editing the human germline (which would involve editing genes of viable human embryos) would be a dangerous and irreversible step for science.[147] This is not to say that the issue could never be revisited at some point down the road.[148] But the lack of understanding and experience we have for this powerful tool creates too many uncertainties and risks.[149]

A. The Problem

Part III.A discusses the Dickey-Wicker Amendment and why the ban on federal funding for embryonic research should be struck.[150] This section also argues that law should be eliminated in order to make way for more modern legislation that properly addresses CRISPR's ethical concerns.[151] Clinical trials are underway using alternative gene-editing tools.[152] In China, four clinical trials involving CRISPR have been announced and a study on human embryos has been conducted in the

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143 *See Pino*, 507 F.3d at 1238 (allowing the review of a wrongful death claim relating to an unviable fetus).

144 *See* Enten & Roeder, *supra* note 142 (discussing Justice Gorsuch's time on the 10th Circuit Court of Appeals in Denver and what can be drawn from his opinions).

145 George P. Smith, II, *Accessing Genomic Information or Safeguarding Genetic* Privacy, 9 J.L. & Health 121, 133 (1994–1995) (quoting former Chief Justice of the United States Supreme Court Warren Burger).

146 *See infra* Part IV (discussing the author's proposal to fund and regulate CRISPR using the relevant ethical concerns as a guide).

147 *See, e.g.*, *id.* (exemplifying one leading argument to halt such research).

148 *See* Regalado, *supra* note 34 (saying that if were are to attempt to permanently remove disease-causing genes from the human germline, editing embryos is the only known way of doing so).

149 *See, e.g.*, Begley, *supra* note 42 (reflecting the continuing improvement to CRISPR that need to be made without having risk of inaccurate genetic alterations to patients).

150 *See infra* Part III.A (arguing that the Dickey-Wicker Amendment bans what is now safe and ethical work and is too broad for what more modern ethical concerns are).

151 *See infra* Part III.A (setting out reasons for why the Dickey-Wicker Amendment is inadequate). *See also infra* Part III.B (discussing various approaches to replacing the Dickey-Wicker Amendment).

152 *See, e.g.*, Hultquist et al., *A Cas9 Ribonucleoprotein Platform for Functional Genetic Studies of HIV-Host Interactions in Primary Human T Cells*, CELL PRESS (2016), http://www.sciencedirect.com/science/article/pii/S2211124716313365 [https://perma.cc/94P5-GS2U] (summarizing a clinical trial using Zinc Finger Nucleases rather than CRISPR).

United States.[153] In the United States, scientists are successfully editing human cell traits on a seemingly weekly basis in the lab.[154] All signs suggest that it is only a matter of time before a treatment for one condition or another is discovered.[155] Whether that occurs in the next year or further down the line, the United States should position itself to take advantage of such a discovery.[156]

One reason this could be difficult is the Dickey-Wicker Amendment, the bill rider that prevents the alteration of a human embryo regardless of viability.[157] This amendment needs to be altered or better yet eliminated and replaced to accommodate further research using CRISPR.[158] Some of the greatest potential from CRISPR comes from studies that involve human embryos; however, when a law that makes such an act illegal, problems predictably arise.[159] Studies on unviable human embryos are accepted among ethicists on a larger scale.[160]

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153 *See* NATIONAL INSTITUTES OF HEALTH, ClinicalTrials.gov, https://clinicaltrials.gov/ct2/results?term=crispr [http://perma.cc/DF5Z-MUXH] (providing basic details about the four planned clinical trials in China). *See also* Mullin, *supra* note 40 (reflecting the rapid progress of CRISPR research to the stages of studying it with human embryos).

154 *See, e.g.*, Sharon Begley, *CRISPR Identifies Genes that Might be Targeted to Hobble HIV Infection,* STAT (Oct. 25, 2016), https://www.statnews.com/2016/10/25/crispr-identifies-hiv-genes/ [https://perma.cc/FZ5E-AWTS] (exemplifying research that has been conducted on the HIV virus as progress that has already occurred in early CRISPR studies).

155 *See generally* Nanette Byrnes, *A Big Bet That Gene Editing Will Cure Human Disease,* MIT TECH. REV. (July 25, 2016), https://www.technologyreview.com/s/601846/a-big-bet-that-gene-editing-will-cure-human-disease/ [https://perma.cc/9JJP-XZXY] (stating the confidence from newly-public Editas Medicine about their planned research with CRISPR and that the results will not disappoint).

156 *See generally id.* (reiterating the confidence within Editas). However, the technology to specifically attack many of these genetic diseases is still being developed. *Id.*

157 *See, e.g.*, The Balanced Budget Downpayment Act of 1996, *supra* notes 65–66 (exemplifying the language of the Dickey-Wicker Amendment in 2015's Consolidated Appropriations Act).

158 *See generally id.* (prohibiting harm to human embryos).

159 *See generally The Guardian's View on Human Genome Editing: Find, Replace – and Cure,* THE GUARDIAN (Sept. 2, 2015), https://www.theguardian.com/commentisfree/2015/sep/02/the-guardian-view-on-human-genome-editing-find-replace-and-cure [https://perma.cc/SZ5R-WX2N] (speaking to the benefits of permanently eliminating genetic mutations that cause diseases). "Editing human embryos is categorically different to editing organs and other tissues. Genetic changes made to an embryo go on to affect all the cells in the adult." *Id.* "That includes their sperm or eggs, so the changes are passed on to their children and all future generations." *Id.*

160 *See generally* Rob Stein, *Breaking Taboo, Swedish Scientist Seeks to Edit DNA of Healthy Human Embryos,* NPR (Sept. 22, 2016), http://www.npr.org/sections/health-shots/2016/09/22/494591738/breaking-taboo-swedish-scientist-seeks-to-edit-dna-of-healthy-human-embryos [https://perma.cc/8MUG-QSDF] (recognizing the value of learning more about embryo development).

The Dickey-Wicker Amendment should be replaced because it no longer serves its original purpose.[161] The law was intended to protect prenatal life at a time when *in vitro* fertilization research was progressing as a promising science itself.[162] But, when a 20-year-old law infringes on further scientific research due to its broad language, changes are in order.[163] While the NIH may have found a way around the amendment by approving a study, research that involves unviable human embryos is still legally dicey.[164] This is because research on viable human embryos is still considered to be a dangerous road to go down, and research involving unviable embryos has reached a larger consensus of being permissible.[165] The Dickey-Wicker Amendment is still an imposing figure to those who aim to advance research in this area.[166] This is because the Dickey-Wicker Amendment was directed toward concerns about the ethical nature of IVF, which has proven to be a safe, and now-common procedure.[167] This

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[161] *See generally* Megan Kearl, *Dickey-Wicker Amendment, 1996*, THE EMBRYO PROJECT ENCYCLOPEDIA (Aug. 27, 2010), https://embryo.asu.edu/pages/dickey-wicker-amendment-1996 [https://perma.cc/A73E-EWDB] (noting the amendment's creation in response to a push for embryonic research in light of *in vitro* fertilization). The Dickey-Wicker Amendment may have passed through Congress quickly because it was attached to an appropriations bill and the legislature had recently "come off two government shutdowns." *Id. See also* Christopher Ingraham, *Congressional Deadlock Has Doubled Since the 1950s*, WASH. P. (May 28, 2014), https://www.washingtonpost.com/news/wonk/wp/2014/05/28/congressional-gridlock-has-doubled-since-the-1950s/ [https://perma.cc/G24Y-6H8Y] (tracing the percentage of issues left unlegislated in a given year). "In 1947–1948, fewer than thirty percent of issues were left unlegislated." *Id.* "In 2011–2012, seventy-one percent of issues were unlegislated." *Id.*

[162] *See generally id.* (determining later that stem cell research was not blocked by this amendment because it was sufficiently different from what the amendment banned).

[163] *See generally* Phillip K. Howard, *The Crippling Hold of Old Law*, THE WALL STREET JOURNAL (Apr. 1, 2016), http://www.wsj.com/articles/the-crippling-hold-of-old-law-1459536718 [http://perma.cc/QCC3-JEMZ] (citing to a problem of "mountains of old statutes and regulations" as one reason why government has become so slow and clunky).

[164] *See* Begley, *supra* note 42 (stating that the NIH's ethics committee approved a clinical trial after altering their grant guidelines, although the study has not yet been approved by the FDA).

[165] *See* Jad Abumrad & Robert Krulwich, *The Primitive Streak*, RADIOLAB (Sept. 23, 2016), http://www.radiolab.org/story/primitive-streak/ [https://perma.cc/M67W-6Y9L] (discussing the 13-day rule, which is used in embryonic stem-cell research). The thirteen-day rule provides that no research should be conducted on embryos once they reach thirteen days old. *Id.* Around the 13-day mark is when embryos begin to develop early human features where cells begin to differentiate. *Id.* At this time the embryo also begins to develop circulatory paths to connect to the womb in order obtain nutrients from the mother. *Id.* Scientists have widely accepted this rule as the furthest one should study an embryo before ending the study and destroying the embryo. *Id.*

[166] *See generally* Kearl, *supra* note 161 (describing the Dickey-Wicker Amendment as the sole barrier to further embryonic research).

[167] *See* Mailee R. Harris, Note, *Stem Cells and The States: Promulgating Constitutional Bans on Embryonic Experimentation*, 37 VAL. U. L. REV. 243–46 (2002) (providing statistics on IVF use).

federal ban should be struck to make way for the implementation of modern, forward-looking law that can adequately address the funding and regulation of CRISPR.[168]

B. The Solution: Current Bills and Proposed Approaches

Others in the legal community agree that the first step to a solution involves repealing the Dickey-Wicker Amendment.[169] However, there is disagreement on how to proceed after a successful repeal.[170] Proposals range from an all-out ban on funding CRISPR, to others suggesting the forming of committees or expanding authority of the Food and Drug Administration.[171] Part III.B critiques the effectiveness and plausibility of different approaches to regulate and fund CRISPR.[172]

The impact of the 21st Century Cures Act on CRISPR cannot be fully understood at this point.[173] One of the goals of the act is to take a more aggressive approach to cancer research.[174] The act includes an investment

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In 2001, the number of frozen embryos for the purposes of IVF was at least 188,000. *Id.* at 245–46.

168 *See* Zaret, *supra* note 107, at 1831 (recommending the elimination of the federal ban on funding embryonic research).

169 *See, e.g.*, *id.* (suggesting to lift the ban on embryonic research).

170 *See, e.g.*, *id.* (proposing a new federal agency similar to what is in place in the United Kingdom, called the Human Fertilisation and Embryology Authority (HFEA)). The author continues by recognizing that lifting this ban would "open the door for regulatory framework" to be put in place. *Id.* This proposal follows with a three-step proposal for how to continue. *Id.* Others, meanwhile recognize that the Dickey-Wicker Amendment prohibits embryonic research funding by the government. Sarah Ashley Barnett, *Comment: Regulating Human Germline Modification in Light of CRISPR*, *51* U. RICH. L. REV. 553, 576 (Jan. 2017).

171 *See* Zaret, *supra* note 107, at 1828–31 (likening a potential agency to HFEA. *See also* Barnett, *supra* note 170 (suggesting an expansion of the FDA); *infra* Part IV (providing this Note's proposal). The act would then direct funds to CRISPR research in four ways. *Id.* First, the language should focus funds to studies seeking to improve CRISPR itself and for human application in clinical trials. *Id.* Second, the legislation would bar research on viable human embryos. *Id.* We simply do not have enough information on the true ramifications of such an act and there is no agreement as to whether we should ever take that step. *Id.* Third, no funds will be provided to studies that seek to accomplish cosmetic goals such as changing a child's eye color. *Id.* Additionally, using CRISPR in an agricultural setting is generally permitted, but is beyond the scope of this discussion. *Id.* Finally, if research institutions violate the guideline of using CRISPR on a viable human embryo, funding for that study will be revoked and future funding will be temporarily revoked. *Id.*

172 *See infra* Part III.B (analyzing approaches from various law review articles on their plausibility and effectiveness if pursued).

173 *See generally Obama Signs 21st Century Cures Act into Law*, ASSOCIATED PRESS (Dec. 13, 2016), https://www.statnews.com/2016/12/13/21st-century-cures-obama-signs/ [https://perma.cc/C53E-2SGJ] (showing how the act was only recently signed).

174 *See generally Weekly Address: Pass the 21st Century Cures Act*, OFFICE OF THE PRESS SECRETARY (Dec. 3, 2016), https://www.whitehouse.gov/the-press-office/2016/12/03/weekly-address-pass-21st-century-cures-act [https://perma.cc/66RJ-XY43] (stating the

in former Vice President Joe Biden's Cancer Moonshot program.[175] While research using CRISPR may see some of these funds, it is difficult to determine how much, if any at all, will go to CRISPR.[176] Because CRISPR is not mentioned specifically in the act, a subsequent act may need to be implemented to assure adequate funding is being directed to CRISPR research.[177] In the alternative, the implementation of the 21st Century Cures Act could be guided by the act proposed in this Note when it comes to directing research funding.[178] This may be possible because the 21st Century Cures Act similarly empowers the National Institutes of Health in dispersing research grants.[179] Ultimately, the 21st Century Cures Act does not detrimentally affect the act proposed in this Note, but reinforces the idea that investing in medical research is an issue susceptible to compromise in a divided Congress.[180]

One offered proposal in the legal community to solve the ethical issues related to CRISPR is through a congressionally-established

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goals of the Act). In President Obama's weekly address, he set out the goals of the 21st Century Cures Act (also known as the Beau Biden Act) in a statement of support before the bill had been passed. *Id.* In addition to seeking out remedies to opioid addiction, the act aims to find cures for Alzheimer's Disease and cancer generally. *Id.*

175 *See generally id.* (reiterating the goal for the United States to lead the charge in finding a cure for cancer). The president goes on to emphasize how many diseases such as Alzheimer's and Epilepsy touch so many lives and that it made compromise possible in this act. *Id.*

176 *See* Sheila Kaplan, *Senate Passes Landmark 21st Century Cures Act – But It Will Take Years to Implement*, STAT (Dec. 7, 2016), https://www.statnews.com/2016/12/07/21st-century-cures-senate-passes/ [https://perma.cc/Q755-J6MR] (noting the lengthy process of implementing the 21st Century Cures Act). However, the act will be difficult to implement and it may take a considerable amount of time to work out all of the details. *Id.*

> [T]he Cures Act, nearly 1,000 pages long, does not lay out many deadlines. The dirty secret is it's going to take many years to implement these things," said Bethany J. Hills, who runs the FDA practice at Mintz Levin Cohn Ferris Glovsky and Popeo. "There are many provisions requiring guidance, and whenever Congress has mandated that FDA provide guidance on something, the FDA historically is perpetually late.

Id. The FDA will require a lot of time to implement regulations for a lengthy bill such as this. *Id.*

177 *See* H.R. 34-114, Dec. 8, 2016 (providing the language of the bill signed December 13, 2016).

178 *See* Regaledo, *supra* note 1 (discussing the ethical concerns related to CRISPR that should guide and direct the government funds to the appropriate research projects).

179 *See* Kaplan, *supra* note 176 (discussing the effect of the 21st Century Cures Act on the National Institutes of Health). The Act will increase the NIH's budget by $4.8 billion. *Id.* This also likely provides more certainty for the NIH with an incoming administration that presented numerous uncertainties about the organization's future. *Id.* Cuts to both regulations and budgets send mixed messages. *See generally id.*

180 *See* Office of the Press Secretary, *supra* note 174 (providing President Obama's statement describing the 21st Century Cures Act as one of compromise).

committee.[181] This committee would attempt to accomplish two goals.[182] First, the committee would be in charge of considering ethical concerns related to specific CRISPR studies, obtain public opinion on the matter, and frame potential legislation.[183] Such a committee may be useful in drafting the official legislation similar to the legislation being proposed in this Note.[184] However, the formation of a committee would otherwise be unnecessary.[185] Congressmen are largely qualified to intake public opinion from their constituents and to consider the relevant lawmaking process, but the same cannot be said for the ability to evaluate scientific proposals.[186] The NIH is already equipped to do this, because they are the entity that approves and distributes grants for scientific and medical research.[187] Specifically, the Recombinant DNA Advisory Committee (RAC) of the NIH approves clinical studies involving DNA (which would include CRISPR).[188]

The second committee goal from this proposal would be to "consider the creation of a standing federal entity that would have authority over both public and private sectors" and would set standards for research.[189] Again, this is quite similar to functions carried out by the NIH.[190] Additionally, it is unlikely that the current political climate would allow

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[181] *See* Zaret, *supra* note 107, at 1831 (proposing a Congressional committee that could sift through potential legislation as well as assist in establishing a new federal agency). The formation of a committee could funnel policy through representatives and senators that have more expertise in science and medicine than the entire body of Congress. *Id.*

[182] *See id.* (calling for a committee that would review legislation and possibly help in the formation of a new federal agency to handle CRISPR and all that comes with it).

[183] *See id.* (suggesting that this committee could serve as a filter for the drafts of proposed legislation coming in, not unlike the current committee system for bills).

[184] *See generally id.* (inferring that committees mark up legislation as part of the bill passage process in both houses of Congress, and a similar function would likely be performed here).

[185] *See infra* Part IV (stating why Congress should allow the NIH to make decisions about the ethical nature of each study within the boundaries set by lawmakers).

[186] *See infra* Part IV (noting how the NIH already has medical and ethical experts that make such considerations a part of the grant-awarding process).

[187] *See generally NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, NATIONAL INSTITUTES OF HEALTH (Apr. 2016), https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf [https://perma.cc/MHX3-ZSAF] (outlining safety considerations made by the NIH). These guidelines apply to all research conducted in the United States. *Id.*

[188] *See id.* (providing the lengthy list of guidelines reviewed by RAC).

[189] *See* Zaret, *supra* note 107, at 1832 (stating that Congress would lay out the ethical boundaries for this new agency). The proposal in this Note specifies those ethical boundaries by stating which studies would be funded, which studies would not be funded, and the consequence for violating such ethical boundaries. *See also infra* Part IV (providing a detailed proposal).

[190] *See generally infra* Part IV (contesting that the NIH is qualified for this task because it already deals with ethical oversight of genetic research).

for the creation of an entirely new federal agency.[191] The new administration that took over in early 2017 has placed a high value on gutting agencies and cutting budgets across the board.[192] The creation of a new federal agency would inevitably cause the creation of new government jobs.[193] But, in a time where there may be a succession of government hiring freezes, it begins to look bleak that a new agency could be created.[194] This is especially true for a potential agency that may overlap duties with the already-existing NIH.[195] Instead, a piece of legislation that sets a government funding plan would have a higher likelihood of success.[196] While budget cuts are currently being emphasized, the current administration has not ruled out shifting spending from one agency to another.[197]

Another proposal to solve CRISPR-related issues is to introduce legislation that would expand or reinforce the Food and Drug Administration's (FDA) role in regulating CRISPR.[198] With or without new legislation, the FDA would be charged with the task of determining what clinical trials, treatments, or technologies would be safe for the public.[199] The FDA does not explicitly cover CRISPR, and this may be

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191 *See, e.g.*, Eric Krupke, *How We Got Here: A Shutdown Timeline*, NPR (Oct. 17, 2013), http://www.npr.org/sections/itsallpolitics/2013/10/16/235442199/how-we-got-here-a-shutdown-timeline [https://perma.cc/G7FZ-ASY6] (chronicling the latest government shutdown).

192 *See, e.g.*, Glenn Thrush, Kate Kelly, and Maggie Haberman, *Trump to Ask for Major Cuts to EPA, Increased Spending for Military*, THE BOSTON GLOBE (Feb. 27, 2017), https://www.bostonglobe.com/news/politics/2017/02/26/trump-ask-for-major-cuts-epa-increased-spending-for-military/bRLCI3ye7Ym0F4SNUNXo4H/story.html [https://perma.cc/2QA4-AAEG] (cutting the EPA's budget by an estimated two-thirds).

193 *Cf. Presidential Memorandum Regarding the Hiring Freeze*, THE WHITE HOUSE, OFFICE OF THE PRESS SECRETARY https://www.whitehouse.gov/the-press-office/2017/01/23/presidential-memorandum-regarding-hiring-freeze [https://perma.cc/K9Q7-8HMJ] (analogizing that this would be off the table during a government hiring freeze).

194 *See, e.g.*, *id.* (stating that this hiring freeze extended to all executive agencies).

195 *See id.* (inferring that a new agency is unlikely considering the memo states that the reduction of the government work force is sought to be made permanent through attrition).

196 *See infra* Part IV (making the case for legislation that would allow for additional or fewer funds to be applied to CRISPR at set time periods).

197 *See* Thrush, *supra* note 192 ("requesting tens of billions of dollars in reduction for the Environmental Protection Agency and State Department").

198 *See* Zaret, *supra* note 107 (noting the FDA's "limited oversight" in this area currently). *See also* Barnett, *supra* note 170, at 580 (recommending the expansion of FDA oversight).

199 *See* Consumer (Biologics), FDA (Sept. 18, 2013), https://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Consumers/default.htm [https://perma.cc/D7NL-XZU8] (defining biologics as "biological products [that] include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins"). CRISPR could fall under "gene therapies" in some instances. *Cf. id.* (pointing out that CRISPR, as a new technology, could be categorized as different types of medical items).

because the potential uses for CRISPR are wide-ranging.[200] This does raise interesting questions for how the FDA will classify CRISPR.[201] Should the evaluation process for approval move forward as it does for biologics, treatments, medical devices, or as a new category altogether?[202] While the FDA does have experience in this area, Congress's focus should first be on the NIH.[203] This is because the FDA will have nothing to approve if the studies and clinical trials are not occurring.[204] Similarly, the NIH is a more effective body for preventing human germline editing before society is ready because they are the entity that sets guidelines for grant-receiving studies and would use those guidelines to direct government funds.[205] When it comes to privately-funded research, the FDA may have more control over whether such medical and genetic practices ever see the light of day.[206] The legislation proposed in this Note deals exclusively with publicly-funded research for CRISPR.[207] Additionally, it may be wise to begin considering regulatory approaches that directly addresses how intentional human germline editing would be approached.[208] However, the use of CRISPR in adults and children to cure disease in single individuals is more pertinent at this time.[209] This is because the emergence of clinical trials to accomplish just that in 2018 and beyond is pushing such uses of CRISPR from the theoretical realm into the practical.[210]

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200 *See* Zaret, *supra* note 107, at 1829 (stating that the FDA has jurisdiction over gene-editing procedure approval). *But see* Barnett, *supra* note 170 (noting that the FDA does not have oversight over human germline editing). This is because human germline editing is still banned in the United States. *Id.*

201 *See* Barnett, *supra* note 170, at 580 (realizing the different ways that CRISPR treatment could be classified when applying for FDA approval).

202 *See id.* (bringing to light the fact that the CRISPR approval process by the FDA may differ based on the type of treatment).

203 *See* (commenting on the FDA's role in approving CRISPR experiments). *But see infra* Part IV (recommending power be reinforced at the NIH and member institutions).

204 *See generally* Zaret, *supra* note 107 (reflecting the FDA's role in approving treatments that are theoretically ready for human application, which CRISPR is approaching in a limited sense).

205 *See generally* NIH Guidelines, *supra* note 187 (covering all research, publicly funded or not, on the ethical and safety concerns of the NIH).

206 *Cf.* NIH Guidelines, *supra* note 187 (referencing the distinct roles of the NIH and FDA when it comes to approving and using public funds for research, compared to approving a treatment or technology for human use).

207 *See infra* Part IV (clarifying that NIH guidelines cover all relevant research conducted in the United States, but has more exclusive control over research receiving grants).

208 *See generally* NAT. INST. OF HEALTH, *supra* note 21 (referencing the fast pace of genetic research, which would lead to a cause for forward-looking legislation beyond what is immediately at hand).

209 *See infra* Part IV (arguing that an investment in public health and trying to cure debilitating diseases should be the force pushing this legislation through Congress).

210 *See* Regaledo, *supra* note 1 (discussing the potential uses of CRISPR in 2017). *See also* Mullin, *supra* note 40 (showing the direction of clinical trials).

Again, expansion of a federal agency seems unlikely under the current administration, but the redirection of funds may be more likely.[211] It could be argued that legislation endorsing human germline editing would not gain enough support to be passed by Congress, and that would likely ring true at this time.[212] However, the use of CRISPR in adults as well as other non-human-germline-editing methods raises fewer issues.[213] This is especially true when the benefits are so tangible as compared to previous gene editing technologies which were slow and inaccurate.[214]

As stated above, CRISPR presents multiple issues that must be confronted.[215] Questions about ethics, previous legislative amendments, financial considerations, scientific progress, the multiple uses for CRISPR across medicine, agriculture, and pharmaceuticals pose a unique challenge.[216] Introducing new legislation allows lawmakers to attack many, if not all, of these problems at once.[217] This is because of the very nature of a legislative bill.[218] Legislators are naturally positioned to work with policy and conflicting interests among citizens, business entities, and public institutions.[219] Therefore, a bill introduced in the United States Congress would be the most logical and natural place to address

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211 *See generally* Krupke, *supra* note 191 (emphasizing how the additional cost of creating a new federal agency is not plausible at this point in time).

212 *See generally* Zaret, *supra* note 107 (referring to questions about human germline editing in humans before the technology is perfected further).

213 *See, e.g.*, Chestnut, *supra* note 19 (comparing old gene-editing technologies such as TALENs to CRISPR, which adds promise through speed, affordability, and accuracy).

214 *See* Kahn, *supra* note 44 (stating various ethical concerns in a Congressional hearing to the House Committee on Science, Space, and Technology). Concerns are shared with many scientists and include frivolous uses as well as misuse in humans. *Id.* Such misuses at this point in time would include consent issues when permanently editing the genes of future generations that have not yet been conceived. *Id.*

215 *See* Regalado, *supra* note 34 (noting the debate for what humans should and should not use CRISPR).

216 *See* Regalado, *supra* note 34 (reviewing the ethical concerns). *See also* Skerrett, *supra* note 49 (citing to the economic concerns associated with the cost of gene therapy using CRISPR). *See also* Maywa Montenegro, *CRISPR is Coming to Agriculture – With Big Implications for Food, Farmers, Consumers, and Nature*, ENSIA (Jan. 28, 2016), http://ensia.com/voices/crispr-is-coming-to-agriculture-with-big-implications-for-food-farmers-consumers-and-nature/ [https://perma.cc/SD59-BSAR] (discussing the use of CRISPR in a variety of agricultural settings).

217 *See generally Introduction and Referral of Bills,* UNITED STATES CONGRESS https://www.congress.gov/legislative-process/introduction-and-referral-of-bills [https://perma.cc/C5LP-QRQ3] (explaining the nature of introducing legislation as a bill).

218 *See generally id.* (discussing the drafting of a bill's language).

219 *See generally What is a Representative?*, THE UNITED STATES HOUSE OF REPRESENTATIVES http://www.house.gov/content/learn/ [https://perma.cc/75BA-5U8D] (explaining how a member of the House of Representatives is meant to represent their constituents in their respective congressional district and advocate for their concerns).

CRISPR.[220] Legislators are also in the unique position of answering to constituents.[221] CRISPR's ethical issues are ones that should require input from the public.[222] Controversial ethical questions in science have never been ones in which our government decides for us.[223] So if we are to conduct a true "worldwide conversation," the United States' decisions will carry considerable weight for the rest of the world.[224] What legislators must do is determine the language of the legislation.[225]

Comprehensive legislation is also a better avenue, because there is still progress to be made in CRISPR's accuracy and overall potential, further research should be directed toward perfecting CRISPR.[226] Eliminating the potential for problems in the human application of CRISPR is a necessary step to making this a treatment option a norm in medicine.[227] Continuing progress in perfecting medical treatment should always be encouraged, but this is especially true for CRISPR, which is only four years old as a technological tool.[228] Additionally, the prospect of curing or treating genetic diseases that have such a profound impact on our society is more likely to encourage compromise than many other issues that we face today.[229] The combination of these issues should create an urgency and

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220 *See id.* (describing the position of a member of congress and their connection to their constituents). *See also infra* Part IV (stating the importance of public input into a controversial issue such as CRISPR).

221 *See generally id.* (commenting on a Congressman's purpose to serve the people).

222 *See generally* Doudna, *supra* note 13, at 11:17 (advocating for a public conversation among citizens and figures of authority in the fields of law, ethics, and science).

223 *See generally Emerging Biotechnologies and the Role of the NIH RAC*, NATIONAL INSTITUTES OF HEALTH (June 16, 2016), http://osp.od.nih.gov/under-the-poliscope/2016/06/emerging-biotechnologies-and-role-nih-rac [https://perma.cc/NWF7-UXXF] (announcing the altering of NIH guidelines that determine how research studies obtain grant funds from the NIH). Even regulations go through a public comment period before being enacted. *See generally id.*

224 *See generally* Doudna, *supra* note 13, at 13:38 (implying that our society must come to some level of agreement on what acts are acceptable before proceeding with further research involving embryos).

225 *See Introduction and Referral of Bills*, UNITED STATES CONGRESS (last visited June 18, 2017), https://www.congress.gov/legislative-process/introduction-and-referral-of-bills [https://perma.cc/C5LP-QRQ3] (noting the job of lawmakers and congressional lawyers to work on the specific language of a bill).

226 *See, e.g.*, Begley, *supra* note 154 (discussing CRISPR's low degree of error, which still needs to be improved).

227 *See id.* (noting the promise involved in one particular use of CRISPR).

228 *See id.* (implying that the technology needs to improve its accuracy before application in humans).

229 *See generally* NATIONAL INSTITUTES OF HEALTH https://www.genome.gov/10001204/specific-genetic-disorders/ [https://perma.cc/BVF4-WEVP] (providing a non-exhaustive list of many of the most common diseases that have a "genetic component").

common purpose to accomplish the difficult issues presented by CRISPR.[230]

One common thread from the proposals discussed above is that the regulation of CRISPR is discussed primarily as a way to curb potential harms from the technology's development.[231] The potential benefits of curing diseases with CRISPR do not go unrecognized by anyone.[232] However, regulation should not be seen purely as a barrier, but also as a facilitator.[233] It is illogical that research would move forward without the relevant ethical concerns being sorted out for the long term with scheduled periods for reassessment.[234] That is what this contribution aims to accomplish: setting the table for legislation that serves as an ethical problem-solver and an enthusiastic endorsement for CRISPR research.[235] New legislation has the unique ability to perform this balancing act.[236]

IV. CONTRIBUTION

This contribution is separated into two subsections.[237] Part IV lays out the goals and intentions of the proposed legislation.[238] Part IV also outlines repealing the Dickey-Wicker Amendment and then the ethical and scientific guidelines that will direct the NIH and individual research institutions in funding research on CRISPR.[239] Part IV.B addresses a few

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230 *See generally The Genetic Disease Foundation (GDF) Encourages Americans to Know Their Genes at KnowYourGenes.org in Observance of World Rare Disease Day*, PR NEWSWIRE (Feb. 28, 2010), http://www.prnewswire.com/news-releases/the-genetic-disease-foundation-gdf-encourages-americans-to-know-their-genes-at-knowyourgenesorg-in-observance-of-world-rare-disease-day-85763017.html [https://perma.cc/8QKQ-RBFW] (stating that over 12 million individuals suffer from genetic diseases of various forms today in the United States).

231 *See* Zaret, *supra* note 107, at 1832–38 (citing the primary downsides of regulation as politicizing science and the effects on procreative autonomy). *See also* Barnett, *supra* note 170, at 581 (permitting the use of CRISPR, even in human germline editing). This proposal sets the standards for approving CRISPR techniques but does not discuss government funding of such contributing research). *Id.*

232 *See* Barnett, *supra* note 170 (recognizing not only the benefits of CRISPR used on adults, but also the benefits of human germline editing when ethically sound).

233 *See infra* Part IV (emphasizing the benefits to federal funding for CRISPR research, which would gain more support if regulations were put in place to satisfy the public's concerns).

234 *See infra* Part IV (proposing an approach that would allow for reassessment of human germline editing in the United States).

235 *See infra* Part IV (laying out ethical boundaries to facilitate research and restrict unethical practices).

236 *See infra* Part IV (proposing a two-goal piece of federal legislation).

237 *See infra* Part IV (discussing the proposed legislation and then counterarguments).

238 *See infra* Part IV (laying out what this proposed piece legislation hopes to accomplish, from repealing the Dickey-Wicker Amendment to implementing guidelines for how CRISPR research will be addressed in the short-term).

239 *See infra* Part IV (outlining the proposition in terms of two larger parts).

arguments likely to be raised against this proposal.[240] This subsection intends to differentiate and reason why this specific proposal would be more efficient and effective than alternative options.[241]

In order to facilitate future research involving CRISPR, the ethical concerns must be addressed immediately.[242] This can be done most efficiently through legislation passed by Congress with a primary goal of investing in public health.[243] Keeping in mind the numerous potential uses for CRISPR, this Note will only focus on one aspect of this proposed act: human application in a clinical trial setting.[244] The scope of this legislation will therefore be tailored to the relevant ethical issues related to human application with the goal of curing and treating diseases and inherited genetic conditions.[245]

A. The Act

The first part of this act will repeal the Dickey-Wicker Amendment.[246] Second, to relieve concerns about the perceived dangers of living in a CRISPR world, this legislation should be narrowly tailored to achieve the goal of improving public health in America.[247] That is why this legislation should fund two types of research involving CRISPR.[248] Next, this legislation should direct funds that more directly achieve the goals of the legislation.[249] More specifically, this act should fund research studies that

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[240] *See infra* Part IV.B (addressing three counterarguments). Specifically, the necessity for such legislation, the cost concerns, and the scope of the act. *Id. See also* Alison Peck, *Re-Framing Biotechnology Regulation*, 72 FOOD & DRUG L.J. 314, 333, 339 (reflecting the growing need and support for new legislation on biotechnology).

[241] *See infra* Part IV.A (noting the unique advantages lawmakers have to address these many issues).

[242] *See* Kahn, *supra* note 44 (telling Congress the importance of resolving these ethical disputes is essential to realizing CRISPR's full potential for medical patients).

[243] *See* UNITED STATES CONGRESS, *supra* note 225 (reiterating the flexibility in changing the law through legislation).

[244] *See generally* Regalado, *supra* note 34 (discussing the CRISPR landscape in the world of ethics).

[245] *See* NATIONAL INSTITUTES OF HEALTH, *supra* note 153 (providing information on three clinical trials scheduled in China). Clinical trials are taking place in China, but are progressing at a slower pace in the United States. *Id.*

[246] *See* The Balanced Budget Downpayment Act of 1996, *supra* notes 65–66 (providing the broad language of the amendment).

[247] *See generally Budget*, NATIONAL INSTITUTES OF HEALTH (last visited June 3, 2017), https://www.nih.gov/about-nih/what-we-do/budget [https://perma.cc/P7AU-VHQA] (reflecting the $32.3 billion dollars the NIH invests in competitive grants each year). That money from the consolidated appropriations act is the only funding coming from the American taxpayer. *Id.*

[248] *See, e.g.*, Begley, *supra* note 42 (exemplifying a clinical trial setting for research).

[249] *See* Zaret, *supra* note 107 (specifying that funding should be directed toward grants for research on CRISPR clinical trials).

intend to treat or cure genetically influenced diseases and conditions.[250] There will be no prioritization of which ailments should receive more or less attention through amount of funds or which studies will be funded earlier rather than later.[251] The NIH and individual research institutions are far more qualified to make such determinations than lawmakers.[252] Accordingly, deference should be provided to the NIH and its member institutions.[253] Further, this Note recommends that it should be made clear in the language of the bill that no ailment is too small to receive attention from CRISPR research.[254] While the destructive nature of diseases such as Muscular Dystrophy and Alzheimer's throughout our society is well-documented, it is not the job of the legislature to determine which populations of patients are in more or less need of aid.[255] Similarly, lawmakers are largely unqualified to determine which ailments have the most hope of receiving a treatment or cure from CRISPR.[256] This act is meant to empower the scientific community, not to step on its feet.[257]

Next, this act would have to set guidelines for not only what types of studies would be included and excluded from eligibility for funding.[258] It would also need to identify specific types of studies that would be prohibited whether the studies were receiving funding from this act or

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250 *See, e.g.*, NAT. INST. OF HEALTH, *supra* note 153 (exemplifying different clinical trials in China planned to research various forms of cancer).

251 *See* Doudna, *supra* note 13, at 7:53 (showing the promise of using CRISPR on diseases that affect the blood). Jennifer Doudna believes that diseases of the blood will be researched heavily early on because of the higher level of access CRISPR has to blood cells. *Id.* She also believes that CRISPR therapies could arise within about ten years. *Id.*

252 *See generally Understand NIH: Finding the Right Fit for your Research*, NATIONAL INSTITUTES OF HEALTH, http://grants.nih.gov/grants/understanding-nih.htm [https://perma.cc/K4YV-2J33] (introducing a background into the NIH's grant program).

253 *See generally id.* (emphasizing the NIH's broad and deep history in determining a study's fitness for grant funding). *See also* Ben Merriman, *"Editing": A Productive Metaphor for Regulating CRISPR*, 15 AM. J. OF BIOETHICS 62 (Dec. 2, 2015) (stating that "regulation is a metaphorical practice"). "In most cases, regulation involves drawing an analogy between something new in science and something that is already regulated." *Id.*

254 *See generally* NAT. INST. OF HEALTH https://www.genome.gov/10001204/specific-genetic-disorders/ [https://perma.cc/BVF4-WEVP] (showing that the number of genetic diseases is large). There is no legitimate way to differentiate between and prioritize treating one disease over another. *Id.*

255 *See, e.g.*, *HIV and AIDS in the United States of America*, AVERT (updated July 22, 2016), http://www.avert.org/professionals/hiv-around-world/western-central-europe-north-america/usa [https://perma.cc/2ARK-YMGW] (reflecting the 1.2 million people inflicted with HIV/AIDS in the United State in 2013).

256 *See* Kahn, *supra* note 42 (stating that different groups need to come together to contribute in order to solve these problems).

257 *See* Regaledo, *supra* note 244 (reiterating the intent of this proposal to facilitate research involving CRISPR to a greater degree).

258 *Cf.* 81 Fed. Reg. 15,315 (Mar. 22, 2016) (Providing the language of the NIH's newly adopted guidelines for awarding research grants).

from private entities.[259] Conducting research on viable human embryos would be entirely prohibited by this act until sufficient progress was made through research that a reassessment would be warranted.[260]

As a final consideration, what consequences should be faced by those institutions that engage in research on what some would consider frivolous, or purely cosmetic uses of CRISPR?[261] This would be addressed two-fold.[262] First, institutions that use private funds to research CRISPR's potential as a cosmetic tool would receive no penalty because no misuse of government funds occurred.[263] Second, and most importantly, institutions that conduct research using CRISPR on viable human embryos would receive monetary sanctions and the research project would be terminated.[264] This is arguably a harsh penalty for an institution not partaking in the use of government funds directly.[265] However, one of the central purposes of this legislation is to dissuade and prevent research that could result in irreparable harm and is still considered to be unethical by some.[266] If institutions that apply for funds with outward intentions that meet the above criteria, but in fact use the funds to study a non-included purpose of CRISPR, possible sanctions could be enforced.[267] This does not appear to be a significant concern at the present time, but the institution would likely have their funding revoked, and would be reviewed further according to NIH guidelines.[268]

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[259] *See* Intellia, *supra* note 27 (discussing two companies competing to use CRISPR in clinical trials).

[260] *See generally* Abumrad & Krulwich, *supra* note 35 (moving in the direction of Jennifer Doudna's proposal that we should not be editing viable human embryos until we know much more about the process, and after coming to a societal consensus on how far we should go with gene editing).

[261] *See, e.g.*, Abumrad & Krulwich, *supra* note 35 (discussing the theoretical possibility of turning a Chihuahua into a Great Dane by using CRISPR).

[262] *See supra* Part IV (breaking down the contribution's proposal into two parts).

[263] *See, e.g.*, Intellia, *supra* note 25 (exemplifying a company that will be using CRISPR in various settings). Intellia was founded by co-inventor of CRISPR, Jennifer Doudna. *Cf. id.* Intellia made its initial public offering (IPO) earlier in 2016. *Id. See also* Editas, *supra* note 25 (adding more information about the company's goals in using CRISPR).

[264] *See, e.g.*, Begley, *supra* note 42 (exemplifying an institution that could theoretically be penalized in such manner). Although the University of Pennsylvania has not been awarded the distinction of housing this study, researchers from the university were the ones that received approval from the NIH. *Id.*

[265] *Cf.* Collins, *supra* note 64 (stating a necessity to combat the ethical concerns held by many; without repercussions, oversight is less likely to be taken seriously).

[266] *See* Doudna, *supra* note 13, at 11:55 (raising concerns about whether our society is ready for human germline editing).

[267] *See, e.g.*, Abumrad & Krulwich, *supra* note 35 (using examples such as changing the species of a dog or raising extinct species of animals like the wooly mammoth).

[268] *See generally* Begley, *supra* note 42 (describing the first clinical trial application to be approved).

B. Commentary

Many may argue that this act would be unnecessary because the NIH has already amended their guidelines to accommodate CRISPR.[269] Indeed, the NIH amended their guidelines in 2015 after previously suggesting it would not do so.[270] However, this act is not simply a directive to the NIH.[271] It is instead Congress taking considerations on how a controversial piece of technology will be handled by independent research institutes.[272] How research institutes will handle ethical considerations as well as what types of studies will be funded by the NIH, and deciding what types of studies will still be impermissible with private funding remain critical issues.[273] Studies are becoming more common, and scientists have been successful in altering traits in human cells.[274] It seems to be only a matter of time before treatments and cures are on the horizon.[275] Therefore, a legislative plan should be put in place for making such medical treatments affordable and available.[276]

The national debt and the use of taxpayer money are hot issues in today's politics.[277] In turn, both issues have been considered in the formation of this proposal.[278] There is tremendous research on the monetary cost of a mentally and physically unhealthy population in America.[279] This act is certainly not capable of curing the country's numerous ailments overnight, but as a long-term investment, an act like

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[269] *See* 81 Fed. Reg. 15,315 (Mar. 22, 2016) (reflecting the recent amendments to the NIH guidelines which were implemented in order to accommodate CRISPR).

[270] *See* Collins, *supra* note 64 (stating that the NIH has no intention to become involved with gene editing at any point in the near future).

[271] *See* NAT. INST. OF HEALTH, *supra* note 245 (reiterating the true purpose of the proposed act).

[272] *See id.* (putting trust in Congress partly because of its unique relationship with the American people, who should be providing their input on this issue).

[273] *See generally Understand NIH*, *supra* note 252 (showing the task set out the NIH and the NIH's partner institutions of determining which studies will receive federal research grants from the NIH).

[274] *See, e.g.*, Begley, *supra* note 154 (discussing progress in a study researching Sickle Cell in mice).

[275] *See generally* Begley, *supra* note 42 (discussing the steps being taken to take CRISPR to human trials).

[276] *See* Skerrett, *supra* note 49 (reflecting concern about CRISPR treatments becoming available to only the wealthy).

[277] *See* Jake Miller, *Issue Brief: Debt and Deficit*, CBS NEWS (October 1, 2012), http://www.cbsnews.com/news/issue-brief-debt-and-deficit/ [https://perma.cc/H3PD-L5KA] (highlighting concerns about mandatory spending contributing toward the deficit).

[278] *Cf.* NIH, *supra* note 247 (noting that the NIH receives about $31 billion in funding annually).

[279] *See, e.g.*, MAYO CLINIC HEALTH SOLUTIONS http://www.tcyh.org/employers/downloads/Extra_MayoCostOfHealth.pdf [https://perma.cc/XB8S-V6DU] (stating that employee illness cost employers $47 billion in productivity loss).

this has the potential to put more money in the pockets of citizens.[280] A healthier population logically leads to a healthier and more vibrant economy at the cost of a short-term investment.[281]

One might criticize this proposal as one that comes woefully short of addressing all of the relevant issues faced with CRISPR, and that individual would not be wrong in saying so.[282] The ethical issues are numerous, the uncertainty in the technology remains, and the potentially beneficial uses of CRISPR grow by the day.[283] However, the issues this proposed legislation raises and attempts to remedy are narrow.[284] Ideally, similar narrowly-tailored acts would follow to address concerns raised in other fields such as animal rights, world hunger, and agriculture.[285] But this act is intended as a remedy to the ailments of public health, and CRISPR is better positioned to accomplish that goal than any other scientific discovery of our time.[286]

V. CONCLUSION

After the advent of CRISPR/Cas9, the scientific community is clamoring not only about CRISPR's medical potential, but also the emanating ethical concerns. Some fear that editing the human germline is dangerous. These types of changes to viable human embryos will be passed down to later generations. There are also concerns about where the technology is right now. There is still progress to be made in accuracy and reliability before CRISPR can be used on humans on a large scale. Others, however, are more concerned about challenges to be faced further down the road such as keeping gene therapy costs low or having too much control over the genes of our children.

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280 *See generally* Anna Louise Sussman, *Burden of Healthcare Costs Shifting to the Middle Class*, WALL ST. J. (Aug. 25, 2016), http://www.wsj.com/articles/burden-of-health-care-costs-moves-to-the-middle-class-1472166246 [https://perma.cc/KK94-H65H] (noting the rapidly increasing healthcare costs for Americans, partly caused by health conditions).

281 *See generally id.* (reflecting the increasing amounts of money Americans are spending on health care).

282 *See* Regalado, *supra* note 34 (discussing the numerous issues with CRISPR that are not directly addressed here).

283 *See, e.g.*, Begley, *supra* note 248 (exemplifying the continuing progress for treating diseases of the blood with CRISPR). The article also notes that the technology is still being perfected as it still has the potential for unintended genetic mutations. *Id.* "The errors occurred in less than 0.10 percent of the cells tested, which is still a concerning number." *Id.*

284 *See supra* note 181 (reiterating the focus of this proposal on the investment in funding for clinical trials for CRISPR while other uses for CRISPR may be just as valid).

285 *See generally* Zaret, *supra* note 107 (proposing the introduction of a committee that would sift through different bills pertaining to CRISPR).

286 *See* Chestnut, *supra* note 19 (discussing the overall purpose of this proposed act to be a step toward curing and treating genetic diseases).

The quickly advancing science surrounding CRISPR is outpacing the relevant law by years, even decades. The Dickey-Wicker Amendment remains as an obstacle for researchers that want to study CRISPR in human embryos. These problems are most efficiently remedied by new legislation introduced and enacted by Congress. Such legislation would not only provide and direct funds to be utilized for research on CRISPR, but it would also address many of the related ethical concerns. Congress should introduce a bill that repeals the Dickey-Wicker Amendment.

Such a unifying cause, such as genetic illnesses, is sufficient reason to come to a compromise on how to fully take advantage of this truly revolutionary technology. Jennifer Doudna has called for a "worldwide conversation" on the ethical considerations of CRISPR. The purpose of which is that we, as a society, should decide what steps we are willing to take to achieve such desired goals as curing and treating genetic disease. The scientific community has come to a consensus on CRISPR's benefits; now it is time for lawmakers and our community as a whole to ensure that this powerful tool will be utilized effectively and responsibly for the years to come.

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