CRISPR's Creatures: Protecting Wildlife in the Age of Genomic Editing

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Abstract

Recent advances in genome editing technology have opened the door for scientists to explore beneficial applications of genome editing for wildlife biodiversity and public health. These advances, referred to as the CRISPR toolkit in this Article, can be combined with gene drives to repair damaged ecosystems, enhance conservation efforts, save endangered species, address climate change, prevent diseases, and promote public health. However, the introduction of edited creatures could also negatively impact the original species and disrupt the surrounding ecosystem. Moreover, humanity's power to manipulate wildlife genes and essentially create evolution by artificial selection also poses significant moral, ethical, and social concerns.

Existing statutes and regulations do not sufficiently address the application of this novel genome editing technology to wildlife. First, the federal regulatory regime for biotechnology is outdated, incohesive, and does not efficiently address concerns stemming from use of the CRISPR toolkit. Second, statutory and regulatory language related to predecessor gene editing technologies' is too narrow to cover the CRISPR toolkit. Third, the CRISPR toolkit and wildlife editing technology are not regulated under environmental statutes and regulations.

Given this regulatory gap, this Article argues that the United States should join the Convention on Biological Diversity and use the treaty's implementing legislation to identify appropriate limitations on the use of the CRISPR toolkit and gene drives. States governments and industry leaders can also prevent negative impacts of wildlife editing by incorporating the ideals expressed in the Convention on Biological Diversity into their regulations and bylaws. Ultimately, the Convention on Biological Diversity provides the best, most forward-looking framework through which to regulate gene editing to protect wildlife during the continued rise of the CRISPR toolkit.

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Introduction

Scientists have discovered a revolutionary molecular tool that can rewrite the code of life and spread genome changes through wild species at an accelerated pace. CRISPR-Cas9, commonly referred to as CRISPR,[1] represents a paradigm shift in genetic modification. CRISPR-Cas9 is just one of many combinations of CRISPR that exist and that will continue to be discovered.[2] In this Article, the CRISPR toolkit is used to refer to existing combinations such as CRISPR-Cas9, and also future combinations of CRISPR systems. Researchers have discovered that CRISPR-Cas9 can be combined with gene drives to disrupt the traditional norms of evolutionary biology. This Article uses "wildlife

1. CRISPR stands for "clustered regularly interspaced short palindromic repeats." Marcy E. Gallo, et al., Cong. Research Serv., R44824, Advanced Gene Editing: CRISPR-Cas9, at 1 (2017) [hereinafter 2017 CRS Report]. Outside of the scientific community, CRISPR is commonly used to refer to CRISPR-Cas9. However, CRISPR-Cas9 is just one of many variations of CRISPR that exist and that will continue to be discovered.

2. Currently, CRISPR-Cas9 is the most widely used combination of CRISPR.

editing" to refer to the combination of gene drives with CRISPR-Cas9, or any subsequent mechanism within the CRISPR toolkit which will be applied to wildlife animals. This process allows scientists to deliberately edit an animal's genome to spread changes through generations of a species.

Today, CRISPR largely escapes regulation under rules that cover traditional genome editing technology, raising the concern that there are no legal constraints to protect against unreasonable risks posed by this new tool. The potential benefits of this technology outweigh calls for a moratorium, but the risks involved demand regulation that strikes a delicate balance between supporting both wildlife protection and scientific innovation. Regulatory protections need to be scientifically based, subjected to interdisciplinary review, and defined broadly enough to cover future applications of the CRISPR toolkit. By officially joining the Convention on Biological Diversity, the United States will have an opportunity to craft a cohesive approach to regulating the CRISPR toolkit in its application to nonhumans by drafting the treaty's implementing legislation. This legislation should incorporate the same precautionary principle that is implicit in the treaty and establish a system that addresses risk management and liability, and incorporates transparency. Further, the legislation should incorporate effective language, define the role of relevant agencies, and facilitate the inclusion of the scientific and local communities and cultures. The states—along with the public and private scientific industries—can also protect wildlife against the consequences of this new technology. If the federal government fails to take action, states can create their own guidelines modeled after the principles and ideals set out in the Convention on Biological Diversity. Additionally, the scientific realm can voluntarily assent to self-imposed limitations, continue identifying benefits and risks of the technology, and help raise public awareness of the potential benefits of this new technology.

Outside the scientific community, most commentary surrounding the CRISPR toolkit ignores consequences to wildlife animals.[3] This Article analyzes the CRISPR toolkit's application to wildlife while considering potential legal and regulatory shortcomings. In Part I, this Article provides a summary of the science behind CRISPR and gene drives.[4] Next, Part II explores which existing legal frameworks are the most applicable to the CRISPR toolkit in its

3. *See, e.g.*, Brendan Parent, *Crispr Lit the Fire: Ethics Must Drive Regulation of Germline Engineering*, ABA SciTech Law, Fall 2016, at 18; Eileen M. Kane, *Human Genome Editing: An Evolving Regulatory Climate*, 57 Jurimetrics J. 301, 305–06 (2017); Tara R. Melillo, *Gene Editing and the Rise of Designer Babies*, 50 Vand. J. Transnat'l L. 757, 760 (2017).

4. This paper is limited in scope to heritable genome editing on wild animals through CRISPR applications, with a particular focus on mammals. The law tends to treat animals differently whether they are categized as domestic, agricultural, wildlife, or research. More scholarly commentary has been written about domestic, agricultural, and research animals in the context of genome editing than about wildlife.

use with wild animals. In Part III, this Article suggests new policies for the federal government, state governments, and the scientific community to adopt in relation to wildlife editing and the CRISPR toolkit.

I. Background

The discovery of CRISPR-Cas9 started a revolution in genome editing technology. CRISPR-Cas9 was first introduced by scientists in 2012.[5] Its introduction was followed by patent litigation and further innovation.[6] The CRISPR-Cas9 technique falls within the umbrella of synthetic biology, which is a subset of biotechnology.[7] It uniquely creates multiple edits along the genome using natural processes, with precision, in a cost-effective manner.[8] CRISPR represents chunks of regularly recurring space sequences that naturally arise as an ancient bacterial defense system against viral invasions.[9] In CRISPR-Cas9, a guide RNA (gRNA) directs and assists an enzyme (Cas9, a nuclease) to specific locations along the genome.[10] A genome is an organism's complete set of DNA, including all of its genes.[11] After reaching a specific location, the enzyme, Cas9, acts as molecular scissors by cutting and pasting along the genome.[12] This process allows scientists to program gRNA to seek

5. CRISPR alone was first identified in the 1980s by researchers studying bacterial genes. Adam J. Gross, Comment, *Dr. Frankenstein, or: How I Learned to Stop Worrying and Love Crispr-Cas9*, 56 Jurimetrics J. 413, 415 (2016); *see also* 2017 CRS Report, *supra* note 1, at 32 (providing a timeline of the milestones and development of CRISPR-Cas9 in Appendix A).

6. Patent litigation arose over ownership of the CRISPR-Cas9 technology between Jennifer Doudna's research team at University of California, Berkley and Feng Zhang's research team at the Broad Institute, which is affiliated with Harvard University. The Broad Institute won the bitter legal dispute for patent ownership over the use of CRISPR-Cas9 in eukaryotic cells pursuant to US patent law, which was recently confirmed by a federal appellate court. *Regents of the Univ. of Cal. v. Broad Inst.*, 903 F.3d. 1286, 1296–97 (Fed. Cir. 2018). The effectiveness and merits of patent law protection is beyond the scope of this paper. For further information about the patent dispute, *see* Gross, *supra* note 5, at 417–19; *see also* Kane, *supra* note 3, at 305–06.

7. Synthetic biology is the "design and construction of new biological parts, devices, and systems, and the redesign of existing, natural biological systems for useful purposes." *Synthetic Biology*, Nature, https://www.nature.com/subjects/synthetic-biology [https://perma.cc/WA5W-5C9U]; 2017 CRS Report, *supra* note 1, at 20 n.77.

8. 2017 CRS Report, *supra* note 1, at 1–2; Gross, *supra* note 5, at 417, 420–21; Alison Peck, *Re-Framing Biotechnology Regulation*, 72 Food & Drug L.J. 314, 317 (2017).

9. Irus Braverman, *Editing the Environment: Emerging Issues in Genetics and the Law*, *in* Gene Editing, Law, and the Environment: Beyond the Human 1, 3 (John Paterson & Julian Webb eds., 2018) [hereinafter Braverman]; *Gene Drives FAQ*, Wyss Inst. at Harv. Univ., https://wyss.harvard.edu/faqs-gene-drives [https://perma.cc/8F7Y-V8RB] [hereinafter Wyss Inst.] ("Scientists drew their inspiration for the CRISPR tool from a sophisticated form of bacterial self-defense.").

10. RNA stands for ribonucleic acid and is a nucleic acid present in all living cells. Guide RNA are essentially space sequences. 2017 CRS Report, *supra* note 1, at 2.

11. *Id.* at 1 n.4.

12. *See* Irus Braverman, *Gene Drives, Nature, Governance: An Ethnographic*

out precise DNA sequences in the genome to be edited through the insertion, replacement, or deletion of the desired gene sequences, and can be used in many different species.[13] Additionally, scientists can use gRNA to target genes along the genome to apply epigenetics, which regulates the expression of genes without modifying the underlying DNA.[14] Although Cas9 is the most commonly used enzyme combination, it is not the only one available with CRISPR.[15] Researchers are constantly searching for other implementations and variations of CRISPR to expand the CRISPR toolkit. The law has been criticized for its slow pace in responding to rapid scientific developments.[16] To avoid such criticism in the future, it is important to consider the development of future CRISPR combinations when designing regulations that will anticipate and address any potential issues.

Not long after the discovery of CRISPR-Cas9, mammalian genes were edited using this tool.[17] CRISPR-Cas9 can genetically modify animal and human cells and shows promise as an *in vivo* method for mammalian genetic modification.[18] As will be discussed below, CRISPR-Cas9 combined with gene drives can disrupt traditional norms of evolution and spread edits rapidly throughout populations. In turn, wildlife editing could be used to help solve climate change problems, promote public health, prevent diseases, improve conservation efforts, as well as solve problems related to invasive species. Yet, the novelty and unique characteristics of the CRISPR toolkit raises various legal, ethical, moral, and cultural questions. For example, wildlife editing has

Perspective, *in* Gene Editing, Law, and the Environment: Beyond the Human 55, 57 (John Paterson & Julian Webb eds., 2018) [hereinafter Braverman II].

13. Wyss Inst., *supra* note 9.

14. 2017 CRS Report, *supra* note 1, at 2; Danielle Simmons, *Epigenetic Influences and Diseases*, Nature Edu. (2008), https://www.nature.com/scitable/topicpage/epigenetic-influences-and-disease-895 [https://perma.cc/T5KD-TPSJ] (describing epigenetics as a process that essentially creates "on-off" switches for the genes to determine which proteins are transcribed without disturbing the targeted gene).

15. Not long after the initial discovery of CRISPR-Cas9, other variations that have already been identified include combining CRISPR with Cas3, Cas13, or Sherlock. *See* Sarah Buhr, *Move over Cas9, CRISPR-Cas3 Might Hold the Key to Solving the Antibiotics Crisis,* TechCrunch, https://techcrunch.com/2016/12/21/move-over-cas9-crispr-cas3-might-hold-the-key-to-solving-the-antibiotics-crisis [https://perma.cc/B528-U7D9] (combination with Cas3); Omar O. Abudayyeh et al., *RNA Targeting With CRISPR-Cas13*, 550 Nature 280 (2017), https://www.nature.com/articles/nature24049 [https://perma.cc/7TSZ-QYLX] (application of Cas13); *Scientists Unveil CRISPR-based Diagnostic Platform*, Broad Inst. (Apr. 13, 2017), https://www.broadinstitute.org/news/scientists-unveil-crispr-based-diagnostic-platform [https://perma.cc/H5HZ-6B6Q] (combination with SHERLOCK).

16. Braverman, *supra* note 9, at 13.

17. Braverman, *supra* note 9, at 3; Ian Tucker, *Genetically Engineered Animals*, Guardian (June 24, 2018), https://www.theguardian.com/environment/2018/jun/24/genetically-engineered-animals-the-five-controversial-science [https://perma.cc/9R7P-7PX9].

18. *In vivo* refers to conducting an experiment with an organism in its natural habitat while *in vitro* refers to experimentation in an artificial environment, such a test tube. Gross, *supra* note 5, at 423.

the potential to wipe out entire species considered harmful to humans—or other animals that are simply disliked by the public. However, these risks can be controlled for, and gene drives can be used to deliver significant benefits to wildlife and humans so long as adequate safety measures are put in place to protect the environment and human health. One way to ensure such protections are brought about is to adopt the precautionary principle, as is ingrained within the Convention of Biological Diversity, which is discussed later in this Article.

A. *CRISPR's Predecessors*

The CRISPR toolkit is unique when compared to predecessor technologies and techniques that edited the genetic code of animals. One professor compared the impact of the CRISPR revolution to that of the creation of the Model-T Ford because it was far from the first technology of its kind to be created, but one whose simplicity of production, dependability, and affordability transformed society.[19] Smaller public and private laboratories can be involved in this innovation due to the CRISPR toolkit's flexibility and availability.[20] To those outside of the scientific realm, the intricacies and distinctions between the CRISPR toolkit and predecessor technologies are not always clear, but at their core, they differ both in their goals and the processes they use to manipulate genetic codes.

Prior to the CRISPR revolution, gene editing techniques allowed scientists to manipulate DNA sequences and create gene-editing varieties within individual animals.[21] These techniques were time-intensive, costly, and constrained to single edits of genes within the genome.[22] In contrast, the CRISPR toolkit can target multiple genes simultaneously, known as genomic editing, with speed and precision while maintaining cost-effectiveness and wide accessibility.[23]

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19. Braverman, *supra* note 9, at 3 (quoting Professor Henry Greely of Stanford Law School).

20. Peck, *supra* note 8, at 315.

21. These gene editing techniques included zinc finger nuclease (ZFNs) and transcription activator-like effector-based nucleases (TALENs). These techniques are similar in that they deliberately manipulate DNA to create desirable changes. *See Gene Editing/CRISPR*, Genetic Literacy Project, (Oct. 23, 2018), https://geneticliteracyproject.org/category/gene-editing [https://perma.cc/3BGE-H9UC]; Jeffrey M. Perkel, *Genome Editing with CRISPRs, TALENs and ZFNs*, Biocompare (Aug. 27, 2013), http://www.biocompare.com/Editorial-Articles/144186-Genome-Editing-with-CRISPRs-TALENs-and-ZFNs [https://perma.cc/TY93-Q3FH].

22. *See What is CRISPR-Cas9*, Your Genome, *https://www.yourgenome.org/facts/what-is-crispr-cas9*; Parent, *supra* note 3 (discussing the downfalls of traditional gene editing techniques such as TALENs and ZFNs as being expensive and time-consuming); 2017 CRS Report, *supra* note 1, at 2.

23. Gross, *supra* note 5, at 420–21 (identifying previous techniques requiring "laborious alterations to conduct the genetic modifications of different organisms" whereas CRISPR-Cas9 "eliminates this need, as the same protein and system works in all organisms."); Parent,

Conventional genetically modified organisms (GMOs), cloning, and other predecessor biotechnology advances are also distinguishable from CRISPR. Mammalian cloning involves the manipulation of an animal or human cell to grow a virtual copy of the animal or human with identical nucleic DNA.[24] Thus, cloning creates identical genes, whereas the CRISPR toolkit *transform*s the genes.[25] Also, in contrast to human cloning, nonhuman mammalian cloning has not been banned in the United States.[26]

Conventional GMOs arose in the 1970s and 1980s and immediately attracted controversy. These forms of genetic engineering were widely criticized by the public for violating the natural order.[27] Conventional GMOs are created by transgenic editing, a process in which the genes of one organism are deliberately introduced and incorporated within another.[28] "Genetically modified" is used to refer to different concepts but is used most often to refer to plants and animals that have been altered in a way that would not have arisen naturally.[29] Many laws drafted in response to GMOs explicitly emphasize that unnatural process, specifically how these transgenic procedures leave behind foreign DNA.[30] Similar to other states, California defines transgenic as "[a]n animal whose genome has been deliberately altered, modified, or engineered, through means not possible under natural conditions, by insertion of a foreign

supra note 3, at 18–19; Elizabeth E. Pennisi, *The CRISPR Craze*, 341 Sci. 833, 836 (2013) (discussing affordability of CRISPR and availability of a repository for guide RNAs in the Addgene database).

24. *See Cloning Fact Sheet*, Nat'l Human Genome Research Inst., https://www.genome.gov/25020028/cloning-fact-sheet/#al-1 [https://perma.cc/4UNY-7B48].

25. To put it another way, with cloning, the genotype in question already exists. *Id.*

26. Unlike with humans, there is no legal ban on cloning animals and federal agencies have even approved cloned animal products. *Animal Cloning*, FDA (last updated Aug. 28, 2018), https://www.fda.gov/animalveterinary/safetyhealth/animalcloning/default.htm [https://perma.cc/32Q7-M4K8]; Rob Stein, *Chinese Scientists Clone Monkeys Using Method That Created Dolly the Sheep*, NPR News (Jan. 24, 2018), https://www.npr.org/sections/health- shots/2018/01/24/579925801/chinese-scientists-clone-monkeys-using-method-that-created-dolly-the-sheep [https://perma.cc/QA6W-ZYXM] (reporting on the how Chinese scientists recently replicated the same method in monkeys that was used on Dolly the Sheep, the first successful animal clone in 1996).

27. David Rotman, *Gene Editing Could Rewrite the GMO Debate*, MIT Tech. Review (Dec. 19, 2017), https://www.technologyreview.com/s/609805/gene-editing-could-rewrite-the-gmo-debate [https://perma.cc/VA5G-MANH].

28. Transgenics refers to the process by which a gene from one species is deliberately introduced and incorporated within another species. Kane, *supra* note 3, at n.9; David Warmflash, *Does CRISPR gene editing = GMO? Biotechnology Skeptics May Split on How to Regulate New Breeding Technologies*, Genetic Literacy Project (Aug. 21, 2016), https://geneticliteracyproject.org/2016/08/21/crispr-gene-editing-gmo-biotechnology-skeptics-may-split-regulate-new-breeding-technologies [https://perma.cc/N9BB-LWPV].

29. *See* Kenneth Chang, *These Foods Aren't Genetically Modified but They Are 'Edited'*, The N.Y. Times (Jan. 9, 2017), https://www.nytimes.com/2017/01/09/science/genetically-edited-foods-crispr.html [https://perma.cc/YK77-HJC6] (discussing the differences between conventional GMOs and CRISPR in the agricultural context).

30. Braverman, *supra* note 9, at 4; Peck, *supra* note 8, at 317.

gene or genes using genetic engineering methods."[31] In contrast, the CRISPR toolkit seeks to change existing DNA, but does not insert foreign DNA.[32] While the CRISPR toolkit can create transgenic editing, such use is uncommon and not the focal point of the new technology.[33] Since the CRISPR toolkit involves the manipulation of naturally-occurring processes, it may differ enough from GMOs to avoid the same criticisms faced by those processes.[34] These crucial distinctions also suggest that the CRISPR toolkit falls within the loopholes of law and policy covering the prior technologies, which are further discussed in Part II of this Article.

B. *Combining CRISPR With Gene Drives*

The CRISPR toolkit provides the possibility for scientists to use man-made gene drives to change the traditional norms of evolutionary dynamics and natural selection of mammalian inheritance. Essentially, wildlife editing can be used to manipulate and distort normal patterns of inheritance. Through reproduction, a mammalian offspring inherits a copy of a gene from each parent.[35] If one parent has a mutated gene, the offspring has a 50 percent chance of inheriting the same mutation.[36] Even if the offspring inherits the mutated gene, natural selection and environmental factors traditionally limit the incidence of mutations over generations, resulting in the mutated gene dying out and not affecting the genetic codes of the overall species.[37]

A gene drive is a systematic technique that creates a bias inheritance pattern during reproduction and causes modified DNA to copy itself into the DNA from the unmodified parent.[38] The idea of gene drives is not new, but previous techniques could not successfully implement them because they were unable to alter multiple genes in one setting.[39] CRISPR-based gene drives

31. *Compare* Cal. Code Regs. tit. 14, § 1.92 (1990) *with* Mich. Comp. Laws Ann. § 286.905(a) (West 2018) (defining genetically modified organism as "substances or their derivatives created by genetic engineering techniques that alter the molecular or cell biology of an organism *by means that are not possible under natural conditions or processes*.") (emphasis added); *see also* Warmflash, *supra* note 28.

32. Braverman, *supra* note 9, at 4.

33. *Gene Editing/CRISPR*, *supra* note 21.

34. Braverman, *supra* note 9, at 4; Peck, *supra* note 8, at 317; *But see* 2017 CRS Report, *supra* note 1, at 23 (doubting the ability of CRISPR-Cas9 to escape criticisms of conventional genetic engineering).

35. *The Promise and Peril of Gene Drives*, The Economist (Nov. 8, 2018), https://www.economist.com/briefing/2018/11/08/the-promise-and-peril-of-gene-drives [https://perma.cc/XL3G-37Q9].

36. *See* Brooke Borel, *Genetic Engineering to Clash with Evolution*, Quanta Mag. (Sept. 8, 2016), https://www.quantamagazine.org/gene-drives-will-clash-with-evolution-20160908 [https://perma.cc/8U39-XVSN].

37. *Id.*

38. *Id.*

39. *The Promise and Peril of Gene Drives*, *supra* note 35; 2017 CRS Report, *supra* note 1, at 2.

have the capability of editing multiple genes and can boost the chances that a particular trait will pass from a parent to its offspring from 50 percent to nearly 100 percent.[40] Thus, successful gene drives can drastically improve the probability that an altered gene (a mutation) will be inherited over subsequent generations and rapidly spread through wild populations.[41]

While the media has focused on the application of CRISPR-based gene drives' to mosquitos in order to combat Zika and malaria,[42] the same technique can be applied to mammals.[43] In theory, gene drives can be combined with the CRISPR toolkit to immunize a species against hazards, suppress a species' population, enhance the species in some beneficial way, or make a species susceptible to an external chemical or biological agent.[44] For example, frogs could be engineered to be resistant to the fungal diseases that are decimating their populations.[45] Populations of invasive rodents, which are among the primary drivers of native species declines on certain islands, could be reduced by editing genetic codes to favor male offspring.[46] For now, however, wildlife editing remains in the early stages of research.

Artificial gene drives are already being introduced into the environment, and scientists are hopeful that they will one day be able to target almost any trait for editing.[47] The U.S. Defense Advanced Research Projects Agency (DARPA), a branch of the U.S. Department of Defense, is currently the world's largest investor in research for applying the combination of gene drives and the CRISPR toolkit to wildlife.[48] Given recent research and invest-

40. Kevin M. Esvelt first identified how CRISPR-Cas9 and gene drives can work together. *See* Kevin M. Esvelt, *Rules for Sculpting Ecosystems: Gene Drives and Responsive Science*, *in* Gene Editing, Law, and the Environment: Beyond the Human 20, 25–27 (John Paterson & Julian Webb eds., 2018).

41. *See* Braverman II, *supra* note 12, at 63; Esvelt, *supra* note 40, at 25–27.

42. *See, e.g.*, Braverman II, *supra* note 12, at 65–69 (discussing gene drive application to mosquitos that has been in popular news sources).

43. Early research indicates that gene drives can work in lab mice, although not yet as efficiently as gene drives in insects. Jon Cohen, *Gene Drive Passes First Test in Mammals, Speeding Up Inheritance in Mice*, Sci. Mag. (Jul. 10, 2018), http://www.sciencemag.org/news/2018/07/gene-drive-passes-first-test-mammals-speeding-inheritance-mice [https://perma.cc/47M6-5BWL].

44. Jennifer Kuzma & Lindsey Rawls, *Engineering the Wild: Gene Drives and Intergenerational Equity*, 56 Jurimetrics J. 279, 280–86 (2016).

45. *See* Ronald Sandler, *Gene Drives and Species Conservation: An Ethical Analysis*, *in* Gene Editing, Law, and the Environment: Beyond the Human 39, 47 (John Paterson & Julian Webb eds., 2018).

46. *Id.* at 44–45.

47. *See* 2017 CRS Report, *supra* note 1, at 3; Braverman, *supra* note 9, at 4–5.

48. In 2017, DARPA announced a $65 million investment in its Safe Genes research initiative. Notably, one of these Safe Genes projects is researching how to reverse the effects of a negative edited gene spreading through wildlife populations. *See* Todd Kuiken, *Vigilante Environmentalism*, *in* Gene Editing, Law, and the Environment: Beyond the Human 95, 101–105 (John Paterson & Julian Webb eds., 2018); Ewen Callaway, *US Agencies Tackle Gene Drives*, 547 Nature 388 (July 27, 2017), (stating that DARPA said it will comply with

ment interest, CRISPR-based gene drives could disrupt the traditional norms of natural selection and establish evolution by artificial selection sooner than previously imagined.

C. *Benefits*

As applied to wildlife editing, the CRISPR toolkit has the potential to turn genetic sequences into revolutionary biological solutions. Supporters come from various industries, including the scientific community at large, conservationists, philanthropists, businesses, and the world's largest biotechnology trade organization.[49] Many enthusiasts are drawn to the CRISPR toolkit because it promotes the greater good by offering humane and efficient strategies for solving numerous problems affecting both wildlife and humans.[50] Wildlife editing offers a solution to "ecological problems using biology, not bulldozers and poisons."[51] This biological tool could be used to benefit society by: (1) providing public health benefits and disease prevention; (2) mitigating climate change impacts and building climate change resilience, (3) restoring ecosystems damaged by human activities and urbanization; (4) strengthening endangered species survival; (5) controlling invasive species damage, (6) generating economic growth, such as through ecotourism; and (7) providing novel solutions to current climate change problems, such as facilitating de-extinction.

One reason to apply the CRISPR toolkit to animals is to improve the health and safety of both animals and humans. Potential animal health benefits include the elimination of disease and improved disease resistance.[52] Animals could also be genetically modified with the CRISPR toolkit in ways that benefit humans by treating and preventing human health issues.[53] Wildlife edits

stringent biosafety conditions, disclose planned experiments to the public, and take measures that should reduce the risk of accidental release); *Building the Safe Genes Toolkit*, Genetic Biocontrol of Invasive Rodents, http://www.geneticbiocontrol.org/building-the-safe-genes-toolkit [https://perma.cc/BAJ5-8TG5] (identifying that the funded research involves gene drive and genetic remediation technologies in mammals).

49. *See* Sandler, *supra* note 45, at 45 (noting support from the conservationist community); *Animal Genome Editing*, Biotech. Innovation Org., https://www.bio.org/toolkit/issue-briefs/animal-genome-editing [https://perma.cc/2NAD-QXK8] (expressing support for animal genome editing from the biotechnology trade organization); *The Promise and Peril of Gene Drives*, *supra* note 35 (conveying support from the Bill & Melinda Gates Foundation).

50. *See e.g.*, Amy Harmon, *Open Season is Seen in Gene Editing of Animals*, N.Y. Times (Nov. 26, 2015), https://www.nytimes.com/2015/11/27/us/2015-11-27-us-animal-gene-editing.html [https://perma.cc/J8HN-3FJV]; Sara Reardon, *Welcome to the CRISPR Zoo*, 531 Nature 160, 161 (2016), https://www.nature.com/news/welcome-to-the-crispr-zoo-1.19537 [https://perma.cc/34EE-6NWD].

51. Esvelt, *supra* note 40, at 23.

52. *See* Braverman II, *supra* note 12, at 60 (pointing to the potential use of CRISPR and gene drives to reduce pain and suffering in animals).

53. Various proposals have been made to edit animals to bring about agricultural, domestic, and research benefits for humans. *See e.g.*, Reardon, *supra* note 50 (describing proposals to make various edits in agricultural animals, such as in chickens to make hypoallergenic eggs, in pigs to eliminate a flu virus affecting humans, and in goats to treat

could be a solution to growing public health concerns over the prevention, treatment, and control of emerging infectious diseases. Infectious diseases are often caused by zoonotic diseases, which are diseases spread between humans and animals.[54] According to the Center for Disease Control, zoonoses cause 2.7 million deaths and 2.5 billion cases of sickness each year throughout the world.[55] Furthermore, more than half of all infectious diseases in humans are spread by animals.[56] Various for-profit companies have made headlines because of their gene drive research related to preventing vector-borne human diseases, considering solutions such as eliminating Zika-carrying mosquitos.[57]

In addition to helping to combat the growing concern surrounding zoonotic diseases, wildlife editing may also be used to alter animals to better withstand diseases and to limit their pain and suffering. For example, wildlife editing could eliminate the deadly heritable diseases currently plaguing bat populations.[58] Gene drives could also be used to prevent mice from transmitting Lyme disease to ticks, thereby reducing the incidence of Lyme disease in the northeastern United States.

Wildlife editing could also be used to preserve genetic diversity that is being lost due to climate change. There is a growing urgency for wildlife and biological diversity protections because climate change is increasingly threatening various species' habitats and survival.[59] Climate change is causing historically high extinction rates by disrupting animal migration patterns, shrinking natural habitats through rising sea levels, and dislocating species through shifting climate zones.[60] These observations were supported by a recent report by the

human illnesses associated with modified goat milk); *Gene Editing May Make Pigs Into Organ Donors for People*, Economist (Aug. 12, 2017), https://www.economist.com/news/science-and-technology/21726057-retrofitting-pig-genomes-gene-editing-may-make-pigs-organ-donors-people [https://perma.cc/7RCJ-5RYS] (describing how CRISPR is being used to edit research animals for xenotransplantation to grow human organs for transplantation).

54. Rabies is one example of a zoonotic disease spread between mammals and humans. *See Managing public health risks at the human-animal-environment interface*, World Health Org., https://www.who.int/zoonoses/en; *Saving Lives by Taking a One Health Approach*, Ctrs. for Disease Control & Prevention 3, https://www.cdc.gov/onehealth/pdfs/OneHealth-FactSheet-FINAL.pdf [https://perma.cc/4H2F-LAXR].

55. *Saving Lives by Taking a One Health Approach*, *supra* note 54.

56. *Id.*

57. *See* Braverman II, *supra* note 12, at 65–66 (discussing Oxitec's application of gene drives to mosquitos); *see also* AquaBounty, http://aquabounty.com/innovation/technology [https://perma.cc/L5GC-MSJU] (salmon); Oxitec, https://www.oxitec.com [https://perma.cc/8U3S-G2AX] (mosquitos); Recombinetics, http://www.recombinetics.com [https://perma.cc/9MF8-GVM9] (agricultural animals).

58. Sandler, *supra* note 45, at 47.

59. Secretariat of the Convention on Biological Diversity, Sustaining Life on Earth: How the Convention on Biological Diversity Promotes Nature and Human Well-Being 5–6 (2000), https://www.cbd.int/doc/publications/cbd-sustain-en.pdf [hereinafter "*Sustaining Life on Earth*"].

60. *Species and Climate Change*, ICUN, https://www.iucn.org/resources/issues-briefs/species-and-climate-change; Sandler, *supra* note 45, at 42; *see, e.g.*, *Conserve Elephants. They*

Intergovernmental Panel on Climate Change that predicts dire consequences for biodiversity due to increasing global temperatures.[61] In fact, the world's four hottest years on record are between 2014 and 2018.[62] Despite growing awareness surrounding the problem of climate change, political leadership on the matter, particularly within the United States, has remained stagnant.[63] Until politicians mobilize against climate change, scientists can buy species time by genetically altering them to make them more resilient to climate change.

In the realm of species conservation, wildlife editing could be used to make threatened and endangered species better equipped to adapt to environmental changes and defend against potentially devastating pathogens.[64] According to the International Union for Conservation of Nature, nearly a quarter of all mammalian species are threatened.[65] Between 1970 and 2012, global populations of fish, birds, mammals, amphibians and reptiles declined by 58 percent.[66] Current policy and preservation efforts to protect threatened or endangered species are costly and largely ineffective. In the United States in 2017, states spent a combined over two million dollars on conservation efforts to protect threatened and endangered mammalian species.[67] The affordability of the CRISPR toolkit could allow more species conservation efforts to take

Hold a Scientific Mirror Up to Humans, Economist (June 17, 2017), https://www.economist.com/science-and-technology/2017/06/17/conserve-elephants-they-hold-a-scientific-mirror-up-to-humans [https://perma.cc/RDE6-HL24/ [hereinafter *Conserve Elephants*] (describing the deliberate killing of elephants by poachers, farmers, and cattle herders); *Ecologists Debate Whether Climate Change Helps or Hurts Reindeer*, Economist (Dec. 23, 2017), https://www.economist.com/science-and-technology/2017/12/19/ecologists-debate-whether-climate-change-helps-or-hurts-reindeer [https://perma.cc/9L4N-6U3R] (discussing how the rapid disappearance of Artic sea ice has harmed reindeer).

61. Intergovernmental Panel on Climate Change, Headline Statements from the Summary for Policymakers (Oct. 2018), https://www.ipcc.ch/site/assets/uploads/sites/2/2018/07/sr15_headline_statements.pdf.

62. Press Release, *WMO Climate Statement: Past 4 Years Warmest on Record*, World Meteorological Org. (Nov. 29, 2018), https://public.wmo.int/en/media/press-release/wmo-climate-statement-past-4-years-warmest-record [https://perma.cc/4JAH-ZE4D].

63. Adam Tooze, *Rising Tides Will Sink Global Order*, Foreign Policy (Dec. 20, 2018, 6:29 AM), https://foreignpolicy.com/2018/12/20/rising-tides-will-sink-global-order-climate-change [https://perma.cc/CH4M-G9A6].

64. *See* Braverman II, *supra* note 12, at 63 (quoting Esvelt's position that gene drives increase the chance of rescuing endangered species from extinction).

65. This report uses 'threatened' to describe species listed as critically endangered, endangered, or vulnerable. *The Red List of Threatened Species*, ICUN, https://cmsdocs.s3.amazonaws.com/keydocuments/IUCN_Red_List_Brochure_2015_LOW.pdf [https://perma.cc/C4UW-9APP].

66. *Wildlife Conservation*, World Wildlife Org., https://www.worldwildlife.org/initiatives/wildlife-conservation [https://perma.cc/3TD4-GGQL].

67. *Program Data Report B-2017 Threatened & Endangered Species Conservation Expenditures, Species Group: Mammal*, APHIS USDA, https://www.aphis.usda.gov/wildlife_damage/pdr/PDR-B_Report.php?fy=2017&fld=SPECIES_GROUP&fld_val=MAMMAL [https://perma.cc/8KB5-LDNR].

place. For example, scientists could genetically engineer rhinos to have stunted horns so that they would be less attractive to poachers.[68]

Additionally, the CRISPR toolkit offers a new remedy to problems facing wildlife management. Modern conservation mechanisms are increasingly intertwined with new technological advances, including the use of costly drones, electronic surveillance collars, and satellite tracking.[69] The CRISPR toolkit offers yet another new technological advancement that conservationists can turn to that is cost-effective. The genetic codes of various wildlife creatures could be edited to help them adapt to changes in their habitats caused by climate change and urbanization. Proponents justify this strategy by comparing it to how humans have historically controlled and manipulated habitats and wildlife reserves.[70] From this viewpoint, wildlife editing enables "conservation biologists to do what they already do, only more effectively."[71]

In the context of invasive species control, wildlife editing provides governmental agencies with a cost-effective and humane solution for increasing protections for endangered species and deterring destruction caused by invasive species.[72] Governments have strong economic incentives to explore the benefits of wildlife editing due to the excessive damage caused by invasive species. For example, invasive feral pigs cost the United States 1.5 billion dollars in damages and control costs each year.[73] Current wildlife control measures include trapping, drowning, shooting, and poisoning, each of which are considered to be inhumane by many animal rights activists.[74] These efforts are often labor-intensive, have exorbitant financial costs, and pose harm to other species

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68. *See e.g.*, Sandler *supra* note 45, at 47.

69. *See Conserve Elephants*, *supra* note 60; *Electronic Surveillance May Save the Rhino*, Economist (Nov. 9, 2017), https://www.economist.com/special-report/2017/11/09/electronic-surveillance-may-save-the-rhino [https://perma.cc/6JCA-49KC].

70. Sandler, *supra* note 45, at 46 (comparing the use of CRISPR for conservation efforts to the historical use of captive breeding programs); Ed Yong, *New Zealand's War on Rats Could Change the World*, Atlantic (Nov. 16, 2017), https://www.theatlantic.com/science/archive/2017/11/new-zealand-predator-free-2050-rats-gene-drive-ruh-roh/546011 [https://perma.cc/V9D7-SAJH] (comparing gene drives to a traditional invasive species control mechanism, dropping poison by helicopter, which risked harming unintended target species).

71. Sandler, *supra* note 45, at 46.

72. *The Promise and Peril of Gene Drives*, *supra* note 35; Genetic Biocontrol of Invasive Rodents, http://www.geneticbiocontrol.org [https://perma.cc/2S3S-QLRJ] (providing a list of current research involving the CRISPR toolkit on controlling invasive species).

73. *Feral Swine-Managing an Invasive Species*, APHIS USDA, https://www.aphis.usda.gov/aphis/resources/pests-diseases/feral-swine [https://perma.cc/FE4K-MWAS] (emphasizing the risk that feral swine diseases pose to livestock, cattle, dogs, native wildlife, game species, threatened or endangered animals, and hunters).

74. *Cruel Wildlife Control*, PETA, https://www.peta.org/issues/wildlife/cruel-wildlife-control; Emma Marris, *Process of Elimination*, Wired (Feb. 20, 2018, 6:00 AM),

https://www.wired.com/story/crispr-eradicate-invasive-species [https://perma.cc/LFR3-ZNX4].

who may incidentally become the targets.[75] In 2018, in response to one such inhumane practice, a lawsuit was filed against the United States government on behalf of various animal rights organizations for its inhumane efforts to control the overpopulation of wild horses across the country by performing outdated surgical sterilization procedures.[76] In addition, gene drives could minimize the harmful ecological effects of insecticide and rodenticide use by using targeted modifications.[77] Many conservationists working on islands, which have extremely high rates endangered species and extinctions primarily due to invasive mice and rats, support using gene drives as a humane and effective mechanism to heal damaged ecosystems by reducing or eliminating rodent populations.[78] The New Zealand government has also identified wildlife editing as an option in the context of its "Predator Free" goal, which seeks to save the country's native birds by eradicating invasive pests.[79] With the CRISPR toolkit, the need to employ inhumane practices drastically goes down.

The CRISPR toolkit and wildlife editing offer cost-effective solutions to areas of the world that are disproportionately burdened with environmental degradation and have had less access to beneficial new technologies. The Global North and Global South are terms frequently used when discussing the inequities stemming from globalization.[80] The Global North refers to affluent, developed nations with colonial and postcolonial origins that have historically contributed the most to climate change and resource exploitation of the Global South.[81] The Global South refers to developing nations that have been

75. Gene drive mechanisms appear to have the potential to address difficulties of traditional conservation methods with lower risks than alternative innovations. For example, spraying pesticides affects more than just the target species. *See* Sandler, *supra* note 45, at 40, 45; Hillary Rosner, *Tweaking Genes to Save Species*, N.Y. Times (Apr. 16, 2016), https://www.nytimes.com/2016/04/17/opinion/sunday/tweaking-genes-to-save-species.html [https://perma.cc/GYH3-3HLC].

76. Ellie Kaufman, *Nonprofits Sue to Stop 'Inhumane' Government Project to Sterilize 100 Wild Horses*, CNN (Sept. 25, 2018, 5:34 PM), https://www.cnn.com/2018/09/25/politics/blm-wild-horses/index.html [https://perma.cc/LG6T-HVLC].

77. Braverman II, *supra* note 12, at 55.

78. *The Promise and Peril of Gene Drives*, *supra* note 35; *Sandler*, *supra* note 45, at 44–45.

79. *Exploring New Approaches*, Predator Free 2050 Limited, https://pf2050.co.nz/science/# [https://perma.cc/6VBH-68HU].

80. *See e.g.*, Carmen G. Gonzalez & Sumudu Atapattu, *International Environmental Law, Environmental Justice, and the Global South*, 26 Transnatl. L. & Contemp. Probs. 229, 230–32 (2017).

81. The "Global South" will be used in this Article to refer to the many developing and resource-limited nations in Africa, Asia, South America and parts of Europe, while the "Global North" will be used to refer to the rich, developed countries including the United States, Canada, Australia, New Zealand, Japan and member states of the European Union. In addition to the North-South divide, it is important to consider the role of strong emerging economies of Brazil, Russia, India, China, and South Africa (commonly referred to as "BRICS"). However, these terms do not represent inequalities and inequities existing *within* rich nations because the Global North-South divide is used to reflect the inequalities

burdened by the Global North's economic and political activities.[82] The Global North has often prioritized its own environmental concerns, ignoring those within the Global South even though many governments in the Global South lack the necessary resources and finances to combat environmental crimes and maintain biodiversity.[83] These countries will likely experience harsher impacts from climate changes and lack the necessary resources to combat these issues.[84] The CRISPR toolkit and wildlife editing provides the developing world an opportunity to address biodiversity and species conservation problems using cost-effective technology.

Cultural identities, community relations, and economic sources are deeply connected to surrounding local biodiversity.[85] There are various aesthetic and cultural values of wildlife and ecosystems held by various people within and across nations.[86] The United Nations has emphasized the significance of the intersection between biodiversity and cultural values.[87] The CRISPR toolkit and wildlife editing may enable communities across the world, including racial and ethnic minorities, indigenous peoples, and the poor, to maintain these valuable and strong biodiversity connections by preserving culturally significant species.

Furthermore, there may be economic benefits associated with using the CRISPR toolkit. Wildlife editing could support ecotourism, which is a key source of economic development in the Global South.[88] The CRISPR tool-

across countries. *See e.g.*, Gonzalez & Atapattu, *supra* note 80, at 230–35; Sumudu Atapattu, *Climate Change, International Environmental Law Principles, and the North-South Divide*, 26 Transnatl. L. & Contemp. Probs. 247, 260 (2017); Antoine Van Agtmael, *Think Again: The BRICs*, Foreign Policy (Oct. 8, 2012, 2:08 AM), https://foreignpolicy.com/2012/10/08/think-again-the-brics [https://perma.cc/T88C-39PV].

82. Gonzalez & Atapattu, *supra* note 80, at 230–35.

83. Gonzalez & Atapattu, *supra* 80, at 230–31; *Environmental Crimes are on the Rise, So are Efforts to Prevent Them*, U.N. Env't Programme (Sept. 21, 2018), https://www.unenvironment.org/news-and-stories/story/environmental-crimes-are-rise-so-are-efforts-prevent-them [https://perma.cc/QG59-F5M6].

84. *See, e.g.*, Headline Statements from the Summary for Policymakers, *supra* note 61.

85. *Linking Biological and Cultural Diversity*, Convention on Biological Diversity, https://www.cbd.int/portals/culturaldiversity/docs/Flyer-CulturalDiversity.pdf; *Sustaining Life on Earth*, *supra* note 59, at 6 ("Plants and animals are symbols of our world, preserved in flags, sculptures, and other images that define us and our societies.").

86. Gonzalez & Atapattu, *supra* note 80, at 239–40.

87. *World Heritage and Biodiversity*, UNESCO, https://whc.unesco.org/en/biodiversity; *Linking Biological and Cultural Diversity*, *supra* note 85 ("Cultural practices depend upon specific elements of biodiversity for their existence and expression.").

88. *See How Does Biodiversity Loss Affect Me and Everyone Else?*, World Wildlife Fund, https://wwf.panda.org/our_work/biodiversity/biodiversity_and_you [https://perma.cc/CZ2T-NJHG] ("Nature-based tourism in Africa generates approximately the same amount of revenue as farming, forestry and fisheries combined"); *but see* Gleb Raygorodetsky, *Indigenous Peoples Defend Earth's Biodiversity—But They're in Danger*, Nat'l Geographic (Nov. 16, 2018), https://www.nationalgeographic.com/environment/2018/11/can-indigenous-land-stewardship-protect-biodiversity- (discussing how ecotourism has displaced

kit has also been proposed as a method of increasing output in agricultural animals (i.e., growing longer wool in sheep), promoting disease resistance in agriculture, developing new drugs, and enhancing hunting and the animal sporting industry (i.e., the Kentucky Derby).[89] Additionally, there may be aesthetic motivations behind wildlife editing to make species more visually appealing or enhance certain characteristics rather than to provide medicinal or survival benefits.[90] Supporters may justify aesthetic applications of wildlife editing in that they more humane and precise than historical selective inbreeding that was used to achieve desired characteristics.[91]

Finally, the possibility of "de-extinction" repeatedly comes up whenever a new genetic technology is invented—and the CRISPR toolkit is no exception.[92] Indeed, the CRISPR toolkit may drastically increase the likelihood of reviving extinct species.[93] Ecologists have argued that recently-extinct species with unique functions that can help restore ecological functions should be the first species targeted for de-extinction.[94] That is why scientists have proposed editing the Asian elephant to bring the woolly mammoth back from extinction.[95] Reviving the woolly mammoth would not just serve human interest in seeing an iconic animal, it could help slow the effects of climate change by converting Arctic tundra, which releases extreme levels of carbon dioxide as it melts, back to grasslands.[96] Thus, bringing species out of extinction presents yet another way in which the CRISPR toolkit and wildlife editing can be used to tackle some of today's most vexing problems.

D. *Concerns*

Human power over wildlife editing is accompanied with significant risk. The CRISPR toolkit gives rise to the recurrent concerns of its predecessor gene editing technologies, such as fears of scientific research initiating global catastrophes, either purposefully or accidentally. Although some of these issues are based on speculation and misinformation, there is a demonstrated need to fully analyze and assess the ethical, social, and moral implications of

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indigenous people from traditional territories, such as the Maasai in Tanzania).

89. *See e.g.*, Reardon, *supra* note 50, Harmon, *supra* note 50.

90. Reardon, *supra* note 50 (identifying a proposal to edit Koi fish through CRISPR to be aesthetically similar in size and vibrant colors as depicted in art and historical stories); *See, e.g.*, Melillo, *supra* note 3, at 760 (discussing the use of CRISPR for purely cosmetic enhancements in humans).

91. *See* Reardon, *supra* note 50.

92. Harvard biologist George Church is leading de-extinction research. David Shultz, *Should We Bring Extinct Species Back From the Dead?*, Sci. Mag. (Sept. 26, 2016, 3:00 AM), http://www.sciencemag.org/news/2016/09/should-we-bring-extinct-species-back-dead [https://perma.cc/5GBE-FBHU].

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

the technology's application to wildlife. Concerns over the CRISPR toolkit and wildlife editing can be grouped into six different categories: (1) hidden scientific research, (2) wide accessibility, (3) unintended edits and effects, (4) ecological consequences, (5) moral, ethical, and social concerns, (6) international relations, and (7) impacts of the anti-science movement.

Some critics of the CRISPR toolkit highlight the extreme lack of transparency involved in its creation, since research on the CRISPR toolkit and wildlife editing are primarily conducted behind closed doors.[97] This lack of transparency also inhibits scientific innovation and prevents the reliable discovery of the detrimental consequences of the CRISPR toolkit and wildlife editing.[98] Closed-door research makes it more difficult to ensure moral and ethical applications of science.[99] Scientists are currently not sufficiently soliciting input from the public regarding their work.[100] As one scientist stated, "Deciding to perform the experiment is itself a decision that could affect others, doing so in secret explicitly denies these others a voice."[101] To help resolve the transparency issue, there needs to be a more inclusive public forum that grants access to information and fosters participation in determining the moral and ethical applications of this technology. Without public involvement, there is a serious risk of derailing progress and deferring potential benefits of wildlife editing.

The technology's accessibility and affordability has been widely criticized for creating greater opportunities for misuse.[102] CRISPR kits have been available for purchase for less than two hundred dollars.[103] The prioritization by some of scientific innovation and economic benefits may outweigh concerns for animal rights, and the allure of profits may distract companies and scientists from addressing important ethical and moral issues.[104] Low income countries of the Global South have expressed concerns about the creation of new routes

97. Braverman II, *supra* note 12, at 63–64; Esvelt, *supra* note 40, at 35 ("Conducting research behind closed doors poses severe moral and practical difficulties when a single experiment can affect many people outside the laboratory, including across international borders, without anyone else taking action.").

98. Esvelt, *supra* note 40, at 29.

99. *Id.*

100. Peck, *supra* note 8, at 328; Esvelt, *supra* note 40, at 28–30.

101. Esvelt, *supra* note 40, at 29.

102. *See* Molly Bond & Deborah Scott, *In an Engineered World, Who Benefits from Biological Diversity?*, Guardian (Dec. 22, 2016, 8:12 AM), https://www.theguardian.com/science/political-science/2016/dec/22/in-an-engineered-world-who-benefits-from-biological-diversity [https://perma.cc/6MNB-3MR5]; *Gene Editing/CRISPR*, *supra* note 21 (describing biohacking and do-it-yourself biology as a movement in which people are experimenting with biotechnology research and development methods outside of traditional research institutions).

103. Gross, *supra* note 5, at 414 n.1.

104. Braverman, *supra* note 9, at 65 (identifying dangerous private interests at play with gene drive research and discovery); 2017 CRS Report, *supra* note 1, at 3–7 (discussing market projections and investment in the CRISPR toolkit and wildlife editing).

for unfair commercial exploitation of their biodiversity with the rise of the CRISPR toolkit and wildlife editing.[105] Using technology for only the benefit of the wealthy will deny access to the poor and only widen equity gaps. Civil society organizations have expressed concern about gene drives being pursued by powerful military and agribusiness interests and a few wealthy individuals.[106] The scientist who first discovered the practice of combining gene drives and CRISPR has also criticized the for-profit development of gene drives.[107] As a result, the wide accessibility of and potentially problematic profit motivations created by the CRISPR toolkit have led many to call for the implementation of limitations on its use.[108]

There is also concern surrounding the scientific community's lack of understanding of the effects of unintended edits made with the CRISPR toolkit.[109] Deliberately manipulating the genome may impact unintended areas, creating off-target effects such as unknown chain reactions and altered genomic relationships.[110] Scientists still do not fully understand how relationships form or fade within the genome, particularly between the modified gene and other genomic regions, the intrarelationships of noncoded regions, or how environmental factors impact these relationships.[111] As a result, critics have scrutinized the benefits of gene drives in light of these unknown, off-target effects, especially since some unintended effects may not be realized until subsequent generations.[112] Altering specific genes to achieve a desired result in a wild creature requires a strong understanding of population dynamics and variables within the ecosystem.[113] Appropriate safeguards can help mitigate these concerns.

105. Bond & Scott, *supra* note 102; *see generally* Gonzalez & Atapattu, *supra* note 80, at 230–35.

106. Catherine Saez, *UN Biodiversity Convention Agrees On Precautionary Approach To Synthetic Biology*, Intellectual Property Watch 2018 WL 6220699 (Nov. 29, 2018).

107. Kevin Esvelt, *Gene Drive Should be a Nonprofit Technology*, Stat News (Nov. 27, 2018), https://www.statnews.com/2018/11/27/gene-drive-should-be-nonprofit-technology [https://perma.cc/2B5U-GFH8] [hereinafter *Gene Drives Should be a Nonprofit Technology*] (explaining how the profit motive may increase public mistrust and has been a key argument for proponents of a moratorium on gene drives).

108. *See* Braverman, *supra* note 9, at 9.

109. *See The Safety of CRISPR-Cas9 Gene Editing is Being Debated*, Economist (July 19, 2018), https://www.economist.com/science-and-technology/2018/07/19/the-safety-of-crispr-cas9-gene-editing-is-being-debated [https://perma.cc/5QJH-BNKN].

110. CRISPR might inadvertently alter regions of the genome other than the intended ones. CRISPR might also cause unintended deletions or rearrangements of strings of DNA; or might stay in cells long after the intended cuts are complete and continue to edit similar off-target sequences. Braverman, *supra* note 9, at 11.

111. The severity of off-target effects is not fully understood within the scientific community and is a source of fervent debate. Parent, *supra* note 3, at 19; *The Safety of CRISPR-Cas9 Gene Editing is Being Debated*, *supra* note 109.

112. *See* Barry R. Furrow, *The CRISPR-Cas9 Tool of Gene Editing: Cheaper, Faster, Riskier?*, 26 Annals Health L. 33, 40 (2017).

113. *Id.*

Gene spills are one particularly troubling category of unintended edits. Gene spills occur when scientists accidentally or prematurely release gene-drive organisms, such as when an edited animal escapes from a field study location and spreads its genes to local wildlife populations.[114] Gene spills can also occur if an animal's gene drive jumps to another species.[115] By introducing artificial gene drives into the wild, these gene spills could cause a cascade of unintended population dynamics and evolutionary processes.[116] Thus, scientists emphasize the necessity of confinement and containment strategies when working with the CRISPR toolkit in order to reduce the potential for unintended releases.[117]

Wildlife editing also inevitably attracts concerns regarding potentially negative ecological consequences of edits, as well as the irreversibility of genome changes. There is an intricate relationship between genetics and the environment.[118] Scientists may not understand ecosystem weaknesses and characteristics well enough to anticipate all potential consequences. By introducing an edited organism into the open environment, scientists may (intentionally or unintentionally) eliminate entire species or weaken a species that previously held an underappreciated ecological role, resulting in unforeseen disruptions to sensitive ecosystems.[119] For example, using wildlife editing to change the number of female panthers to increase the panther population may have the unintended consequence of eliminating or suppressing other species in the ecosystem.[120] Similarly, eliminating invasive weasels by reducing their fertility could crush the surrounding food web where predators adapted to using them as prey. Gene drives might also become invasive and irreversible, unintentionally causing widespread, undesired effects in nature.[121] Further, animal rights advocates may consider manmade edits to the genetic code of species for the purpose of eradication to be species genocide.

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114. Antonio Regalado, *Stop "Gene Spills" Before They Happen*, Tech. Review (Oct. 20, 2016), https://www.technologyreview.com/s/602633/stop-gene-spills-before-they-happen [https://perma.cc/BK9G-3RA5]; Paul Knoepfler, *A New Possible Environmental Disaster: The Gene Spill*, The Niche (Feb. 8, 2016), https://ipscell.com/2016/02/a-new-possible-environmental-disaster-the-gene-spill [https://perma.cc/T9P9-8JDC].

115. Braverman, *supra* note 9, at 55–56, 59.

116. *Id.* at 58.

117. These strategies may include physical designs of laboratories, clear demarcation between wild and artificial geographies, and designation of field studies far from organisms that are closely related to the edited creatures. *Id.* at 58–67.

118. *Id.* at 57–63.

119. 2017 CRS Report, *supra* note 1, at 25–26; Braverman, *supra* note 9, at 4 ("There has never been a more powerful biological tool, or one with more potential to both improve the world and endanger it."); Heidi Ledford, *Fast-spreading Genetic Mutations Pose Ecological Risk*, Nature (June 8, 2016), https://www.nature.com/news/fast-spreading-genetic-mutations-pose-ecological-risk-1.20053 [https://perma.cc/2J6D-CNHV].

120. Sandler, *supra* note 45, at 47.

121. The likelihood of this occurring is debated within the scientific community, which lacks a consensus view. Esvelt, *supra* note 40, at 25.

Moral, ethical, and social concerns also surround the CRISPR toolkit and wildlife editing. Structural power relations may allow the Global North to determine what species are worthy of saving or destroying. This preferential treatment could develop into a form of nonhuman eugenics where dominant cultures determine the value and desirable characteristics of wildlife.[122] One author cautioned that wildlife editing could implicate ecological xenophobia, despite a creature's inclusion within an ecosystem for decades.[123] In turn, this could have socioeconomic ripple effects within and across countries on a global scale, where minority cultures' human-animal relationships are devalued and ignored.[124] Traditional conservation methods lack sociocultural assessments. For example, in Hawaii, a conservation strategy to eradicate wild pigs that pose a threat to native tropical plants may be desirable from an ecosystem management perspective. However, implementation of such a strategy ignores the historical and cultural values of Native Hawaiian communities, who use wild pigs as a component of cultural events and cuisine.[125]

Moreover, wildlife editing for public health purposes may ignore benefits and harms affecting marginalized populations. Certain promising public health interventions that benefit minorities may be viewed by the world's most powerful countries as unprofitable and unworthy of implementation. Further, instead of bringing about public health solutions, editing creatures for public health benefits may backfire and cause the creation of new diseases. This unintended effect threatens to increase the already rising levels of infectious diseases, particularly zoonoses, which were discussed above. Ultimately, despite altruistic intentions, wildlife editing may inflict more harm to the animal than it intends to prevent, and might distract policymakers from addressing the real causes of harms facing wildlife.[126]

Noneconomic applications of wildlife editing mirror the ethical and moral concerns surrounding the "designer baby" issue in the human context of the CRISPR toolkit.[127] Engineering animals to change their visual appear-

122. Eugenics is a common concern with the use of the CRISPR toolkit in genetic modification as applied to humans. Amy Dockser Marcus, *Scientists Confront the Ghost of Eugenics*, Wall St. J. (Aug. 17, 2018, 12:38 PM), https://www.wsj.com/articles/scientists-confront-the-ghost-of-eugenics-1534523929 [https://perma.cc/4DFC-U3F8].

123. Yong, *supra* note 70.

124. Kuzma & Rawls, *supra* note 44, at 281.

125. *Id.*

126. To illustrate, policymakers might incorrectly assume that the CRISPR toolkit is the best and *only* solution rather than address the fact that pollution stemming from poor industrial practices, for instance, is a leading contributor to the species' declining habitat. The CRISPR toolkit should not be used to the benefit of polluting industries in retaining high pollution levels even if wildlife can be edited to better acclimate to pollution. Rosner, *supra* note 75 ("Genomic solutions are not a replacement for traditional conservation strategies, like . . . reducing the widespread use of toxic pesticides and synthetic fertilizers . . . ."); *see e.g.*, Sandler, *supra* note 45, at 48–49.

127. Many critics of CRISPR-Cas9 are concerned that the selection of desirable traits will eventually lead to the creation of a market for designer babies where parents preselect

ances to satisfy idiosyncratic desires could harm the animals' wellbeing and result in pain and suffering if an edit exacerbates or creates poor health conditions.[128] For example, genetically modifying a wild animal to better represent historical tales might end up creating or exacerbating an underlying health condition that leads to animal suffering.

Gene drives could also have cataclysmic impacts on national and global stability. The ability of organisms to travel across international borders and self-propagate their edits throughout wild populations could cause international relations conflicts.[129] An individual country's wildlife editing activity could quickly reshape the ecosystems of neighboring countries.[130] Some officials within national security agencies have voiced their own concerns about weaponizing gene drives, which parallel concerns about the technology's potential human application for creating super-soldier armies.[131] With the help of wildlife editing, bioweapons could be deployed against adversaries by recreating viruses and releasing disease-causing organisms that either affect humans directly by spreading diseases, or indirectly, for example, through the destruction of food supplies.[132] As the largest known global investor in gene drive research, the United States' military investment will likely cause other countries to become suspicious of the general direction of the United States' military power, particularly of how it plans to use this new technology offensively.[133]

The growing anti-science movement further complicates the future of the CRISPR toolkit and wildlife editing. Historically, science has intentionally been ignored and left out of legislative decisionmaking. More recently, scientists have not only been ignored, but also silenced. Public alarmism is the public response to new scientific techniques that challenge traditional

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the traits for their children, including height, eye color, and athletic ability. This could create a new form of eugenics. *See* Melillo, *supra* note 3.

128. *See e.g.*, Reardon, *supra* note 50; Harmon, *supra* note 50 (citing dissent for the technologies application from a spokesman for People for the Ethical Treatment of Animals); *The Safety of CRISPR Being Debated*, *supra* note 109 (discussing concerns that CRISPR-Cas9 gene-editing might trigger cancers).

129. *See* Borel, *supra* note 36; Kuiken, *supra* note 48, at 107 ("[G]ene drives are not going to respect a country's border.").

130. Yong, *supra* note 70.

131. *See* 2017 CRS Report, *supra* note 1, at 31 (noting the U.S. Director of National Intelligence's concern that the CRISPR toolkit allows easy access for someone to engineer harmful biological agents); Reardon, *supra* note 50; Brian Farley, *No, CRISPR Won't be Engineering Super-Soldiers or Designer Babies Anytime Soon*, Forbes (Nov. 17, 2016), https://www.forbes.com/sites/quora/2016/11/17/no-crispr-wont-be-engineering-super-soldiers-or-designer-babies-anytime-soon/#76319776122c [https://perma.cc/6E6H-YNHP].

132. *The Promise and Peril of Gene Drives*, *supra* note 35; Antonio Regalado, *U.S. Military Wants to Know What Synthetic-biology Weapons Could Look Like*, MIT Tech. Review (June 19, 2018), https://www.technologyreview.com/s/611508/us-military-wants-to-know-what-synthetic-biology-weapons-could-look-like [https://perma.cc/G3XL-P2HA].

133. *See* Callaway, *supra* note 48.

norms, and it is often caused by false or misleading news reports and political campaigns.[134] For example, the Trump Administration has taken nearly two hundred government actions aimed at restricting or prohibiting scientific research and education on climate change since the November 2016 presidential election.[135]

Politicians also misuse open records laws to try and discredit scientists who work on politically contentious topics, especially by cherry-picking phrases from reports and using them out of context.[136] This misuse "damages the scientific endeavor by diverting researchers' time, threatening their privacy, and chilling candid scientific discussions."[137] One legal scholar argued that constitutional scrutiny is necessary whenever the government regulates scientific inquiry in an effort to suppress knowledge production because *de facto* censorship of scientific speech implicates the First Amendment.[138]

The anti-science movement has likely contributed to the closed doors of genomic research. Professional reputations of private labs may then suffer due to the lack of transparency involved in research, regardless of whether they have altruistic motives. The public's lack of understanding of the scientific research process also leads to a negative public perception of scientists and creates the image of an evil scientist who is prone to using new technologies in malicious ways.[139] This negative public perception may negatively impact small biotechnology companies to a greater extent than "Big Biotech," making it more difficult for new companies to join the growing market. In addition, one survey showed that while a majority of interviewed Americans think companies have a moral obligation to make a positive impact on society and biodiversity,[140] only a few of them actually believed companies valued such obligation.[141]

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134. *See* Esvelt, *supra* note 40, at 26–27 (arguing that gene drives need to avoid bad public perception for successful implementation); *see also Attacks on Science*, Union of Concerned Scientists, https://www.ucsusa.org/center-science-and-democracy/attacks-on-science#.W2hrgFVKi72 [https://perma.cc/YZ4J-H42F] (discussing how the current presidential administration and 115th Congress are "actively dismantling science-based health and safety protections, sidelining scientific evidence, and undoing recent progress on scientific integrity").

135. *See Silencing Science Tracker*, Colum. L. Sch. Sabin Ctr. for Climate Change L., http://columbiaclimatelaw.com/resources/silencing-science-tracker/silencing-climate-science [https://perma.cc/KD6P-B4S2].

136. *A Guide to Open Records Laws and Protections for Research Materials*, Climate Sci. Legal Def. Fund, https://www.csldf.org/resources/open-records-laws [https://perma.cc/AM6W-A88B].

137. *Id.*

138. Natalie Ram, *Science as Speech*, 102 Iowa L. Rev. 1187, 1237 (2017).

139. *See, e.g.*, Peck, *supra* note 8, at 319, 324–28.

140. *Id.* at 323.

141. *Ten Years of Consumer Survey in USA*, Biodiversity Barometer (2018), http://www.biodiversitybarometer.org/2018-usa [https://perma.cc/2C8Q-7TXH].

Science should not be made a partisan issue and innovation should not be pushed behind closed doors by misleading news and negative political rhetoric. Increasing the transparency of scientific research through appropriate public awareness and education campaigns on the potential harms and benefits of the research may enhance public perception and increase public participation in the process.[142] This way, the public can help shape the direction of scientific research conducted to help address growing environmental concerns without causing long-lasting damage to the CRISPR toolkit's reputation.

II. Legal Protections for Wildlife Edits

The rise of this revolutionary genome editing technology, CRISPR-Cas9, reveals the absence of a cohesive regulatory approach to genomic editing in wildlife. No comprehensive legal regime specifically addresses the CRISPR toolkit and wildlife editing on the national or local levels within the United States. On the international level, only the Convention on Biological Diversity provides a regulatory regime broad enough to encompass these concerns. For wildlife editing specifically, this means there is a lack of legal protections, even at the intersection of environmental and biotechnology laws. Only scientific self-regulation through self-imposed standards and private licensing agreements restrict the various applications of the technology. This adds to the public's mistrust related to industry accountability and increases skepticism over self-imposed safe guidelines related to wildlife editing processes. Both scientists and animal rights activists have expressed concern over the lack of effective regulatory mechanisms for overseeing gene drive research and field trials.[143] The "power to directly alter, not just a singular form of life, but also the genetics of entire populations and species and thus the composition of ecosystems, is currently under-regulated and under-theorized."[144]

Due to this regulatory gap, plaintiffs will likely have to resort to common law theories of liability when bringing legal challenges and can seek injunctive relief or the recovery of damages based on nuisance, negligence, strict liability, or trespass claims.[145] Litigation might be pursued, for example, after individuals or their property are harmed by edited creatures.

142. *See Sustaining Life on Earth*, *supra* note 59, at 9 ("Education efforts on the importance of biodiversity as well as the effects of the technology.").

143. Braverman, *supra* note 9, at 10–11, 59 (noting inadequacy of current legal mechanisms to regulate gene drives; stating that National Academy of the Sciences is against a moratorium on gene drives; and identifying environmental leaders and organizations calls for a moratorium on the deployment of gene drives and synthetic biology in 2016); Esvelt, *supra* note 40, at 27 ("Existing legal mechanisms cannot adequately regulate new technologies such as gene drives."); Saez, *supra* note 106 (noting the various calls by civil society groups to impose a moratorium on gene drives).

144. Braverman, *supra* note 9, at 1.

145. *See, e.g.*, Tracy Hester & Michael B. Gerrard, *Going Negative: The Next Horizon in Climate Engineering Law*, 32 Nat. Resources & Env't 3, 5 (2018) (advancing these litigation strategies in the climate engineering context).

A public nuisance is the unreasonable interference with the health, safety or property rights of the community, whereas a private nuisance is the substantial and unreasonable interference with another person's use or enjoyment of his or her property.[146] For both public and private nuisances, an interference is unreasonable if the severity of the injury inflicted on the property owner outweighs the utility of the defendant's conduct, or alternatively, if "the harm caused by the is serious and the financial burden of compensating for this and similar harm to others would not make the continuation of the conduct not feasible."[147] State and local governments may bring public nuisance claims, as well as private individuals in limited circumstances.[148] Property owners can bring private nuisance claims.[149] For public nuisance, the release of modified wild animals into the environment could be viewed as a grave public health and safety threat. For private nuisance, property owners could be so scared of modified wild animals entering their land that a modified wild animal's release could significantly interfere with the property owner's use and enjoyment of their property. For both types of nuisances, the interferences caused by the release of modified wild animals are likely to be viewed as unreasonable due to the negative public perception of new gene-modifying technologies and the skepticism surrounding the CRISPR toolkit.

Negligence occurs where a defendant breaches a duty of care to conform to a specific standard of conduct, established to protect others from unreasonable harm, that actually and proximately causes the plaintiff's injury, which generates actual damages.[150] Actual cause is the cause-in-fact (but for the defendant's actions, the harm would not have occurred), whereas proximate cause limits the defendant's liability by excluding unforeseeable consequences stemming from the defendant's conduct.[151] It will likely be difficult for courts to determine whether there is an applicable minimum standard of care that individuals must comply with in these cases due to the lack of consensus and clear guidelines within the scientific industry over the safety of and best practices related to the CRISPR toolkit and gene drives. Actual causation will depend on the type of harm caused and whether or not it is apparent that the harm stemmed from the wildlife editing. Proximate causation will be a huge barrier to success in negligence claims because of the large amount of uncertainty and unforeseeable consequences of the CRISPR toolkit and wildlife editing. Courts will likely view such consequences as too remote to impose liability.

Strict liability is another route to recourse plaintiffs may seek against the owner of a CRISPR-edited wild animal that has caused damage. Strict liability attaches "to harm that results from a dangerous propensity that is

146. *Nuisance*, Black's Law Dictionary (10th ed. 2014).
147. Restatement (Second) of Torts § 826 (Am. Law Inst. 1979).
148. Restatement (Second) of Torts § 821C (Am. Law Inst. 1979).
149. Restatement (Second) of Torts § 821E (Am. Law Inst. 1979).
150. *Negligence*, Black's Law Dictionary, 14(c) (10th ed. 2014).
151. *Cause*, Black's Law Dictionary, 17(c) (10th ed. 2014).

characteristic of wild animals" without regard to fault.[152] The harm caused by a modified wild animal may automatically implicate strict liability. Generally, there is no liability for harm done by a wild animal, if it is indigenous to the locality, if it was once possessed but has left one's possession and returned to its natural state of being.[153] Courts may apply this same general principle to genetically altered animals.

In a successful claim for trespass to chattels, a defendant intentionally interferes with the plaintiff's right of possession in chattels, resulting in damages.[154] This claim is limited to actions that constitute intentional interferences with a person's agricultural or domesticated animals. This would provide recourse for malicious wildlife editing but is unlikely to remedy damage caused by unintended consequences, such as gene spills.

Wildlife editing-related lawsuits could also be brought based on legal theories related to the public trust doctrine, which is "the concept that the government holds resources such as land, air, water, wildlife, or fisheries in trust for its citizens and, therefore, must consider and protect the environment and public by promulgating rules and taking government action."[155] However, to successfully bring such a claim, a plaintiff will likely have to provide significant evidence related to more than one harmful event. Even if any of the above-mentioned claims are successful in court, these options are unlikely to provide adequate safety and deterrence from the potential harms posed by the CRISPR toolkit and wildlife editing as they are available only after harm has already occurred.

Current laws related to the environment and technology are too narrow to apply to edits resulting from the revolutionary CRISPR toolkit because they were enacted in response to predecessor technologies.[156] Most existing regulations assume that only unnatural additions, like transgenics, trigger regulatory authority.[157] They do not, however, regulate the natural process that is manipulated by the CRISPR toolkit. In order to identify existing protections and loopholes, the following discussion analyzes the treatment of wildlife editing under current biotechnology and environmental legal frameworks from the international to local levels.

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152. Restatement (Second) of Torts § 507 (Am. Law Inst. 1977).

153. Restatement (Second) of Torts § 508 (Am. Law Inst. 1977).

154. *Trespass to Chattels*, Black's Law Dictionary (10th ed. 2014).

155. Lisa A. Decker, *Citizen Enforcement Under the Public Trust Doctrine*, 32 Nat. Resources & Env't 50, 50–53 (2018).

156. *See supra* Part I for a discussion of distinctions from predecessor technologies. Warmflash, *supra* note 28 (describing how common statutory phrases include "foreign DNA" in the context of genetic engineering).

157. Braverman, *supra* note 9, at 7.

A. *International Law*

Treaties can establish international obligations and norms to bind member nations because they are a primary source of international law.[158] The rule of *pacta sunt servanda*, which states that "[e]very treaty in force is binding upon the parties to it and must be performed by them in good faith," is the foundation of international treaty law and requires states to follow through with implementing treaty obligations.[159] As discussed below, the Convention on Biological Diversity (CBD)[160] is the only existing international instrument broad enough to cover nonhuman applications of the CRISPR toolkit and wildlife editing. The CBD implements two subsequent protocols—Cartagena and Nagoya—that were promulgated in response to the rise of conventional biotechnologies.[161] The CBD officially adopted a precautionary approach towards synthetic biology that encompasses the CRISPR toolkit and wildlife editing in November 2018 at its biennial Conference of Parties.[162] The National Academy of Sciences has also recommended using the CBD as a platform for regulating gene drives on an international scale.[163] However, the United States has failed to ratify the CBD, despite originally signing it well over a decade ago.[164]

The CBD provides a better approach for regulating wildlife editing than the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).[165] CITES aims to protect the survival of wild ani-

158. Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331. While the United States is not a party of the Vienna Convention on the Law of Treaties, the United States "considers many of the provisions of the Vienna Convention on the Law of Treaties to constitute customary international law on the law of treaties." *Vienna Convention on the Law of Treaties*, Office of the Legal Advisor, U.S. Dep't of State, https://www.state.gov/s/l/treaty/faqs/70139.htm [https://perma.cc/5GBM-XBJD].

159. *See Vienna Convention on the Law of Treaties*, *supra* note 158, at art. 26.

160. *See* Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79 [hereinafter CBD].

161. Not all parties to the original CBD have ratified the two subsequent CBD protocols but U.S. leadership could change this. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *opened for signature* Jan. 29, 2000, 2226 U.N.T.S. 208 (entered into force Sept. 11, 2003) [hereinafter Cartagena Protocol]; Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, *opened for signature* Feb. 2. 2011, U.N.T.S. A-30619 (*entered into force* Oct. 12, 2014), https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf [https://perma.cc/HC4F-3FDS] [hereinafter Nagoya Protocol].

162. Conference of the Parties to the Convention on Biological Diversity, Rep. of Working Group II on Synthetic Biology, U.N. Doc. CBD/COP/14/L31 (2018), https://www.cbd.int/doc/c/2c62/5569/004e9c7a6b2a00641c3af0eb/cop-14-l-31-en.pdf [hereinafter Synthetic Biology 2018 Decision].

163. Braverman, *supra* note 9, at 6.

164. *List of Parties*, Convention on Biological Diversity, https://www.cbd.int/information/parties.shtml [https://perma.cc/5ASP-X2QN] (noting the United States signed the CBD on June 4, 1993 but never ratified it).

165. *What is CITES?*, Convention on the Int'l Trade on Endangered Species, https://www.cites.org/eng/disc/what.php [https://perma.cc/YE3W-GHWH].

mals and plants in international trade by instituting reporting requirements and guiding the implementation of national legislation to protect against wildlife crime.[166] Unlike with the CBD, the United States is a member to CITES.[167] In contrast to the CBD, the CITES treaty's scope is limited to endangered species and their international trade.[168] CITES does not consider biodiversity or the survival of the species, aspects which will be necessary in regulations addressing the CRISPR toolkit and its implications, because these issues are beyond the scope of its mission to protect against international crime against wildlife. While this international legal instrument has the potential to increase transparency by tracking research that relates to species conservation, it allows nations to exempt scientific research involving specimens from the reporting requirements.[169] This leaves the transparency mechanism incomplete. Therefore, CITES is largely inadequate to regulate the impacts of wildlife editing.

The United States' absence from the CBD harms its global leadership in biodiversity conservation and biotechnology advancements. U.S. membership would help create norms, practices, rules, and expectations surrounding wildlife editing. By ratifying the CBD and its subsequent protocols, the United States can reaffirm its commitments to combatting climate change, strengthen the treaty's compliance with other nations, and encourage biodiversity conservation efforts and scientific innovation of the CRISPR toolkit.

By joining the convention, the United States will also gain an official voice in negotiations and decisionmaking, while repairing relations with other countries and expanding opportunities for scientific innovation and wildlife protection. Other countries will gain confidence in the United States' government for committing to collaborate and coordinate on biodiversity issues. Membership will likely help reverse the strain on U.S. foreign relations caused by the current presidential administration's expression of its desire to withdraw from the Paris Agreement.[170] This decision aggravated distrust between

166. *Id.*

167. *List of Contracting Parties*, Convention on the Int'l Trade on Endangered Species, https://www.cites.org/eng/disc/parties/chronolo.php [https://perma.cc/G3AU-NSKQ] (identifying 183 member nations).

168. Species are grouped into different levels or types of protection from overexploitation by international trade. Appendix 1 identifies species that are threatened with extinction whereas Appendix II includes species that are not threatened with extinction currently but "may become so unless trade is closely controlled." Appendix 3 is the lowest rung of protection and includes species requested by nations concerned about the species survival with illegal exploitation. *How CITES Works*, Convention on the Int'l Trade on Endangered Species, https://www.cites.org/eng/disc/how.php [https://perma.cc/Y42P-4AT3]; *The CITES Appendices*, Convention on the Int'l Trade on Endangered Species, https://www.cites.org/eng/app/index.php [https://perma.cc/C4NB-WKZ9].

169. *How CITES Works*, *supra* note 168.

170. Dov Zakheim, *Trump Should Rethink Leaving the Paris Agreement Before It's Too Late*, Foreign Policy (June 2, 2017, 2:47 PM), https://foreignpolicy.com/2017/06/02/trump-should-rethink-leaving-the-paris-agreement-before-its-too-late [https://perma.cc/2E9E-QR8N].

the Global South and the Global North.[171] By joining the subsequent protocols, American membership may also encourage the original parties to the CBD to ascend to the subsequent protocols through the United States' political power.[172] The CBD's recent biennial meeting discussing the impacts of the CRISPR toolkit and wildlife editing barely made the news, despite its significance, but American membership could increase media coverage of the treaty in the future. Overall, the CBD represents the most active international legal forum on wildlife editing and is instilled with multidisciplinary input and scientific validity. Both the United States and the rest of the world could benefit from the United States joining the CBD.

1. Convention on Biological Diversity

The CBD is a global platform for regulating genome editing and gene drives that ensures broad protections of biological diversity. Entering into force in 1993, the purpose of the CBD is to protect natural environments, species, and ecosystems across the world.[173] Its main focuses are biodiversity conservation, sustainable use, equitable sharing of genetic resources, and recognizing the sovereign rights of member nations to genetic resources within their boundaries.[174] To supplement and clarify the treaty, the Cartagena and Nagoya Protocols have been added to the CBD.[175] These protocols focus and expand on specific aspects of the CBD in much greater detail.[176] The Cartagena Protocol does so with respect to accountability and liability, whereas the Nagoya Protocol expands on issues surrounding transparency, fairness, and equitable sharing and utilization of genetic resources.[177]

171. Joseph Curtin, *Trump Has Officially Ruined Climate Change For Everyone*, Foreign Policy (Dec. 12, 2018, 6:16 PM), https://foreignpolicy.com/2018/12/12/trump-has-officially-ruined-climate-change-diplomacy-for-everyone [https://perma.cc/SQ5J-EY9G].

172. There are a number of signatories to the original treaty who did not elect to sign and ratify the subsequent Cartagena Protocol and/or Nagoya Protocol. Of the 196 CBD members, the Cartagena Protocol has 171 members and the Nagoya Protocol has 114 members. Parties to the Cartagena Protocol and its Supplementary Protocol on Liability and Redress, Convention on Biological Diversity, http://bch.cbd.int/protocol/parties [https://perma.cc/5K8L-2BS5]; Parties to the Nagoya Protocol, Convention on Biological Diversity, https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml [https://perma.cc/RZ6R-BJQT].

173. 2017 CRS Report, *supra* note 1, at 29; CBD, *supra* note 160, at 143.

174. The term 'genetic resources' refers to "genetic material of actual or potential value." CBD, *supra* note 160, at art. 1, 2, 3, 15(1).

175. Cartagena Protocol, *supra* note 161; Nagoya Protocol, *supra* note 161; U.N. Office of Legal Affairs, Treaty Section, Treaty Handbook, at 69, U.N. Sales No. E.12.V.1 (2012), *https://treaties.un.org/doc/source/publications/thb/english.pdf* [hereinafter Treaty Handbook] (defining "protocol").

176. Treaty Handbook, *supra* note 175.

177. Cartagena Protocol, *supra* note 161; Nagoya Protocol, *supra* note 161.

The CBD is a non-self-executing treaty,[178] and each member nation is required to prepare its own National Biodiversity Strategy.[179] A National Biodiversity Strategy is essentially an integrated, multisectoral, participatory legal instrument for domestic biodiversity planning and conservation that contains compliance and enforcement provisions.[180] The CBD is universally recognized by 196 member nations that have ratified the international treaty—but not the United States.[181] For a non-self-executing treaty to become enforceable within the United States, the president must sign it and Congress must ratify it by a two-thirds vote in the Senate.[182] The CBD was signed by President Clinton, but was never ratified by Congress, and thus never took effect in the United States.[183]

The CBD is governed by periodic meetings of the Conference of the Parties, held every two years, where member nations and observers meet to discuss and make decisions on the ecological implications of new technology.[184] The CBD emphasizes inclusion of the scientific community in its decisionmaking process through the treaty's creation of an intergovernmental scientific advisory body, which meets annually to discuss new developments and advises the Conference of the Parties on the intersection of biological diversity

178. *See* Cartagena Protocol, *supra* note 161, at art. 6 (guidelines for the implementing legislation called National Biodiversity Strategies and Action Plans). A non-self-executing treaty requires legislation to be implemented in the United States. For the United States, this means that the treaty is not effective until implementing legislation is enacted. Conversely, if the treaty is self-executing, then the treaty automatically becomes internal law when the agreement enters into force. *See* Restatement (Fourth) of Foreign Relations Law § 310 (Am. Law Inst. 2018); Frederic L. Kirgis, *International Agreements and US Law*, 2 Am. Soc'y Int'l L. Insights 5 (May 27, 1997).

179. The CBD is explicitly non-self-executing. Member states are required to ensure that National Biodiversity Strategy (or an equivalent instrument) is mainstreamed in the planning and activities of all those sectors whose activities may impact biodiversity (positively or negatively). Article 6 creates an obligation for national biodiversity planning. CBD, *supra* note 160, at art. 6, 15; *What is a NBSAP?*, Convention on Biological Diversity, https://www.cbd.int/nbsap/introduction.shtml [https://perma.cc/K7BY-WZUU].

180. CBD, *supra* note 160, at art. 6, 10; *What is a NBSAP?*, *supra* note 179.

181. *See List of Parties*, *supra* note 164.

182. U.S. Const. art. II, § 2, cl. 2 (granting the president power "by and with the Advice and Consent of the Senate, to make Treaties, provided two-thirds of the Senators present concur"). Treaties can carry a significant amount of legal weight in the U.S. *See* U.S. Const. art. VI, cl. 2 (making treaties the supreme law of the land); The Paquete Habana, 175 U.S. 677, 700 (1900) ("International law is part of our law . . . ."); Whitney v. Robertson, 124 U.S. 190, 194–95 (1888) (applying the later in time rule that allows treaties to supersede an act of Congress if the treaty is most recent, and vice versa).

183. *See List of Parties*, *supra* note 164.

184. CBD, *supra* note 160, at art. 23 (identifying the Conference of Parties as the governing body). The fourteenth Conference of Parties was a two-week meeting between November 13–29, 2018 in Sharm El-Sheikh, Egypt. *COP14—CP/MOP9—NP/MOP3*, Convention on Biological Diversity (2018), https://www.cbd.int/conferences/2018 [https://perma.cc/T5VW-LUA4].

conservation and new scientific methods.[185] The periodic meetings offer a range of organizations across multiple industries the opportunity to collaborate and ensure that cross-sectional issues are given due consideration and effect.[186] For instance, the International Union for Conservation of Nature has obtained official observer status to represent environmental interests and has been involved with the Conference of Parties since the CBD's commencement.[187]

The CBD incorporates the precautionary principle within its preamble, asserting that "where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat."[188] Furthermore, the treaty covers both on-site and off-site conservation,[189] which gives scientists greater opportunities to implement the creative strategies that will be needed to address the negative impacts of climate change while protecting the public at large.

The CBD is at the forefront of global discussions on synthetic biology, biotechnology advancements, and wildlife editing. At the fourteenth Conference of Parties in November 2018, the governing body officially clarified and asserted that the precautionary approach does in fact apply to synthetic biology and gene drives.[190] This decision calls upon member nations to only introduce gene drives into the environment, including those being used for research purposes, when the following requirements are met: (a) case-by-case risk assessments are conducted and are scientifically based; (b) risk management mechanisms are identified to avoid or minimize potential adverse effects stemming from the use of synthetic biology; and (c) prior informed consent or involvement of "potentially affected indigenous groups and local communities is sought or obtained."[191] The decision also urges nations to share informa-

185. CBD, *supra* note 160, at art. 25; *Subsidiary Body on Scientific, Technical and Technological Advice* (SBSTTA), Convention on Biological Diversity, https://www.cbd.int/sbstta/default.shtml [https://perma.cc/YXT9-NF6W].

186. *See* Bond & Scott, *supra* note 102 (noting how scientists in various sectors, biotech industry delegates, and social science scholars participated as observers at the 2016 Conference of Parties).

187. *Convention on Biological Diversity (CBD)*, ICUN, https://www.iucn.org/theme/global-policy/our-work/convention-biological-diversity-cbd.

188. CBD, *supra* note 160, at pmbl.

189. *In-situ* conservation refers to "the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings." *Ex-situ* conservation means the conservation of components of biological diversity outside their natural habitats. Ex-Situ conservation involves collecting genetic codes to store within gene banks for the purposes of education, research, and in preparation of near-extinction in order to reintroduce and restore disappearing species. CBD, *supra* note 160, at art. 2, 8, 9.

190. Synthetic Biology 2018 Decision, *supra* note 162.

191. *Id.* at 2.

tion regarding scientific assessments on potential benefits and adverse impacts related to the CRISPR toolkit and wildlife editing through an online database.[192]

Until the next Conference of Parties in 2020, the Ad Hoc Technical Expert Group on Synthetic Biology will be researching and analyzing issues surrounding gene drives.[193] During this time, civic groups and governments are encouraged to nominate representatives to take part in an online forum to discuss the risks and benefits associated with the new technology, and to help facilitate the development of more efficient policy responses.[194] This momentous decision illustrates how the CBD's large membership, platform, and information sharing mechanisms are consistent with its desire to increase transparency and the availability of open science related to the CRISPR toolkit, while also instituting safeguards.

International law skeptics criticize the CBD—as they do most treaties—for having an inadequate enforcement mechanism.[195] However, these skeptics disregard the fact that the CBD establishes international norms that push for greater coordination and cooperation to address challenges related to biodiversity loss, land degradation, and climate change, as well as shared risks stemming from modern biotechnology, including wildlife editing.[196] The biennial Conference of the Parties serves to check compliance and evaluate the effectiveness of different policies. This international body pressures nations to develop successful national policies through their National Biodiversity Strategies and ensure compliance through reporting on the nations' successes and efforts.[197] These policies can also confirm nations' commitments to antiweaponization of CRISPR-edited animals. Biosecurity is related to biodiversity because of the domino effects that biosecurity, or the lack thereof, can have on the stability of local ecologies and subsequent environmental use and conservation.[198] As climate change increasingly causes harm to biodiversity and

192. The online database mentioned refers to the Biosafety Clearing-House established under the Cartagena Protocol, which is discussed below. *Id.*

193. *Id.*

194. *Id.*

195. Gross, *supra* note 5, at 429–30.

196. International law sceptics often criticize international conventions for either having too little or too much authority and ability to achieve their goals. *See* Gross, *supra* note 5, at 427–30 (criticizing the CBD's lack of enforcement mechanism and explicit monitoring requirements for compliance)*; but see* Karrigan S. Börk & Rachael E. Salcido, *Through the Looking Glass: Using Trade Agreements to Enforce Environmental Law*, 32 Nat. Resources & Env't 36 (Fall 2017) (advocating how international treaties can be strategically used to achieve domestic policy outcomes).

197. *See Law and National Biodiversity Strategies and Action Plans*, U.N. Environment (2018), https://wedocs.unep.org/bitstream/handle/20.500.11822/25655/LawBiodiversity_Strategies.pdf?sequence=1&isAllowed=y [**https://perma.cc/9E3K-J3V6**] [hereinafter "UNEP Biodiversity Strategies"].

198. The Cartagena Protocol defines the term "biosafety" to "describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products." *Frequently Asked Questions (FAQs) on the Cartagena Protocol*, Convention on Biological diversity,

scientists continue to innovate and create technologies that offer potential solutions, there is a growing urgency to maintain an effective global forum in which these technologies can be considered. The CBD's periodic meetings and focus groups create a platform from which to raise ethical questions surrounding the CRISPR toolkit, respond to scientific uncertainty, and debate the applicability of the Convention to unprecedented technology.

2. Cartagena Biosafety Protocol

The Cartagena Protocol, which was adopted in January 2000 and entered into force in September 2003, furthers the impact of the CBD by adding protections against risks to public health and biological diversity posed by the handling, transport and use of living organisms modified through modern biotechnology.[199] The protocol defines 'living modified organism' as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[200] This definition is broad enough to cover wildlife creations developed with the CRISPR toolkit and wildlife editing.[201]

To emphasize transparency and information sharing, this protocol created the Biosafety Clearinghouse, which is a publicly available online platform available in all six of the official U.N. languages.[202] This is a global platform where parties can exchange scientific, technical, and legal information, and share their experiences with living modified organism.[203] It manages national shipment records of the living modified organisms, among other reports, and includes various online forums and collaborative portals.[204] This provides a virtual platform for experts to continuously interact and share experiences with the use and development of the CRISPR toolkit and wildlife editing. These online forums facilitate informed decisionmaking for future meetings of the Conference of Parties, allowing international leaders and scientists to debate and clarify the scope of these definitions as the CRISPR toolkit continues to expand. This could help avoid the constant outdating of statutory and regulatory instruments.

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http://bch.cbd.int/protocol/cpb_faq.shtml#faq10 [https://perma.cc/QAM3-PUA3] [hereinafter *FAQ Cartagena*].

199. Cartagena Protocol, *supra* note 161, at art. 1, 2, 3(g), 17, 32.

200. *Id.* at art. 3(g).

201. *See generally* Cartagena Protocol, *supra* note 161, art. 3(g); Gross, *supra* note 5, at 427–28.

202. For countries with limited internet accessibility, the Secretariat of the CBD provides offline copies. Cartagena Protocol, *supra* note 161, at art. 20; *Information Sharing and the Biosafety Clearing-House*, Convention on Biological diversity, http://bch.cbd.int/protocol/cpb_factsheets.shtml#bch [https://perma.cc/96VE-PSA2].

203. Cartagena Protocol, *supra* note 161, at art. 20.

204. Cartagena Protocol, *supra* 161 at art. 20, 30; *Information Sharing and the Biosafety Clearing-House*, *supra* note 202.

Through the Protocol, procedures are established for the import and export of living modified organisms from one country to another in a safe manner.[205] These living modified organisms must be accompanied with documentation that identifies the modified organism and specifies any special requirements for safe handling, storage, transport, and use.[206] The information required on these documents varies depending on the intended use of the modified organisms.[207] For intentional releases, the exporter must notify the importing party of where the release will occur before the export happens.[208] This is "to ensure that importing countries have both the opportunity and the capacity to assess risk that may be associated with [the import of] living modified organisms."[209]

The Protocol also reaffirms commitments to the precautionary principle[210] and requires parties to conduct effective risk assessments and management that balances public health and conservation factors.[211] When conducting risk assessments, member nations are instructed to scientifically evaluate overall risks posed by a living modified organism to biological diversity and human health.[212] After performing the risk assessment, member nations are required to determine whether the anticipated risks are acceptable or manageable, and if so, to identify strategies to manage and mitigate the identifiable risks.[213] The parties may also evaluate socioeconomic impacts, particularly with regard to the value of biodiversity to indigenous and local communities, when determining the appropriate transport and use of modified creatures.[214] These socioeconomic issues may include impacts on the local economy, market access, food security, conservation efforts, and sustainable development.[215]

Further, the Cartagena Protocol minimizes the economic and environmental costs associated with transboundary movements of modified organisms to neighboring countries. If a party becomes aware of an unintentional transboundary movement of edited organisms from their country, the country is required to immediately inform potentially affected nations to enable them to appropriately respond, and the Biosafety Clearinghouse for analysis.[216] This

205. Cartagena Protocol, *supra* note 161, at art. 6–9, 18.

206. Identification information may be incorporated into a commercial invoice. *Id.* at art. 18.

207. *FAQ Cartagena*, *supra* note 198.

208. *Id.*

209. *Id.*

210. Cartagena Protocol, *supra* note 161, at art. 1, 10(6), 11(8). *See also* FAQ Cartagena, *supra* note 198.

211. Cartagena Protocol, *supra* note 161, at art. 15–16.

212. *Id.* at art. 15, Annex III.

213. *Id.* at art. 16.

214. *Id.* at art. 26.

215. *Socio-economic Considerations*, Convention on Biological diversity, http://bch.cbd.int/protocol/cpb_art26.shtml [https://perma.cc/AV8A-9DWQ].

216. Cartagena Protocol, *supra* note 161, at art. 17.

international legal instrument is the first of its kind to consolidate the intersections of public health, environment, and biosafety concerns within one global regulatory scheme.[217] Yet critics continue to accuse the Protocol of having inefficient enforcement mechanisms.[218] Such criticism overlooks the Cartagena Protocol's liability and redress system, which requires governmental parties to develop frameworks for redressability of damage and also informs scientists and public society about the existence and applicability of legal constraints surrounding experiments.[219]

As a result of this criticism and to address liability issues, the Nagoya–Kuala Lumpur (NKL) Supplementary Protocol was added to the Cartagena Protocol on Biosafety (not to be confused with the Nagoya Protocol discussed below) in October 2010 and entered into force in March 2018.[220] Essentially, the NKL Supplementary Protocol is an amendment to an amendment to the CBD, and serves to clarify the scope of liability.[221] It applies when damages to biodiversity are incurred that were caused by the transboundary movement of living modified organisms, whether through trade or unintentional releases.[222] Damages may also be recovered when an individual, organization, or government reasonably failed to mitigate foreseeable risks involved with wildlife editing.[223] In addition, the NKL Supplementary Protocol calls on member nations to incorporate liability provisions within the national legislation they craft to comply with the CBD.[224] With only forty-two members currently, there is significant opportunity to expand the amount of nations that adhere to this liability amendment.[225]

The Cartagena Protocol helps increase transparency, institute governmental accountability, and enhance geopolitical relations by establishing clear guidelines. With the Cartagena Protocol in place, countries are less financially

217. Matthew Hubbard, *Barometer Rising: The Cartagena Protocol on Biosafety As A Model for Holistic International Regulation of Ocean Fertilization Projects and Other Forms of Geoengineering*, 40 Wm. & Mary Envtl. L. & Pol'y Rev. 591, 612 (2016).

218. Gross, *supra* note 5, at 428–30.

219. Hubbard, *supra* note 217, at 620.

220. Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, Convention on Biological Diversity, opened for signature Oct. 15, 2010, U.N.T.S. A-30619 (entered into force March 15, 2018), https://bch.cbd.int/protocol/NKL_text.shtml [hereinafter NKL Supplementary Protocol].

221. NKL Supplementary Protocol, *supra* note 220, at Preamble, art.16; Treaty Handbook, *supra* note 175, at 69.

222. Damage refers to "an adverse effect on the conservation and sustainable use of biological diversity that is measurable or otherwise observable and significant, taking also into account risks to human health." NKL Supplementary Protocol, *supra* note 220, at art. 1–5.

223. *Id.* at art. 5.

224. *Id.* at Preamble, art. 3, art. 5.

225. *The Nagoya–Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety*, Convention on Biological Diversity, https://bch.cbd.int/protocol/supplementary [https://perma.cc/MMT8-YSHB].

vulnerable to a neighboring country's use of wildlife editing. The NKL Supplementary Protocol's liability provisions are extremely valuable for addressing concerns that surround the CRISPR toolkit and wildlife editing because they discourage risky and reckless scientific experiments. The provisions for redressability do not discourage the development of science and protect scientists from innocent accidents that may occur from well-intentioned research.

The escalating impacts of climate change on biodiversity are a global problem that demands global cooperation, particularly from the Global North. Under the principal of common but differentiated responsibility, the United States can help take leadership and responsibility for its historic contributions to climate change while also committing to a brighter future by focusing on including nations from the Global South with the rise of genomic editing.[226] Altogether, the Cartagena Protocol and its supplement offers a real opportunity for America to show leadership and teamwork in solving grave concerns that loom over the world's global commons.

3. Nagoya Protocol

The Nagoya Protocol, a supplement to the CBD and the Cartagena Protocol which seeks to address fairness and equity concerns associated with the use of genetic resources, went into effect in October 2014.[227] The Nagoya Protocol strives to create greater legal certainty, fairness, and transparency for providers and users of genetic resources.[228] At its core, the Nagoya Protocol mandates authorization for access to certain resources, controls and tracks subsequent uses, establishes benefit sharing, and creates compliance mechanisms.[229] The Nagoya Protocol is triggered when potential foreign users want to obtain samples of genetic resources located within another nation's borders for the purposes of research, conservation, commercial, or industrial application.[230] Prior to the CBD and the Nagoya Protocol, genetic resources were freely accessible to foreign users who wanted to extract them from countries without authorization or any obligation to share benefits.[231]

Before taking samples of genetic resources in a foreign country, the Nagoya Protocol instructs a potential user of these genetic resources to obtain prior

226. *UNEP Biodiversity Strategies*, *supra* note 197, at 26; *see e.g.*, Gonzalez & Atapattu, *supra* note 80, at 230–33 ("The Global North has generally prioritized the environmental concerns of the affluent, such as nature preservation, while ignoring the environmental problems that disparately burden the Southern poor, thereby generating resistance, suspicion, and ill will.").

227. *See* Nagoya Protocol, *supra* note 161, at art. 1.

228. *About the Nagoya Protocol*, Convention on Biological Diversity, https://www.cbd.int/abs/about [https://perma.cc/3YCZ-SFLV].

229. *See* Nagoya Protocol, *supra* note 161, at art. 6, 17, 29, 30.

230. *Access to Genetic Resources: Article 6 of the Nagoya Protocol on Access and Benefit-sharing*, IUCN, https://www.iucn.org/sites/dev/files/import/downloads/short_paper___article_6.pdf [https://perma.cc/F3JQ-UV59].

231. *Id.*

informed consent from the country in which the resource is located and create mutually agreeable terms and conditions of access and use of this resource.[232] This agreement should also address the equitable sharing of benefits arising from the utilization of the resources that are taken, "as well as subsequent applications and commercialization."[233] Benefit sharing may be monetary, such as through royalty payments, or nonmonetary, for example, through research exchanges.[234] These genetic resources are then monitored after they leave the country of origin through an online platform called the "Access and Benefit-sharing Clearing-House," that tracks the resources export process at various stages (i.e., research, development, innovation, pre-commercialization or commercialization) to ensure compliance with the formed agreement.[235]

The Nagoya Protocol also seeks to address the socioeconomic concerns surrounding the rise of new technologies and the use of genetic resources. Provisions within this protocol recognize the value of traditional knowledge and uses of certain genetic resources that are held by local and indigenous communities.[236] Article 21 of the Nagoya Protocol provides that "[e]ach Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues," and contains a list of suggested measures.[237]

Research indicates that "indigenous peoples make up less than 5% of the total human population, they manage or hold tenure over 25% of the world's land surface and *support about 80% of the global biodiversity*."[238] Notably, the Nagoya Protocol is the first international instrument of particular relevance to indigenous and local communities negotiated since the adoption of the United Nations Declaration on the Rights of Indigenous Peoples in 2007.[239] The Nagoya Protocol's text also explicitly includes women.[240] This is significant because international treaties often ignore gender equality issues, despite the fact that women and girls bear the brunt of environmental, economic, and social shocks, particularly in relation to climate change.[241]

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232. Nagoya Protocol, *supra* note 161, at art. 6.

233. *Id.* at art. 5.

234. *Id.* at Annex.

235. *Id.* at art. 14–17; *About the Nagoya Protocol*, *supra* note 228.

236. Nagoya Protocol, *supra* note 161, at art. 6–7, 12.

237. *Id.* at art. 21.

238. Raygorodetsky, *supra* note 89.

239. *The Nagoya Protocol on Access, Benefit-sharing, and Traditional Knowledge*, Convention on Biological Diversity, https://www.cbd.int/traditional/Protocol.shtml [https://perma.cc/AJ9R-2NGQ].

240. Nagoya Protocol, *supra* note 161, at art. 12(3), 22(3), (4).

241. *See Climate Change and the Environment*, UN Women, http://www.unwomen.org/en/how-we-work/intergovernmental-support/climate-change-and-the-environment [https://perma.cc/S4TD-9Q92]; *In Focus: Climate Action by, and for, Women*, UN Women, http://www.unwomen.org/en/news/in-focus/climate-change [https://perma.cc/JCW9-K2ZG].

The Nagoya Protocol has been criticized for failing to help track the flow of biological assets from their countries of origin.[242] New technological developments such as blockchain, however, might help international groups diligently monitor the flow of biological assets and profits.[243] The Nagoya Protocol aspires to protect the Global South from being burdened with the resource curse, where global superpowers exploit smaller, more biodiverse countries and leave those local communities unable to benefit from their land.[244] The resource curse refers to the paradox of resource-abundant countries faring worse in economic development and governmental stability than resource-poor countries.[245] In the pharmaceutical context, foreigners have extracted unique plant and animal species from the Amazon rainforest to help create billion-dollar industries, while leaving the local communities within the Amazonian basin with no benefits.[246] Nations within the Global South, such as the Amazon basin, are still at risk for further exploitation of biological materials that include the genomes of unique animal species, particularly with the rise in technology and biological knowledge.[247] The CBD, as well as the Cartagena and Nagoya Protocols, if adopted by the United States, may offer an opportunity to reshape the United States' global image and role, particularly with regards to wildlife editing, and remediate the negative historic actions that have contributed to climate change and environmental degradation.[248] Within the United States, the adoption of the Nagoya Protocol would also create a platform for Native American communities to participate in decisionmaking in this realm.

The CRISPR toolkit and wildlife editing have the potential to expand the global equity gap, perpetuate the cycle of the resource curse, and create new mechanisms of discrimination if not used responsibly. Wildlife editing should not "increase 'disadvantage, discrimination or division in society.'"[249] Climate change may incentivize the Global North to replenish their local wildlife by editing wildlife from biologically rich countries in the Global South, which could implicate environmental justice issues.[250] However, the Nagoya

242. *Sequencing the World*, Economist (Jan. 23, 2018), *https://www.economist.com/science-and-technology/2018/01/23/sequencing-the-world* [https://perma.cc/H2ES-8RGB].

243. *Id.*

244. *See, e.g.*, *Sequencing the World*, *supra* note 242; Renard Sexton, *Mineral Extraction Makes Countries Richer but There's a New Resource Curse*, Wash. Post (April 25, 2018), https://www.washingtonpost.com/news/monkey-cage/wp/2018/04/25/mineral-extraction-makes-countries-richer-right-but-theres-a-new-resource-curse/?noredirect=on&utm_term=.cca9f440498a [https://perma.cc/4686-E4X2].

245. Sexton, *supra* note 244.

246. *Sequencing the World*, *supra* note 242.

247. *Id.*

248. Gonzalez & Atapattu, *supra* note 80, 230–32.

249. *The Safety of CRISPR Gene Editing is Being Debated*, *supra* note 109.

250. "Environmental justice is the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development,

Protocol's emphasis on including indigenous communities and women in decisionmaking processes could create a global platform for the voices of those who are all too often ignored. It seeks to ensure that local cultural values regarding human-animal relationships are not lost to dominant cultural preferences. By working with local communities rather than against them, potential users of genetic resources can benefit by including traditional and indigenous knowledge in their future research. Ultimately, the Nagoya Protocol helps address inequalities and inequities within and across nations. The CBD and the Nagoya Protocol together provide an international mechanism that seeks to avoid perpetuating the cycle of the resource curse and attempts to cure the imbalance of structural power relations. These safeguards further promote the public's interest in ecological protection.

B. *Federal Law*

The U.S. federal government has several environmental laws and a regulatory framework for biotechnology that provide fragmented protections for wildlife from the application of the CRISPR toolkit. Both state and federal law have traditionally treated animals as property.[251] The value of animals is expressed by their worth to humans, whether economic or cultural.[252] The U.S. Supreme Court has partially protected the value of animals to various cultures, religions, and ethnicities under the U.S. Constitution.[253] Courts have even protected animals that lack any cultural value in their local communities.[254] Increasingly, courts and legislatures have been asked to redefine animal rights to expand upon traditional limiting positions.[255] Advances in the CRISPR

implementation, and enforcement of environmental laws, regulations, and policies." *Environmental Justice*, U.S. EPA, https://www.epa.gov/environmentaljustice [https://perma.cc/3M87-SGE7].

251. *Animals' Legal Status*, Animal Legal Defense Fund, https://aldf.org/issue/animals-legal-status [https://perma.cc/6DC9-QFYK].

252. Braverman II, *supra* note 12, at 68 ("The biopolitical considerations of relative worthiness is supported by existing regulations and guidelines, the value ascribed to certain animals translated into their mode of governance and vice versa.").

253. Laws burdening religious practice that are not neutral or of general application must undergo the most rigorous of scrutiny. This includes conduct motivated by religious belief as it is essential to protect rights guaranteed by the free exercise clause. U.S. Const. amend. I; Church of Lukumi Bablu Aye, Inc. v. City of Hialeah, 508 U.S. 520, 543–544 (1993) (holding that ordinances dealing with religious ritual slaughters of animals were not of general applicability despite the claim that they prevented cruelty to animals because the ordinance intended to target this specific religion).

254. TVA v. Hill, 437 U.S. 153 (1978) (enforcing a strict interpretation of the Endangered Species Act to protect the critical habitat of the endangered snail darter).

255. Scholars have advocated for new approaches in defining animals and their rights. One approach is viewing animals as sentient property such that the government recognizes that animals experience pain. Another approach advocates viewing animals as nonhumans with independent rights, without regard to the utility of the animals to humans. *Animals' Legal Status*, *supra* note 251; Richard L. Cupp Jr., *Animals As More Than "Mere Things," But Still Property: A Call for Continuing Evolution of the Animal Welfare Paradigm*, 84 U. Cin. L.

toolkit will undoubtedly play a role in the evolution of legal concepts surrounding animal rights, raising questions about whether modified wildlife created with CRISPR is property, or nonhuman beings with independent rights.

1. Coordinated Framework for Regulation of Biotechnology

The only existing approach to regulate new biotechnology at the federal level is more than three decades old and fails to provide protections for the inherent risks of the CRISPR toolkit and wildlife editing. This approach, the Coordinated Framework for Regulation of Biotechnology, was established by the White House Office of Science & Technology in 1986.[256] This framework uses existing public health and environmental laws to divide regulation of new biotechnology among three federal agencies: the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).[257] The USDA uses the Animal Health Protection Act to regulate testing and commercialization of potentially harmful agricultural biotechnology products.[258] The EPA uses its statutory authority from the Toxic Substances Control Act and Federal Insecticide, Fungicide, and Rodenticide Act to regulate genetically engineered pesticides and new chemical substances derived from microbial biotechnology.[259] The FDA uses the auspices of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to regulate the introduction and commercialization of animal drugs or other biological products created by genetic engineering.[260] Overall, while

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Rev. 1023, 1045 (2016); *see also* Non-Human Rights Project, https://www.nonhumanrights.org [https://perma.cc/6X5V-7A2M] (promoting the application of nonhuman personhood to define animal rights).

256. 2017 CRS Report, *supra* note 1, at 9; *Coordinated Framework for Regulation of Biotechnology*, 51 Fed. Reg. 23302 (June 26, 1986).

257. 2017 CRS Report, *supra* note 1, at 9.

258. Specifically, the Animal and Plant Health Inspection Service within the USDA is responsible for agency oversight. Plant Protection Act, 7 U.S.C. §§ 7701–86 (2018); Animal Health Protection Act, 7 U.S.C. §§ 8301–22 (2018); *see also Coordinated Framework: How the Federal Government Regulates Biotech Plants*, USDA-APHIS, https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations/ct_agency_framework_roles [https://perma.cc/87X9-8HS4].

259. The EPA issues Experimental Use Permits for field testing of pesticides. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 (2018); Toxic Substances Control Act, 15 U.S.C. §§ 2601–97 (2018); *see also Pesticide Registration Manual: Chapter 12—Applying for an Experimental Use Permit*, U.S. EPA, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit [https://perma.cc/J9D4-XSH3]; *Regulation of Biotechnology under TSCA and FIFRA*, U.S. EPA, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra [https://perma.cc/7JQ9-C9FW].

260. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–34 (2018); Public Health Service Act, 42 U.S.C. §§ 201–50 (2018); 21 C.F.R. § 312.20 (requiring application submissions to the FDA for both new drugs and biological products); *see also Modernizing the Regulatory System for Biotechnology Products*, U.S. FDA, https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMAnimalsandAnimalFood/ucm520998.htm [https://perma.cc/5RCE-JAL6].

the Coordinated Framework attempts to provide a federal system of evaluation for modern biotechnology products, it has proven to be an ineffective, incomplete, and outdated approach.[261]

This existing approach has been widely criticized as a tangled web of agency action, particularly because of the lack of clear agency authority, inefficiency and incompatibility for scientific innovation.[262] Since the Coordinated Framework was created through executive order, it was not subject to a notice-and-comment period.[263] Any new changes to this executive order will similarly not be required to consider comments from the public, including from the scientific community or animal rights activists.[264] To date, attempts to make these federal regulations more cohesive have failed.[265]

Critics contend that the CRISPR toolkit advancements—including wildlife edits—largely fall outside the scope of federal jurisdiction.[266] Depending on the CRISPR toolkit's characteristics, however, it may be subject to regulation by one or more federal agencies, but the initial hurdle of establishing jurisdiction could be challenging. "Confusion regarding which agencies are responsible (if any) for gene drives can lead to public mistrust."[267] Recently, the current USDA administration declined to exert regulatory authority over plants edited by the CRISPR toolkit.[268] The agency focused on how this novel genome editing mechanism quickly and precisely replicated traditional breeding techniques using the natural biological processes, rather than inserting foreign genetic sequences.[269] This suggests that other federal agencies may follow suit and decline to extend regulatory authority over edited CRISPR

261. Peck, *supra* note 8, at 320–21.

262. 2017 CRS Report, *supra* note 1, at 11 (outlining concerns of the Coordinated Framework with regards to the CRISPR toolkit); Peck, *supra* note 8, at 315 ("The new generation of biotechnologies already does and increasingly will create products that do not fall within the statutory triggers that the Coordinated Framework directed FDA, USDA, and EPA to use to justify regulation.").

263. Peck *supra* note 8, at 315, 324.

264. 5 U.S.C. § 553 (2018) (outlining the rulemaking procedures); Peck *supra* note 8, at 315.

265. Prior to his departure from office, President Barack Obama called for a more cohesive effort with regard to the CRISPR toolkit in 2016. John P. Holdren et al., *Improving Transparency and ensuring Continued Safety in Biotechnology*, White House Blog (July 2, 2015, 2:57 PM EST), https://obamawhitehouse.archives.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology [https://perma.cc/9M-HD-VHU2].

266. 2017 CRS Report, *supra* note 1, at 2, 15; Braverman, *supra* note 9, at 7; Peck *supra* note 8, at 315.

267. Kuiken, *supra* note 48, at 107.

268. Press Release, *Secretary Perdue Issues USDA Statement on Plant Breeding Innovation*, U.S. Dep't of Agric. (Mar. 28, 2018), https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation [https://perma.cc/CCT3-5BEA].

269. *Id.*

creatures.[270] The EPA's regulation of pesticides and chemical substances could extend to edited plants and insects, but is unlikely to affect the editing of mammalian wildlife since the Coordinated Framework narrowly directs the agency to regulate consumer products in response to new biotechnologies. The FDA's statutory authority over "animal drugs" has been asserted over gene-edited fish and has been proposed to extend to CRISPR altered DNA in other animals.[271] However, even if doing so did not stretch their statutory mandate, their regulatory authority is hardly broad enough to encompass edited wildlife and the corresponding risks to surrounding ecosystems.

Accordingly, the use of the CRISPR toolkit to edit wildlife simply escapes the current jurisdictional reach of the Coordinated Framework. This regulatory system assumes "that only unnatural additions constitute a 'regulatable' change."[272] The system's fractured approach has served only to stunt genuine scientific research and cast a controversial shadow over a potentially valuable environmental tool.[273] Consequently, the complexity and uncertainties of the regulatory maze of the CRISPR toolkit deters smaller companies and laboratories from participating in innovation, thereby allowing big business to dominate and prioritize the direction of research.[274]

2. National Environmental Protection Act

Present-day environmental statutes are also inadequate to protect against the harms raised by wildlife editing. The National Environmental Protection Act (NEPA) requires federal agencies to analyze "major federal actions significantly affecting the quality of the human environment."[275] First, any federal agency developing a proposal must determine if its proposal qualifies as a "major federal action" and is not categorically excluded from the NEPA process.[276] If the proposal is a major federal action that is not categorically excluded, the agency will then typically prepare an Environmental Assessment

270. *See e.g.*, Peck, *supra* note 8, at 321–22 (discussing how the other agencies have historically focused on transgenic additions in asserting regulatory authority).

271. Public reluctance and distrust have stalled the agency's push for animal drug regulatory authority over CRISPR edited creatures. FDA Proposed Regulation, 82 Fed. Reg. 6561 (Jan. 19, 2017); 2017 CRS Report, *supra* note 1, at 26 (noting that the FDA distinguished its own regulatory authority over the genetically modified mosquito from that of the EPA by focusing on its intended use); *see also* Nick Stockton, *FDA Wants to Regulate Edited Animals Genes as Drugs*, Wired (Jan. 24, 2017, 9:00 AM), https://www.wired.com/2017/01/fda-wants-regulate-edited-animal-genes-drugs [https://perma.cc/Q7GZ-9ZET] Kuiken, *supra* note 48, at 107.

272. Braverman, *supra* note 9, at 7.

273. *Id.* at 13.

274. Peck, *supra* note 8, at 315, 323–24 ("[T]he tangled web of agency oversight over even just one new plant or animal variety threatens more than ever to chill important innovations.").

275. National Environmental Policy Act of 1969 § 102(2)(C), 42 U.S.C. § 4332; 40 C.F.R. 1508.14, 1508.18, 1508.27 (2017).

276. *Id.* §§ 1508.5, 1508.18.

(EA), unless it decides to skip that step and go directly to preparing an Environmental Impact Statement (EIS).[277] An EA is a document that is meant to help the agency determine if it should issue a Finding of No Significant Impact (FONSI) or prepare an EIS.[278] If the EA indicates that the proposal is likely to have a significant effect on the human environment, the agency must prepare an EIS, which is a detailed written statement required by section 102(2)(C) of NEPA.[279] After consulting with the appropriate federal agencies and seeking input from the public, the agency proposing the project must publish an EIS that describes the environmental impacts of its proposed action and any alternatives to the proposed action.[280]

NEPA encourages transparency by requiring that EISs be made publicly available, outlining mandatory notice-and-comment rulemaking procedures, and emphasizing the necessity of public hearings.[281] However, NEPA is limited by the fact that it only covers major federal agency actions,[282] leaving the actions of private companies and individuals outside of its authority. The Supreme Court has further limited NEPA's applicability by ruling that agencies are not required to select the alternatives identified in their EISs, or change their projects in any way to mitigate environmental harms.[283]

In theory, NEPA provides a safety net for agency action outside the Coordinated Framework because agencies may be required to undergo NEPA review for actions that otherwise slip through the regulatory grasp of the Coordinated Framework. Nonetheless, NEPA has been criticized for being a mere procedural check, rather than providing substantive mitigation analysis and incorporating scientific opinions.[284] The current analysis for an EIS insufficiently considers the consequences of wildlife editing on the surrounding ecological web.[285] NEPA is inattentive to scientific opinions because wildlife editing may be viewed as too speculative and remote to trigger NEPA obligations.[286] This could open the door to dangerous field studies since they may

277. *Id.* § 1501.3.

278. *Id.* § 1508.9.

279. *Id.* §§ 1508.9, 1508.11.

280. National Environmental Policy Act of 1969 § 102(2)(C), 42 U.S.C. § 4332(C).

281. Upon request, agencies are required to make their EISs available. *See* Freedom of Information Act, 5 U.S.C. § 552 (2018).

282. 40 C.F.R. 1508.18 (2017).

283. Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 359 (1989) ("[N]EPA does not require a fully developed plan detailing what steps will be taken to mitigate adverse environmental impacts").

284. Daniel R. Mandelker, *The National Environmental Policy Act: A Review of Its Experience and Problems*, 32 Wash. U. J.L. & Pol'y 293, 294 (2010) (criticizing NEPA for inadequately assuming a more predictive and less complicated environment).

285. *Id.*

286. NEPA imposes more procedural than substantive requirements on agencies. The EIS need only discuss reasonable impacts with credible scientific evidence, not pure conjecture. The document doesn't need to discuss impacts that are purely speculative. 40 C.F.R. § 1502.22.

not require environmental review, and thus may more easily ignore long term consequences of risky gene drives. For example, there was a FONSI issued in Florida to Oxitec, a biotechnology company that has plans to release gene edited mosquitos.[287]

Since NEPA covers major federal agency actions, minor agency actions that involve significant wildlife editing are not explicitly required to undergo environmental review. For example, the U.S. Department of Defense's research on wildlife editing appears to fall outside of NEPA's public participation requirements even though the agency is one of the largest players in gene editing.[288] The agency could be escaping public participation requirements under the view that these gene drives are a national security, rather than an environmental, issue.[289] This makes it less likely that the agency will address actual ethical and moral concerns raised by the surrounding communities, or at least gives the perception of such. Further, the National Academy of Sciences has asserted that NEPA is inadequate to address the potential ecological benefits and harms of gene drives because "'neither an EA nor an EIS requires a clear formulation of the problem that provides a quantitative cause-effect model.'"[290] NEPA does not protect wildlife and surrounding communities from the potential misuse of wildlife editing because agencies will likely find that wildlife editing is a minor agency action. Even if considered major actions, agencies will argue national security concerns allow the agency to move forward with actions without ever providing a forum for public input.

3. Endangered Species Act

Wildlife editing also raises unique issues related to the legal applicability of wildlife protection laws. The Endangered Species Act (ESA), which strives to protect species and their ecosystems,[291] is considered the hallmark of U.S. biodiversity conservation law.[292] The ESA is also the United States' implementing legislation for the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).[293] The ESA's protections only extend to

287. *Gene Editing/CRISPR*, *supra* note 21; Kuiken, *supra* note 48, at 106–07.

288. No EA or EIS could be located for projects in the Safe Genes initiative. *See* sources cited *supra* note 48.

289. Daniel R. Mandelker, Robert L. Glicksman, et al., *National security*, NEPA Law and Litig. § 5:15 (2018) ("The federal government has claimed an implied exemption from NEPA for actions taken in aid of national defense and security."); *See e.g.*, San Luis Obispo Mothers for Peace v. NRC, 635 F.3d 1109, 1116 (9th Cir. 2011) (finding that the agency had no obligation under NEPA to disclose to citizen group in closed hearing sensitive security information exempted from disclosure under FOIA where the agency recognized NEPA but used its expertise).

290. 2017 CRS Report, *supra* note 1, at 27–28.

291. Endangered Species Act of 1973, 16 C.F.R § 1531(b) (2018).

292. TVA v. Hill, 437 U.S. 153, 180 (1978) (referring to the ESA as "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation"). Endangered Species Act of 1973, 16 U.S.C. §§ 1531–44 (2018).

293. 50 C.F.R. § 1537a. CITES is not analyzed in this Article because it does not

species of plants and animals that are listed as threatened or endangered, as well as their critical habitat.[294] The listing process is subject to the notice-and-comment procedures outlined in the rulemaking section of the Administrative Procedures Act.[295] Both the Department of the Interior, for terrestrial and freshwater species, (subsequently delegated to the Fish and Wildlife Services) and the Department of Commerce, for marine species, (subsequently delegated to the National Marine Fisheries Service) have the authority to list animal species as threatened or endangered, as well as to designate critical habitat.[296] The ESA imposes significant penalties on federal and private actors who "take" listed species.[297] To "take" a species is "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct."[298] Since the statute's inception, courts have struggled with how to define "harm."[299] By obtaining an incidental take permit, however, public and private actors are permitted to take species and can escape the harsh statutory penalties.[300]

The ESA may protect endangered and threatened wildlife species within the United States from editing. The ESA's focus on specific species, as opposed to whole ecosystems, has been criticized as inadequate to prevent extinction

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consider biodiversity and the survival of the species, which is necessary for addressing all implications of the CRISPR toolkit. *See What is CITES?*, *supra* note 165.

294. 16 U.S.C. § 1532(5) (defining critical habitat); *Id.* § 1532(6) (defining endangered species as "any species which is in danger of extinction throughout all or a significant portion of its range other than a species of the Class Insecta determined by the Secretary to constitute a pest whose protection under the provisions of this chapter would present an overwhelming and overriding risk to man"; *Id.* § 1532(20) (defining threatened species as "any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range"); *Id.* § 1533 (describing process for listing endangered species).

295. Administrative Procedures Act, 5 U.S.C. § 552–53.

296. 16 U.S.C. § 1533 (identifying criminal liability for habitat modification where "the defendant also knew or reasonably should have known that his actions would be likely to injure endangered or threatened species"); 46 Fed. Reg. 29, 490 (June 2, 1981); 16 U.S.C. §§ 1531(b)–(c), 1533(a)(3) (2018).

297. Subsequent regulation and case law further define what these terms mean. 16 U.S.C. § 1536 (placing obligations on federal agencies to abide and providing penalties for violations); *id.* § 1538 (prohibiting private parties' actions that take listed species and providing penalties for violation).

298. 16 U.S.C. § 1532(19).

299. Controversy in case law arose over what type of habit modification would result in harm. *See* Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or., 515 U.S. 687, 696–708 (1995) (discussing whether the Secretary permissibly construed "harm" to mean habitat modification); TVA v. Hill, 437 U.S. 153, 172–93 (1978) (permanently enjoining an agency from completing a project that would eradicate the snail darter).

300. U.S. Fish and Wildlife Services may issue a permit to legally allow the taking of a listed species by both a public or private actor through an incidental take permit so long as the taking is incidental to, and not the purpose of, an otherwise legal activity, and such taking will not jeopardize the species' continued survival. 16 U.S.C. § 1539(a)(1)(B).

and promote biological diversity.[301] Public and private actors engaged in field research may be able to avoid ESA liabilities by obtaining an incidental take permit.[302] Additionally, wildlife editing will further complicate the definition of "harm." The ESA likely does not prevent wildlife editing for purposes of invasive species management if it increases the likelihood of survival of a listed species.[303] It is unclear, however, whether the ESA would protect threatened or endangered wildlife that have been edited, regardless of whether such edits were intentional. Advancements in "de-extinction" through the CRISPR toolkit also raise unique concerns, such as whether the revived species would be automatically listed as endangered or threatened. Overall, the ESA is largely unable to provide sufficient safeguards for wildlife against potential harm caused by editing with the CRISPR toolkit.

C. *State Law*

State law could also provide protections against the negative risks of wildlife editing. Through their inherent police power, states have the authority to legislate to protect the general welfare, public health, and safety of their citizens.[304] This broad power has historically been invoked in the creation of public health laws passed in reaction to public health emergencies, such as bioterrorism or infectious disease outbreaks, which may require quarantine or vaccinations.[305] Enabling wildlife editing similarly falls within the states' inherent police powers, particularly when the novel tool is being used to promote public health in response to emerging infectious diseases.[306] States might invoke traditional police powers to regulate CRISPR-edited creatures and wildlife editing in the event that these creatures are used to help stop a public health threat (i.e., an infectious zoonotic disease); or, alternatively, present a public health threat. Especially in the absence of federal preemption, states can proactively address technological developments.[307] Nevertheless, current legal frameworks for wildlife protection, biotechnology, and conventional GMOs vary from state to state.

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301. Laura Spitzberg, *The Reauthorization of the Endangered Species Act*, 13 Temp. Envtl. L. & Tech. J. 193, 205–07 (1994).

302. *Id.* at 202–03.

303. *Id.* at 201–02.

304. U.S. Const. amend. X.

305. *See, e.g.*, Kathleen Hoke, *What is Public Health Law?*, Am. Pub. Health Ass'n, https://www.apha.org/-/media/files/pdf/factsheets/what_is_public_health_law_factsheet.ashx?la=en&hash=7BCB29295AD654F171D55D4F9CF1A3D9DCF79400 [https://perma.cc/BB73-TQLD]; Braverman, *supra* note 9, at 10 (noting that state police power has been raised in the context of gene drive applications to mosquitos).

306. *See e.g.*, Hoke, *supra* note 305 (identifying that state police power has been used in response to controlling infectious diseases).

307. U.S. Const. art. IV, cl. 2; *see e.g.*, Hoke, *supra* note 305 (discussing preemption and the Supremacy Clause in relation to public health).

States have the primary power to control and protect wildlife within their borders. In general, states provide similar protections to the U.S. ESA through state-level ESAs, but differ in their definitions of "wild animal."[308] Many states strictly prohibit the introduction of non-native wildlife and aim to protect local ecosystems by statutorily protecting native wildlife against invasive species.[309] Most states do not protect all wildlife from all harm, however. To illustrate the difference in views on animal protections, as one author accurately argues, "the death of certain species is grievable while others are merely killable."[310] For instance, almost half of states explicitly recognize a right to hunt and fish in their constitutions.[311] It is important, therefore, to know whether CRISPR's edited wild creatures would fall within a state's statutory definition of "wild animal." On one hand, edited creatures could be viewed as native wild species that result from the manipulation of natural processes that simply speed up evolution. Conversely, edited creatures could be viewed as invasive species because of the threats they present to native plants and animals within surrounding ecosystems. Potentially magnifying the problem is the fact that states have an economic incentive to introduce edited creatures into the wild to enhance profits resulting from the hunting and tourism industries, as these activities raise significant revenues for states.[312] As most states permit harm to wildlife,[313] it will likely be permissible to employ gene drives that have the potential to harm the target species or surrounding area.

States also have the power to limit or incentivize scientific innovation and technological advancement. Numerous states have already responded to

308. Some states limit the wild animal definition to species that are native to the state. *See, e.g.*, Kan. Stat. Ann. § 21–6411 (2012) ("a living mammal or marsupial which is normally found in the wild state, but shall not include a farm animal"); Mich. Comp. Laws, ch. 324, art. III, ch. 2, pt. 435 § 324.43508(4) (2013) ("a mammal, bird, fish, reptile, amphibian or crustacea of a wild nature indigenous to this state or introduced to this state by the department or a species determined by the department to be of public benefit"); VT. Stat Ann., tit. 10A, § 9(2)(d) (2013) ("all animals including birds other than domestic animals, whether or not native to Vermont, including the family canidae, any hybrid with domestic dogs"); W.Va. Code, tit. 20, § 20–1-2 (2013) ("all mammals native to the state of West Virginia either in a natural state or in captivity, except house mice or rats").

309. Jennifer Schultz, *State Action on Invasive Species*, Nat'l Conf. of St. Legislatures (July 12, 2016), http://www.ncsl.org/research/environment-and-natural-resources/displaced-by-invaders-state-action-on-invasive-species.aspx [https://perma.cc/Q25B-4AZ8] (providing a compilation of state statutes and regulations covering invasive species).

310. Braverman II, *supra* note 12, at 68.

311. *State Constitutional Right to Hunt and Fish*, Nat'l Conf. of St. Legislatures (Apr. 20, 2017) http://www.ncsl.org/research/environment-and-natural-resources/state-constitutional-right-to-hunt-and-fish.aspx [https://perma.cc/RJ7Z-SU68] (identifying twenty-one state constitutions that guarantee the right to hunt and fish, and two states that statutorily recognize the right to hunt and fish).

312. *Fishing, Hunting, and Wildlife*, Nat'l Conf. of St. Legislatures, http://www.ncsl.org/research/environment-and-natural-resources/fishing-hunting-and-wildlife.aspx [https://perma.cc/5H6G-MNN9].

313. *State Constitutional Right to Hunt and Fish*, *supra* note 311.

CRISPR's predecessor technologies by adopting laws regulating, limiting, or promoting the use of biotechnology.[314] States have also responded to the use of conventional genetic engineering methods to create genetically modified organisms by drafting legislation.[315] However, a majority of state statutes, if not all, are incapable of covering wildlife editing because they are limited by language focusing on human-animal chimeras, agricultural animals and plants, transgenic aquaculture, intentional alterations, and food labeling.[316] Wildlife edits through the CRISPR toolkit, however, may result in unintentional alterations, off-target effects, and other unforeseen consequences, so flexible safety policies should be instituted. In comparison to predecessor technologies, CRISPR is unique in its replication of naturally occurring processes to encode genes for desired purposes.[317] Current state statutes alone are therefore inadequate to protect against the considerable risks involved with the CRISPR toolkit and wildlife editing.[318] For the most part, state statutes are currently too outdated to cover the CRISPR toolkit and the editing of wildlife.

D. *Professional Self-Regulation*

Professional self-regulation exists as a minimum level of protection against misuse and any unintended consequences from the CRISPR toolkit. Self-policing is the only quasi-regulatory system specifically addressing

314. *See State Biotech Statutes*, Nat'l Conf. of St. Legislatures (2011), http://www.ncsl.org/research/agriculture-and-rural-development/state-biotech-statutes.aspx. [https://perma.cc/VH5V-59WZ]; *See e.g.*, Me. Rev. Stat. Ann. tit. 36, § 1760 (2007) (providing a sales and use tax exemption for machinery and equipment used for biotechnology research); Md. Code Ann., Nat. Res. § 4-11A-01 to 02 (West 2007) (limiting the geographic region for permits of transgenic or genetically-altered fish).

315. *See State Legislation Addressing Genetically-modified Organisms*, Nat'l Conf. of St. Legislatures (June 16, 2016), http://www.ncsl.org/research/agriculture-and-rural-development/state-legislation-addressing-genetically-modified-organisms-report.aspx [https://perma.cc/W74Z-CCYH] (providing a compilation of state laws addressing GMOs).

316. No state statute references "synthetic biology" or "genome editing" as applied to nonhumans. It is unclear whether the CRISPR toolkit or wildlife editing will fall within the scope of any previous state legislation covering concerns of GMOs and other predecessor technologies. Most state definitions focus on protecting agricultural animals. *See e.g.*, *50 State Statutory Surveys: Genetically Modified Food*, 0070 Surveys 1 Thomson Reuters (Aug. 2017); Vt. Stat. Ann. tit. 6, § 1030(6) (West 2018) (defining genetically modified organism in the agricultural context); Haw. Rev. Stat. Ann. § 321–11.6 (LexisNexis 2013) ("Any applicant to any federal agency for any permit for or approval of any bioproduct, *field testing of genetically modified organisms*, or environmental impact assessment of genetically modified organisms shall submit one copy of that application to the department, at the same time that the application is submitted to the federal agency.") (emphasis added).

317. *See* discussion *supra* Part I.

318. *Cf.* Joshua Busby & Johannes Urpelainen, *Are States, Cities, and Companies Taking the Lead on Climate Action*, Wash. Post (Sept. 17, 2018), https://www.washingtonpost.com/news/monkey-cage/wp/2018/09/17/are-states-cities-and-companies-taking-the-lead-on-climate-action/?noredirect=on&utm_term=.ab24c8c5c24d [https://perma.cc/XD25-MHD5] (illustrating the weaknesses of subnational and nonstate actors' involvements in climate change efforts).

wildlife editing.[319] Professional self-regulation involves self-policing through rules and norms created within certain professional organizations (i.e., official positions of scientific bodies).[320] These actions are examples of "private environmental governance," which refers to private organizations performing the environmental functions traditionally assigned to government.[321] In general, the private sector is becoming increasingly socially responsible and engaged in climate change issues, as demonstrated by the significant amount of private sector support for the Paris Agreement.[322] The strength of this approach is the lack of governmental oversight and need for complex regulatory approvals.

In the past, the industry successfully self-regulated in response to the discovery of recombinant DNA technology (i.e., GMOs).[323] However, self-restraint alone is now insufficient because of the wildlife editing technology's affordability and accessibility. Further, increasing profitability pressure from the booming biotechnology industry may encourage corporate greed and bad business behaviors.[324] Consequently, this negatively affects the direction of development of this potentially cutting-edge technology.[325] Concerns over the lack of transparency are unlikely to be resolved by the scientific community on its own.[326] Unlike when recombinant DNA was discovered, the scientific community today is broader and lacks uniform consensus on how to control dangerous applications of the CRISPR toolkit.[327]

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319. Braverman II, *supra* note 12, at 71 ("In place of state regulations, what seems to be emerging is a form of self-regulation by the gene drive scientists themselves.").

320. Braverman II, *supra* note 12, at 64–65; Esvelt, *supra* note 40, at 27–30; Michael P. Vandenbergh & Ben Raker, *Private Governance and the New Private Advocacy*, 32 Nat. Resources & Env't 2, 45, 45–49 (2017) (discussing the effectiveness of self-policing).

321. Vandenbergh & Raker, *supra* note 320, 45.

322. For example, hundreds of companies made individual commitments to taking action on climate change under the Paris Agreement, such as becoming carbon neutral and investing in clean energy projects and technology. One notable coalition comprised of over one-hundred companies was the Science Based Targets initiative, which aimed to set strict, science-based emissions targets. Martin Wilder et al., Baker & McKenzie, The Paris Agreement: Putting the first universal climate change treaty in context 19 (Jan. 2016), https://www.bakermckenzie.com/-/media/files/insight/publications/2016/01/the-paris-agreement/ar_global_climatechangetreaty_apr16.pdf?la=en; Camila Domonoske, *Mayors, Companies Vow to Act on Climate, Even As U.S. Leaves the Paris Accord*, NPR News (June 5, 2017), https://www.npr.org/sections/thetwo-way/2017/06/05/531603731/mayors-companies-vow-to-act-on-climate-even-as-u-s-leaves-paris-*accord* [https://perma.cc/Y42S-X5WH].

323. Gross, *supra* note 5, at 432.

324. Braverman II, *supra* note 12, at 65; *see e.g.*, *Gene Drives Should Be a Nonprofit Technology*, *supra* note 107 (stating how this is a current concern among civil society groups calling for a moratorium).

325. *See* discussion *supra* Part I.

326. Esvelt, *supra* note 40, at 35 (stating that "self-policing by the scientific community has proven unreliable, if only because scientists keep their plans and ongoing work secret from one another, while rapid progress has rendered tentative government attempts at regulation painfully outdated.").

327. Gross, *supra* note 5, at 432.

Licensing agreements are one existing method of self-regulation. The Broad Institute exercises control over licensing agreements of CRISPR-Cas9 due to its patent ownership, and its agreements explicitly prohibit the use of CRISPR-based gene drives.[328] However, licensing agreements created pursuant to patent law will create inconsistent approaches across the industry and could further damage public perception and trust in this technology.[329] For instance, this self-regulation may only exacerbate public concerns over accountability and safe guidelines, particularly when companies promise to do something but give the perception they will do the opposite.[330] The commercialization of licensing also demonstrates potential pitfalls of this quasi-regulatory approach. For example, the growing interest in wildlife editing amongst the private sector could adversely impact scientific reasoning and discretion. The growing amount of commercial interest in wildlife editing has the potential to plague scientific reasoning and discretion within the private sector if decision-makers decide to pursue large profits instead of societal benefits.[331] Although most scientists balk at the idea of further regulation, protective guidelines are needed in the field of wildlife editing because self-regulation alone is insufficient when catastrophic negative impacts could occur.

III. Recommendations

While wildlife editing technology is still developing, one thing is certain—it is not going anywhere. The world has only begun to harness its potential benefits and consequences. Currently, there is an urgent need for flexible legal and regulatory protections surrounding the CRISPR toolkit and wildlife editing. While CRISPR-based gene drives are still in the early stages of implementation, a regulatory approach to manage wildlife editing needs to be coherently articulated in order to limit the likelihood of unintended, negative risks. Ultimately, risks need to be identified and justified. The current U.S. biotechnology regulatory approach, wildlife protection statutes, and scientific self-policing are ineffective at protecting animals from the inherent risks involved with the use of the CRISPR toolkit. As CRISPR toolkit technology advances, the CBD offers the United States a framework through which it could clearly and coherently address the toolkit's nonhuman applications

328. David Cameron, *DuPont Pioneer and Broad Institute Join Forces to Enable Democratic CRISPR Licensing in Agriculture*, Broad Inst. (Oct. 18, 2017), https://www.broadinstitute.org/news/dupont-pioneer-and-broad-institute-join-forces-enable-democratic-crispr-licensing-agriculture [https://perma.cc/R3RX-7J4H].

329. *See* Furrow, *supra* note 112, at 45 (stating that "it is unlikely that we can rely on patent licensing agreements to resolve concerns about the risks of CRISPR or to control them in any significant way").

330. Esvelt, *supra* note 40, at 27–30 (discussing the public concerns and safe guidelines over gene editing and gene drives; Vandenbergh & Raker, *supra* note 320, at 47 (discussing the growing importance of public perception and the "social license to operate").

331. Braverman II, *supra* note 12, at 64–65; Esvelt, *supra* note 40, at 27–30; Gross, *supra* note 5, at 432.

by creating its own implementing regulations. While treaties themselves are not agents of change, they may require the implementation of actions that are, including effective domestic policies, public involvement, and scientific inclusion. Moreover, states and the scientific community can continue to provide safeguards to mitigate the technology's potentially harmful impacts even if regulations are adopted.

A. *Federal Level Solutions*

The United States should join the CBD and the two subsequent protocols. Joining the CBD would provide the United States with an opportunity to improve its foreign relations by signaling its commitment to the positive underlying goals of wildlife editing. However, to join the Convention, the Senate must ratify the treaty and Congress has to draft implementing legislation so the CBD's goals can be effectuated within the U.S.[332] The U.S.'s implementing legislation should adopt a uniform, risk-based approach for considering and managing future applications of the CRISPR toolkit in nonhumans and gene drives that is consistent with the treaty's goals and requirements for members' National Biodiversity Strategies.[333] Constitutionally, this type of legislation can be justified under the Commerce Clause.[334] The legislation should incorporate the precautionary principle and mandate risk assessments, management, and mitigation, while also establishing a system for deterrence, monitoring liability, and redress. In drafting this legislation, Congress needs to consider four additional factors to establish effective safeguards: (1) effective language, (2) agency roles, (3) involvement of the scientific community, and (4) inclusion of local communities and cultures.

First, the statutory language needs to be broad enough to cover current and future applications of the CRISPR toolkit and wildlife editing. As the weaknesses of past regulations have demonstrated, science moves much faster than the regulatory mechanisms that govern it.[335] One way to achieve comprehensive protections is to draft legislation that focuses on the risks and purposes of the gene editing technologies. Additionally, Congress may need to consider how to define animal rights in the context of this new technology. For wildlife editing and other CRISPR-based gene drives, the legislation needs to establish conditions for carefully controlled field studies, containment strategies, and reporting requirements for accidental releases. Ultimately, the framework needs to ensure prompt and effective prevention of harm and remedial measures.

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332. Since the CBD has already been signed by a U.S. president, Congress can ratify the treaty by a two-thirds vote in the Senate. U.S. Const. art. II, § 2, cl. 2.

333. CBD, *supra* note 160, at art. 6, 15.

334. U.S. Const. art. I, § 8, cl. 3. *See also* Lacey Act of 1900, 16 U.S.C. §§ 3371–78 (2018) (regulating trade and commerce of wildlife across state and national boundaries relying upon the Commerce Clause as a source of federal power).

335. *See* discussion *supra* Part I; Braverman, *supra* note 9, at 13.

Second, Congress should clearly identify primary agencies and delegate appropriately so as to avoid any ambiguities in authority. For example, Congress could designate the Department of the Interior as the primary agency in charge of wildlife editing, since the U.S. Fish and Wildlife Service already falls within the umbrella of this agency. A primary agency can use its expertise to provide strategic plans addressing potential harms to human health, the environment, and property. This agency can also create an advisory board or a task force specifically dedicated to genome editing. When the primary agency decides a particular regulatory issue is beyond its expertise, it can refer the question to other agencies. Agencies could then issue subsequent memoranda of understanding to guide future interagency coordination and clarify interagency response protocols for the industry. This type of clarity should help fix the problems of the outdated Coordinated Framework, not replicate it.

Congress should also consider incorporating a variety of methods that will increase clarity and transparency. The legislation could establish a national database based on information submitted to primary agencies, similar to CBD's Biosafety Clearinghouse. This national database would help guide applicants and disseminate information to the public. Similar to the Cartagena Protocol, Congress could mandate certain documentation and notification requirements for the import and export of CRISPR edited creatures and wildlife editing between states. Congress can also mandate that respective agencies provide it with annual reports on safety issues, or alternatively, make them available to the public. In turn, agencies should engage in public awareness campaigns by using official websites and social media to educate the public on the importance of biodiversity and the various concerns and benefits related to the CRISPR toolkit and wildlife editing. To address concerns over dangerous commercial interests, Congress could consider using the primary agencies to impose a licensing scheme and establish definitions for statutory violations by private license holders, such as those issued by the Broad Institute.

Third, Congress must involve the scientific community in drafting this legislation. Congress should craft its requirements for parties using the CRISPR toolkit in a way that incentivizes companies to discover benefits, as well as mitigate risks. Various scientific specialties need to be involved in shaping policy and legislation because there is no benefit in pitting the scientific community against the public.[336] In general, scientific innovation should involve more interdisciplinary perspectives from various scientific fields and needs to be balanced with the public interest and input from social scientists.[337] Due to its considerable influence over the technology's use and widespread societal impacts, the

336. Legislatures must carefully analyze the purposes for which they enact legislation regulating or restricting scientific inquiry, and they should take care to promote the progress of science while preventing harms sustained in its conduct. Ram, *supra* note 138, at 1237.

337. *See* discussion *supra* Part I; Braverman, *supra* note 9, at 14 (quoting Michael Spector) ("The science and some of the researchers may be ready but society clearly is not, and these decisions are far too consequential to be left to scientists alone.").

scientific community cannot monopolize nor be abandoned in policy discussions. Further, "biodiversity issues are best handled with the participation of all concerned citizens."[338] Proposals for the implementing legislation should be carefully proposed in the Senate to avoid the prevailing congressional polarization, prevent comparisons to previous biotechnology movements, and allay the general fear of rapid improvements in science. Maintaining the public trust is paramount in continuing the CRISPR revolution.

Continued dismissal of concerns—even those concerns that are ill-informed—will only exacerbate public resistance to pathbreaking technologies.[339] However, alarmism and the public's fear of unknown consequences do not justify a blanket prohibition like a moratorium.[340] Although many environmental proponents and animal rights activists advocate for a moratorium, imposing one could instead create a black market and further reduce research transparency. Further, a moratorium will not halt global advancements by other nations. Rather, instituting clear safeguards and limiting the availability of the CRISPR toolkit in the United States will help protect the world as scientists use the technology and increase their understanding of the dynamics of genome editing. For example, Congress can incentivize research that is conducted in a responsible and environmentally conscious manner. For wildlife editing specifically, Congress can create safe guidelines for field studies while simultaneously creating safety nets and constraints.

In drafting the legislation, Congress has the option of attaching a condition requiring that research be conducted on the dangers and benefits of the CRISPR toolkit to activities that receive federal funds. If the state grant research is tied to federal funds, then Congress will be able to dictate guidelines within those research programs. This review process will encourage regulatory compliance, and researchers will not be eligible to receive federal funds unless they comply. Congress has power over this funding because of its constitutionally enumerated taxing and spending powers.[341] Congress should also create mechanisms that encourage the development of environmentally responsible applications of the CRISPR toolkit. Field research proposals on gene drives could be reviewed by a multidisciplinary independent review board before they are eligible to receive federal funds.

338. UNEP Biodiversity Strategies, *supra* note 197, at 26 (referencing "the public participation and access to information and justice principle").

339. Peck, *supra* note 8, at 316.

340. Braverman, *supra* note 9, at 10–11, 59 (noting that the CBD rejected various calls for a moratorium on gene-drive research from nonprofits and environmentalists in 2016).

341. Congress may tax and spend to provide for any public purpose for the general welfare and may require entities that accept government money to act in a certain manner through the Taxing and Spending Clauses. Any reasonable conditions may be attached to the expenditure. U.S. Const. art. I, § 8 (giving Congress the limited power to tax and spend for the general welfare and does not include general federal police power).

Multidisciplinary independent review boards could include scientific experts from a variety of subspecialties, attorneys, social scientists, epidemiologists, and more. If a board is comprised predominantly of scientific officials, the other specialties represented would provide an additional check for matters involving significant risk. The inclusion of professionals from fields outside of the scientific realm could even be a benefit to scientists as these experts can help counter public alarmism in reaction to new scientific findings. This independent review board can also encourage flexibility in scientific innovation by using its expertise to craft clear approval requirements and subsequently review research proposals.[342]

Fourth, local communities and cultures need to be involved when Congress is addressing potential risks and benefits of the CRISPR toolkit. Socioeconomic assessments could be mandated prior to the implementation of wildlife editing. At a minimum, engagement with local communities should be required where edited creatures are likely to enter the local environment.[343] Through legislation and committee hearings, Congress should develop a strong legislative record that addresses socioeconomic impacts and entrenched inequities within American society, and advances structural change to promote inclusivity. For example, consistent with the Nagoya Protocol, provisions could mandate consideration and consent from Native American tribes and local communities before conducting field studies of gene drives on wildlife. This detailed legislative record will help courts in the event of future litigation. Another issue for Congress and agencies to consider is how to help ensure equity in public health campaigns and strategic efforts. This is particularly important to prevent minority and low-income communities from being the "guinea pigs" of potential risks posed by wildlife editing field studies. Overall, though, the complexity involved in drafting effective legislative mechanisms to ensure safety in wildlife editing should not deter federal policymakers from taking action.

B. *State Level Solutions*

Due to the intensity of Congress's polarization, the federal government is unlikely to ratify the treaty and agree on acceptable statutory language for implementing legislation. Particularly in the absence of clear federal guidance,

342. The board's reviewability should be limited to actual field studies, excluding basic laboratory experiments. Mandating reviewability of all minor research proposals would inhibit the ability of scientists to further study the consequences and benefits of the technology. For example, upon denial of a request, the board should provide for an opportunity to cure the defects identified by the board in the plan and to represent that plan within a specified time limit set by reasonable customs within the scientific realm for an expedited review process.

343. *See* UNEP Biodiversity Strategies, *supra* note 198, at 26 (referencing "the principle of nondiscrimination"); Gonzalez & Atapattu, *supra* note 80, at 234 ("environmental justice requires procedural equity and inclusiveness, including the right of all communities to participate in governmental decisions related to the environment.").

state legislatures should consider ways in which they can protect wildlife while balancing scientific innovation with the public's input on the appropriate use of this technology. States should look to the CBD and its supplemental protocols to draw inspiration and craft their own laws. Legislation may be crafted through the state's plenary police power in response to the creation of revolutionary technology surrounding wildlife edits. In certain situations, wildlife editing legislation can be premised on this police power due to its impacts on welfare and public health.[344] States could then employ similar tactics as identified above for Congress. Further, rather than expanding previous efforts to regulate biotechnology, new legislation should be drafted to avoid the stigma of the past movements. In drafting new legislation, state legislatures could commit themselves to the precautionary principle identified in the CBD and the supplemental protocols. State agency roles and responsibilities could be clarified. Inspired by the Nagoya Protocol, states could incorporate local communities and Native American tribes in the process of gaining benefits from this novel technology. Statutes could include a strict reporting requirement, provide for nuisance claims to be brought if edited animals cause harm, and identify any tort liabilities for any accidental releases of edited species or alterations of native wildlife species. Additionally, states could explicitly state that strict liability attaches to any torts resulting from the release of edited creatures into the wild.

C. *Scientific Community Solutions*

The private and public scientific communities should continue to self-police and set publicly available voluntary standards related to the application of the CRISPR toolkit to nonhumans. Voluntary compliance helps gain public confidence, which in turn helps business.[345] Researchers should draft proposed codes outlining principles that govern conduct for research on wildlife editing. With or without U.S. ratification of the CBD, the scientific community can voluntarily assent to the treaty's proposed limitations and participate as observers at the convention's Conference of Parties. For example, scientists could commit to advancing the Nagoya Protocol's equity goals by incorporating local and indigenous communities within the decisionmaking processes and prior to environmental releases.

In the private sector, corporate social responsibility initiatives could promote internal performance standards, provide training on socioeconomic implications of technologies, incorporate social and environmental concerns into board committee oversight charters, and issue public statements to make the company's goals and safety mechanisms more transparent. Companies should develop credible and effective strategies to anticipate and address adverse impacts and pronounced risks. Communities that will be impacted

344. *See* discussion *supra* Part II.C.

345. Vandenbergh & Raker, *supra* note 320, at 45–47.

by field studies should be informed of potential risks and prepared for potential emergencies, if necessary. Trade associations could also codify industry standards. Ultimately, businesses and laboratories should demonstrate that they have standards and management systems in place to manage their wildlife editing research and operations so as to avoid and mitigate adverse social and environmental impacts.

There should also be more emphasis placed on scientific journalism from writers with interdisciplinary backgrounds who seek to educate the public in order to help combat the anti-science movement. Economists, social scientists, and other professionals need to unite with scientists to educate the public and analyze risks.[346] Additionally, scientific innovation should be more inclusive of women and minorities; this will not only add value to the scientific realm but will also help accelerate women's empowerment and create pathways to equality in the industry.[347] Public awareness campaigns can also help educate the public and reduce alarmism that comes with the rise of each new technology or application. Another was to improve public perception and provide safeguards related to impacts of gene editing is using public-private partnerships to both research the CRISPR toolkit's applications to nonhumans and conduct field studies of wildlife editing. Ultimately, the scientific community should engage with the public because the success of scientific innovation rests in part on public trust.

D. *Additional Issues*

This Article aspires to lay the foundation for further exploration into regulating the CRISPR toolkit and the use of CRISPR-based gene drives on mammals. Implementing the CBD is only part of the solution, not a panacea. The rise of the CRISPR toolkit and corresponding wildlife editing will bring a variety of new legal challenges that are beyond the scope of this Article. The CRISPR toolkit impacts certain categories of animals differently than others, and such differences have been ignored by the media, in large part due to the predominant focus on human applications. Gene drives may alter current legal standards governing animal welfare and alter our understanding of how animals suffer.[348] Philosophical issues are also implicated in determining

346. *See e.g.*, *Global Biodiversity Outlook 4*, Convention on Biological Diversity, 34 (2014) https://www.cbd.int/gbo/gbo4/publication/gbo4-en.pdf.

347. *Science Benefits from Diversity*, Nature (June 6, 2018), https://www.nature.com/articles/d41586-018-05326-3 [https://perma.cc/3XU3-FBEU].

348. Some animal rights advocates may argue that gene editing is simply a means to prop up an industry that causes animals to suffer. For example, the CRISPR toolkit may create a loophole within the Animal Welfare Act, which is designed to protect animals in research, and challenge the underlying meaning of animal welfare in the research context. The efficacy of the Animal Welfare Act is already controversial among animal advocates. R. Scott Nolen, *50 years later, animal welfare act is a work in progress*, Journal of the Am. Veterinary Med. Ass'n (Sept. 14, 2016), https://www.avma.org/News/JAVMANews/Pages/161001a.aspx [https://perma.cc/Z3VX-LEAX]; Animal Welfare Act, 7 U.S.C. §§ 2131–59 (2012).

what type of suffering matters and should be prevented. Additionally, wildlife editing and other uses of the CRISPR toolkit have various implications for how to define the subsequent modified creatures within current legal frameworks.[349] To make this situation more complex, there is no current legal framework addressing the creation of entirely new species or drastic changes in existing species.

The future of the CRISPR toolkit in biodiversity efforts may also be impacted by the recent increase in climate change lawsuits and evolving judicial views on climate change litigation.[350] Gene drives and the CRISPR toolkit raise the issue of whether regulatory structures should include nonhumans and future human generations in their views of the relevant public, which would present new standing issues.[351] As climate change impacts magnify, courts and legislatures may increasingly consider future generations' enjoyment and use of the environment. As the CRISPR toolkit continues to develop, so too should legal and policy commentary on the various issues implicated, including how to close liability loopholes.

Conclusion

The CRISPR toolkit's revolution is undoubtedly only just beginning. The rise of these new technologies is introducing novel approaches for addressing growing global problems. However, with these benefits come considerable risks and pronounced concerns. Adding further complexity, CRISPR-based gene drives create a new terrain for legal frameworks. Current laws targeting predecessor technologies contain large holes, leaving them inadequate to cover risks posed by the CRISPR toolkit, let alone wildlife editing. Still, the fear of opening Pandora's box with scientific research on genome editing and gene drives does not justify a ban. The CBD and its incorporation of the precautionary principle provides a mechanism for balancing the potential risks and benefits. If the United States ratifies the CBD, the international treaty provides an excellent opportunity to craft uniform national safeguards that

349. Typically, if an owned wild animal escapes, the owner loses property rights in it unless the animal is marked, the owner is endeavoring to recapture the animal, or if the animal periodically returns to its owner. However, species changes and subsequent species ownership could lead to monopolistic big companies owning wildlife around the world. *See* Stuart M. Speiser, Charles F. Krause, Alfred W. Gans, *Wild and dangerous domestic animals, generally*, 7 Am. Law of Torts § 21:39 (Nov. 2018).

350. *U.S. Climate Change Litigation*, Climate Change Litigation Database, http://climatecasechart.com/case-category/endangered-species-act-and-other-wildlife-protection-statutes [https://perma.cc/YS8Q-U2XS] (identifying over eighty cases that have been brought regarding climate change and wildlife protection statutes, include the ESA); *New Green advocates: Climate-Change Lawsuits*, Economist (Nov. 4, 2017), https://www.economist.com/international/2017/11/02/climate-change-lawsuits [https://perma.cc/E74P-7NHX] ("Globally, the number of national climate-change laws and policies has swelled from nearly 60 in 1997 to nearly 1,400 [in 2017].").

351. *See* Kuzma & Rawls, *supra* note 44, at 281–85.

encompass both nonhuman applications of the CRISPR toolkit and wildlife editing. This legislation can establish incentives to prevent pernicious research by outlining risk assessments, management, and mitigation. Fundamentally, any such laws need to be scientifically-based and analyzed through interdisciplinary perspectives to avoid unjust socioeconomic impacts, among other concerns. Congress also needs to draft language to cover future applications of the technology, identify the primary agencies in charge of regulating different aspects of the technology, invite scientists to Capitol Hill, and include local communities and cultures in the regulatory process. In the event of congressional inactivity, state governments and the scientific community should gain inspiration from the international treaty and act independently to implement their own protections. By harnessing the power of transforming genetic sequences into biological solutions with appropriate safeguards, this novel technology promises to open the doors to an unprecedented frontier for solving complex challenges affecting flora and fauna surrounding the world.