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A BLACK-FOOTED FERRET AND U.S. LAW: LESSONS LEARNED FROM THE FIRST SUCCESSFUL CLONE OF A NATIVE U.S. ENDANGERED SPECIES

Lauren Corey*

Over thirty years ago, the DNA of a black-footed ferret was placed in the San Diego Zoo Global's Frozen Zoo. After decades of advancements in biotechnology, scientists recently used that same DNA to clone a black-footed ferret: the first clone of an endangered species native to the United States. Through a process called somatic cell nuclear transfer, scientists replaced the genetic material of an egg with the nucleus of a black-footed ferret somatic cell and implanted the egg into a non-endangered, domestic ferret surrogate. The U.S. Fish & Wildlife Service intentionally selected the black-footed ferret with the hope of restoring its population and expanding genetic variation of the species (a significant impediment to the species' viability); if the clones are able to reproduce, cloning could become an effective method to recover endangered species. Similarly, scientists are working to revive extinct species, such as the woolly mammoth, through a process known as "de-extinction," theorizing that reintroducing certain species could provide ecological benefits amidst the effects of climate change. For example, some say reintroducing woolly mammoths into the Arctic might recompress permafrost and prevent the release of stored carbon. Despite the potential ecological benefits of using biotechnology to restore imperiled species, the practice of cloning species for conservation raises significant concerns regarding ecological stability, animal welfare, and the allocation of human resources. Currently, it is unclear whether existing U.S. laws

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provide sufficient oversight of this rapidly-developing intersection of conservation and biotechnology. Accordingly, this Article considers whether: (1) the Environmental Protection Agency, the Food and Drug Administration, and the Department of Agriculture can collaboratively regulate and assess the risks of cloning imperiled species under their current respective statutory authority; and (2) whether the protections afforded by the Endangered Species Act extend to clones of species listed as endangered under the Act, as well as clones of extinct species.

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I. INTRODUCTION

In December 2020, the first clone of an endangered species native to the United States was born.[1] The birth of this animal, a black-footed ferret, marked "[t]he first significant milestone" of the U.S. Fish & Wildlife Service's ("USFWS's") partnership with scientists from various companies and organizations in an effort to "explore solutions to genetic diversity challenges and disease resistance" for the species.[2] The black-footed ferret, created from the frozen DNA of a ferret that lived decades ago,[3] could have ameliorative effects on ecosystems around the world.[4] This conclusion follows from the fact that the black-footed ferret has been identified by conservation biologists as a flagship species,[5]

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[1] Douglas Main, *A Black-Footed Ferret Has Been Cloned, a First for a U.S. Endangered Species*, NAT. GEO. (Feb. 18, 2021), https://www.nationalgeographic.com/animals/article/black-footed-ferret-clone-conservation-milestone [https://perma.cc/H2W2-V66U].

[2] *Black-Footed Ferret Cloning Research*, U.S. FISH & WILDLIFE SERV. (Feb. 23, 2021), https://www.fws.gov/mountain-prairie/es/blackFootedFerretcloning.php [https://perma.cc/R7D4-ZKHG].

[3] Main, *supra* note 1.

[4] *Reintroduction*, BLACK-FOOTED FERRET CONNECTIONS, http://blackfootedferret.org/reintroduction [https://perma.cc/SM3T-5ERR] (last visited Nov. 21, 2021) (describing the reintroduction of twenty-nine ferrets across the United States, Mexico, and Canada).

[5] Robert Home et al., *Selection Criteria for Flagship Species By Conservation Organizations*, ENV'T CONSERVATION 1 (June 2009) ("Flagship species are

which means the species "serve[s] as a symbol or focus point to raise environmental consciousness."[6]

Anthropogenic activities, such as habitat destruction,[7] fossil fuel emissions,[8] and hunting, have contributed—either directly or indirectly via the effects of climate change—to the extinction of many plant and animal species.[9] In fact, the world is currently in the midst of a mass extinction event caused primarily (if not entirely) by humans.[10] Although human intervention has significantly damaged the environment, human intervention can potentially restore biodiversity through a biotechnological process known as "de-extinction."[11] De-extinction utilizes various facets of

among key marketing tools used by conservation organizations to motivate public support.").

[6] *Id.* (quoting Samways et al., *Scales, Planning and Approaches to Inventoring and Monitoring*, GLOBAL BIODIVERSITY ASSESSMENT 491).

[7] Habitat destruction is defined as: "When a natural habitat, such as a forest or wetland, is altered so dramatically that it no longer supports the species it originally sustained. Plant and animal populations are destroyed or displaced, leading to a loss of biodiversity." *Habitat Destruction*, BIODIVERSITY A-Z, https://www.biodiversitya-z.org/content/habitat-destruction (Dec. 16, 2019) [https://perma.cc/JML8-GJMA].

[8] *Species and Climate Change*, IUCN, https://www.iucn.org/resources/issues-briefs/species-and-climate-change [https://perma.cc/N3VV-EE7Z] (last visited Oct. 23, 2021) ("Climate change currently affects at least 10,967 species on the IUCN Red List of Threatened Species™, increasing the likelihood of their extinction.").

[9] *See* Erin Okuno, *Frankenstein's Mammoth: Anticipating the Global Legal Framework for De-Extinction*, 43 ECOLOGY L. Q. 581, 584 (2016) ("Although scientists do not agree about the exact rates, species extinction rates are much higher now than the background extinction rates that would exist without humans—some studies suggest at least 1000 times higher.").

[10] Ivana Kottasová, *The Sixth Mass Extinction is Happening Faster Than Expected. Scientists Say It's Our Fault*, CNN (June 1, 2020), https://www.cnn.com/2020/06/01/world/sixth-mass-extinction-accelerating-intl/index.html [https://perma.cc/7253-EWN3] ("Humans have already wiped out hundreds of species and pushed many more to the brink of extinction through wildlife trade, pollution, habitat loss and the use of toxic substances.").

[11] *See* Okuno, *supra* note 9, at 589 ("One argument in favor of de-extinction is that reviving species that humans led to extinction is a matter of justice . . . .").

biotechnology, such as genetic engineering,[12] back-breeding,[13] and cloning[14] to recover extinct species.[15] Scientists can also use these technologies to prevent species from going extinct in the first place; and, although cloning an endangered species is not technically "de-extinction," the two processes raise similar issues.[16] This Article addresses the potential benefits and ramifications of both processes, referring to them collectively as "imperiled-species cloning." Proponents of imperiled-species cloning consider the process a way for humans to counteract their environmental destruction.[17] Opponents, however, believe imperiled-species cloning, especially resurrecting extinct species, could do more harm than good.[18] Ecological consequences remain uncertain, and the animals involved in the cloning process could be abused as the individuals merely become a means to an end.[19] Additionally, the technology is ripe for exploitation by unsavory actors.

Further, despite the conceivable positive ecological impacts of imperiled-species cloning, some conservationists have expressed valid concerns about the opportunity costs related to environmental

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[12] *Id.* at 592 ("Through genetic engineering, scientists fill gaps in the incomplete genetic sequence of an extinct species using DNA fragments from a closely related living species.").

[13] *Id.* ("[F]or selective back-breeding or strategic mating, scientists identify certain traits and selectively breed close living relatives of an extinct species until the living specimens begin to resemble the extinct species.").

[14] *Id.* ("Cloning involves inserting a nucleus from the extinct animal's cells into a host animal's unfertilized egg cell and then implanting the cell into a surrogate.").

[15] *Id.* at 588 ("De-extinction is 'the process of resurrecting species that have died out, or gone extinct.'").

[16] *Id.*

[17] Okuno*, supra* note 9, at 589–90 ("Some suggest that de-extinction may restore the ecological, instrumental, and intrinsic value that was lost when a species went extinct and that de-extinction might be used to help restore biodiversity and increase ecosystems' resilience . . . .").

[18] Some opponents of de-extinction "argue that the concept is unnatural and hubristic[,]" and "others worry that revived species may cause serious ecological or human health problems and that animals who are involved in the de-extinction process may suffer." *Id.*

[19] *Id.*

protection.[20] Funding for conservation efforts is already generally scarce.[21] Consequently, imperiled-species cloning efforts, especially de-extinction whose value and viability remain uncertain, could divert the already-limited resources from other conservation and biodiversity initiatives whose value and viability is more certain.[22] Additionally, Professor Beth Shapiro predicted that "our partiality toward charismatic megafauna will lead to a taxonomic imbalance among de-extinction projects that is not unlike the imbalance that exists in conservation work."[23] Thus, conservation funding may primarily be allocated in furtherance of the resurrection of charismatic mammals[24] at the expense of promoting biodiversity in less popular species that would likely have a more beneficial impact on ecosystems if reintroduced.[25]

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[20] *See, e.g.*, Jessica Allen et al., *De-Extinction, Regulation and Nature Conservation*, 32 J. ENV'T L. 309 (2020).

[21] *Id*. An analysis by the Defenders of Wildlife "found that the U.S. Fish and Wildlife Service needs more than double the amount of funding it currently receives for implementing the ESA in order for the law to do its job as Congress intended." Megan Evansen, *The Solution is Clear: Conservation Needs Funding*, DEFENDERS OF WILDLIFE (Sept. 19, 2019), https://defenders.org/blog/2019/09/solution-clear-conservation-needs-funding [https://perma.cc/XUF8-DXWN] [hereinafter DEFENDERS OF WILDLIFE, *Conservation Needs Funding*].

[22] Allen et al., *supra* note 20, at 314.

[23] Tiffany Taylor, *How to Clone a Mammoth: The Science of De-extinction, by Beth Shapiro*, TIMES HIGHER EDUC. (May 21, 2015), https://www.timeshighereducation.com/books/how-to-clone-a-mammoth-thescience-of-de-extinction-by-beth-shapiro/2020229.article [https://perma.cc/VP73-7XBZ]; *see* BETH SHAPIRO, HOW TO CLONE A MAMMOTH: THE SCIENCE OF DE-EXTINCTION (Princeton Univ. Press 2015). Beth Shapiro is a Professor in the Department of Ecology & Evolutionary Biology at the University of California. Taylor, *supra* note 23.

[24] *See* Ben Jacob Novak, *De-Extinction*, GENES, Nov. 2018, at 15. *But see* Taylor, *supra* note 23 ("But in reality, most de-extinction efforts are working to create notably ecologically significant proxies. However, the choice to focus on charismatic species is not a phenomenon unique to de-extinction projects. Charismatic species serve to stimulate public interest. Known as flagship species, charismatic and beloved species are a mainstay of conservation campaigns.").

[25] For example, mollusks are not the large megafauna that typically garner public attention. *See* Frédéric Ducarme et al., *What Are "Charismatic Species" for Conservation Biologists?*, BIOSCIENCES MASTER REVS. (2013). But the invertebrates have tremendous ecological value, "helping to structure aquatic bottom environments and providing habitat, protection, and food to a wide array

Moreover, scientists have posed a variety of questions regarding the reintroduction of extinct species into present ecosystems. For instance, how might the woolly mammoth, whose numbers plummeted over 10,000 years ago, survive in an ecosystem with which the species did not evolve?[26] Can enough land be secured for a mammoth's recovery, when acquiring land for endangered birds and frogs is already a significant challenge?[27] Would flocks of extinct passenger pigeons disrupt current forest ecosystems?[28] How can scientists predict species' behavior in the wild by observing their behavior in captivity? Could resurrected animals bring diseases and parasites? Would resurrected animals affect the human environment? How would they interact with livestock?[29]

Finally, technology capable of reviving an extinct species is susceptible to exploitation. Individuals or corporations with ulterior motives might abuse the technology, prioritizing their personal and pecuniary interests over animal conservation, animal well-being, and environmental health, for example.[30] As Researcher Jessica Allen and her colleagues framed the issue: "Might private sector for-profit genetic editing companies ignore public-good science arguments and misuse scientific breakthroughs in the interests of

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of other taxa." Helena Fortunato, *Mollusks: Tools in Environmental and Climate Research*, 33(2) AM. MALACOLOGICAL BULL. 310 (2015) https://doi.org/10.4003/006.033.0208 [https://perma.cc/7DM5-FY8V].

[26] *Scientists Say They Could Bring Back Woolly Mammoths. But Maybe They Shouldn't*, NPR (Sept. 15, 2021), https://www.npr.org/2021/09/14/1036884561/dna-resurrection-jurassic-park-woolly-mammoth [https://perma.cc/3LBH-BRFU].

[27] *See* DEFENDERS OF WILDLIFE, *Conservation Needs Funding*, *supra* note 21.

[28] Stanley Temple, a professor of conservation at the University of Wisconsin, has said: "It's not altogether clear that putting one of these extinct species from the distant past back into an ecosystem today would be much more than introducing an exotic species. It would have repercussions that we're probably not fully capable of predicting." Barry Yeoman, *Why the Passenger Pigeon Went Extinct*: *and Whether It Can, and Should, Be Brought Back to Life a Century After It Disappeared*, AUDUBON (May–June 2014), https://www.audubon.org/magazine/may-june-2014/why-passenger-pigeon-went-extinct [https://perma.cc/NCD8-5W22].

[29] *See* Hope M. Babcock, *The Genie Is Out of the De-Extinction Bottle: A Problem in Risk Regulation and Regulatory Gaps*, 37 VA. ENV'T L. J. 170 (2019).

[30] Allen et al., *supra* note 20, at 313.

shareholders?"[31] Although Allen's scenario refers to genetic engineering, a de-extinction method distinct from cloning,[32] her concern is applicable to any form of de-extinction and imperiled-species cloning as a whole. Without adequate oversight of imperiled-species cloning, the best interest of the species, the health of the environments into which these species are introduced, and human resources, such as livestock, might very well fall second to financial incentives and the pursuit to control the technology—motives that are so often intertwined.

This Article does not take a position as to whether de-extinction and the recovery of endangered species through cloning are ethical conservation practices. This Article does, however, address the controversy surrounding these technologies, since their use, or lack thereof, will have both legal and practical implications for many crucial issues including animal welfare, ecosystem stability, and the preservation/allocation of human resources. Now that the first successful cloning of an endangered species native to the United States has taken place,[33] it is essential that the United States regulate the use of cloning technology, particularly in the context of animal cloning. The implications of cloning for de-extinction versus cloning for endangered species recovery differ and so do the processes for each. However, there are significant parallels that merit discussing de-extinction cloning and species recovery via cloning in tandem. For example, cloning is the only method where the clone created is genetically identical[34] to the original (endangered or extinct) animal, which means the clone may automatically be subject to greater regulatory oversight since the animal would qualify as a member of that endangered or extinct population. Consequently, this Article specifically addresses how existing regulatory frameworks apply to the process of cloning endangered and extinct species, referred to collectively as

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[31] *Id.* (arguing that "the de-extinction space may be guided by multiple and varied agendas").

[32] *See, e.g.*, Allen et al., *supra* note 20, at 310.

[33] Main, *supra* note 1.

[34] Cloning produces a "genetic replica." Allen et al., *supra* note 20, at 310. Back-breeding does not produce genetic replicas, as it entails strategic breeding to create an animal *similar* to an extinct species. *See id.*

"imperiled-species cloning."[35] When referencing "de-extinctees," this Article is specifically referring to the clones created by the recovered DNA of extinct species.

This Article contributes to the broader cloning regulation dialogue by applying existing U.S. laws to the cloning of the black-footed ferret. Commentators previously suggested that the best time to address the issue of de-extinction cloning regulation would be when the technology actually became viable.[36] That time is now. Accordingly, Part II of this Article investigates the recent cloning of the endangered black-footed ferret, including who cloned the ferret and what technology was used. Part III addresses animal welfare issues that arise during, and as a consequence of, the cloning process. Part IV considers the takeaways of the black-footed ferret's cloning. Collectively, Parts V and VI analyze whether the current regulatory framework in the United States is sufficient to reduce the risks and potential negative impacts of using cloning for conservation purposes: Part V discusses how the Endangered Species Act ("ESA") can adequately protect a newly-created clone; Part VI focuses on how the Coordinated Framework for the Regulation of Biotechnology, a collaborative effort between regulatory agencies to assess the risks of reintroducing new biotechnology, can assess risks prior to the creation of a clone.

II. HOW THE FIRST SUCCESSFUL CLONE NATIVE TO THE UNITED STATES WAS CREATED

By the 1970s, the black-footed ferret was thought to be extinct when its populations, once widespread in the Western part of the United States, dwindled due to the poaching of its main prey, prairie dogs.[37] As "a slender, wiry, animal with black feet, a black face mask, and a black-tipped tail" that weighs two pounds on average, the black-footed ferret's charm made it a flagship species for the

[35] That is not to say that this framework could not potentially be extended to other technologies. Cloning is the focus here for purposes of simplicity of applying existing law. Perhaps amendments to the Endangered Species Act would adequately expand the scope of regulation.

[36] *See, e.g.*, Allen et al., *supra* note 20, at 310.

[37] *See* Main, *supra* note 1.

prairie ecosystem.[38] Its aesthetic appeal generated public support for conservation efforts.[39] The USFWS likewise supported its conservation and has been working to restore black-footed ferret populations since 1978, when the USFWS's Recovery Plan for the Black-footed Ferret Conservation was first approved.[40]

However, conservation of the black-footed ferret proved difficult, since the species does not have sufficient genetic variation to thrive.[41] Little genetic variation often makes a species "more susceptible to diseases and genetic abnormalities, and results in limited adaptability to conditions in the wild and a decreased fertility rate."[42] This vulnerability made the species an ideal candidate for cloning, since cloning can actually increase genetic diversity.[43] In fact, as discussed in more detail below, scientists used the DNA from a ferret that lived thirty years ago to create a ferret with three times the genetic diversity of most black-footed ferrets living today.[44] Thus, in addition to increasing an endangered species' population, "[t]his infusion of genetic diversity could help the

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[38] *Black Footed Ferret: Mustela Nigripes*, U.S. FISH & WILDLIFE SERV., https://www.fws.gov/mountain-prairie/factsheets/black-footed-ferret.pdf [https://perma.cc/ND25-YU4V] (last visited Nov. 13, 2021) [hereinafter *Black Footed Ferret: Mustela Nigripes*].

[39] *The Black-Footed Ferret: Flagship Species for the Prairie Ecosystem*, N. FORTY NEWS (Sept. 15, 2011), https://northfortynews.com/category/uncategorized/the-black-footed-ferret-flagship-species-for-the-prairie-ecosystem/ [https://perma.cc/C6M7-SX54] ("If Helen of Troy's beauty once 'launched a thousand ships and burnt the topless towers of Ilium,' the U.S. Fish and Wildlife Service hopes that the charm of the black-footed ferret's whiskered nose and masked eyes will help resurrect the fallen fortunes of short grass prairie habitat.").

[40] *Black-footed Ferret Recovery Plan: Second Revision*, U.S. FISH & WILDLIFE SERV. (Nov. 2013), https://www.fws.gov/mountain-prairie/es/species/mammals/blackfootedferret/2013NovRevisedRecoveryPlan.pdf [https://perma.cc/TLN7-Q33C].

[41] *See* Main, *supra* note 1.

[42] *Innovative Genetic Research Boosts Black-footed Ferret Conservation Efforts by USFWS and Partners*, U.S. FISH & WILDLIFE SERV. (Feb. 18, 2021), https://www.fws.gov/mountain-prairie/pressrel/2021/02182021-USFWS-and-Partners-Innovative-Genetic-Cloning-Research-Black-footed-Ferret-Conservation.php [https://perma.cc/P64R-R49W].

[43] *See* Main, *supra* note 1.

[44] *Id.*

animals reproduce more easily and be more resilient to diseases and stressors."[45]

How a clone's genetic makeup compares to its ancestors depends on what cloning technique is used.[46] Animals can be cloned in one of two methods: embryo splitting or nuclear transfer.[47] Embryo splitting is the process whereby an embryo is split during the early stages of development and then inserted into a surrogate.[48] The surrogate can then give birth to offspring that are genetically identical to each other and are a combination of genes from the parents but have no genetic similarity to the surrogate.[49] In contrast, the process of nuclear transfer creates clones genetically identical to the genetic donor.[50]

During somatic cell nuclear transfer, a somatic cell is taken from one animal ("animal A"), and an egg cell is taken from another animal ("animal B").[51] Then, the egg's genetic material from animal B is replaced with a nucleus from the somatic cell of animal A, and animal B's egg, which contains animal A's nucleus, is inserted into

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[45] *Id.*

[46] *See* Karl Illmensee & Mike Levanduski, *Embryo Splitting*, 15 MIDDLE E. FERTILITY SOC. J. 57, 58 (2010), https://doi.org/10.1016/j.mefs.2010.05.001 [https://perma.cc/VZ54-8QXF].

[47] Alison L. Van Eenennaam, *Cloning*, ANIMAL BIOTECH. U.C. DAVIS, https://animalbiotech.ucdavis.edu/cloning [https://perma.cc/24W8-E3S8] (last visited Nov. 13, 2021).

[48] *Id.*

[49] *See* Illmensee & Levanduski, *supra* note 46 ("Over the past 25 years, mammalian embryo splitting for the creation of genomically identical twins or multiples has advanced to a variety of applications in veterinary and human medicine.").

[50] DNA Learning Center, *Cloning* 101, YOUTUBE (Aug. 3, 2010), https://www.youtube.com/watch?v=q0B9Bn1WW_4 [https://perma.cc/S54A-QHQ3]. Nuclear transfer created Dolly the sheep, the first mammal cloned from an adult somatic cell. In Dolly's case, the egg cell came from a sheep with a black face, while the somatic cell came from a white face sheep. *Id.* Dolly had a white face, because somatic cell nuclear transfer creates a clone of the somatic cell donor. *See id.*

[51] Kenneth R. Bondioli, *Cloning of Livestock by Somatic Cell Nuclear Transfer in* ANIMAL BIOTECH. 2 at 1, 1 (Heiner Niemann & Christine Wrenzycki, eds. 2018) https://doi.org/10.1007/978-3-319-92348-2_1 [https://perma.cc/5A59-M4Q6].

a surrogate female.[52] Should the egg successfully germinate, the surrogate will give birth to a clone genetically identical to animal A.[53] Cloning an endangered or extinct species involves this process: injecting the DNA nucleus of the to-be-cloned species inside an egg, and then inserting that egg into a surrogate.[54] However, as discussed in more detail below, the surrogate for an endangered animal's genetic material should not be that particular endangered species, since the animal would be legally protected under the ESA. Instead, the surrogate should be a similar species, thereby eliminating the risk of unnecessary harm to an animal listed as "endangered" under the ESA.[55]

This procedure is precisely how the black-footed ferret was cloned. Many groups contributed to this milestone, including USFWS, as well as other corporate entities: ViaGen Pets & Equine, San Diego Zoo Global, and Revive & Restore.[56] ViaGen Pets & Equine is a company that primarily provides genetic preservation

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[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] This scenario would certainly be the case where an extinct species' DNA is recovered (as were fragments of woolly mammoth DNA from fossils) because an adult female of that species would not exist to act as a surrogate. A new company aims to "edit elephant DNA, adding genes for mammoth traits like dense hair and thick fat for withstanding cold" with the goal of "produc[ing] embryos of these mammoth-like elephants in a few years, and ultimately produce entire populations of the animals." *See* Carl Zimmer, *A New Company with a Wild Mission: Bring Back the Woolly Mammoth*, N.Y. TIMES (Sept. 30, 2021), https://www.nytimes.com/2021/09/13/science/colossal-woolly-mammoth-DNA.html [https://perma.cc/VVR2-WHH7].

[56] Main, *supra* note 1 ("'We're pretty excited—more along the lines of ecstatic,' said Shawn Walker, chief scientific officer with ViaGen Pets and Equine, a private pet cloning company that led the effort in partnership with the Fish and Wildlife Service, San Diego Zoo Global, and biotech conservation group Revive and Restore."); *see also The Black-footed Ferret Project: Partners and Advisors*, REVIVE & RESTORE, https://reviverestore.org/projects/black-footed-ferret/partners-and-advisors/ [https://perma.cc/Z8VG-SXT9] (last visited Nov. 16, 2021) [hereinafter *The Black-footed Ferret Project: Partners and Advisors*].

and cloning services for pets,[57] largely working with cats and dogs.[58] However, the company is branching into wildlife conservation because it "believe[s] that moving the promising and exciting area of animal genetic research forward will benefit all animals."[59] Revive & Restore is an organization that promotes biotechnology use for conservation by "introduc[ing] conservationists . . . to the academic and commercial labs advancing genetic and genomics sciences"[60] and by funding "transformative early-stage bio-science research and proof-of-concept projects."[61] San Diego Zoo Global, member of the "San Diego Zoo Wildlife Alliance,"[62] manages a frozen zoo of "germplasm"[63] for "conservation, assisted reproduction, evolutionary biology, and wildlife medicine."[64]

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[57] Not only did ViaGen clone the black-footed ferret; but, in August 2020, the group cloned the endangered Przewalski horse. *Conservation*, VIAGEN PETS & EQUINE, https://www.viagenpets.com/conservation/ [https://perma.cc/3ET9-DPH7] (last visited Nov. 21, 2021).

[58] *See Our Values & Mission*, VIAGEN PETS & EQUINE, https://www.viagenpets.com/values-mission/ [https://perma.cc/8JA2-GRZY] (last visited Nov. 21, 2021) ("ViaGen Pets is committed to the health and well-being of each and every dog and cat with whom we work.").

[59] *Id.*

[60] Revive & Restore "act[s] as a convener, advancer, and funder" to promote biotechnology conservation. *What We Do*, REVIVE & RESTORE, https://reviverestore.org/what-we-do/ [https://perma.cc/Z49Y-B55G] (last visited Nov. 21, 2021) (providing additional information about Revive & Restore).

[61] *Id.*

[62] San Diego Zoo Global and San Diego Zoo Safari Park rebranded under the name "San Diego Zoo Wildlife Alliance" in hopes of "better reflect[ing] the organization's focus on conservation and the interconnectedness of animal and human health, said CEO Paul Baribault." Jonathan Wosen, *Zoo and Safari Park Parent Organization Rebrands as San Diego Zoo Wildlife Alliance*, SAN DIEGO UNION-TRIB. (Mar. 3, 2021, 5:30 AM), https://www.sandiegouniontribune.com/business/story/2021-03-03/zoo-and-safari-park-parent-organization-rebrands-as-san-diego-zoo-wildlife-alliance [https://perma.cc/G7B3-MZK6].

[63] Germplasm is living tissue "contain[ing] the information of a species' genetic makeup." *Seed Biotechnologies: Germplasm*, SEED QUEST, https://www.seedquest.com/keyword/seedbiotechnologies/primers/germplasmresources/introduction.htm [https://perma.cc/K5TH-QJDL] (last visited Nov. 21, 2021) (information presented by the Seed Biotechnology Center at UC Davis).

[64] The Frozen Zoo contains over "10,000 living cell lines, gametes, and embryos" from "1,000 taxa, including one extinct species, the po'ouli." *Science*, SAN DIEGO ZOO WILDLIFE ALL., https://science.sandiegozoo.org/resources/

In the late 1980s, San Diego Zoo Wildlife Alliance's Frozen Zoo received the genes of a black-footed ferret named Willa.[65] In 2013 the USFWS asked Revive & Restore to "explore the potential use of genomic technologies to increase [b]lack-footed ferret genetic diversity."[66] After researching genetic variation[67] and planning recovery efforts, Revive & Restore received a permit from USFWS allowing Revive & Restore to: (1) "determine the potential for using [nuclear transfer] cloning techniques to bring genetic diversity from historic cell lines back into the population";[68] and, (2) "test a variety of hypothetical sylvatic plague resistance solutions in cell culture."[69]

In December 2020, these entities' efforts came to fruition when the black-footed ferret clone, Elizabeth Ann, was born at the USFWS's Black-footed Ferret Conservation Center.[70] Revive & Restore facilitated the cloning of Willa's DNA to create the

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frozen-zoo%C2%AE [https://perma.cc/R9WY-J4XY] (last visited Nov. 21, 2021).

[65] *News Release: Innovative Genetic Research Boosts Black-footed Ferret Conservation Efforts by USFWS and Partners*, SAN DIEGO ZOO WILDLIFE ALL. (Feb. 18, 2021), https://sandiegozoowildlifealliance.org/pressroom/news-releases/innovative-genetic-research-boosts-black-footed-ferret-conservation-efforts [https://perma.cc/MT62-NW3A].

[66] *The Black-footed Ferret Project: Major Milestones*, REVIVE & RESTORE, https://reviverestore.org/projects/black-footed-ferret/major-milestones [https://perma.cc/R3YR-SRYV] (last visited Nov. 21, 2021).
with the goal of increasing the effective population size of the species.

[67] *See, e.g.*, Samantha M. Wisely et. al, *A Road Map for 21st Century Genetic Restoration: Gene Pool Enrichment of the Black-Footed Ferret*, AM. GENETIC ASSOC. 581, 583 (Aug. 24, 2015) ("Curated, frozen repositories of somatic and germ cells (biological resource banks) have been created for the purpose of both assisted breeding and reproductive cloning. These collections provide unique genetic resources to these critically endangered species.").

[68] REVIVE & RESTORE, *supra* note 56.

[69] *Id.*

[70] Main, *supra* note 1. The Center was built in Carr, Colorado in 2005. *History of the Black-footed Ferret*, BLACK-FOOTED FERRET CONNECTIONS, http://blackfootedferret.org/history/ [https://perma.cc/JK98-JU96] (last visited Nov. 21, 2021). Its purpose is the recovery of the black-footed ferret species, and it houses 60% to 70% of all captive black-footed ferrets. National Black-footed Ferret Conservation Center, FACEBOOK, https://www.facebook.com/Ferret Center/?ref=page_internal [https://perma.cc/NGM3-85NM] (last visited Nov. 1, 2021).

genetically identical black-footed ferret, Elizabeth Ann.[71] First, eggs were taken from a related species of ferrets "to avoid putting endangered female black-footed ferrets at risk."[72] Then, scientists from ViaGen Pet & Equine "used pipettes to remove the nucleus and genetic material" from the eggs.[73] This material was replaced with the contents of Willa's cell, and scientists then used an electric charge to divide the eggs.[74] This process created embryos, which were implanted into a domestic ferret.[75] One of these embryos gestated in the host ferret, which resulted in the endangered, black-footed ferret clone, Elizabeth Ann, marking a milestone for both the viability and applicability of cloning technology.[76]

III. SHOULD SPECIES CONSERVATION TAKE PRECEDENCE OVER ANIMAL WELFARE?

Imperiled-species cloning raises both animal conservation and animal welfare concerns; yet these concerns, oddly enough, do not always align. Although considered by some to be a technological success for conservation, the black-footed ferret's cloning demonstrates how efforts to bring a species back from the brink of extinction could involve harming animals that society views as less valuable. Specifically, cloning necessarily involves the imposition of extremely invasive procedures on an individual host, as well as harmful testing on other animals. For example, black-footed ferrets are "highly specialized predators that depend upon prairie dogs" as their primary food source,[77] but prairie dogs are incredibly vulnerable to the sylvatic plague, a disease with mortality rates over 90% during outbreaks.[78] To reduce the risk of outbreaks so that black-footed ferrets have a sufficient food source, Revive & Restore

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[71] Main, *supra* note 1.
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Black Footed Ferret: Mustela Nigripes*, *supra* note 38.
[78] For more information about the sylvatic plague, see Tonie Rocke, *Sylvatic Plague,* USGS (Feb. 23, 2018), https://www.usgs.gov/centers/nwhc/science/sylvatic-plague?qtscience_center_objects=0#qt-science_center_objects [https://perma.cc/R9L4-XMW8].

is testing a method of protection against the plague that involves exposing mice to "plague-binding antibodies" with the hope of "establish[ing] inheritable immunity."[79] Essentially, in attempting to conserve the black-footed ferret, Revive & Restore is harming mice—an animal viewed as less important in society—to develop a vaccine for not even the black-footed ferret but for the black-footed ferrets' prey of choice.[80]

This conservation experiment raises questions regarding the ethicality of trying to recover a species when a species does not naturally thrive in a given environment. Should society bring a species back from extinction if environments must be manipulated in order for the species to survive? Why subject value-less species, such as mice, to torturous experiments in order to do so? Animal activists take issue with the notion that animals can be used in experiments to further human objectives, even if for the purposes of conservation.[81] For example, People for the Ethical Treatment of Animals ("PETA") has condemned cruelty to mice in laboratory experiments.[82] Currently, mice are not regulated by the Animal Welfare Act; therefore, laboratories need not provide mice with adequate food, water, space, or painkillers after experimental and intensive surgeries and have no duty to consider the interests of the mice.[83] PETA has advocated for the regulation of (in their view) unjust experiments: Mice "are mammals with nervous systems similar to our own. It's no secret that they feel pain, fear, loneliness, and joy just as we do."[84] Putting mice at risk of the highly-fatal sylvatic plague, in addition to "fever, chills, weakness, and swollen

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[79] *The Black-footed Ferret Project: Partners and Advisors*, *supra* note 56.

[80] *Id.*

[81] *See Mice and Rats in Laboratories*, PETA, https://www.peta.org/issues/animals-used-for-experimentation/animals-laboratories/mice-rats-laboratories/#:~:text=More%20than%20110%20million%20mice,anxiety%2C%20depression%2C%20and%20helplessness [https://perma.cc/F2VD-LW8B] (last visited Nov. 21, 2021).

[82] *Id.*

[83] PETA asked Congress to amend the Animal Welfare Act ("AWA") because "as many as 800 U.S. laboratories . . . experiment exclusively on mice, rats, and other animals" unregulated by the AWA. *Id.*

[84] *Id.*

and painful lymph nodes,"[85] is surely not in the best interest of the animals.

Some conservationists, on the other hand, are primarily concerned about the survival of various species populations (as opposed to protecting individual animals) and might be more willing to overlook abuses of more-prevalent and even overpopulated animals if doing so means saving imperiled (extinct or endangered) species. Defenders of Wildlife, for example, has indicated its support for cloning the black-footed farret, likely because the species has a strong chance of thriving in the wild today.[86] But, Defenders of Wildlife has also taken the position that species conservation should not always come before animal welfare.[87] The organization questions the ethics of bringing back an extinct species for the animal to "spend its days on life support, intensively managed at a zoo or other artificial environments[.]"[88] Perhaps the risks of animal welfare and the benefits of species conservation should be weighed against each other on a case-by-case basis. For instance, when a given species will likely not survive in the wild and therefore must remain in captivity, animal welfare concerns should outweigh conservation goals and cloning the species would thus be improper. Additionally, excessive use and abuse of non-endangered animals as cloning surrogates, such as the domestic ferret used to clone Elizabeth Ann, puts the host species at risk. Consequently, scientists should take care to limit harm to the animals involved in the cloning process, regardless of whether or not the species is

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[85] *Sylvatic Plague Vaccine Frequently Asked Questions*, USGS, https://www.fs.usda.gov/Internet/FSE_DOCUMENTS/stelprdb5426466.pdf [https://perma.cc/U5NB-D4VV] (last visited Nov. 21, 2021).

[86] Defenders of Wildlife is a member of the Black-Footed Ferret Recovery Team, which advises recovery efforts of the ferret. *Black-Footed Ferret Recovery Implementation Team*, BLACK-FOOTED FERRET CONNECTIONS, http://blackfootedferret.org/bff-rit/ [https://perma.cc/MCK7-DDDL] (last visited Nov. 21, 2021).

[87] *See* DEFENDERS OF WILDLIFE, *De-Extinction: The Reality Behind the Hype*, https://defenders.org/sites/default/files/publications/DeExtinction-Factsheet-The-Reality-Behind-the-Hype.pdf [https://perma.cc/L32G-Q576] (last visited Nov. 21, 2021).

[88] *Id.*

presently endangered, for the sake of both animal welfare and conservation.

IV. KEY TAKEAWAYS FROM THE CLONING OF THE BLACK-FOOTED FERRET

In 2018, after providing an opportunity for public comment,[89] the USFWS granted Revive & Restore a permit to research cloning the black-footed ferret in 2018.[90] This permit was "a first-of-its-kind Endangered Species Recovery Permit from the [USFWS] to initiate the foundational laboratory research for the genetic rescue of the [b]lack-footed ferret."[91] The permit authorized Revive & Restore to research: (1) "[t]he viability of using cloning techniques to bring cryopreserved cell lines and the genetic diversity they possess back into the population," and (2) "[t]he viability of various potential methods to provide inheritable resistance for sylvatic plague."[92]

In effect, the USFWS's issuance of a recovery permit for research regarding the cloning of an endangered species signals that the ESA can regulate cloning. By issuing the permit, the USFWS crucially recognized that "genetic research efforts"[93] further the

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[89] According to the FWS's notice, the permit was sought to "develop, test, and optimize model cisgenic and novel disease-resistance pathways in the black-footed ferret, both in vitro and in vivo, leveraging domestic ferret resources for comparative genomics, comparative proteomics, and interspecies somatic cell nuclear transfer (iSCNT) reproductive techniques for the purpose of enhancing the species' survival." U.S. Endangered Species; Receipt of Recovery Permit Application, 83 Fed. Reg. 15597, 15597 (Apr. 11, 2018) https://www.federalregister.gov/documents/2018/04/11/2018-07446/us-endangered-species-receipt-of-recovery-permit-application [https://perma.cc/4F3J-Q28M].

[90] *The Black-footed Ferret Project*, REVIVE & RESTORE, https://reviverestore.org/projects/black-footed-ferret/ [https://perma.cc/A8B9-A2UK] (last visited Nov. 21, 2021) [hereinafter *The Black-footed Ferret Project*].

[91] *Id.*

[92] *Id.*

[93] FWS issued permits for the recovery of the black-footed ferret that authorize "propagation, plague mitigation, monitoring, and genetic research efforts—all of which have contributed to the recovery and conservation of this iconic species, which is coming back from the brink of extinction." *Examples of Activities Conducted Under Recovery Permits*, U.S. FISH & WILDLIFE SERV.,

purpose of the ESA.[94] However, many questions remain unanswered, such as, do cloned ferrets enjoy the same protections as non-cloned ferrets? Should Elizabeth Ann be capable of reproducing young,[95] would her kits be protected by the ESA? Elizabeth Ann is the only clone for now, but "[s]he may soon be joined by other kits cloned from Willa's cell line as well as a historic male cell line."[96]

Revive & Restore claims that if Elizabeth Ann and other clones can breed, their reproductive ability "will . . . validate cloning as a legitimate, safe, and useful reproductive technology for the conservation management of black-footed ferrets and other U.S. endangered species."[97] Yes, that ability would greatly benefit a species; however, does the fact that a cloned animal can reproduce prove that cloning is legitimate, safe, and useful, as Revive & Restore suggests?

This claim begs the question: was there a risk assessment conducted in determining whether to clone these ferrets? According to Revive & Restore, the "[r]esearch to follow will evaluate the clones' health and safety before any of the clones are integrated into the breeding population."[98] The scientists involved in cloning Elizabeth Ann consider her creation an advancement in conservation sciences;[99] however, these scientists consider the reintroduction of a cloned black-footed ferret to be no different than reintroducing a non-cloned, black-footed ferret from captivity.[100] The scientists claim that the risks of reintroduction would be mitigated because

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https://www.fws.gov/endangered/permits/recovery-permits-examples.html [https://perma.cc/D98E-KTW3] (last visited Nov. 13, 2021).

[94] "Recovery permits may be issued for purposes that are consistent with the Endangered Species Act (ESA) to assist in the recovery of endangered and threatened species." *Recovery "10(a)(1)(A)" Permits Program*, U.S. FISH & WILDLIFE SERV., https://www.fws.gov/endangered/permits/recovery-permits.html [https://perma.cc/M66Z-ZYB8] (last visited Nov. 13, 2021).

[95] Revive & Restore is not yet certain whether Elizabeth Ann can successfully reproduce. *Id.*

[96] *The Black-footed Ferret Project*, *supra* note 90.

[97] *Id.*

[98] *Id.*

[99] *Id.*

[100] *Id.*

"[l]ike all black-footed ferrets reintroduced to the wild, [Elizabeth Ann's] descendants would first be acclimated and observed in an outdoor enclosure beforehand"[101] to ensure they are able to hunt and survive in the wild.[102] But, until scientists make these observations and corresponding predictions and until these predictions can be compared with the actual results of reintroduction, the severity of the ecological and health risks of reintroduction, as briefly described above, will remain uncertain.

V. BIOTECHNOLOGY AGENCIES CAN ASSESS & REGULATE CLONING TO MITIGATE RISKS

The successful cloning of the black-footed ferret provides a tangible context to apply existing U.S. laws and assess whether these statutes and regulations can effectively regulate the cloning of endangered and extinct species. In regulating cloning in this context, two key issues require consideration: (1) whether or not to clone a particular endangered or extinct species in the first place; and (2) if an endangered or extinct species is cloned, what protections that clone should receive. Legal scholars have expressed concern that a cooperative framework between existing governmental entities overseeing de-extinction would likely lead to a regulatory gap in application.[103] However, this concern conflates general regulatory concerns with the inherent characteristics of cloning because adequately regulating imperiled-species cloning is multifaceted and thus would actually benefit from the coordinated participation of various governmental entities. Moreover, a framework for such cloning must not only address the regulation over the cloning process and technology but must also provide protection for the cloned species. Fortunately, for cloning endangered species,

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[101] *Id.*

[102] *Id.*

[103] Hope M. Babcock writes that the Coordinated Framework for the Regulation of Biotechnology has received criticism. *See* Babcock, *supra* note 29, at 191 ("Some critics argue that the Coordinated Framework's 'regulatory regime has resulted in regulatory passivity as agencies have equated providing similar treatment for conventional and biotechnological products with limited regulation.' These critics would like to see 'a more precautionary regulatory approach,' but this seems unlikely.").

existing laws likely provide a sufficient framework for agencies to collaboratively accomplish these tasks so that "starting from scratch" will be rendered unnecessary. De-extinction cloning, on the other hand, is less clearly covered by existing law.

Cloning endangered and extinct species for conservation entails a myriad of ecological risks. Even a well-known endangered species like the state bird of Hawaii, the nēnē, can be conservation-reliant, meaning the species "require[s] ongoing management to prevent extinction even after reach[ing] a sustainable population size."[104] Clones of extinct species would likely be even more conservation-reliant in instances where the species' historical habitat[105] has changed significantly over time,[106] and thus the species is no longer compatible with its historical habitat.[107] Therefore, improperly assessing the reintroduction of a cloned imperiled species—endangered or extinct—would hinder the species' ability to survive, making the cloning of the species a potential waste of conservation resources.

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[104] *See* Lee Brawn, *Rise of the Nēnē: Cautious Hope for Hawaii's State Bird*, DEFENDERS OF WILDLIFE (Jan. 3, 2020), https://defenders.org/blog/2020/01/rise-of-nene-cautious-hope-hawaiis-state-bird [https://perma.cc/RA67-ZG8Z] ("Ninety percent of native Hawaii species, including the nēnē, are endemic - found only in Hawaii and adapted to its unique island conditions. This trait often makes them especially vulnerable to novel threats like invasive species (since many evolved with few or no predators) and habitat alteration and more reliant on ongoing conservation efforts.").

[105] There are significant potential risks in introducing "organisms to existing ecological systems of which these organisms have either never been a constituent or from which they have been absent for a substantial period of time." Alejandro E. Camacho, *Going the Way of the Dodo: Deextinction, Dualisms, and Reframing Conservation*, 92 WASH. UNIV. L. REV. 849, 859 (2015).

[106] For more information about how time affects habitats, see *Ecosystem Change*, GREEN FACTS (July 30, 2021), https://www.greenfacts.org/en/ecosystems/millennium-assessment-2/7-ecosystem-change-time.htm [https://perma.cc/G2TR-5Z6A] ("[T]he sudden switch in 1983 from coral to algal domination of Jamaican reef systems . . . followed several centuries of overfishing of herbivores, which left the control of algal cover almost entirely dependent on a single species of sea urchin, whose populations collapsed when exposed to a species-specific pathogen. As a result, Jamaica's reefs shifted (apparently irreversibly) to a new low-diversity, algae-dominated state with very limited capacity to support fisheries.").

[107] *See* Camacho, *supra* note 105, at 859.

Additionally, reintroduction could have unintended repercussions, impacting existing ecosystems, as well as human resources.[108] For example, in 2019, NASA astrobiologist Dr. Lynn J. Rothschild warned against cloning and reintroducing the extinct woolly mammoth because even reintroducing an endangered species often has "all sorts of ripple effects and unintended consequences," and surely these effects and consequences would be exacerbated when reintroducing a species that has not roamed the Earth in thousands of years.[109] Rothschild provided another example: the gray wolf's reintroduction into Yellowstone National Park where the wolves hunted elk and deer so extensively that aspen trees in Yellowstone thrived and resulted in more materials for the native beavers to use for their dams.[110] The gray wolf's reintroduction "continues to astonish biologists with a ripple of direct and indirect consequences through the ecosystem."[111] Although the gray wolf's impact on the beaver population was a pleasant surprise, this conservation decision illustrates how unpredictable a species' reintroduction can be. Given the intricacy of ecological relationships, introducing an extinct species may cause even more unpredictable impacts than the grey wolf's reintroduction to Yellowstone, and the impact might not be so positive—in fact, it could be devastating.[112]

Even where scientists believe they can predict how a species' reintroduction would impact the environment, others strongly disagree. For example, some scientists believe that reintroducing mammoths into the Arctic could help mitigate climate change because their stomping could compact the ice, "slow[ing] down permafrost thaw and the release of carbon."[113] However,

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[108] *See id.* ("[S]uch introductions may serve to erode biodiversity, disrupt ecosystems, and contribute to extinctions at receiving sites.").

[109] Dr. Lynn J. Rothschild, *Seven Reasons We Shouldn't Bring Extinct Animals Back to Life*, QUARTZ (Mar. 15, 2019), https://qz.com/1566083/we-shouldnt-bring-back-extinct-animals-like-the-woolly-mammoth/ [https://perma.cc/R72T-PMLN].

[110] *Id.*

[111] Brodie Farquhar, *Wolf Reintroduction Changes Ecosystems in Yellowstone*, NAT. GEO. (June 30, 2021), https://www.yellowstonepark.com/things-to-do/wildlife/wolf-reintroduction-changes-ecosystem/ [https://perma.cc/34VW-V6VX].

[112] *See id.*

[113] *Id.*

evolutionary scientists and mammoth experts Love Dalén and Tori Herridge found no evidence to support such a theory.[114] Additionally, what if woolly mammoths cannot thrive in the climate of today's Arctic, or what if they interact with their Arctic habitat in a way that exacerbates the effects of climate change? If so, then would the cloning of the woolly mammoth have been solely for the species to exist in captivity indefinitely?[115] The answers to these questions suggest the danger that cloning could simply become a means to demonstrate technological prowess at the expense of the ecological "greater good," considering the many uncertainties surrounding the reintroduction of species. Thus, experts should conduct a thorough risk assessment before an endangered species is cloned and certainly before an extinct species is cloned. Otherwise, animal cloning could simply become a "conservation" initiative for humans to bring back species populations in order to feel better about their past ecological destruction, without actually promoting species conservation or animal welfare.

Before an entity engages in imperiled-species cloning, thorough environmental risk assessments should be conducted. Accordingly, this Article proposes that these risk assessments should be guided by the U.S. Coordinated Framework for the Regulation of Biotechnology ("CFRB"). The CFRB is a collaboration between the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA"), and U.S. Department of Agriculture ("USDA") and was created "to protect health and the environment without impeding innovation."[116] In 1992, the CFRB updated its policy to reflect the principle that the "oversight of biotechnology products introduced in the environment" should be premised on "a risk-based, scientifically sound basis" that "focus[es] on the characteristics of the product and the environment into which [the biotechnology] is being introduced, not the process by which the [biotechnological] product is created."[117] In 2017, the CFRB again

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[114] *See id.*

[115] *See* DEFENDERS OF WILDLIFE, *De-Extinction*, *supra* note 87.

[116] *About the Coordinated Framework*, UNIFIED WEBSITE FOR BIOTECH. REG., https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about [https://perma.cc/DB3P-WH99] (last visited Sept. 30, 2021).

[117] *Id.*

updated its policy and expressly established the scope of the CFRB's authority to provide "a rational, scientific evaluation of products," including assessments on "how the processes used in the development or manufacture of [a] product may introduce, mitigate, or avoid risk."[118] The CFRB's focus on assessing risks of biotechnology products makes the three-agency entity an appropriate authority for regulating cloning, a form of biotechnology. Thus, as explained below, the CFRB can ensure a thorough risk assessment is conducted before a determination is made regarding whether a particular imperiled species should be cloned.[119] Moreover, the three agencies can combine their varied expertise to oversee the processes through which imperiled-species cloning are developed and implemented.[120]

The three agencies—the EPA, the FDA, and the USDA—all have unique expertise and authority that, in amalgamation, can comprehensively regulate the cloning of endangered and extinct species and their potential reintroduction by assessing the associated risks according to their explicit statutory authorizations. The agencies' regulatory mechanisms are ideal for overseeing cloning experiments, ensuring the well-being of newly-created clones and evaluating potential environmental impacts should the clones be reintroduced into the wild. For instance, the EPA could use its expertise in conducting ecological risk assessments[121] under the National Environmental Protection Act (colloquially known as "NEPA") to identify how reintroducing a clone could impact the

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[118] Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology, BIOTECH. WORKING GRP. (2017) [hereinafter "BWG"] https://usbiotechnologyregulation.mrp.usda.gov/2017_coordinated_framework_update.pdf [https://perma.cc/W934-W2JZ].

[119] *See* Babcock, *supra* note 29, at 189–90.

[120] *See id.*

[121] *Ecological Risk Assessment*, EPA, https://www.epa.gov/risk/ecological-risk-assessment [https://perma.cc/5BLC-BA79] (June 7, 2021); *see also Our Mission and What We Do*, EPA, https://www.epa.gov/aboutepa/our-mission-and-what-we-do [https://perma.cc/L6YT-9WVK] (July 2, 2021).

ecosystem, the clone itself, and the species' continued viability.[122] Significantly, the FDA has exercised its general regulatory authority over cloning for years. In 1998, the FDA published a letter stating the agency had jurisdiction over human cloning.[123] Moreover, the FDA already oversees the health risks of agricultural animals involved in cloning and therefore can readily oversee imperiled-species cloning as well.[124] In fact, the FDA published a *Risk Management Plan for Clones and Their Progeny* in 2008, which reported that surrogate animals, as well as young clones, are susceptible to an increased risk of adverse health outcomes.[125]

The third agency, the USDA, has regulatory experience "preventing, controlling and/or eliminating animal diseases, and monitoring and promoting animal health and productivity" through a variety of livestock-protection programs.[126] One such program is the Cattle Fever Tick Eradication Program, which works to "systematically detect, treat, and eradicate tick infestations."[127]

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[122] For more information on the importance of ensuring the de-extinctee will not only thrive in its new environment, but also will not harm its new environment, see Camacho, *supra* note 105, at 859–60.

[123] *Letter About Human Cloning*, FDA, https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/letter-about-human-cloning [https://perma.cc/ML5B-55LQ] (Mar. 15, 2018).

[124] *See Risk Management Plan for Clones and Their Progeny*, USDA (Jan. 15, 2008), https://www.fda.gov/animal-veterinary/animal-cloning/risk-management-plan [https://perma.cc/864P-5SVU].

[125] *Id.* ("Specific health issues of concern for the surrogate dams include the increased incidence of prenatal hydroallantois and/or hydrops in the surrogate dams carrying clone pregnancies to term. Health issues of concern for the clones themselves include perinatal symptoms related to LOS including, but not limited to, pulmonary and/or renal insufficiency, difficulty maintaining body temperature, and umbilical hernias.").

[126] *Animal Disease Information*, ANIMAL HEALTH & INSPECTION SERVS., USDA, https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information [https://perma.cc/KG3W-6BLB] (June 29, 2021) ("Veterinary Services protects and improves the health, quality, and marketability of our nation's animals, animal products and veterinary biologics.").

[127] For more information about the USDA's efforts to eradicate vector-borne illnesses affecting cattle, see *Vector-Borne Diseases*, ANIMAL HEALTH & INSPECTION SERVS., USDA, https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/cattle-disease-information/cattle-vector-borne-diseases [https://perma.cc/KG3W-6BLB] (Jan. 15, 2021).

Thus, the USDA likewise has the ability to systematically detect, treat, and eradicate diseases and pests that may spread from cloned animals to livestock. These past and current agency practices are just some examples of how these agencies' expertise make them particularly well-suited to undertake the regulation of imperiled-species cloning.

A. Delegating Species Viability and Environmental Risk Assessments to the EPA

The EPA should serve as the primary agency in assessing the future viability of the cloned species, as well as the potential environmental harms associated with the potential reintroduction of the cloned species. Specifically, under the Toxic Substances Control Act ("TSCA"), the EPA regulates chemical substances or mixtures that may pose risks to the environment.[128] Under the TSCA, a chemical substance is defined as "any organic or inorganic substance of a particular molecular identity, including any combination of these substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical."[129]

Importantly, the DNA inserted into the host animal surely could constitute a "chemical substance" since the EPA has taken the stance that "chemical substance" should be defined broadly, and the EPA has adhered to this broad interpretation in many instances.[130] Specifically, the EPA has stated that "chemical substances do not 'exclude life forms which may be manufactured for commercial purposes.'"[131] Further, the EPA has explained that the "TSCA regards generally recombinant DNA molecules as 'chemical substances.'"[132] Thus, a somatic cell or an egg cell extracted from an animal for cloning via nuclear transfer could fall under this definition, as an organic substance occurring in part. Accordingly, the DNA inserted into the surrogate animal would be regulated by the EPA under the TSCA, subject to certain restrictions regarding

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[128] 15 U.S.C. § 2603 (2019) ("Testing of chemical substances and mixtures").
[129] *Id.* § 2602(2)(A).
[130] *See* Babcock, s*upra* note 29, at 189–90.
[131] *Id.*
[132] *Id.*

how the "chemical substance" can affect or interact with the environment.

However, Professor Hope M. Babcock highlighted that, "it remains uncertain whether . . . a de-extinct species that contains 'recombined DNA molecules[,] fits . . . that definition.'"[133] Thus, perhaps the DNA of an imperiled-species is a "chemical" under the TSCA, but the cloned animal created from that DNA is not. Consequently, a challenging regulatory dichotomy could emerge where the TSCA applies to the cloning *process*, but does not apply once the cloning process has taken place, effectively hindering the EPA's authority to regulate under the TSCA.

B. The FDA Can Assess Potential Harms to Host Animals

A discussion on imperiled-species cloning would be incomplete without a discussion on animal welfare, as the de-extinction process inherently involves humans invasively experimenting with animals in laboratories. Currently, most federal laws (and state laws) do not expressly recognize rights for animals regarding the utilization of their DNA; however, Americans generally condemn animal abuse.[134] Animal welfare advocates in particular have expressed fundamental moralistic concerns regarding the application of biotechnology to animals. For instance, "[a]nxiety, distaste, or even revulsion" may arise from the genetic engineering of animals, since the process unnaturally mixes genes by "cross[ing] the species barrier."[135] Additionally, to pose a thought-provoking question: "Do animals, whether wild or domestic, have an inherent right to have their genetic codes intact and untouched?"[136]

The FDA, via the Federal Food, Drug, and Cosmetic Act ("FDCA") could address the animal welfare concerns posed above and oversee animal welfare assessments during cloning processes.

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[133] *Id.* at 190.

[134] *See generally* Cass R. Sunstein, *The Rights of Animals*, 70 U. CHI. L. REV. 387 (2003) (describing how, although animals do not have rights, humans generally frown upon animal abuse).

[135] Chad West, *Economics and Ethics in the Genetic Engineering of Animals*, 19 HARV. J.L. & TECH. 413, 427 (2006), http://jolt.law.harvard.edu/articles/pdf/v19/19HarvJLTech413.pdf [https://perma.cc/2HMK-ZHLY].

[136] *Id.*

Under the FDCA, the FDA is authorized to assesses newly developed animal drugs for safety and subsequently approves their distribution and use upon meeting the FDA's established criteria.[137] A "drug" under the FDCA includes "articles (other than food) intended to affect the structure or any function of the body."[138] In 2008, the FDA recognized its ability to regulate genetically-engineered animals, as their creation requires integrating genetic material or rDNA "into the DNA of an animal and is *intended to affect the animal's structure or function*."[139] In 2017, the FDA proposed expanding its authority to regulate genome editing as well.[140] The FDA collectively refers to the results of genetic engineering and genome editing as an intentional genomic alteration ("IGA"), and although animals with IGAs are not inherently drugs, the FDA views "animals produced through the use of genome editing technologies and genetic engineering" as within its regulatory purview.[141]

Thus, how do cloned animals relate to this undertaking by the FDA to manage genetically engineered animals? According to the FDA, a copy of a "conventionally-bred animal[]" would not have an IGA and thus would not be covered by the IGA framework.[142] However, a clone that was created by genetically altering the DNA of an animal, or an animal with an IGA that was cloned, would fit within the framework's application.[143] Like genetic engineering and genome editing, somatic cell nuclear transfer involves the insertion

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[137] *See Q&A on FDA Regulation of Intentional Genomic Alterations in Animals*, FDA (Apr. 22, 2020), https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/qa-fda-regulation-intentional-genomic-alterations-animals [https://perma.cc/9JCE-V5GS] [hereinafter *Q&A on FDA Regulation*] ("FDA's regulation of these animal products differs from its regulation of plant products because, under the law, FDA's review for animals includes determining whether IGAs are safe to the target animal, in addition to a determination of food safety (for food-producing animals), and efficacy.").

[138] 21 U.S.C. § 321(g)(1)(C) (2019).

[139] BWG, *supra* note 118, at 18 (emphasis added).

[140] *Q&A on FDA Regulation*, *supra* note 137.

[141] *Id.*

[142] *Consumer Q&A*, FDA, https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/consumer-qa [https://perma.cc/RAR9-6JAR] (Dec. 14, 2020).

[143] *Id.*

of genetic material into the surrogate animal, which inherently affects the surrogate animal's "function." Regardless of whether a clone is considered to have an IGA, the genetic material inserted into a surrogate to clone an endangered or extinct species likely constitutes "a drug," thereby subjecting the cloning practice to regulation under the FDCA.

C. The USDA Has the Authority to Assess the Potential Impact on Livestock

Clones of endangered and extinct species are likely to pose a variety of risks to human resources, exacerbated by the uncertainty surrounding how clones will interact in the environment.[144] For example, scholars worry that de-extinctees (members of a previously extinct species) will endanger livestock by transmitting unusual pests, viruses, and diseases.[145] Moreover, as Professor Babcock explained, the "small size of possible sub-populations of a de-extinct species, the species' concentration in relatively small geographic areas during its early release years, and the uncertainty of how the species would respond to its new environment would make it vulnerable to predators and diseases."[146] Accordingly, Professor Babcock's concerns highlight that the potential impacts of de-extinctees to human resources, via their impact on the environment, is unpredictable, especially compared to clones of animals today, such as agricultural animals. Clones of an endangered species, particularly a species in steep decline with few

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[144] *See, e.g.*, Babcock, *supra* note 29, at 181 ("There is a risk that reintroduced species could also adversely affect the human environment by threatening livestock and commercial fisheries, agriculture and recreational land uses, and even human safety.").

[145] See *id.* at 188, for a comparison between genetically modified crops and de-extinct species; *see also id.* ("[S]cientists have used genetic engineering to create genetically modified ("GM") crops that are more resistant to diseases, pests, and pesticides. Like de-extinct species, 'the ecological impacts of GM crops are scientifically uncertain and difficult to predict prior to release.' Although the field of GM crops is significantly more established than de-extinction, it too remains largely unregulated because a bewildering array of potentially applicable policies and laws have created a regulatory void. De-extinct species probably occupy the midpoint on the spectrum of concern between genetically modified crops and genetically modified human beings.").

[146] *Id.* at 178.

of its kind in the wild, may pose a similar risk if released into a new environment.

The USDA has the necessary expertise and mechanisms to assess and limit the risks that cloned extinct and endangered species pose to livestock via the Animal Health Protection Act ("AHPA").[147] Under the AHPA, the Veterinary Services within the USDA's Animal and Plant Health Inspection Service ("APHIS") conducts risk assessments of any product of biotechnology that could pose a risk to livestock.[148] In particular, APHIS regulates biotechnology products that "could introduce pests to or cause disease in livestock with the goal to protect livestock."[149] Such regulated items cannot be introduced into the environment before APHIS grants a permit, which, for cloning de-extinct species, would serve as a regulatory "check."[150] Notably, the Center for Veterinary Medicine at the USDA conducted a study that analyzed how cloning agricultural animals could impact "the health of animals involved . . . and food consumption hazards that may arise in animal clones and their progeny . . . ."[151] Although, clones of endangered and extinct species are obviously not intended for human consumption, the USDA could conduct a similar risk assessment considering the likelihood that these clones will introduce pests or cause diseases amongst livestock.

Additionally, the USDA can likely mitigate the impacts of releasing clones of endangered and threatened species into the environment because the agency has jurisdiction over a similar biotechnology: genetic engineering of animals.[152] The USDA can conduct assessments of potential risks to livestock health caused by genetically engineered animals.[153] Genetically engineered livestock

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[147] The USDA's Food Safety and Inspection Service has expertise conducting risk assessments of how various meat-industry technologies could affect public health. *See Risk Assessments*, USDA (Apr. 20, 2020), https://www.fsis.usda.gov/science-data/risk-assessments [https://perma.cc/V7ZM-2WJM].

[148] BWG, *supra* note 118, at 23.

[149] *Id.*

[150] *See id.*

[151] U.S. DEPT. OF AGRIC., ANIMAL CLONING: A RISK ASSESSMENT 3 (2008).

[152] BWG, *supra* note 118, at 23.

[153] *Id.*

share an essential similarity with clones of extinct species: their biotechnical creation and environmental introduction could spread diseases to nearby livestock, thereby threatening the U.S. food supply.[154] Consequently, regulating species cloned and released for conservation purposes furthers the statutory goal of the AHPA. Namely, the USDA will satisfy its obligation to assess risks to livestock to ensure public health.[155] Thus, the USDA likely has authority to conduct similar risk assessments regarding cloned imperiled species.

VI. CLONES OF ENDANGERED, AND POSSIBLY EXTINCT, SPECIES CAN BE PROTECTED UNDER THE ENDANGERED SPECIES ACT

The ESA likely applies to regulate the cloning of endangered species because both the ESA's purpose and the purpose of cloning endangered species is to conserve endangered species.[156] The USFWS, one of the agencies that enforces the ESA, has stated that "[t]he purpose of the ESA is to protect and *recover* imperiled species and the ecosystems upon which they depend."[157] Although this Article refers to both endangered and extinct species collectively as "imperiled," the term is generally understood to mean endangered

[154] *See* Babcock, *supra* note 29, at 178.

[155] Congressional findings for the Act state that "the prevention, detection, control, and eradication of diseases and pests of animals are essential to protect: (A) animal health; (B) the health and welfare of the people of the United States; (C) the economic interests of the livestock and related industries of the United States; (D) the environment of the United States; and (E) interstate commerce and foreign commerce of the United States in animals and other articles." 7 U.S.C. § 8301.

[156] *See, e.g.*, *Summary of the Endangered Species Act*, EPA, https://www.epa.gov/laws-regulations/summary-endangered-species-act [https://perma.cc/2SB5-W29S] (last visited Nov. 21, 2021) ("The Endangered Species Act (ESA) provides a program for the conservation of threatened and endangered plants and animals and the habitats in which they are found.").

[157] *ESA Basics: 40 Years of Conserving Endangered Species*, U.S. FISH & WILDLIFE SERV., https://www.fws.gov/endangered/esa-library/pdf/ESA_basics.pdf [https://perma.cc/9RVF-BAA3] (last visited Sept. 30, 2021) (emphasis added) [hereinafter *ESA Basics*].

species.[158] Thus, the USFWS's use of the term "imperiled" does not necessarily establish protection for extinct species, although that practice may fall within the agency's jurisdiction, discussed in more depth below.

Though it is debatable whether cloning should serve as a method of recovery for an endangered species, and is even more debatable for an extinct species, cloning has the ability to recover imperiled species by expanding genetic diversity and population size.[159] For example, the USFWS leads the Black-footed Ferret Recovery Implementation Team ("BFF RIT"), a collaboration by government agencies, zoos, private landowners, and nonprofits to recover the black-footed ferret.[160] The BFF RIT was formed "pursuant to Section 4(f)(2) of the amended [ESA,] which authorizes the Secretary of the Interior to procure [] services . . . to help implement endangered species recovery plans."[161] Similarly, a well-regulated cloning field under the ESA could create institutions and collaborations that advise how cloning should be used to recover imperiled species.

Notably, regulating imperiled-species cloning still must be a reasonable interpretation of the ESA.[162] Since Congress clearly did not account for the availability of cloning technology when the ESA was enacted, legal scholars have debated whether the Act permits

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[158] International Union for Conservation of Nature's Red List distinguishes imperiled from extinct. J. Berton C. Harris et al., *Conserving Imperiled Species: A Comparison of the IUCN Red List and U.S. Endangered Species Act*, 5 CONSERVATION LETTERS 157 (2012), https://www.biologicaldiversity.org/programs/biodiversity/endangered_species_act/pdfs/Harris_et_al_2011_ESA_and_IUCN.pdf [https://perma.cc/B44K-837M].

[159] For a study of a threatened species' genetic variation, see generally Mary Jo W. Godt et. al, *Genetic Diversity in a Threatened Wetland Species, Helonias bullata (Liliacea)*, 9 CONSERVATION BIOLOGY 596 (1995).

[160] Black-Footed Ferret Recovery Implementation Team, *supra* note 86.

[161] *Id.*

[162] *See* Chevron, U.S.A., Inc., v. NRDC, Inc., 467 U.S. 837, 844 (1984) ("Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.").

regulation and protection of cloned species.[163] In order for the ESA to be able to protect a cloned species, the species must be listed as "endangered" or "threatened" and satisfy the critical habitat requirement. However, even in its current framework, the ESA likely applies because clones of endangered species can be listed as "endangered," and the critical habitat designation requirement can be satisfied. In contrast, the ESA might not—unless amended—protect clones of extinct species because, as explained more thoroughly below, the listing criteria and critical habitat requirement pose serious, and perhaps fatal, hurdles for de-extinctees.

A. Listing Clones of Endangered and Extinct Species as "Endangered" Under the Endangered Species Act

Section 9 of the ESA protects endangered species by prohibiting their subjection to certain human activities, which fall under the broader definition of "tak[ing]" an endangered species.[164] Harassing, harming, pursuing, hunting, shooting, wounding, killing, trapping, capturing, collecting, or even *attempting* any of these actions constitute an illegal "taking" under Section 9 of the Act.[165] The ESA defines an endangered species as "any species which is in danger of extinction throughout all of or a significant portion of its range," and a 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."[166] To determine whether a species

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[163] *See generally* Allen et al., *supra* note 20 (analyzing how the ESA applies differently to clones of endangered species compared to a species that is extinct and is being recreated).

[164] The Act prohibits the importation, taking, possession, sale, and delivery of endangered species. Endangered Species Act, 16 U.S.C. § 1538 ("Prohibited acts"). Some states prohibit these acts against species designated as endangered *or* threatened by their state law. *See, e.g.*, *Species Protection Basics*, TEX. PARKS & WILDLIFE, https://tpwd.texas.gov/huntwild/wild/wildlife_diversity/nongame/listed-species/species-protection.phtml [https://perma.cc/S2YD-Q5UP] (last visited Nov. 21, 2021) ("TPWD regulations prohibit the taking, possession, transportation, or sale of any of the animal species designated by state law as endangered or threatened without the issuance of a permit.").

[165] *See* Endangered Species Act of 1973, 16 U.S.C. § 1532(19).

[166] But specific insecta "determined by the Secretary to constitute a pest" are excluded from protection. Endangered Species Act of 1973, 16 U.S.C. § 1532 ("Definitions").

is endangered or threatened, the Secretary of the Interior looks to the likelihood of extinction.[167] The likelihood of extinction is determined by weighing five factors.[168] Notably, protection does not require that all five factors be implicated. Instead, the USFWS will protect a species "[w]hen one or more of these factors imperils [its] survival."[169] The two factors most relevant to this analysis are: (1) the "overutilization for commercial, recreational, scientific, or educational purposes";[170] and, (2) the presence of "other natural or manmade factors affecting its continued existence."[171]

1. Clones of Endangered Species Can Be Listed as Endangered Under the Endangered Species Act

Applied to a cloned endangered species, these factors indicate that a clone is entitled to protection under the ESA. First, overutilization[172] is likely to be satisfied, as humans have many incentives to exploit clones of rare species near extinction. Such rare animals, as well as their pelts, tusks, or other elements, could be incredibly lucrative.[173] In 2017, endangered species, such as "[r]hinos, serow, helmeted hornbill, gaur, leopards and turtles" were all "openly sold in a region that is Ground Zero in the illegal wildlife trade."[174] Second, other natural or manmade factors affect a cloned species' existence, such as the success rate of its cloning.[175] Where

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[167] Endangered Species Act of 1973, 16 U.S.C. § 1533(a)(1).

[168] *Id.*

[169] *ESA Basics*, *supra* note 157.

[170] Endangered Species Act of 1973, 16 U.S.C. § 1533(a)(1).

[171] *Id.*

[172] The Endangered Species Act does not define overutilization. *See* 16 U.S.C. § 1532. For more information about the concept of overutilizing natural resources, see *What Are the Consequences of the Overexploitation of Natural Resources?,* IBERDROLA, https://www.iberdrola.com/environment/overexploitation-of-natural-resources [https://perma.cc/TPA2-T7NC] (last visited Nov. 21, 2021).

[173] *See, e.g.*, *The Tragic Price of Ivory*, THE WEEK (Jan. 8, 2015), https://theweek.com/articles/449437/tragic-price-ivory [https://perma.cc/A2VF-HAFQ] ("A single male elephant's two tusks can weigh more than 250 pounds, with a pound of ivory fetching as much as $1,500 on the black market.").

[174] *Top 10 'Most Wanted' Endangered Species in the Markets of the Golden Triangle*, WWF (Nov. 2, 2017), https://wwf.panda.org/wwf_news/?315491/Top-10-Most-Wanted-Endangered-Species-in-the-Markets-of-the-Golden-Triangle [https://perma.cc/N3X2-QZ7F].

[175] Camacho, *supra* note 105, at 867–68.

only one animal of a species exists, its continued existence is understandably fragile.[176] Should the imperiled species' population increase, this improvement could lead to the redesignation of the species from endangered to threatened under the ESA.[177] Assuming the population continues to increase, the species would eventually be delisted when it no longer needs the protection of the ESA.[178] The foundational purpose of the ESA is to recover a species to the point where the species can be self-sustaining.[179] Thus, cloning could be a way for this legislative goal to be achieved more quickly.[180] Moreover, clones of endangered species would likely enjoy the same protections as their original counterparts given that the cloned individuals are genetically identical to the listed species, and thus the clones would essentially be listed as well.[181]

2. Whether Clones of Extinct Species Can Be Listed Under the Endangered Species Act is Unclear

While the ESA may protect clones of endangered species, protection is more uncertain for clones of extinct species.[182] Once a species becomes extinct, any clones derived from its recovered

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[176] If a cloned animal "is treated as akin to a representative of the previously existing species, then given the likely small number of cloned animals existing, one might consider that it may benefit from protection on the grounds that it is the identical genetic copy of an extinct animal and, if only in existence in small numbers, that it is threatened or in danger of extinction." *See* Allen et al., *supra* note 20, at 317.

[177] Camacho, *supra* note 105, at 868.

[178] *See e.g.*, *Recovery of Species Under the Endangered Species Act*, NOAA, https://www.fisheries.noaa.gov/national/endangered-species-conservation/recovery-species-under-endangered-species-act [https://perma.cc/5NBL-UZBY] (last visited Nov. 21, 2021) ("A recovery plan serves as a road map for species recovery—the plan outlines the path and tasks required to restore and secure self-sustaining wild populations.").

[179] *See id.*

[180] *But see* Camacho, *supra* note 105, 870–72 (arguing that the ESA's dichotomy of natural vs. unnatural lends the statute's purpose to be to conserve existing biodiversity rather than human-created animals).

[181] *See id.*

[182] *See* Allen et al., *supra* note 20, at 317. However, Allen concludes that clones of extinct species would not be listable pursuant to section 4 because "[i]f extinct, then the animal will have no habitat *per se*, making it questionable how one could define damage or destruction of their habitat." *Id.*

DNA might not receive the same automatic protection; such protection could be lost once the species is delisted due to extinction.[183] However, Researcher Jessica Allen and her colleagues, referenced above, proposed that, since "the majority of delisting decisions have been taken in response to species recovery" rather than extinction, delisting may not be a barrier for de-extinctees after all.[184] But recent activity by USFWS suggests otherwise. In September 2021, the USFWS proposed twenty-three species for delisting due to extinction.[185] The USFWS explained this decision as follows: "The purpose of the ESA is to protect and recover imperiled species and the ecosystems upon which they depend. For the species proposed for delisting today, the protections of the ESA came too late, with most either extinct, functionally extinct, or in steep decline at the timing of listing."[186]

This reasoning indicates that the USFWS might not consider extinct species as falling within the purview of the ESA if the USFWS likewise reasons that the ESA simply "came too late" for the species.[187] However, the "came too late" rationale may be inapplicable in light of the reality that de-extinction cloning exists: the de-extinctee itself serves as evidence that the ESA in fact is not too late. There is a similar counterargument for the listing of clones of endangered species. Concededly, species in "steep decline" are subject to delisting and, consequently, clones of endangered species approaching extinction may not have protection under the ESA either.[188] However, the cloning of an endangered species in and of itself proves that the species is no longer in decline and instead is on the rise. Perhaps multiple clones would need to be created or

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[183] *See id.*

[184] *See id.*

[185] Press Release, *U.S. Fish and Wildlife Service Proposes Delisting 23 Species from Endangered Species Act Due to Extinction*, U.S. FISH & WILDLIFE SERV. (Sept. 29, 2021), https://www.fws.gov/news/ShowNews.cfm?ref=u.s.-fish-and-wildlife-service-proposes-delisting-23-species-from-&_ID=37017 [https://perma.cc/A9HJ-5LFV] [hereinafter *USFWS Proposes Delisting 23 Species*].

[186] *Id.*

[187] *Id.* ("Based on rigorous reviews of the best available science for each of these species, the Service has determined *these species are extinct, and thus no longer require listing under the ESA*.") (emphasis added).

[188] *USFWS Proposes Delisting 23 Species*, *supra* note 185.

multiple births from a clone would need to occur before the species could be listed under the ESA to provide ample evidence that the species is no longer in "steep decline."

Although the USFWS's proposal to delist twenty-three species is not insignificant, the proposal should be considered within the context of how many species are listed under the ESA. According to USFWS's Environmental Conservation Online System, over 700 animal species in the United States are listed as endangered.[189] Clones of these species may still be protected, so long as the species itself is not delisted from the current list of endangered species. The clone of an already-listed species would likely qualify for protection under the ESA, but, as mentioned, whether the clone of a formerly-extinct species would qualify is less clear.

B. Identifying the Critical Habitat for Clones of Endangered and Extinct Species

Additionally, the ESA generally requires a critical habitat designation at the time the species is listed as endangered.[190] The ESA defines a critical habitat as "the specific areas within the geographical area occupied by the species, at the time it is listed . . . on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection."[191] After the USFWS designates a species as endangered or threatened, a particular area generally must be designated as the "critical habitat" for the species' recovery.[192] This requirement may not pose an issue for endangered species, as the clone's critical habitat could be that of the endangered species. But, how does the ESA apply to a de-extinct species that has not "occupied" a geographical area since the last ice age, for example? This question is particularly relevant to a group of

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[189] FWS provides population sizes of species listed for different categories of animals, such as mammals, birds, reptiles, and more at *U.S. Species,* U.S. FISH & WILDLIFE SERV., https://www.fws.gov/endangered/species/us-species.html [https://perma.cc/R64R-928A] (Sept. 2, 2020). In the aggregate, there are 720 animal species listed. *Id.*

[190] Endangered Species Act of 1973, 16 U.S.C. § 1533(a)(3)(i).

[191] *Id.* § 1532(5)(i).

[192] *Id.* § 1533 (Determination of endangered species and threatened species).

scientists and entrepreneurs who are trying to resurrect the woolly mammoth through bioengineering elephant DNA to resemble mammoth traits.[193]

De-extinction expert Alejandro E. Camacho believes that the critical habitat requirement poses a significant barrier to protecting de-extinctees under the ESA.[194] For clones of extinct species, rather than endangered species, a substantial amount of time may have passed since the species became extinct.[195] Over time, natural processes and human activities, such as development, pollution, and anthropogenic climate change, alter environmental factors that initially made an ecosystem ideal for a particular species.[196] Thus, blindly reintroducing animals into their historical habitats may have devastating consequences for their survival.[197]

Despite the foregoing valid concerns, the critical habitat requirement may not necessarily preempt de-extinctees from the ESA's protections. First, a critical habitat can include "specific areas *outside* the geographical area occupied by the species at the time it [was] listed . . . upon a determination by the Secretary that such areas are essential for [its] conservation."[198] Thus, a de-extinctee's designated critical habitat could be located in an entirely different area from where the species originally lived.[199] The broad geographic reach of critical habitat classifications can allow for greater flexibility when reintroducing populations.[200] Furthermore, the authorizes the Secretary of the Interior to periodically revise a

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[193] Zimmer, *supra* note 55.

[194] *See* Camacho, *supra* note 105, at 868 ("[T]he ESA's conception of endangerment for purposes of listing is fundamentally reliant on an evaluation of the species by reference to its historical and existing native range, making its applicability to de-extinct species confounding.").

[195] *See* Camacho, *supra* note 105, at 860–61.

[196] *See, e.g.*, *id.*

[197] *Id.*

[198] 16 U.S.C. § 1532(5)(ii) (emphasis added).

[199] *But see* Camacho, *supra* note 105, at 873 (arguing that FWS intends for non-native introductions to be rare).

[200] *See* Allen et al., *supra* note 20, at 320 ("Here, the scope of what constitutes a critical habitat is broad, with the capacity for the creation or establishment of a new habitat implying that it need not be entirely organic and free of human intervention and ecosystem engineering.").

species' designated critical habitat after considering "the best scientific data available" and any relevant impact.[201] This ability to revise a critical habitat provides an opportunity to afford de-extintees the same protections as non-cloned species listed under the ESA.[202] Thus, although a habitat may have belonged to a species at the time of its extinction, if that same habitat is now uninhabitable,[203] the Secretary of the Interior can designate its critical habitat as an ecosystem that presently best suits the species.

VII. CURRENT U.S. LAWS, AS APPLIED TO IMPERILED-SPECIES CLONING: PENALTIES AND ENFORCEMENT

The TSCA, FDCA, AHPA, and ESA provide extensive opportunities for enforcement of improper conduct related to the cloning of imperiled species. These laws authorize their respective agencies to impose severe financial penalties upon violators of the Acts. In their totality, these penalties can provide a strong deterrence against the exploitation of imperiled species, as well as against the harming of host animals.

A. The EPA's Enforcement Authority Under the Toxic Substances Control Act

The EPA regulates chemical substances through "reporting, record-keeping[,] . . . testing requirements, and restrictions" regarding their "production, importation, use, and disposal."[204] If

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[201] 16 U.S.C. § 1532(15) (defining "Secretary" as "the Secretary of the Interior or the Secretary of Commerce as program responsibilities are vested pursuant to the provisions of Reorganization Plan Numbered 4 of 1970; except that with respect to the enforcement of the provisions of this Act and the Convention which pertain to the importation or exportation of terrestrial plants, the term also means the Secretary of Agriculture"); *Id.* § 1533(b)(2) (detailing requirements for Secretary to designate critical habitat).

[202] *See* Allen et al., *supra* note 20, at 320 ("Here, the scope of what constitutes a critical habitat is broad, with the capacity for the creation or establishment of a new habitat implying that it need not be entirely organic and free of human intervention and ecosystem engineering.").

[203] *See* Camacho, *supra* note 105, at 860–61.

[204] *Summary of the Toxic Substances Control Act*, EPA (Sept. 9, 2020), https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act [https://perma.cc/QA6G-XXVF].

cloning endangered species falls under the purview of the TSCA, which it likely does, as discussed above, the EPA can require risk assessments prior to the clone's creation, similar to current risk assessments for chemical substances.[205] Such risk assessment could consider: (1) whether there is a natural habitat fit for the species' success; (2) whether the species was once a keystone species and would accordingly provide significant benefits to the existing ecosystem; and (3) how capable the species is of inter-species breeding and therefore capable of altering existing species populations.[206] Failure to comply with the TSCA can result in civil penalties of up to $37,500 per violation, per day.[207] In addition to civil penalties, a violator may be subject to criminal penalties of up to $50,000 for each day of violation and/or imprisonment for up to a year.[208]

B. The USDA's Enforcement Authority Under the American Health Protection Act

Additionally, the Veterinary Services of the USDA's APHIS requires entities to obtain permits before they release biotechnology products that "could introduce pests to or cause disease in livestock with the goal to protect livestock."[209] Violators of this requirement, and any other portion of the AHPA, can face civil penalties ranging from $50,000 to $1,000,000.[210] These large fines can deter reintroducing clones into the environment without engaging in a thorough risk assessment.

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[205] *See id.*

[206] Camacho, *supra* note 105, at 890–905. Camacho has explained the importance of risk assessments in introducing de-extinctees and has proposed an approach to conduct such assessments. *Id.* ("A sensible risk-based approach should incorporate into relevant wildlife management laws both (1) a provisional assessment of the risks and benefits for an introduction and (2) adaptive management that incorporates a framework for periodic monitoring and adjustment of such provisional decisions to account for new information and changes in conditions.").

[207] 15 U.S.C. § 2615(a)(1).

[208] *Id.* § 2615(b)(1).

[209] BWG, *supra* note 118, at 23.

[210] 7 U.S.C. § 8313(b)(1).

C. The FDA's Enforcement Authority Food, Drug, and Cosmetic Act

The FDA can regulate imperiled-species cloning pursuant to the new animal drug provisions of the FDCA and the FDA's related regulations.[211] Significantly, the FDA can subject animal cloning to "premarket approval requirements . . . before they are marketed [ ] and [require that] potential environmental impacts . . . be examined prior to approval."[212] The FDA partnered with the International Embryo Transfer Society to draft standards of care for animals involved in cloning.[213] Similarly, the FDA could partner with biotechnology, conservation, and animal welfare experts to establish a risk assessment approach that recommends appropriate care for host animals utilized in cloning endangered and extinct species.[214] However, the FDA's requirements also provide the necessary flexibility for cloning research; the requirements do not apply to *investigational* new animal drugs that are shipped to experts "qualified by scientific training and/experience to evaluate the safety and/or effectiveness of the new animal drug" and meet the other statutory requirements.[215] Notably, since imperiled species is a new and developing biotechnology, a large proportion of cloning processes for conservation, especially de-extinction, may fall within this exception.

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[211] *See* 21 C.F.R § 511.

[212] BWG, *supra* note 118, at 18.

[213] FDA, *Risk Management Plan for Clones*, *supra* note 124.

[214] *See also* MOU 225-16-010, U.S. FOOD & DRUG ADMIN. (June 24, 2021), https://www.fda.gov/about-fda/domestic-mous/mou-225-16-010 (Memorandum of Understanding between the FDA, USDA, and U.S. Dept. of Health and Human Services concerning Laboratory Animal Welfare) [https://perma.cc/9ZZ2-HD7A].

[215] 21 C.F.R § 511(b)(7)(i). The FDA's Staff Manual also sets forth recommendations regarding animal welfare and is available on the IETS website at *IETS Manuals*, IETS, https://www.iets.org/Publications/IETS-Manual [https://perma.cc/C5CP-4QK7] (last visited Nov. 14, 2021).

D. The EPA's Enforcement Authority Under the Endangered Species Act

Under the ESA, as briefly discussed in section above, it is generally unlawful to "take" an endangered species.[216] The ESA defines "take" to mean "harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct."[217] Additionally, the ESA prohibits many commercial activities involving endangered species.[218] An individual cannot "deliver, receive, carry, transport, or ship in interstate or foreign commerce" any endangered species.[219] Endangered species also cannot be sold or offered for sale in interstate or foreign commerce.[220] However, just like the FDCA, the ESA provides flexibility. Those wishing to engage in acts otherwise prohibited by the ESA may apply for a permit "for scientific purposes or to enhance the propagation or survival of the affected species."[221]These permitted activities under the ESA allow for progress and advancements in the field of imperiled-species cloning.[222] As was the case for Revive & Restore's cloning of the black-footed ferret, an individual or entity seeking to engage in the cloning of an endangered species can obtain a permit since the biotechnology of cloning in and of itself serves a scientific purpose.[223] Likewise, engaging in otherwise impermissible acts for the purpose of de-extinction may qualify for a permit because cloning extinct species enhances survival in perhaps the most impactful of ways—resurrecting a species on the brink of extinction.[224] Thus, any

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[216] 16 U.S.C. § 1538(a)(1)(B).
[217] *Id.* § 1532(19).
[218] *Id.*
[219] *Id.* § 1538(a)(1)(E).
[220] *Id.* § 1538(D).
[221] *Id.* § 1539(a).
[222] *See* Camacho, *supra* note 105, at 876 n.130 ("Another possible exception to the ESA's restrictive prohibitions might be a permit under section 10(a)(1)(A) 'for scientific purposes or to enhance the propagation or survival of the affected species.'").
[223] *See* REVIVE & RESTORE, *supra* note 60.
[224] *See* Camacho, *supra* note 105, at 876 n.130 ("[A] permit under section 10(a)(1)(A) might better fit continued revival activities, though it might be available for introductions as well.").

research group could likely obtain a permit, allowing the group to engage in recovery activities via cloning.[225]

Those who violate the ESA by either taking a clone without a permit, or by violating a permit, can face harsh civil and criminal penalties.[226] For instance, anyone who knowingly violates the ESA, or imports or exports an animal in violation of the ESA, may be forced to pay as much as $25,000 in civil penalties per violation.[227] Those that knowingly violate a regulation enacted in furtherance of a civil provision under the ESA are subject to up to $12,000 in penalties.[228] Failure to pay a penalty puts the violator at risk of civil action by the U.S. Attorney General. [229] Criminal penalties are even more severe, imposing up to $50,000 in fines in addition to imprisonment.[230] Those that knowingly violate a regulation enacted in furtherance of a criminal provision under the ESA are subject to a fine of up to $25,000, as well as imprisonment.[231] The severe financial punishments for both civil and criminal violations, as well as the risk of imprisonment, would both deter taking a clone without a permit and ensure permitholders abide by permit restrictions.

Potential loopholes may exist regarding these ESA permits. For example, a financially motivated cloning entity with little to no concern for conservation or public welfare, could purport to sell cloned species to further the species' survival. Likewise, a cloner could sell the cloned animal to a scientific institution with ill intentions and claim the animal is for "scientific research." To mitigate this potential, "bad actor" problem, the Secretary of the Interior, as authorized under the ESA, can utilize Federal and State agency personnel, services, and facilities to enforce the ESA.[232] Any person authorized by the Secretary "may detain for inspection and inspect any package, crate, or other container, including its contents, and all accompanying documents, upon importation and

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[225] *Id.*
[226] 16 U.S.C. § 1540(a).
[227] *Id.* § 1540(a)(1).
[228] *Id.*
[229] *Id.*
[230] 16 U.S.C. § 1540(b).
[231] *Id.*
[232] *Id.* § 1540(e).

exportation."[233] If such inspection leads the authorized person to believe someone is violating the ESA, that authorized person can arrest without a warrant.[234] Thus, the ESA, as applied to the clones of endangered and extinct species, can provide significant authority to monitor potentially harmful activities associated with their cloning.

VIII. CONCLUSION

The EPA, with the assistance of the FDA and the USDA—the other regulatory agencies within the CFRB—provide a solid basis for regulating imperiled-species cloning. Under the ESA, the EPA could be responsible for the protection of the clones, including the prohibition of activities that might harm them and the provision of permits to cloning scientists. Guided by the CFRB, the three agencies would be responsible for engaging in risk assessments, seeking to ensure safe and ethical creation and reintroduction of cloned species into their critical habitats. Between protecting the cloned species and analyzing the environmental and health risks the species pose, the respective expertise of each agency makes them particularly well-suited for their respective tasks. And because the regulation of this nascent area of biotechnology is a significant undertaking, spreading responsibility amongst agencies helps ensure no one agency is drained of its inherently limited resources.

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[233] *Id.* § 1540(e)(3).
[234] *Id.*