# THE GENIE IS OUT OF THE DE-EXTINCTION BOTTLE: A PROBLEM IN RISK REGULATION AND REGULATORY GAPS

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#### Introduction

Once the province of horror films and fantasy, the idea of recreating extinct life forms is poised to move from science fiction to laboratories and from there to the world at large. While "de-extinction is not something that will take place tomorrow . . . scientists are making major

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advancements, and eventual success appears inevitable." Spurred on by the burgeoning field of genetic engineering, it was only a matter of time before scientists turned their attention to recreating extinct life forms, either for the thrill of it or in atonement for the human role in the extinction process.

But science appears to be outpacing the ability of government agencies to respond to the legal, moral, and practical questions that these endeavors raise. Existing laws, like the Endangered Species Act ("ESA"),² are inadequate to respond to the environmental and public welfare risks these ventures pose. At the same time, the overlapping and conflicting policies governing genetic engineering, upon which deextinction depends, have created a dysfunctional regulatory commons in which no single agency is responsible for creating, implementing, and enforcing applicable rules. Changes to this situation, even if politically possible, will be too slow to respond to the intentional or unintentional release of resurrected species into the environment. Thus, the existing regulatory gap will enable de-extinction activities to continue unrestrained, and there is little hope of government action closing this gap any time soon.

This article proposes that participants in the field of de-extinction undertake traditional governmental functions, including setting, implementing, and enforcing performance standards,<sup>3</sup> until external regulations are developed.<sup>4</sup> However, self-regulation or private governance may not arise on its own. Therefore, this article suggests that pressure from the application of social norms, like those pertaining to the environment and human health, and a motivated, educated public might encourage participants in the field of de-extinction to self-regulate. While using social norms to encourage behavioral change is not new,<sup>5</sup> the

<sup>&</sup>lt;sup>1</sup> Erin Okuno, Frankenstein's Monster: Anticipating the Global Legal Framework for Deextinction, 43 ECOLOGY L.Q. 581, 590 (2016); see also C. Josh Donlan, De-Extinction in a Crisis Discipline, 6 FRONTIERS OF BIOGEOGRAPHY 25, 25-26 (2014) (arguing that de-extinction "is likely to become commonplace—sooner rather than later" due to "the rate of technological innovation, which is currently doubling every decade and accelerating," finding many of the criticisms of deextinction unwarranted, and observing that the challenges to succeeding are "substantial," particularly that of "moving from a few individuals to a functioning, viable population.").

<sup>&</sup>lt;sup>2</sup> 16 U.S.C. § 1531 et seq. (1973).

<sup>&</sup>lt;sup>3</sup> Michael P. Vandenbergh, *Private Environmental Governance*, 99 CORNELL L. REV. 129, 146-47 (2013) (defining private environmental governance as private actions "that are designed to achieve traditionally governmental ends such as managing the exploitation of common pool resources, increasing the provision of public goods, reducing environmental externalities, or more justly distributing environmental amenities.").

<sup>&</sup>lt;sup>4</sup> *Id.* at 186 ("Private governance could fill gaps where public governance cannot reach because of political, territorial, or expertise gaps.").

<sup>&</sup>lt;sup>5</sup> See, e.g., Hope M. Babcock, Why Norm Change Is a Better Solution to the Failed International Regulatory Regime to Protect Whales than a Trading Program in Whale Shares, 32 STAN. ENVIL.

linkage between norms and private governance to fill a regulatory gap that encompasses an entire field—de-extinction—is novel.

In support of this somewhat unique proposition, this article first introduces the reader to the phenomenon of de-extinction and the risks posed by the process of creating and reintroducing formerly extinct species to the environment. Unlike genetic engineering, which offers both potential benefits and risks to humans and the environment, de-extinction appears to offer mainly risks, slightly offset by economic benefits for a few. In Part II, the discussion turns to the existing regulatory framework—principally the ESA and policies governing genetic engineering—that might be applied to de-extinct species and the process of de-extinction. This Part concludes that the ESA would have to be substantially amended to cover de-extinction—likely a futile proposition in this period of anti-regulation. Even in the absence of anti-regulatory politics, interests that stand to benefit from an unregulated field's development often exert almost unstoppable pressure to prevent regulation. Thus, government action is unlikely to end the dysfunction of the regulatory commons governing genetic engineering.<sup>6</sup>

Private governance initiatives might correct this situation. However, such initiatives require incentives to encourage self-regulation and the right circumstances to emerge and take hold. Here, where traditional market incentives are nonexistent because there will be few customers for de-extinct species, the norms of environmental protection and personal responsibility might help encourage self-governing measures in the niche community of de-extinction scientists. Accordingly, Part III discusses both the phenomenon of private governance and the potential use of social norms to drive the scientific community to self-regulate to avoid the potentially harmful activities associated with de-extinction. The article then concludes that private governance aided by social norms might provide a transition from no control to some control. However, an informed, active public is a necessary predicate to the successful deployment of social norms. This may require the use of Cass Sunstein's norm entrepreneurs<sup>7</sup>—environmental, public health, and religious

L.J. 3 (2013); Hope M. Babcock, Corporate Environmental Social Responsibility: Corporate "Greenwashing" or a Corporate Culture Game Changer? Symposium, 21 FORDHAM ENVTL. L.J. 1 (2010); Hope M. Babcock, Responsible Environmental Behavior, Energy Conservation, and Compact Fluorescent Bulbs: You Can Lead a Horse to Water, But Can You Make It Drink?, 37 HOFSTRA L. J. 943 (2009); Hope M. Babcock, Assuming Personal Responsibility for Improving the Environment: Moving Toward a New Environmental Norm, 33 HARV. ENVTL. L. REV. 117 (2009).

<sup>&</sup>lt;sup>6</sup> See generally William W. Buzbee, Recognizing the Regulatory Commons: A Theory of Regulatory Gaps, 89 IOWA L. REV. 1 (2003).

<sup>&</sup>lt;sup>7</sup> Cass R. Sunstein, Social Norms and Social Roles, 96 COLUM. L. REV. 903, 909 (1996).

activists, for example—who can publicize useful and trusted information about these harms.<sup>8</sup>

This article assumes that de-extinction will eventually succeed, making this paper more than an academic exercise in the fanciful. Its contribution is to identify de-extinction as occurring in a regulatory gap, the product of a dysfunctional regulatory commons, which norm-assisted private governance might temporarily fill to prevent environmental and public health harms from occurring. While this article builds off the work of others, it is distinguished by its unique focus on private governance and social norms to fill the de-extinction regulatory gap.

#### I. DE-EXTINCTION

Human activities have had an overwhelming effect on global ecology that continues to increase in scope and intensity, so much so that it is evident to at least some eminent scientists that "we live on a human-dominated planet."<sup>11</sup>

#### A. What is De-Extinction?

Human activities have had an overwhelming effect on global ecology. Nowhere is this effect felt more keenly than in the extinction of species over the past several hundred years. 12 Humans are a primary contributor to this phenomenon by over-exploiting certain species, destroying their habitat, and introducing invasive species which prey on them or outcompete them for food and space. 13 Beyond the "negative moral implications" of extinction, extinction has "drastic ecological consequences." 14 For example, the extinction of one species affects the population size of remaining species, contributes to the co-extinction of these species, and disrupts basic ecosystem functions. 15

<sup>&</sup>lt;sup>8</sup> See generally Babcock, Assuming Personal Responsibility, supra note 5.

<sup>&</sup>lt;sup>9</sup> Okuno, *supra* note 1, at 634 ("The future of de-extinction may be unclear, but one thing is certain—acting too early is better than acting too late.").

<sup>&</sup>lt;sup>10</sup> See, e.g., id. at 581; Alejandro E. Camacho, Going the Way of the Dodo: De-Extinction, Dualisms, and Reframing Conservation, 92 WASH. U. L. REV. 849 (2015); Norman F. Carlin, Ilan Wurman, & Tamara Zakim, How to Permit Your Mammoth: Some Legal Implications of "De-Extinction", 33 STAN. ENVTL. L. J. 3 (2014); see also Brooke Elizabeth Hrouda, "Playing God?" An Examination of the Legality of CRISPR Germline Editing Technology Under the Current International Regulatory Scheme and the Universal Declaration on the Human Genome and Human Rights, 45 GA. J. INT'L & COMP. L. 221 (2016).

<sup>11</sup> Camacho, supra note 10, at 896.

<sup>12</sup> Okuno, *supra* note 1, at 585.

<sup>13</sup> Camacho, supra note 10, at 896.

<sup>&</sup>lt;sup>14</sup> Okuno, *supra* note 1, at 585.

<sup>&</sup>lt;sup>15</sup> Camacho, *supra* note 10, at 859.

As commonly understood, extinction occurs when a species "has died out completely." Functionally, the concept of extinction is more complicated. Hence, under the ESA, a species that can be found in zoos may be considered extinct "only in the wild or only in a certain geographical area." There is no separate legal definition of extinction in the ESA, even though preventing extinction is a goal of the statute. Declaring a species extinct has serious implications under the ESA because once declared extinct, the members of that species are no longer entitled to the statute's protection. Thus, while extinction is a "probabilistic determination," the *timing* of such a declaration is important. Declaring a species extinct prematurely may perversely contribute to that species' complete extinction because interest in protecting the species may wane.

Extinctions are common. There have been five mass extinctions, "at which times the Earth is estimated to have lost over 75 percent of its species." Putting aside the human contribution to extinction, one might argue that resurrecting extinct species interferes with a natural process. Such an argument is akin to the one made by those who find the process of curing genetic diseases "unnatural" because, by looking at the vast span of human history, "it is normal for the human population to be reduced by epidemics." <sup>23</sup>

De-extinction, then, is "the process of resurrecting species that have died out, or gone extinct." This can be done by selective breeding, also

<sup>&</sup>lt;sup>16</sup> Okuno, supra note 1, at 586.

<sup>&</sup>lt;sup>17</sup> Id. at 588 (confounding the finding of extinction is the existence of species, called "Lazarus species," once considered extinct, which are then found to be alive).

<sup>&</sup>lt;sup>18</sup> See, e.g., 16 U.S.C. § 1532(3) ("The terms 'conserve', 'conserving', and 'conservation' means to use and the use of all methods and procedures which are necessary to bring any endangered of threatened species to the point at which the measures provided pursuant to this chapter are no longer necessary.").

<sup>&</sup>lt;sup>19</sup> Okuno, *supra* note 1, at 586-87 ("Determining that a species is extinct has serious legal consequences because the ESA does not protect extinct species.").

<sup>&</sup>lt;sup>20</sup> *Id.* at 587.

<sup>&</sup>lt;sup>21</sup> Id. at 587-88 ("The IUCN maintains the IUCN Red List of Threatened Species (Red List)....Among other things, the Red List categorizes the status of species (including identifying species that are at risk of going extinct), and a species may be declared extinct on the Red List." According to the Species Survival Commission, "[a] taxon is [e]xtinct when there is no reasonable doubt that the last individual has died. A taxon is presumed [e]xtinct when exhaustive surveys in known and/or expected habitat, at appropriate times . . . , throughout its historic range have failed to record an individual.").

<sup>&</sup>lt;sup>22</sup> Id. at 585.

<sup>&</sup>lt;sup>23</sup> Rebecca Rodriguez, Note, *Beyond Frankenstein's Monster: Human Germline Editing and the Implications of Waiting to Regulate*, 38 N. ILL. U. L. REV. 585, 615 (2018).

<sup>&</sup>lt;sup>24</sup> Okuno, *supra* note 1, at 588 (quoting Kara Rogers, *De-Extinction*, THE ENCYCLOPEDIA BRITANNICA (last updated Dec. 5, 2018), available at https://www.britannica.com/science/de-extinction).

referred to as "functional de-extinction," or by genetically engineering new species and releasing them into the environment.<sup>25</sup> Functional de-extinction involves "selectively breeding organisms exhibiting the phenotypic or functional characteristics of extinct target organisms with the intent of aggregating those desired characteristics into individual organisms over several generations."<sup>26</sup> Genetic engineering, if used to accomplish de-extinction, will employ a "suite of technologies" in which the "DNA segments from extinct and extant species are combined to make a new "recombinant" DNA.<sup>27</sup> There are a number of de-extinction projects under way, such as those to revive the passenger pigeon, the Woolly Mammoth, and the gastric brooding frog.<sup>28</sup>

# B. Methods That Can Be Used to Bring an Extinct Species Back to Life

There are three ways to resurrect an extinct species: cloning, genetic engineering, and selective back-breeding or strategic mating. The latter two are touched on above.<sup>29</sup> "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." <sup>30</sup> This process is also described as a "somatic cell nuclear transfer" ("SCNT").<sup>31</sup> In genetic engineering, scientists fill "gaps in the incomplete genetic sequence of an extinct species using DNA fragments from a closely related living species." <sup>32</sup> Alternatively, in "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." <sup>33</sup> A combination of these methods may be used in the revival of some extinct species.<sup>34</sup>

While scientists have modified genes for a very long time, they have done so principally through selective back-breeding.<sup>35</sup> The purposeful manipulation of genes to create genetically-modified organisms is much newer. Both approaches have resulted in "plant and animal varieties that

<sup>&</sup>lt;sup>25</sup> Camacho, *supra* note 10, at 852.

<sup>&</sup>lt;sup>26</sup> Id. at 852 n.12 (suggesting that it might be possible to recapture some of the characteristics and functions of the extinct auroch, but the resulting animal would not be an auroch, only the "ecological functional approximation" of one).

<sup>&</sup>lt;sup>27</sup> *Id.* at 853.

<sup>&</sup>lt;sup>28</sup> Id. at 854.

<sup>&</sup>lt;sup>29</sup> Okuno, *supra* note 1, at 592.

<sup>30</sup> *Id* 

<sup>&</sup>lt;sup>31</sup> Carlin, Wurman & Zakim, *supra* note 10, at 7-8.

<sup>32</sup> Okuno, supra note 1, at 592.

<sup>33</sup> Id.

<sup>&</sup>lt;sup>34</sup> *Id*.

<sup>&</sup>lt;sup>35</sup> Rekha K. Rao, Note, *Mutating Nemo: Assessing the Environmental Risks and Proposing the Regulation of the Transgenic Glofish*<sup>TM</sup>, 57 ADMIN. L. REV. 903, 906 (2005).

do not formally exist in nature."<sup>36</sup> As a general rule, the more recent the extinction, the greater the chance it might be resurrected.<sup>37</sup> It also may be easier to resurrect a species through genetic engineering if that species has close living relatives or has "simpler genomic sequences, . . . as invertebrates [do]."<sup>38</sup> However, regardless of the procedure used, no currently available technique can "create living specimens that are genetically identical to the extinct species," although such organisms "could be close" to their extinct ancestors.<sup>39</sup>

Using genetic engineering to create a de-extinct species involves gene splicing, a process through which the genome of a related species is "modified to incorporate sequences from the extinct species." "By selecting specific genes that code for traits that distinguish the two species, and inserting those genes from the extinct species into the living relative," the hope is that "the resulting hybrids would come to resemble the extinct form."41 Professor Alejandro Camacho describes what might be involved in creating a viable Dodo: namely, "inserting preserved fragments of Dodo genomic DNA into its closest living relative, an existing, complete Nicobar pigeon (Caloenas nicobarica) genome. The result would be a genomic hybrid Dodo/Nicobar pigeon." 42 After multiple generations of engaging in this effort, "DNA from extinct target species would make up increasing proportions of genomes of de-extinct individuals—eventually resulting in the genomes of de-extinct species being derived entirely, and with high fidelity, from the genomes of their extinct relatives."43 This has not occurred yet, however.

The most "noteworthy" way to modify genes is through the use of CRISPR-Cas 9 technology, which can modify DNA in the nuclei of reproductive cells.<sup>44</sup> "The change is achieved by going in while the cells are still dividing to remove a portion of the DNA sequence and replace it with another, different, pre-selected, and pre-created sequence"<sup>45</sup>—

<sup>&</sup>lt;sup>36</sup> *Id*.

<sup>&</sup>lt;sup>37</sup> Okuno, *supra* note 1, at 592.

<sup>&</sup>lt;sup>38</sup> *Id*.

<sup>39</sup> Id.

<sup>&</sup>lt;sup>40</sup> Carlin, Wurman & Zakim, *supra* note 10, at 11-12; *see also* Hrouda, *supra* note 10, at 225 ("Biotechnology often uses genetic engineering, a method of creating new life forms and organic material by gene-splicing and other techniques, as one of its main processes.").

<sup>&</sup>lt;sup>41</sup> Carlin, Wurman & Zakim, *supra* note 10, at 11.

<sup>42</sup> Camacho, supra note 10, at 853.

<sup>43</sup> Id

<sup>&</sup>lt;sup>44</sup> Hrouda, *supra* note 10, at 222, 225-26 (CRISPR is short for "clustered regularly interspersed short palindrome repeats.").

<sup>&</sup>lt;sup>45</sup> *Id.* at 225-26; *see also id.* at 223 (CRISPR-CAS-9 will facilitate "easier and more efficient gene modification than previous technologies, which tend to be time consuming, expensive, and sometimes dangerous."); Rodriguez, *supra* note 23, at 594 ("CRISPR-Cas9 has brought cost, speed, accuracy, and efficiency improvements to genome editing.").

somewhat analogous to "using the find and replace function of a computer program." Since scientists using CRISPR-Cas 9 technology can modify fertilized embryos both in vivo and in vitro, the alteration in the genetic makeup of the embryo will be permanent and will be passed onto the parents' offspring. This alteration is called germline editing, and it is controversial because of the possibility that errors in the editing process may permanently alter the species' genetic makeup. Despite the complexity of the CRISPR process, almost anyone can engage in changing a species' genes at a more basic level. For example, there are reasonably priced, publicly available do-it-yourself kits to conduct genetic experiments at home, which allow for inserting "jellyfish DNA into yeast to make it fluoresce."

No de-extinct species have been genetically engineered yet through CRISPR or any other technology. Selective or back-breeding has had some success, resulting in the creation of animals that resemble extinct species of zebra and wild cattle, among others.<sup>50</sup> Cloning, on the other hand, can "only succeed, if at all, in those few cases for which the necessary raw material is available."<sup>51</sup> Unless the extinction was fairly recent, this method is unlikely to succeed. Regardless of the methodology used to resurrect an extinct species, none of them would be an "exact copy" of the original extinct species.<sup>52</sup> At most, they would "to some degree" be "facsimiles or likenesses of the original species"<sup>53</sup>—not "an extinct species truly brought back from the dead."<sup>54</sup>

### 1. Costs and risks of de-extinction

Before de-extinct species are released into the environment, a sufficiently large quantity of individuals must be created in a laboratory to enable their offspring to be introduced into the wild.<sup>55</sup> Then, the species

<sup>&</sup>lt;sup>46</sup> Rodriguez, *supra* note 23, at 594.

<sup>47</sup> Hrouda, supra note 10, at 226.

<sup>&</sup>lt;sup>48</sup> Somatic gene editing affects only the individuals who receive the treatment and, therefore, does not make permanent changes to the gene pool and does not create "a permanent genetic trait in the future bloodlines." *See id.* at 232 (discussing germline genetic editing); *see also* Rodriguez, *supra* note 23, at 591.

<sup>&</sup>lt;sup>49</sup> Rodriguez, *supra* note 23, at 596.

<sup>&</sup>lt;sup>50</sup> Carlin, Wurman & Zakim, *supra* note 10, at 8; *see also id.* at 8-15 (describing each of these approaches in detail).

<sup>&</sup>lt;sup>51</sup> Carlin, Wurman & Zakim, *supra* note 10, at 8.

<sup>52</sup> Id. at 16 (emphasis omitted).

<sup>&</sup>lt;sup>53</sup> *Id.* (emphasis omitted).

<sup>&</sup>lt;sup>54</sup> *Id.*; *see also* Rodriguez, *supra* note 23, at 588-89 (including among the benefits of CRISPR-Cas9, a recent and hugely popular method of gene editing, bringing back to life once extinct animals, "outside a movie theater.").

<sup>&</sup>lt;sup>55</sup> Carlin, Wurman & Zakim, *supra* note 10, at 17.

must actually be released into the environment. Both phases generate costs and create risks.

#### a. Costs

There are some obvious costs associated with recreating an extinct species and managing and monitoring its release into the wild. For example, the process of using wildlife captive breeding and release as a surrogate for the extinct species is expensive.<sup>56</sup> The monitoring and adaptive management of captive-reared species can be extensive and last for decades.<sup>57</sup> The known costs associated with captive breeding will only multiply in the case of the release of a newly resurrected species that has never been a part of or has long been absent from the environment into which it will be introduced.<sup>58</sup> Any resurrected species may face the same threats to its survival that led to its extinction in the first place: loss of habitat or food supply, or diseases or predators against which it has no defense. Any or all of these could require costly human intervention.

These expenditures may not be recaptured if the de-extinct species does not survive, which is more than likely. The small population size of the resurrected species would affect the species' prospect of survival.<sup>59</sup> Additionally, 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.60 Unlike captive-bred species, a resurrected species confined to a laboratory or some other kind of "breeding facility" can hardly be said to have a "habitat or range" to which it is being returned. 61 If a de-extinct species, however, can be returned to its original habitat, it may well face the same threats that led to its extinction in the first place. 62 Moreover, in the case of a species that has been extinct for a substantial amount of time, it may have no natural habitat to which it can return because its former one may have been lost as a result of human activity or taken over by other species that "occup[y] the same ecological

<sup>&</sup>lt;sup>56</sup> Camacho, *supra* note 10, at 859 ("A number of scientists have identified the considerable administrative expenditures from active reintroduction interventions for existing species.").

<sup>&</sup>lt;sup>57</sup> *Id*.

<sup>58</sup> See id.

<sup>&</sup>lt;sup>59</sup> Carlin, Wurman & Zakim, *supra* note 10, at 25.

<sup>60</sup> Okuno, supra note 1, at 600.

<sup>61</sup> Carlin, Wurman & Zakim, supra note 10, at 25.

<sup>62</sup> Id. at 40.

niche."<sup>63</sup> Its food supply may be gone, and it also may face predators, diseases, and parasites that did not exist when it was alive. Additionally, by the time a member of a de-extinct species is released, climate change may have reduced the carrying capacity of its original habitat to a point where the natural environment can no longer support that species.<sup>64</sup> These species may also face inadequate regulatory protection as it is unclear to what extent the ESA or other wildlife laws might apply to them.<sup>65</sup>

De-extinction efforts also create potential opportunity costs, such as the diversion of scarce resources from protecting endangered species and existing ecological systems toward costly, undemonstrated, and potentially harmful efforts to resuscitate extinct ones. <sup>66</sup> Additionally, the ability to resurrect an extinct species could "reduce the sense of urgency for preventing extinctions, which has served as a rare effective catalyst for regulatory efforts toward endangered species conservation." It is also possible that those who oppose species conservation efforts might use the possibility of de-extinction to undermine laws requiring species conservation. Thus, de-extinction, in general, might unintentionally "erode" resources set aside for the preservation of endangered species or protection of existing ecological resources. <sup>69</sup>

#### b. Risks

The first set of risks involved in de-extinction has to do with the creation of a formerly extinct species, especially if CRISPR-CAS9 techniques are used. CRISPR-Cas9 modifications have generated a "high percentage of off-target mutations." Because CRISPR technology "requires precision cuts of very specific gene sequences," accidentally splicing the gene in incorrect places could cause "unintended mutations." Even if "the gene is spliced in the correct location, the

<sup>&</sup>lt;sup>63</sup> *Id.* at 26; *see also id.* at 41-42 ("The regions they inhabit may be more vulnerable to disruption now, as a result of human development, climate change, and the disappearance of habitat and other species, while their historic range may no longer contain habitat that is suitable for them.").

<sup>64</sup> Id. at 42

<sup>65</sup> See id. at 25; see also infra Part II.A. (discussing the poor fit of the ESA to de-extinct species).

<sup>66</sup> Camacho, supra note 10, at 861.

<sup>67</sup> Id.

<sup>68</sup> Id.

<sup>&</sup>lt;sup>69</sup> *Id.*; *see also* Carlin, Wurman & Zakim, *supra* note 10, at 6-7 ("Some are concerned that the ability to revive dead species may undercut conservation efforts for still-living species that are endangered or threatened, detracting from the perceived need to protect them if they are reliably replaceable and eroding society's understanding of what constitutes "nature." Moreover, "concerns also exist about the impact of novel organisms on the integrity of existing ecosystems.").

<sup>&</sup>lt;sup>70</sup> Rodriguez, *supra* note 23, at 615; *see also id.* ("While these initial studies seem concerning, no new biomedical technology is 100% safe and reliable.").

<sup>71</sup> Hrouda, *supra* note 10, at 240.

newly inserted sequence may still bind to different locations upon insertion."<sup>72</sup> If the genetic engineering process involves germline gene modifications,<sup>73</sup> the genetic changes will be passed to the species' offspring, which will then carry the gene as a portion of their genetic makeup upon birth,<sup>74</sup> making the change permanent, for better or for worse.

The next set of risks arise when an animal is introduced into a new environment. In the case of a de-extinct species, the usual risks of introduction are magnified by the limited ability to anticipate and then mitigate harms that might occur. Resurrected species are not recreations of species that were reasonably well known to nineteenth-century science, but something that never before existed. Peen observations about them from their time in a breeding facility or laboratory would imperfectly predict their behavior in the wild. Consequently, almost nothing is known about how a de-extinct species will adapt, conduct itself in the wild, and coexist with the life it finds there. This will be particularly true the further away from extinction the introduction occurs. Moreover, climate change will exacerbate these uncertainties by making it even more difficult to assess and manage any introduction of de-extinct species due to the fluidity of the natural environment's response to that phenomenon.

"The artificiality and novelty of de-extinction" amplifies concerns about "unlikely but potentially catastrophic outcomes." For example, a resurrected species might bring with it unexpected diseases and parasites and thus act as a "vector" for the inter-species spread of these

<sup>72</sup> Id

<sup>&</sup>lt;sup>73</sup> See id. at 227 ("Human germline modification can be separated into two distinct processes, germline treatment, also known as germline transfer, and germline enhancement. Germline treatment or transfer is considered negative genetic engineering and aims to prevent or treat disease. On the other side of the spectrum is germline enhancement or positive genetic engineering, which aims to enhance a particular capability or trait.").

<sup>&</sup>lt;sup>74</sup> *Id.* at 225 ("In a germline gene transfer, the germinal cells of the subject's parents' egg and sperm cells are targeted prior to implantation and genetically modified with the goal of passing on the changes to the offspring, who will then carry the gene as a portion of its genetic makeup upon birth."); *see also* Rao, *supra* note 35, at 908 ("The process of genetic modification occurs by identifying one gene carrying a particular characteristic in an organism, and transferring that same characteristic by inserting the gene from one organism into another.").

<sup>75</sup> Camacho, *supra* note 10, at 860.

<sup>&</sup>lt;sup>76</sup> Carlin, Wurman & Zakim, *supra* note 10, at 42.

<sup>77</sup> Id

<sup>&</sup>lt;sup>78</sup> Camacho, *supra* note 10, at 861; *see also* Carlin, Wurman & Zakim, *supra* note 10, at 25.

<sup>&</sup>lt;sup>79</sup> Camacho, *supra* note 10, at 861; *see also* Carlin, Wurman & Zakim, *supra* note 10, at 25.

<sup>80</sup> Camacho, supra note 10, at 860.

<sup>81</sup> Carlin, Wurman & Zakim, *supra* note 10, at 42.

contagions.82 De-extinct species may kill prey, thus generating unexpected impacts on existing predators and upsetting the food chain.83 Even though de-extinct species may be put back into their historic ranges, if they have been gone for a long time, it is unlikely that the ecosystem that greets them will be the same, as other species may have occupied their ecological niche. 84 If resurrected species are superior with respect to catching prey and reproducing, they may "outcompete or displace the species that replaced them, or cause habitat destruction or disrupt food chains in ecosystems established since their time."85 Similar to crosspollination between genetically modified and unaltered crops, "unintended cross-breeding may occur between genetically modified facsimiles and the species from which they were derived, potentially further spreading their altered traits"86 and thus permanently changing the native population. 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.87

According to Professor Alejandro Camacho, the history of natural resources management contains numerous examples of the introduction of non-native species to reduce or offset other human effects on ecological resources; nonetheless, these initiatives led to extensive unintended ecological harm to those resources. Some may even view the introduction of a de-extinct species into a biotic community of which it was never a part as reducing the quality of native biotic communities and natural ecosystems—"akin to an invasive species that makes the existing community ostensibly less authentic." Any reintroduction of a species, whether resurrected or existing elsewhere, risks "disrupting receiving biological communities and, rather than increase biodiversity or ecological function, may serve to decrease it." Thus, rather than contributing an ecological benefit to the receiving environment, these deextinct species may "erode biodiversity, disrupt ecosystems, and

<sup>82</sup> *Id.* at 42-43.

<sup>83</sup> Id. at 25.

<sup>84</sup> Id. at 41.

<sup>85</sup> *Id.* at 42-43.

<sup>86</sup> Id.

<sup>87</sup> Carlin, Wurman & Zakim, supra note 10, at 43.

<sup>&</sup>lt;sup>88</sup> Camacho, *supra* note 10, at 860 n.46 (citing as examples of this the introduction of the kudzu vine in the southeast to control erosion and the cane toad in Australia to control the cane beetle).

<sup>&</sup>lt;sup>90</sup> *Id.*; *see also* Rao, *supra* note 35, at 913 (discussing Glofish<sup>TM</sup> and arguing that "the potential environmental impacts of a transgenic fish's exposure to the environment include: interbreeding with wild species, hybridization with varieties of other fish, disturbance of habitat, or displacement of the native fish as a consequence of competition for resources").

contribute to extinctions at receiving sites."<sup>91</sup> For example, if a genetically modified de-extinct species outcompetes its unmodified ancestors, it might cause the unaltered members of the species to go extinct and completely displace the native population.<sup>92</sup>

## 2. Benefits of de-extinction

Given all the risks and possible non-recoverable costs associated with resurrecting extinct species, what would motivate anyone to engage in the process? One reason often given is that it would be "thrilling" to resurrect an extinct species. While Jurassic Park may be infeasible, a "somewhat more plausible Pleistocene Park, populated with mammoths and aurochs, would generate nearly as much popular excitement." And then there is the money to be made<sup>94</sup> from the possible sale of de-extinct species or from using them as exhibit animals.

De-extinction may also contribute to biodiversity conservation. <sup>95</sup> For example, if de-extinction produced a resurrected animal that functioned as a keystone species, its reintroduction could revive an entire ecosystem, creating "substantial environmental benefits." <sup>96</sup> De-extinction would also give scientists an "unprecedented opportunity to study their research subjects as living species." <sup>97</sup>

De-extinction could also function "as a last resort conservation tool (sort of like an insurance policy for endangered species)." It might be used to help with the recovery of endangered species populations. For example, what has been learned from cloning efforts for extinct species

<sup>91</sup> Camacho, supra note 10, at 859.

<sup>&</sup>lt;sup>92</sup> Rao, *supra* note 35, at 914-15.

<sup>&</sup>lt;sup>93</sup> Carlin, Wurman & Zakim, *supra* note 10, at 5; *see also* Okuno, *supra* note 1, at 590 ("The concept of de-extinction is intriguing and exciting.").

<sup>&</sup>lt;sup>94</sup> Carlin, Wurman & Zakim, *supra* note 10, at 5. *But see id.* at 17 ("A final point that should be emphasized is that the ultimate objective of de-extinction efforts is not to produce laboratory curiosities, but to restore lost species to independent existence in nature. No de-extinction proponent has yet admitted a desire to produce mammoths solely for zoos or Carolina parakeets solely as pets. Rather, the aim of these efforts is to create, release, and reestablish self-sustaining breeding populations in the wild.").

<sup>95</sup> Okuno, *supra* note 1, at 590.

<sup>&</sup>lt;sup>96</sup> Carlin, Wurman & Zakim, *supra* note 10, at 5. For a discussion of the controversy surrounding the reintroduction of the gray wolf in the Northern Rocky Mountains, see generally Hope M. Babcock, *The Sad Story of the Northern Rocky Mountain Gray Wolf Reintroduction Program*, 24 FORDHAM ENVIL. L. REV. 25 (2013) (noting that the wolf's reintroduction into its former habitat produced environmental benefits but also threatened economic harm).

<sup>&</sup>lt;sup>97</sup> Carlin, Wurman & Zakim, *supra* note 10, at 5.

<sup>98</sup> Okuno, *supra* note 1, at 590.

<sup>&</sup>lt;sup>99</sup> *Id.*; *see also* Camacho, *supra* note 10, at 857 ("A number of proponents of de-extinction contend that technologies developed in the pursuit of de-extinction may have considerable cobenefits for efforts to recover critically endangered populations.").

could be used to clone existing endangered species, particularly when only a few or no reproducing individuals remain. <sup>100</sup> Insights about genetic manipulation gleaned from de-extinction experiments may be used "to increase the genetic diversity of existing endangered species populations or to engage in the 'genetic rescue' of endangered species that are genetically depauperate." <sup>101</sup> De-extinction may teach scientists how to insert new genes into the genome of at-risk species to improve their fitness in the face of threats like "introduced pathogens or parasites." <sup>102</sup>

Introducing de-extinct species, especially ones that could replace extinct keystone species, might help ecosystems that have lost "constituent species" to recover their integrity and functionality. As with the reintroduction of existing endangered species, the "strategic introduction of members of a revived species could provide benefits not only for the introduced species but also other components of the ecological community." Thus, introducing a resurrected species into its former habitat could be seen as "a form of (or at least analogous to) rewilding or restoration ecology." 105

Some proponents of de-extinction "suggest" that successfully resurrecting an extinct species would benefit ecological conservation by providing a concrete example of the ability of humans "to shape and repair past and ongoing anthropogenic damage to ecosystems." This might galvanize people to "try to develop solutions that cultivate ecological health." Using de-extinction as "an example of the capacity for ecological manipulation" also might "combat resignation in some quarters that humans are incapable of mending past and continuing harm to ecological resources." 108

Some argue that "humans have a moral obligation to attempt to bring back at least some of those species we ourselves exterminated," making the revival of species that humans caused to go extinct "a matter of justice." But others argue that the concept is "unnatural and hubristic," and thus another instance of humanity's lack of humility. 112

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100 Camacho, supra note 10, at 857.
101 Id. at 858.
102 Id.
103 Id. at 856-57.
104 Id.
105 Camacho, supra note 10, at 856-57.
106 Id. at 858.
107 Id.
108 Id.
109 Carlin, Wurman & Zakim, supra note 10, at 6.
110 Okuno, supra note 1, at 589.
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<sup>112</sup> Carlin, Wurman & Zakim, *supra* note 10, at 6.

Carlin and his co-authors find the "specter of humans 'playing God' on this scale—wiping out entire species that inconveniently inhabit some desirable property, then bringing them back at will—is certainly distressing." On one hand, de-extinction is certainly disruptive of the natural cycle, which includes extinction. Some opponents of de-extinction also are concerned that "the process of producing a resurrected animal is cruel or harmful to the animal itself" or might trigger "serious ecological or human health problems." On the other hand, proponents of de-extinction "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." <sup>116</sup> The debate over the costs and benefits of de-extinction continues without a clear resolution.

As this Part has shown, the value of de-extinction is contested. Its risks are unknown, and therefore difficult to quantify. Although the concept of de-extinction might stimulate interest in conservation, "there are many reasons to question whether de-extinction of species, such as the Dodo, will be an effective tool for restoring or advancing ecological health." Regardless of its contribution to conservation strategy, the current problem is that de-extinction is critically under-regulated, as the next Part shows.

#### II. THE EXISTING LEGAL FRAMEWORK AND CURRENT REGULATORY GAP

[R]eliance on native/exotic and human/nature dichotomies for invasive species and public lands law and management conflicts with current scientific understanding, disregards the pervasive effects of humans on natural systems, and ultimately fails to foster the effective protection of ecological resources and their services.<sup>118</sup>

Existing wildlife protection statutes, such as the ESA, do not envision the existence of species that were once extinct, but are now resurrected. In fact, one of the primary purposes of the ESA is to prevent species from

<sup>&</sup>lt;sup>113</sup> *Id.* at 6-7.

<sup>&</sup>lt;sup>114</sup> *Id*.

<sup>&</sup>lt;sup>115</sup> Okuno, *supra* note 1, at 590 (noting "trepidations about animal welfare and potential negative effects of introducing de-extinct species into the environment").

<sup>16</sup> *Id*.

<sup>117</sup> Camacho, supra note 10, at 905.

<sup>118</sup> Id. at 879.

<sup>&</sup>lt;sup>119</sup> There are other wildlife laws like the Migratory Bird Treaty Act of 1918, 39 Stat. 1702 (1916) and laws that protect wildlife habitat, like the Federal Land & Policy Management Act of 1976, 43 U.S.C. § 1701 *et. seq.* These laws are not considered here because their protective importance for wildlife is secondary to the ESA.

going extinct by protecting them from harms that might push them to the brink. <sup>120</sup> Consequently, the ESA offers no guidance on the process of deextinction or the protection of, or from, de-extinct species in the wild. The ESA would have to be substantially amended to offer adequate protection. But expanding the ESA's protective reach is unlikely in this era of de-regulation, which has had an especially strong impact on wildlife laws. <sup>121</sup> Nor do the statutes and regulations governing biotechnology and genetic engineering, which play an important role in the de-extinction process, offer much help. These sources of law are scattered across various agencies and levels of government, embodying the antithesis of a coherent regulatory program. The result is a dysfunctional regulatory commons with respect to genetic engineering and a regulatory gap that encompasses the entire field of de-extinction. This Part describes this regulatory gap, the regulatory commons, and the consequences of each for de-extinction.

# A. A Regulatory Gap—Existing Domestic Wildlife Laws Do Not Cover De-Extinct Species<sup>122</sup>

The ESA focuses on preserving "existing species in their historical and existing habitat, while minimizing those resources deemed to be artificial or artifactual." Protecting de-extinct species would shift the focus of the Act from protecting existing habitat to protecting a de-extinct species'

<sup>&</sup>lt;sup>120</sup> See, e.g., 16 U.S.C. § 1532(3) ("The terms 'conserve', 'conserving', and 'conservation' mean to use and the use of all methods and procedures which are necessary to bring any endangered of threatened species to the point at which the measures provided pursuant to this chapter are no longer necessary.").

<sup>121</sup> Since January 3, 2017, when the 115th Congress was sworn in, there have been 75 legislative attempts to weaken the ESA, including legislation that would weaken the consultation, listing, and consultation processes of the statute, strip current protections from specific species like gray, red, and Mexican wolves and grizzly bears and prevent the listing of certain species like the greater sage grouse. Center for Biological Diversity, *Politics of Extinction*, available at https://www.biologicaldiversity.org/campaigns/esa\_attacks/trumptable.htlm (last visited Mar. 4, 2019).

<sup>122</sup> This article does not discuss the possible applicability of international treaties, international law in general, or patent law to de-extinct species, such as the Convention on Biological on Biological Diversity or the Cartagena Protocol on Biosafety to that Convention, because "[i]n its current form, the international legal framework likely will be ill suited to meet the challenges associated with controlling and safeguarding de-extinct species." Okuno, *supra* note 1, at 620; *see also id.* at 584 (discussing a more inclusive list of such treaties, such as the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the Convention on the Conservation of Migratory Species of Wild Animals, the Paris Convention for the Protection of Industrial Property, the Patent Cooperation Treaty, and the Patent Law Treaty).

<sup>123</sup> Camacho, supra note 10, at 863.

former habitat.<sup>124</sup> Additionally, the emphasis in the ESA, and in other laws like the Wilderness Act, <sup>125</sup> on minimizing human involvement in species recovery does not "map" easily onto the introduction of de-extinct species, which is dependent on substantial human involvement. Therefore, while this result is not surprising—de-extinction was not in the minds of the drafters of these laws—the ESA and other similar laws may impede the return of many resurrected species, even if environmentally beneficial.<sup>126</sup>

A de-extinct species is only "a facsimile of an extinct species," and, therefore, "inherently artificial, the product of human manipulation in the laboratory or breeding facility." The purpose of the ESA, however, is not "to provide protection for new organisms invented by human beings ab initio"; applying the ESA in this way would certainly be "a novel interpretation of the statute." Moreover, theories of dynamic statutory interpretation, which arise when new circumstances require the adjustment of a statutory directive, 129 offer little help. Any accommodation to overcome these problems would be so contrary to the law's expected application that it would stretch its original meaning beyond any recognizable interpretation. 130

In all likelihood, laws that promote wilderness preservation and emphasize the importance of natural processes over human involvement, such as the Wilderness Act of 1964,<sup>131</sup> would likely consider the introduction of a de-extinct species "exotic" because humans are responsible for its presence.<sup>132</sup> As exotic species, de-extinct species would be viewed as harmful, "their introduction prohibited, and their existence

<sup>&</sup>lt;sup>124</sup> *Id.* at 855 (noting that other wildlife laws might "perversely" allow re-introduction of a resurrected species where it might be unsuited to current conditions, but not allow that to happen where the reintroduction might provide substantial ecological benefits).

<sup>125 16</sup> U.S.C. § 1311(c).

<sup>126</sup> Camacho, supra note 10, at 864.

<sup>&</sup>lt;sup>127</sup> Carlin, Wurman & Zakim, *supra* note 10, at 22.

<sup>&</sup>lt;sup>128</sup> *Id.* at 31 ("The text and purpose of the ESA may be interpreted as qualifying resurrected species for listing, even though they are facsimiles rather than true revivals of extinct species.").

<sup>&</sup>lt;sup>129</sup> *Id.* (citing WILLIAM N. ESKRIDGE JR., DYNAMIC STATUTORY INTERPRETATION 176 (1994)).

<sup>&</sup>lt;sup>130</sup> But see id. ("Fundamentally, the purpose of the ESA is to protect and restore species most at risk. Recreating and reintroducing close facsimiles of extinct species seems not so very different from rediscovering them, as happened with the Franciscan manzanita.").

<sup>&</sup>lt;sup>131</sup> 16 U.S.C. §§ 1131-36.

<sup>132</sup> Camacho, supra note 10, at 880; see also id. at 885 ("Under such a definition of native or exotic that hinges nativeness on the lack of human intervention, however, any de-extinct species proposed to be introduced would almost certainly be considered exotic."). According to Professor Camacho, the "NPS in fact expressly states that genetically modified organisms exist solely due to human activities and therefore are managed as exotic species in parks." Id. (internal quotation omitted).

subject to a range of management strategies that seek to control or eliminate their presence."<sup>133</sup> Being labelled exotic would mean these species would not be protected by laws that promote native species.<sup>134</sup> This may also result in their being labelled invasive, which would subject them to control or possible eradication.<sup>135</sup> The fact that many jurisdictions do not protect exotic species may force the selection of introduction sites for resurrected species to be based on where the species once existed, even if the area's conditions have changed substantially.<sup>136</sup>

Laws that focus on the "natural" environment and on "minimizing human influences" result in species management regulations that "inhibit or prohibit human-directed program[s]." Because humans play an essential part in these species' creation and eventual return to the wild, these statutes thus are ill-suited to managing the reintroduction of deextinct species. This emphasis "on nativity" in domestic wildlife laws has resulted in "legal categories such as 'endangered,' 'native,' and 'exotic." Professor Camacho believes that these categories are "erroneously premised on ecological stasis and make little sense applied to the management of de-extinct species." 139

Therefore, laws like the ESA offer little guidance on how to approach de-extinct species. In fact, these statutes create barriers to their introduction. Any amendment to those laws to reach de-extinct species would have to be more substantial than adding a separate provision or a few words to cover them, though even that small adjustment would be difficult to achieve in the current anti-regulatory environment. Still, because these statutes are incompatible with the world of de-extinction, an entirely new statute regulating the process and effects of de-extinction is probably necessary—a solution which is even less politically feasible.

<sup>133</sup> Id. at 888.

<sup>&</sup>lt;sup>134</sup> *Id.* at 885; *see also id.* at 878 ("Generally, the predominant motivation of this strain of wildlife law is to protect or promote native preexisting species, combined with seeking to keep exotic species from ecologically significant areas.").

<sup>&</sup>lt;sup>135</sup> Camacho, *supra* note 10, at 885; *see also id.* at 878 ("If considered invasive, however, an organism generally also will be vulnerable to laws that seek to minimize, control, or eradicate its species in that jurisdiction.").

<sup>136</sup> Id. at 889.

<sup>&</sup>lt;sup>137</sup> *Id.* at 892; *see also id.* ("As a result of these dichotomies, de-extinct species will often be obstructed as non-native and/or introduced—even if they might promote ecological function in a particular area—and may be allowed or promoted in locations they used to exist—even if likely to cause ecological damage.").

<sup>138</sup> *Id*.

<sup>&</sup>lt;sup>139</sup> *Id.*; see also id. at 855 ("De-extinction illustrates the limitations of the law's reliance on these simplistic dichotomies").

### B. A Regulatory Commons—Genetically Engineered Organisms

Since the start of this century, scientists have been discovering "new technologies and processes in genomic engineering and gene modification." Most commonly, scientists 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.

# 1. Existing Regulatory Bodies and Regimes

In 1986, the U.S. Food and Drug Administration ("FDA"), the EPA, and the U.S. Department of Agriculture ("USDA") developed the Coordinated Framework for the Regulation of Biotechnology ("Coordinated Framework"), apportioning responsibility for biotechnology oversight among various federal agencies. The Coordinated Framework contains policy statements from a number of federal agencies, collectively suggesting that existing laws can adequately regulate genetically engineered products. Indeed, the Coordinated Framework reflects more than ten of these laws—all of which were written for some purpose other than the regulation of biotechnology. As a consequence, Professor Carlin comments, the

<sup>140</sup> Hrouda, supra note 10, at 222.

<sup>&</sup>lt;sup>141</sup> Heather Hosmer, Outgrowing Agency Oversight: Genetically Modified Crops and the Regulatory Commons Theory, 25 GEO. INT'L ENVTL. L. REV. 647, 663-64 (2013).

<sup>&</sup>lt;sup>142</sup> Rao, *supra* note 35, at 910 ("In the 1986 Coordinated Framework for Regulation of Biotechnology (Coordinated Framework), three federal agencies published the federal government's policy toward the regulation of biotechnology, allowing the FDA, the USDA, and the EPA to use existing statutes to regulate different biotechnologies. Under the FDCA, the FDA reviews food, food additives, human drugs, animal drugs, and biologics. Generally, the USDA's Food Safety Inspection Service (FSIS) has jurisdiction over food products prepared from domestic livestock and poultry. In addition, the Animal and Plant Health Inspection Service of the USDA regulates animal biologics, plants, seeds, plant pests, animal pathogens, and certain genetically-modified organisms containing plant pest genetic material.").

<sup>&</sup>lt;sup>143</sup> Carlin, Wurman & Zakim, *supra* note 10, at 45 (quoting Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986)).

<sup>&</sup>lt;sup>144</sup> *Id.* at 46 (citing Rosie Mestel, *Genetic Modification Strains Old Food and Drug Laws*, L.A. TIMES (Mar. 23, 2013), http://articles.latimes.com/2013/mar/23/science/la-sci-gmoregulations-20130324). For example, some of the regulations referred to in the Framework "address issues such as tainted drugs, wheat spiked with sawdust and pollution by industrial chemicals." *Id.* 

results under the Coordinated Framework can be "odd." The Obama Administration's 2017 Update to the Coordinated Framework did little to change the regulatory structure imposed in the original version, maintaining the assumption about the adequacy of existing laws. Instead, it focused on "increasing [process] transparency, clarifying agency authority, and reducing regulatory hurdles" to the use of genetically engineered products. The operating assumptions in both versions continues to be that "continued advances in biotechnology are desirable, that genetic engineering processes are not inherently risky, and that it is possible to manage risks presented by specific genetically-engineered products using the same regulatory mechanisms that apply to conventional products." <sup>147</sup>

Under the Coordinated Framework, the FDA regulates transgenic animals—animals containing genetic material into which DNA has been artificially introduced into the germ line—under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 148 and the EPA has authority "to regulate all microorganisms produced for environmental, industrial, or consumer uses," under the Toxic Substances Control Act ("TSCA"). 149 Moreover, the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") grants the EPA power "to regulate genetically-engineered microorganisms formed by deliberate combinations of genetic material from dissimilar source organisms." 150

For the EPA to use its TSCA authority to regulate de-extinct species, it must find that the resurrected species contains a "chemical substance," the manufacture, use, sale or disposal of which poses "an unreasonable risk of injury to health or the environment." Chemical substances are defined in the TSCA as "any organic or inorganic substance of a particular molecular identity including – i) any combination of such substances occurring in whole or in part as a result of chemical reaction

<sup>&</sup>lt;sup>145</sup> *Id*.

<sup>&</sup>lt;sup>146</sup> Jonas J. Monast, *Editing Nature: Reconceptualizing Biotechnology Governance*, 59 B.C. L. REV. 2377, 2389 (2018).

<sup>147</sup> Id. at 2415.

<sup>&</sup>lt;sup>148</sup> Rao, *supra* note 35, at 919; *see* 21 U.S.C. § 301 *et seq.* (2000).

<sup>&</sup>lt;sup>149</sup> Rao, *supra* note 35, at 910. *See also* 15 U.S.C. § 2601 *et seq.* (2000) (giving EPA authority to track and monitor chemicals as well as to ban any that pose an unreasonable risk of harm to human health or the environment).

<sup>150</sup> Rao, *supra* note 35, at 910-11. TSCA's exclusion of "any food, food additive, drug, [or] cosmetic . . . when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device" from the definition of a "chemical substance" has no relevance for resurrected animals because it is highly unlikely that they would end up as food or a food additive. *Id.* at 922 (citing 15 U.S.C. § 2602(B)(vi)).

 $<sup>^{151}~15</sup>$  U.S.C.  $\S~2601(b)(2).$  The more limited scope of FIFRA makes its application to de-extinct species highly unlikely.

or occurring in nature and any ii) element or uncombined radical."<sup>152</sup> The risk of ecological and human harm posed by the release of resurrected species might be sufficient to regulate them under the TSCA, as long as the chemical substances definitional barrier can be overcome.

The EPA's original position on "whether transgenic animals constitute chemical substances" was that "chemical substances do not 'exclude life forms which may be manufactured for commercial purposes" and that "TSCA regards generally recombinant DNA molecules as 'chemical substances . . . . "153 But it remains uncertain whether "a host organism," like a de-extinct species that contains "recombined DNA molecules[,] fits . . . that definition." 154

Although the USDA has said that it would use its existing policies to regulate genetically engineered animals, <sup>155</sup> it has made no move to assert this jurisdiction. Perhaps driving this hesitancy is a belief that given the agency's focus on meat products consumed by humans, it would be a stretch for the agency to regulate de-extinct animals that would not be eaten by anyone. <sup>156</sup> The FDCA and Public Health Safety Act impose some requirements on the development of gene therapies, to the extent that they must be "subject to clinical trials for Investigational New Drugs." <sup>157</sup> None of these laws, however, offers a secure hook for regulating de-extinct species. <sup>158</sup>

This Part shows that the Coordinated Framework consists of little more than the under-developed, changing policy positions of multiple federal agencies with unclear regulatory boundaries. The Coordinated Framework "relies on a fragmented and inefficient regulatory patchwork"<sup>159</sup> to regulate biotechnology and genetic engineering. Moreover, if the Coordinated Framework's statements about various agencies' regulatory authority over resurrected species are not consistent with each agency's statutory authority, those statements would be

<sup>&</sup>lt;sup>152</sup> 15 U.S.C. § 2602(2)(A); *see also* Rao, *supra* note 35, at 922 ("For the EPA to regulate GloFish<sup>TM</sup>, it must find that GloFish<sup>TM</sup> consist of chemicals comprised of a particular molecular composition resulting from a chemical reaction.")).

<sup>153</sup> Rao, *supra* note 35, at 922.

<sup>154</sup> Id.

<sup>155</sup> Id. at 920.

<sup>156</sup> Id.

<sup>&</sup>lt;sup>157</sup> Hrouda, *supra* note 10, at 230. A less relevant agency with respect to the regulation of resurrected animal species is the Center for Veterinary Medicine (CVM), which "has primary jurisdiction over 'modifications that affect the performance of the animal or attributes of the products derived from the animal through the action of the expression product of an inserted gene," and 'animals modified to produce drugs, biologics, or other substances of commercial value." Rao, *supra* note 35, at 919.

<sup>158</sup> Hrouda, supra note 10, at 230.

<sup>159</sup> Camacho, supra note 10, at 901.

unenforceable because they would be beyond the agency's delegated authority. 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 given the strength of the biotechnology industry discussed in the next subsection. It is also worth noting that the Coordinated Framework does not incorporate any adaptive management measures, which, if applied, would consider initial assessments to be only provisional and require periodic evaluations of and revisions to decisions to stimulate agency learning over time. In Nor do any of the laws encompassed in it impose any ethical requirements on activities taken under their authority.

### 2. Potential for Regulation Under Patent Law

A less likely, but nonetheless noteworthy, source of potential regulation of de-extinct species is patent law. Applying patent law to de-extinct species rests on the theory that a de-extinct species is "novel, useful, and non-obvious." Whether living organisms are patentable varies from country to country and is an unsettled issue even within many countries," as is the question of whether these laws apply nationally or regionally. Even if one could patent a de-extinct species, however, that species would only be protected as intellectual property. While this might be commercially beneficial from the perspective of individuals involved in the de-extinction process who hold a patent, it would offer limited protection or benefit to either the de-extinct species itself or to the public as a whole. 165

Somewhat surprisingly, no current law directly regulates the genetic modification of human embryos. <sup>166</sup> Nor are there regulations that apply to germline modifications, the most controversial use of CRISPR

<sup>&</sup>lt;sup>160</sup> *Id.* at 902; *see also* Okuno, *supra* note 1, at 626 ("The precautionary approach or its underlying concepts should be applied to the protection *of* de-extinct species and to the protection of biodiversity and the environment *from* de-extinct species.").

<sup>161</sup> Camacho, supra note 10, at 902.

<sup>162</sup> Okuno, supra note 1, at 619.

<sup>&</sup>lt;sup>163</sup> *Id*.

<sup>164</sup> Id. at 621.

<sup>&</sup>lt;sup>165</sup> *Id*.

<sup>&</sup>lt;sup>166</sup> Hrouda, *supra* note 10, at 229-30 ("Presently in the United States, there is huge diversity in state regulations, and it is not clear whether any federal law or federal regulations directly address the genetic modification, particularly germline enhancements, of embryos. Most likely the uncertainty is because until recently the technology was only speculative.").

technology.<sup>167</sup> Despite the lack of regulations, "[t]he FDA approved a gene therapy for the first time in August 2017,"<sup>168</sup> and gene therapy research useful to humans is moving forward quickly because of its perceived benefits. In that same month, a group of scientists announced "the successful editing of a human embryos [sic] to address a genetic blood disorder—the first successful human germline editing involving U.S. scientists."<sup>169</sup> A month later, an FDA advisory committee proposed authorizing a second gene therapy.<sup>170</sup> Although the National Institutes of Health (NIH) prohibits the use of federal funds for human germline modifications, private funding is enabling the use of CRISPR technology for non-inheritable treatments.<sup>171</sup> For example, the first authorized clinical trial of a CRISPR gene therapy in humans was privately funded.<sup>172</sup>

This discussion should make clear that there are no generally applicable federal environmental laws that would apply to species that have been resurrected through the use of genetic engineering technology. 173 It is possible that under the Coordinated Framework these species might be "subject to a range of laws and regulations that apply generally to 'GMOs' [genetically modified organisms] without specifying particular uses (such as food, pesticides, etc.)."174 While some of these regulations might apply to the de-extinction process or to the release of de-extinct species into the wild, 175 definitional hurdles may have to be overcome, like those under TSCA. Additionally, some state or local anti-GMO ordinances might prohibit de-extinction experiments. 176 It remains to be seen whether the policies under the Coordinated Framework might preempt those laws and allow these experiments to move forward. Certainly, nothing in the ESA would. The unregulated landscape in which genetic engineering technologies are being developed has resulted in growing ethical, political, and legal concerns, especially

<sup>&</sup>lt;sup>167</sup> Id. at 229 ("Unfortunately, U.S. law on germline modification technologies is relatively non-existent, and what does exist is questionable as to whether CRISPR technology specifically fits underneath its umbrella.").

<sup>&</sup>lt;sup>168</sup> Monast, *supra* note 146, at 2425.

<sup>169</sup> Id.

<sup>&</sup>lt;sup>170</sup> *Id*.

<sup>&</sup>lt;sup>171</sup> *Id*.

<sup>172</sup> Id

<sup>&</sup>lt;sup>173</sup> Carlin, Wurman & Zakim, *supra* note 10, at 46 ("The web of regulations used to govern genetically engineered species draws on more than 10 laws, all written for other purposes.").

<sup>&</sup>lt;sup>174</sup> *Id*.

<sup>&</sup>lt;sup>175</sup> *Id*.

<sup>&</sup>lt;sup>176</sup> *Id.*; see also Rao, supra note 35, at 912 ("Although the federal government has yet to regulate the release of transgenic fish into the food supply and for ornamental use, one state has acted to control its release. California has banned the production of transgenic salmon, exotic (non-native), and transgenic fish in state waters.").

with regard to human subjects.<sup>177</sup> Many of these concerns transfer to the application of such methods to the resurrection of extinct species.

# C. The Effect of a Regulatory Commons in the Field of Genetic Engineering

The preceding discussion of the Coordinated Framework illustrates how the field of genetic engineering, which plays a key role in the deextinction process, functions as a regulatory commons. The resultant "splintered agency jurisdiction and political disincentives for regulatory expansion," characteristic of a regulatory commons, not only lead to "under regulation," but can also result in no regulation at all. 178 Powerful opponents of regulation, operating in a vacuum created by a regulatory commons, can prevent nascent regulation from arising, aided by the costs of trying to coordinate across agency jurisdictions. <sup>179</sup> The failure to clearly allocate regulatory authority creates problems for policymakers and the public when it comes to identifying and improving agency deficiencies. 180 Additionally, the existence of a regulatory commons steers states away from attempting to regulate.<sup>181</sup> The Coordinated Framework, even though it is ineffective, might block states from regulating the use of genetic engineering in the production of de-extinct species if that activity falls within the purview of one of the laws included in the Coordinated Framework.

In the absence of control by a single agency or a designated agency leader, there is an increased likelihood of "overlapping and mismatched regulatory jurisdictions that will create oversight gaps." As reflected in the Coordinated Framework, "fragmented regulatory oversight" without a designated lead agency makes it difficult for individuals seeking change in how the government manages an issue to identify the agency in charge

<sup>177</sup> Hrouda, supra note 10, at 222.

<sup>&</sup>lt;sup>178</sup> Hosmer, *supra* note 141, at 651.

<sup>179</sup> *Id.* at 668. The strength of the biotech industry is illustrated by Recombinetics, Inc., a firm seeking to market genetically bred homless cows. The company argues that gene editing is no different than selective breeding as it simply speeds up the selective breeding process farmers have used for thousands of years and, thus is not only harmless, but should also be perfectly legal since "new techniques that achieve the same result should be legal as well," and thus avoid any type of stringent legal review. Monast, *supra* note 146, at 2399. However, there are important differences between CRISPR and selective breeding. For example, the latter takes time and allows ecosystems and systems of governance to adjust; whereas CRISPR speeds up that process to the point where it outpaces traditional regulatory responses. In addition, gene editing may produce different results than conventional breeding. *Id.* at 2400.

<sup>&</sup>lt;sup>180</sup> Hosmer, *supra* note 141, at 668.

<sup>&</sup>lt;sup>181</sup> *Id*.

<sup>&</sup>lt;sup>182</sup> *Id.* at 649.

of that issue, let alone assign blame or influence that agency.<sup>183</sup> Thus, regulatory commons theory predicts that

[w]here numerous regulators could be blamed for the ill, or sought out for relief, demanders of regulation encounter substantial informational and strategic hurdles confounding attribution decisions. If no single regulator is perceived as the institution most responsible for a problem or its correction, no particular regulator will likely be blamed for governmental inattention.<sup>184</sup>

Simultaneously, "the political disincentives of being blamed for current problems, transaction costs of working with other agencies, and free rider problems dissuade agencies from expanding their authority and taking the lead on GM regulations." Regulatory commons theory also "cautions" that collective action problems make it "difficult" to garner support for corrective legislation. 186

Regulatory commons theory also predicts that fragmented oversight creates "beneficiaries of the status quo," i.e., those who profit from weak oversight and who "have a vested interest in maintaining a low level of regulation." The biotechnology industry is a multi-billion dollar per year industry responsible for creating thousands of job. 188 It can afford the high cost of influencing fragmented agencies as well as the expense of conducting the scientific research needed to inform agency decisions. As a result, this industry has become a powerful force supporting limited regulation of the field. 189 The sheer size of the industry has made state and federal policymakers "hesitant to increase regulation" of it. 190

Additionally, federal agencies are dependent on biotech industries for the technical data they need to support their decisions in the field.<sup>191</sup> Often, only members of the regulated industry have the necessary interest and resources to influence agency decision making because they are "better organized, better funded, more expert, and better informed."<sup>192</sup>

<sup>&</sup>lt;sup>183</sup> *Id.* ("Without a staunch public mandate, agencies fail to perceive and react to flaws in their practices, which results in under regulation.").

<sup>&</sup>lt;sup>184</sup> *Id.* at 664 (quoting William W. Buzbee, *Recognizing the Regulatory Commons: A Theory of Regulatory Gaps*, 89 IOWA L. REV. 1, 31 (2003)).

<sup>185</sup> Id. at 649.

<sup>186</sup> Hosmer, supra note 141, at 668.

<sup>&</sup>lt;sup>187</sup> Id. at 665.

<sup>188</sup> *Id*.

<sup>&</sup>lt;sup>189</sup> *Id.* at 650.

<sup>190</sup> Id. at 665.

<sup>&</sup>lt;sup>191</sup> *Id.*; see also id. ("Thus, agencies overseeing GMOs have become increasingly dependent on, and influenced by, the very industries they regulate.").

<sup>&</sup>lt;sup>192</sup> Hosmer, *supra* note 141, at 665.

This gives these regulated entities a unique position of power to persuade agencies to accede to their goals.<sup>193</sup>

In sum, de-extinction is going forward unregulated. Existing environmental laws do not apply, and any effort to adjust these statutes through amendments or through new legislation will likely fail. Policies that currently govern genetic engineering have fallen victim to the dysfunctions of a regulatory commons—"political disincentives, fragmented authority, and agency reliance on the bioindustries stymic regulatory expansion"—while the possibility of preemption "leaves states with minimal regulatory discretion" to fill the gap. <sup>194</sup> As a result, a strong public interest in regulating biotechnology industries, including genetic engineering, has not been realized. Needless to say, this situation has spillover consequences for the regulation of de-extinction.

# III. A HAIL MARY PASS—NORM-ENFORCED PRIVATE GOVERNANCE MIGHT FILL THE GAP AND CIRCUMVENT THE REGULATORY COMMONS

Legal scholars, politicians, professors, and law students rarely claim that the law evolves quickly in response to new technology. Science, on the other hand, moves at breakneck paces that are substantially faster than the regulatory bodies that govern it. This leaves such governing bodies at a great disadvantage while many scientists are confined mostly by the ethics imposed upon them by their own profession. <sup>195</sup>

This is exactly the situation facing de-extinction. The process of creating de-extinct animals using genetic engineering is moving forward rapidly. It is only a matter of time before the first genetically engineered de-extinct species is created, at which point its release into the environment is foreordained. It should be clear by now that there is no existing legal framework within which these activities will take place, and there is little hope that one can be created in time to manage these events. However, as discussed in this Part, a combination of private governance and social norms might fill the regulatory gap created by the existence of a regulatory commons and a lack of applicable laws, sidestepping completely the ineffectual Coordinated Framework.

<sup>193</sup> Id.

<sup>&</sup>lt;sup>194</sup> *Id.* at 651.

<sup>&</sup>lt;sup>195</sup> Rodriguez, supra note 23, at 586.

#### A. Private Governance

Private governance occurs when private parties implement policies designed to achieve traditional governmental goals. 196 Although government agencies can promote or discourage the development and enforcement of private policies, they are unable to participate in creating or implementing these policies and thus have little control over outcomes. 197 Private governance can include having non-governmental entities set, implement, and enforce standards. 198 Privately set standards can induce a business or an individual to meet a traditional governmental objective—like creating and protecting a public good—or to fulfill a traditional governmental function—like monitoring or enforcing private action. 199 While "private environmental governance is not a substitute for public governance[,]... it can fill temporal or other gaps in the public governance response to environmental issues." 200

Private governance can emerge for a number of reasons. For example, it can arise in response to the government's complete failure to act or its failure to act in a timely and effective manner.<sup>201</sup> This may be due to the presence of jurisdictional gaps, agency capture, or stress from a lack of funding.<sup>202</sup> At least the first two explanations appear to apply here. Gaps in timing can occur when the government's response to an identified problem is too slow, or where the government's response requires "time to generate and enforce public measures,"<sup>203</sup> either of which may be applicable to de-extinction non-regulation.

Private governance frequently fills gaps in or supplements public governance. As a result, private governance measures may "succeed

<sup>&</sup>lt;sup>196</sup> Vandenbergh, *supra* note 3, at 147 ("[P]rivate environmental governance is the development and enforcement by private parties of requirements designed to achieve traditionally governmental ends.").

<sup>&</sup>lt;sup>197</sup> *Id.* ("Instead, private parties overcome collective action barriers or bypass the need for collective action altogether to achieve environmental protection.").

<sup>198</sup> Id. at 146.

<sup>&</sup>lt;sup>199</sup> *Id.*; see also Michael P. Vandenbergh & Ben Raker, *Private Governance and the New Private Advocacy*, 32 NAT. RES. & ENVT. J. 45, 46 (2017) (describing the various functions private governance can perform).

<sup>&</sup>lt;sup>200</sup> Vandenbergh, *supra* note 3, at 163. The existence of an open commons may also inhibit the government from acting or conversely, when "the regulatory space is so crowded that a regulatory anti-commons problem exists," creating a situation with no regulatory or management controls—however, neither of these situations are relevant here. *Id. at* 161-62. Also, not relevant here is when private governance can complement public governance by "offering incentives for higher performance . . . or [by] supplementing existing enforcement." *Id. at* 162. The almost complete absence of public governance means it cannot serve as a baseline for higher performance.

<sup>&</sup>lt;sup>201</sup> *Id.* at 161.

<sup>&</sup>lt;sup>202</sup> *Id*.

<sup>&</sup>lt;sup>203</sup> *Id.* at 162.

without solving the problem or being the optimal solution."<sup>204</sup> But even though private governance measures often present a suboptimal or incomplete solution, they still "may be part of an optimal mix of public and private measures."<sup>205</sup> The only relevant question for determining whether a private governance measure has succeeded is "whether the change from what would have happened in the absence of the private governance measure is worth the cost[,]" not whether a particular metric of environmental improvement has been achieved.<sup>206</sup>

Here, where nothing is happening and nothing is likely to happen in the future, to the extent private governance measures may reduce the risk of harm to the environment and public welfare, their employment would seem to be worth whatever costs that may occur. Even if business entities participate in private government activities with the goal of undermining initiatives to impose more stringent government measures, <sup>207</sup> these measures may be the only way to place any controls on the de-extinction process, and perhaps business participants may be coopted by the process.

"Private governance measures often are under consideration because ideal options are not viable." This is the case with de-extinction. Private governance has some benefits when there is no public governance. According to Michael Vandenbergh, private governance can show the feasibility of a public program, build a constituency to support future government action, or lower the cost to private firms of eventual government action because such firms may have helped shape or may already have started to conform to privately set standards. By inducing action, private initiatives may also reduce the cost of public initiatives by inviting private entities to take on some of the public governance functions. Private actors may persuade businesses to support public or private regulatory programs, and this support can "strengthen public measures, making it more likely that they will withstand challenges" in the future. Additionally, since there are no current governmental programs available to control de-extinction, private initiatives may be a

<sup>&</sup>lt;sup>204</sup> *Id.* at 185. This avoids both the good and the bad of many private governance initiatives to the extent that they can "undermine, enhance, delay, accelerate, or complement government action in situations where government can act." *Id.* at 186.

<sup>&</sup>lt;sup>205</sup> Id. at 186.

<sup>&</sup>lt;sup>206</sup> Vandenbergh, *supra* note 3, at 186.

<sup>&</sup>lt;sup>207</sup> Id. at 162.

<sup>&</sup>lt;sup>208</sup> *Id.* at 186; *see also id.* ("Another important factor in assessing the success of private governance actions is the effect of a private governance option on existing governance measures and on the likelihood of adopting other public or private governance options.").

<sup>&</sup>lt;sup>209</sup> *Id.* at 187.

<sup>&</sup>lt;sup>210</sup> *Id*.

<sup>&</sup>lt;sup>211</sup> *Id*.

<sup>&</sup>lt;sup>212</sup> Vandenbergh, *supra* note 3, at 188.

way of experimenting with different approaches to the problem at "low risk" and low cost to the government,<sup>213</sup> improving the likelihood of future government action if the approaches gain some traction.

Private governance can work where the participants have "adequate information, iterative relationships, opportunities for social sanctions[] and rewards, and when there is limited pressure on the resource."<sup>214</sup> These factors are present more often in small groups than in large organizations.<sup>215</sup> Although de-extinction will likely have a global impact, its initial influence will be limited to the species' local release sites, and only a few scientists or companies will be involved. Thus, de-extinction likely will meet the small group criteria. The participants in de-extinction will be limited to scientists and genetic engineering companies possessing the relevant information, and this small number of actors should enable reiterative experiences as well as opportunities for sanctions and rewards. Unfortunately, since so little is known about how de-extinct species will behave outside of a laboratory, the amount of pressure these species will place on specific local environments is unknown.<sup>216</sup> This could create a problem for private governance, as the problems may be too big to control other than through public governance means.

Typical private governance measures, such as labeling, make little sense in the case of de-extinction because, in most situations, there will be no product for sale.<sup>217</sup> Nonetheless, private governance can involve "private behavior that often has the effect of or is motivated by the desire to manage a common pool resource, provide a public good, or reduce a negative externality."<sup>218</sup> Here, the public good would be facilitating de-extinction while reducing the negative externalities of environmental and public harm.

<sup>&</sup>lt;sup>213</sup> *Id*.

<sup>&</sup>lt;sup>214</sup> *Id.* at 164.

<sup>&</sup>lt;sup>215</sup> *Id.* (citing Richard H. McAdams, *The Origin, Development, and Regulation of Norms*, 96 MICH. L. REV. 338, 382–83 (1997) (noting that small groups are not necessary for norm influence if adequate information and opportunities for social sanctions exist)); Lior Jacob Strahilevitz, *Social Norms from Close-Knit Groups to Loose-Knit Groups*, 70 U. CHI. L. REV. 359, 359–60, 365 (2003) (distinguishing group size and relationship among group members).

<sup>&</sup>lt;sup>216</sup> See supra Part I.B.1.a (discussing how little is known about the potential impact of resurrected species on the environment and the resultant risks).

<sup>&</sup>lt;sup>217</sup> Vandenbergh, *supra* note 3, at 167 ("To the extent environmental protection is in a consumer's preference set, labeling systems provide the information about the provenance and performance of the good necessary to enable the consumer to act on the preference."); *see also* Hosmer, *supra* note 141, at 669 ("In order to preserve these markets, GM crop manufacturers have an interest in ensuring government-prescribed food safety measures and have engaged in voluntary labeling for exports.").

<sup>&</sup>lt;sup>218</sup> Vandenbergh, *supra* note 3, at 182.

When business entities participate in private governance measures to control their activities, public trust in these businesses will increase. Conversely, when corporations weaken accountability procedures, they have more difficulty defending against claims that their interests are adverse to those of the public.<sup>219</sup> Or, put another way, "[w]ithout mechanisms to ensure responsibility, the industry cannot effectively claim to be responsible. Without trust markets corrode."220 This is especially true of the chemical industry, which includes genetic engineers, and which depends on "public trust and support in its institutional and societal justification and performance." <sup>221</sup> It is also the responsibility of members of that industry "to create trust through a high degree of credibility and reliability as experts when it comes to (public) discourses on risks and benefits of science and technology or the ethical and social implications of scientific and technological progress."222 Because so much is unknown when it comes to de-extinction, trust will be at a premium.

The Asilomar Guidelines ("Guidelines") are an example of private governance in the field of genetic engineering. Formulated by a group of concerned biotechnology scientists who met in Asilomar, California, in 1975, the Guidelines were norms and standards for conducting research that are grounded in the "precautionary principle"—"a research policy that calls for higher safety standards for experiments that could potentially cause irreparable environmental or health harms."<sup>223</sup> The Guidelines' strict laboratory procedures were designed to contain and prevent any unintended release of GMOs into the environment.<sup>224</sup> Later, they formed "the basis of the [National Institutes of Health]'s guidelines for government-funded rDNA research."<sup>225</sup> Even though the Guidelines applied only to government-financed research, many scientists voluntarily acceded to them out of a fear of negative publicity.<sup>226</sup> One may assume that the Guidelines had the intended effect of quieting public anxiety about genetic engineering, since such activity is proceeding in an

<sup>&</sup>lt;sup>219</sup> Rick Reibstein, *A more ethical chemistry*, 8 GREEN & SUSTAINABLE CHEMISTRY 36, 37 (2017) ("When too much money, advertising, legal expertise and lobbying is evident, distrust of the entity that seeks a dominating influence is inevitable.").

<sup>&</sup>lt;sup>220</sup> *Id.* at 36.

<sup>&</sup>lt;sup>221</sup> *Id.* at 37.

<sup>&</sup>lt;sup>222</sup> Id. (quoting Jan Mehlich et al., The ethical and social dimensions of chemistry: reflections, considerations, and clarification, 23 CHEM. EUR. J. 1210, 1216 (2017).

<sup>&</sup>lt;sup>223</sup> Hosmer, *supra* note 141, at 655.

 $<sup>^{224}\,</sup>$  Id.; Sheldon Krimsky, Biotechnics & Society: The Rise of Industrial Genetics 14, 100-01 (1991).

<sup>&</sup>lt;sup>225</sup> Hosmer, supra note 141, at 655.

<sup>&</sup>lt;sup>226</sup> Id.

era of public transparency under the 2017 Update to the Coordinated Framework.<sup>227</sup>

While private governance measures have public utility to the extent that they can fill a gap in regulation and may lead eventually to more effective and inclusive public regulation, they also run the risk of undermining those efforts as less rigorous alternatives. Since this article has suggested the low likelihood that any public regulations will emerge in time to control de-extinction, it is important to impose some controls on that process soon. Private governance offers controls on an interim basis. However, since there will only be a very limited market for de-extinct species and thus no market-based incentives at play, what will encourage scientists to self-regulate and engage in such socially positive, outward-looking behavior? This article suggests that the encouragement rests in social norms.

### B. Social Norms

Norms can be informal obligations or social rules that do not depend on government for their creation or enforcement.<sup>228</sup> They can be explanatory or aspirational, as they depict how people behave and can also suggest what people should do to conform to community expectations.<sup>229</sup> Any obligation people feel to conform their behavior to a communally accepted norm is independent of the government telling them how to behave and is reinforced by abstract norms, like the personal responsibility norm.<sup>230</sup> Martha Nussbaum believes that "a suitably flexible and realistic normative theory is actually very valuable, as a road map that will help us move toward our destination."<sup>231</sup> That destination here would be controlling risky behavior by scientists and companies engaged in de-extinction, and any road map of how to get there would be

<sup>&</sup>lt;sup>227</sup> See Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology, Exec. Office of the President (Jan. 4, 2017).

<sup>&</sup>lt;sup>228</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 134.

<sup>&</sup>lt;sup>229</sup> *Id*.

<sup>&</sup>lt;sup>230</sup> *Id.* at 142.

<sup>&</sup>lt;sup>231</sup> Martha C. Nussbaum, *Climate Change: Why Theories of Justice Matter*, 13 CHI. J. INT'L L., 469, 486 (2013); *see also* Yuval Feldman & Doron Teichman, *Are All Contractual Obligations Created Equal?*, 100 GEO. L.J. 5, 16 (2011) ("On the one hand, rational-choice theory suggests that promisors behave in a purely selfish manner to further their own goals. On the other hand, an array of alternative theories [moral obligation, motivated reasoning, and social norms] argue that the motivation for performance is far richer and more complex and is driven by a range of internal and external forces."). For a rich description of how contract performance decisions are not motivated "solely by monetary incentives," but "reflect a far more complex decision-making process. Forces such as moral obligations, motivated reasoning, and social norms affect people's perception of their contractual obligations and the way in they are expected to behave," see also *id.* at 48-49.

helpful. With those thoughts in mind, this article discusses how norms might operate in a system of private governance to encourage judicious behavior by the scientific community with regard to de-extinction.

Social norms "reflect 'widely held beliefs about social obligations with respect to which noncompliance may trigger external social sanctions," like shaming or loss of reputation. Because social norms "embody general expectations about public behavior," they are responsive to "more external forms of enforcement like gossip, shaming, and even exclusion from the community." This makes their enforcement easy and inexpensive because there is very little cost associated with negative gossip or expressions of admiration about a person's conduct. Thus, there is no need for private enforcement organizations to develop, monitor or enforce these norms. There are no legal remedies for norm violations that are not codified in statutes or implicit in the common law, which makes sense given that norms are enforced through the application of nonlegal sanctions to violators. 235

The positive reward for an individual complying with a social norm is an improved reputation in the community. Businesses care about their reputations, especially since advocacy groups can mobilize public opposition quickly if a business's reputation is negative. Because norms are not dependent on the government for their existence or implementation, they "provide a private, decentralized, and competitive alternative to government control of social behavior. Ann Carlson suggests that norms work best "when social problems arise in small, homogeneous groups of individuals who experience some personal benefit from complying with the norm and where there are no viable regulatory tools to address the problem. Both these circumstances may be present in the case of resurrecting extinct species, as there are no regulatory tools to address the problem and the community of scientists working on de-extinction is still small.

Environmental protection is a "general, widely held abstract norm."<sup>241</sup> There is also an "abstract 'personal responsibility norm,' summarized in

<sup>&</sup>lt;sup>232</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 135 (quoting Michael P. Vandenbergh, Beyond Elegance: R A Testable Typology of Social Norms in Corporate Environmental Compliance, 22 STAN. ENVTL. L.J. 55, 69 (2003)).

<sup>&</sup>lt;sup>233</sup> *Id.* at 135-36.

<sup>&</sup>lt;sup>234</sup> Id. at 136.

<sup>&</sup>lt;sup>235</sup> Feldman & Teichman, *supra* note 231, at 15.

<sup>&</sup>lt;sup>236</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 136.

<sup>&</sup>lt;sup>237</sup> Vandenbergh, *supra* note 3, at 168-89.

<sup>&</sup>lt;sup>238</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 137.

<sup>&</sup>lt;sup>239</sup> Id. (citing Ann E. Carlson, Recycling Norms, 89 CAL. L. REV. 1231, 1233-34 (2001)).

<sup>&</sup>lt;sup>240</sup> See supra Part II.A.

<sup>&</sup>lt;sup>241</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 136.

the euphemism 'do no harm to others.'"<sup>242</sup> Since a norm is a reflection of a community's belief, an individual's community—or society more broadly—defines the "appropriate behavior" that generates a norm.<sup>243</sup> Both norms are relevant to the behavior of companies and individuals involved in the de-extinction process. However, since no laws currently govern de-extinction, the norm of law compliance—another powerful, widely held abstract norm—does not come into play.<sup>244</sup> However, law compliance and its internalization by individuals<sup>245</sup> illustrates how a personal abstract norm can become "a moral inhibition, often reinforced by a sense of personal shame when the prohibited act is actually engaged in."<sup>246</sup> This reaction is what one would expect with the triggering of the environmental protection and personal responsibility norms.

Norms work to the extent that they are internalized by the relevant community. Here, the relevant community is comprised of scientists and genetic engineering firms working on de-extinction projects.<sup>247</sup> Norms can help influence behavior when there is "some communal consensus about the validity of the norm, and people also believe that actions inconsistent with the norm might harm others or harm something of value to them."<sup>248</sup> Assuming that affected individuals engaged in de-extinction value biological diversity and environmental integrity, and assuming that these actors can visualize a connection between the development of resurrected species and harm to those environmental values, then the norms of environmental protection and personal responsibility may take root and influence behavior.

Norms can change or direct behavior when the norm violator feels "guilt and remorse"; these feelings should affect behavior automatically without outside prompting and should not be dependent on discovery by others.<sup>249</sup> In order for a norm violator's behavior to influence that of other

<sup>&</sup>lt;sup>242</sup> Id. at 136-37.

<sup>&</sup>lt;sup>243</sup> *Id.*; see also Robert D. Cooter, *Decentralized Law for a Complex Economy: The Structural Approach for Adjudicating the New Law Merchant*, 144 U. PA. L. REV. 1643, 1665 (1996) (opining that for a social norm to influence individual behavior, the individual's community must have internalized it).

<sup>&</sup>lt;sup>244</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 136.

<sup>&</sup>lt;sup>245</sup> *Id.* ("One of the things that motivates people to be law-abiding is 'internalization of legal norms or moral commitment to comply with the law" (quoting Michael P. Vandenbergh, *Beyond Elegance: R A Testable Typology of Social Norms in Corporate Environmental Compliance*, 22 STAN. ENVIL. L.J. 55, 68 (2003))).

<sup>&</sup>lt;sup>246</sup> *Id*.

<sup>&</sup>lt;sup>247</sup> Feldman & Teichman, supra note 231, at 15 (citing Robert Cooter, Normative Failure of Theory of Law, 82 CORNELL L. REV. 947, 958-68 (1997)); Richard D. McAdams, The Origin, Development, and Regulation of Norms, 96 MICH. L. REV. 338 (1997).

<sup>&</sup>lt;sup>248</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 142.

<sup>&</sup>lt;sup>249</sup> Feldman & Teichman, supra note 231, 15-16.

actors, the community must publish information about the norm violation and sanction the violator through shaming.<sup>250</sup>

People are more likely to internalize norms and to change their behavior if violations of norms are sanctioned.<sup>251</sup> Shaming a norm violator is a common sanction for norm violations.<sup>252</sup> Shame can create a sufficiently unpleasant experience for the norm offender, as well as for potential offenders, that the offense is unlikely to be repeated.<sup>253</sup> Shaming can also be used for company officials.<sup>254</sup> However, sometimes shaming can "backfire" when an individual's reduced status in their community and public humiliation lessens the desire to stop the offending behavior because there is nothing else to lose.<sup>255</sup> Additionally, if shaming sanctions are used too frequently, the public will lose interest in them, lessening their deterrent effect.<sup>256</sup>

There must be a "common understanding that an offender's irresponsible environmental behavior is bad," and until that understanding emerges, shame fails as a sanction. Here, the environmental and public health risks associated with de-extinction should be commonly understood by those working on it. And while "shaming works best in 'relatively bounded, close-knit communities whose members 'don't mind their own business' and who rely on each other," the places in which de-extinction scientists and others work create those bounded and close-knit circumstances. These communities are likely to share information about the risks of resurrecting extinct species. They are also dependent on the risk-averse behavior of others to create an atmosphere of public trust enabling their own work. This

<sup>&</sup>lt;sup>250</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 159-60.

<sup>&</sup>lt;sup>251</sup> Id. at 165.

<sup>252</sup> Id. at 160-61.

<sup>&</sup>lt;sup>253</sup> *Id*.

<sup>&</sup>lt;sup>254</sup> Jayne W. Barnard, *Reintegrative Shaming in Corporate Sentencing*, 72 S. CA. L. REV. 959, 968 (1999) ("High status business leaders may be especially susceptible to shaming rituals. 'They are the people most likely to worry about public appearances, to be vulnerable to moralistic or judgmental social groups, to defer to authority and to be relative conventional in attitudes toward 'law and order.' They are also the people most likely to be concerned about maintaining the appearance of business competence and professional accomplishment. Also, because they regard themselves as participants in a 'culture of honor,' they are especially sensitive to the opinions of peers" (quoting Toni M. Massaro, *Shame, Culture, and American Criminal Law,* 89 MICH. L. REV. 1880, 1934 (1991))).

<sup>&</sup>lt;sup>255</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 163.

<sup>&</sup>lt;sup>256</sup> *Id*.

<sup>&</sup>lt;sup>257</sup> *Id.* at 164.

<sup>&</sup>lt;sup>258</sup> *Id.* at 163.

<sup>&</sup>lt;sup>259</sup> Similarly, while education can change behavior, one must assume that the participants in the de-extinction field are well aware of both the benefits and costs of de-extinction.

workplace pressure and the threat of shame may make these actors avoid risky behavior.<sup>260</sup>

The public, particularly environmental advocates, concerned scientists, and religious figures, must persuade participants in the de-extinction process to agree to self-regulate their behavior. Public education motivating people to put pressure on individuals whose behavior is publicly perceived to be counter-productive can be an effective tool. This is true even though "people use a variety of heuristics to process and internalize information, especially information about risk, which may distort the information's accuracy." <sup>261</sup>

The effectiveness of information strategies for changing behavior depends in large part on the degree to which the public can understand and act on information about the risks posed by questionable behavior and the degree to which the public values the environment—in other words, how much the public has been environmentally "socialized." 262 However, the problem with trying to educate people about environmental risks is that the information about those risks may be "contentious, complex, contestable, and frequently from non-credible sources."263 Additionally, "[t]he sheer complexity and volume of often conflicting information about environmental harms makes it extremely difficult to convey the magnitude of a particular environmental risk."264 Too much information, which is not uncommon in the environmental area, can be overwhelming to the lay public and can cause people to "tune out." <sup>265</sup> Professor Cass Sunstein recommends the use of norm entrepreneurs<sup>266</sup> to help the public understand risk information. Norm entrepreneurs focus interest by constructing "cognitive frames" to help interpret and dramatize issues; if successful, "the new frames resonate with broader public understandings and are adopted as new ways of talking about and understanding issues."<sup>267</sup> Indeed, the principal task of norm entrepreneurs is persuasion.<sup>268</sup>

<sup>&</sup>lt;sup>260</sup> See Vandenbergh & Raker, supra note 199, at 47 (discussing the increased importance of reputation and the social license to operate in a private governance regime).

<sup>&</sup>lt;sup>261</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 166.

<sup>&</sup>lt;sup>262</sup> *Id*.

<sup>&</sup>lt;sup>263</sup> Id. at 168.

<sup>&</sup>lt;sup>264</sup> *Id*.

<sup>&</sup>lt;sup>265</sup> *Id*.

<sup>&</sup>lt;sup>266</sup> Sunstein, *supra* note 7, at 909 (defining "norm entrepreneurs" as "people interested in changing social norms," who when successful, produce "norm bandwagons," which are created when small changes in behavior result in large ones, and "norm cascades," which happen when there are "rapid shifts in norms.").

 $<sup>^{267}\,</sup>$  Babcock, Assuming Personal Responsibility, supra note 5, at 144.

<sup>&</sup>lt;sup>268</sup> Martha Finnemore & Kathryn Sikkink, *International Norm Dynamics and Political Change*, 52 INT'L ORG. 887, 914 (1998).

In the case of risks from de-extinction, environmental and public health advocates, religious leaders, and concerned scientists—to name just a few—might serve as these entrepreneurs and publicize the concerns about de-extinction, helping people understand the risks and costs of de-extinction and turning them into advocates for safe action. To the extent that motivating public action is inherent in any norm enforcement approach, as is suggested here, then motivational information must arrive when and where a decision is about to be made. This information must be linked to the available choices and delivered personally from trusted sources.<sup>269</sup> Norm entrepreneurs can serve as those trusted sources.

Market-based incentives such as tax relief and subsidies, or disincentives like fees or taxes, are often proffered as ways to induce desired behavior by the targeted industry.<sup>270</sup> Any of these might be viable with respect to participants in the de-extinction industry.

Current regulatory conditions surrounding de-extinction are conducive to the emergence of private governance. Private governance can fill the regulatory gap and end—at least temporarily—the current regulatory commons problem that de-extinction efforts face. However, in order to assure that self-regulation arises in the field of de-extinction, there must be a possibility of reputational injury for bad behavior and rewards for good behavior. Certain well-established, widely-approved norms, like those underpinning environmental protection and civic responsibility, might assist in the effort. For reasons that are similar to those favoring self or private governance, such norms might arise and help guide more prudent behavior by those seeking to resurrect extinct species, even in the absence of market inducements.

#### CONCLUSION

Scientists probably will soon be able to bring back extinct species. Whether for the thrill of seeing de-extinct species roaming the Earth again, for commercial gain, or for an array of potentially beneficial scientific and moral reasons, resurrected species will be created in laboratories through genetic engineering. It is then only a matter of time before these species are placed back into the wild. However, there are no laws or policies currently on the books that can be used to adequately protect these species, the environment, or the public from potential harm. On the one hand, existing laws do not apply, and it is highly unlikely that they will be modified in time to respond. On the other hand, the field of genetic engineering has all the dysfunctional properties of a regulatory

<sup>&</sup>lt;sup>269</sup> Babcock, Assuming Personal Responsibility, supra note 5, at 167.

<sup>&</sup>lt;sup>270</sup> *Id.* at 170.

commons with no clear decisional center or dominant policy. The problem is that in this regulatory vacuum, the potential for harm to the environment, public welfare, and even to the de-extinct species themselves is high.

Commentators have noted that when private governance emerges, it "often occurs in areas where public preferences for environmental protection are widespread but government has not acted at all or a gap remains."

This is the situation facing participants in the de-extinction field. It is in the public interest for participants in this field to self-regulate in order to avoid disasters and preserve their reputations. But a vague idea of the public interest may not be enough to inspire these actors to cooperate. Thus, this article proposes that the public—educated and energized by environmental and public health advocates, members of religious communities, and even by concerned scientists—might enforce well known social norms, like environmental protection and personal responsibility, to encourage self-regulation. The invocation of norms that are familiar and frequently enforced can be an effective and inexpensive way to encourage positive, conscientious behavior by potential transgressors without government involvement.

If de-extinction is to happen, which appears more likely than not, the safest course would be to wait until there is an effective, viable federal regulatory framework to assure environmental protection and human safety. The best course would be to avoid these experiments in general and to focus instead on protecting existing endangered species and preventing their extinction. But that quagga<sup>272</sup> has left the barn, and self-regulation offers a way forward that may actually encourage and foreshadow public regulation.

<sup>&</sup>lt;sup>271</sup> Vandenbergh, *supra* note 3, at 197.

<sup>&</sup>lt;sup>272</sup> A quagga is an extinct subspecies of zebra. Carlin, Wurman & Zakim, *supra* note 10, at 8.