Establishing a Regulatory Framework for Cloning in Wild Animal Conservation

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Executive Summary: The regulatory framework governing animal cloning in the US contains a significant gap: while domestic species are covered by commercial laws, there are no federal rules specifically dedicated to the cloning and genetic engineering of wild, endangered, or extinct species. This allows private companies to pursue "de-extinction" projects focused on spectacle, which risks resource diversion and undermines public trust in cloning technologies. To the director of the US Fish and Wildlife Service (USFWS), I recommend adopting a Recovery-Based Necessity Test that formalizes the USFWS's authority to exclusively approve cloning permits based on verified species recovery goals. This would effectively prioritize genetic rescue efforts, while limiting non-conservation-driven projects. Immediate rulemaking is necessary to utilize the Endangered Species Act to close this gap.

I. Background: Regulatory gaps and the rise of speculative biotech

Ongoing conservation issues have prompted researchers to seek innovative solutions, including cloning and genetic engineering, to restore Earth's ecosystems and biodiversity (Corey 2021; Cowl et al. 2024; Erwin 2023; Magoffie 2023; Turner et al. 2025). However, the existing legal framework governing animal cloning is currently a limited mix of unsuitable regulations primarily designed for agricultural and medical applications rather than conservation (Corey 2021; Fiester 2005). The resulting regulatory void has enabled private biotech firms to pursue projects that prioritize media attention and spectacle over meaningful conservation initiatives (Pilcher 2025; Turner et al. 2025). These hype-driven experiments are not only distracting, but fundamentally at odds with the US Fish and Wildlife Service's (USFWS's) mission to recover threatened and endangered species (Erwin 2023; Pilcher 2025).

i. Cloning as a tool for conservation

While traditional methods like selective breeding are essential, they are often limited in scope because outcomes cannot always be precisely anticipated or controlled (Corey 2021). In contrast, cloning through somatic cell nuclear transfer allows scientists to introduce specific genetic material from a larger, more diverse gene pool, including samples from deceased individuals (Corey 2021; Novak et al. 2024). This technology is particularly vital for species experiencing "genetic bottlenecks," where low genetic variability threatens long-term survival through inbreeding and increased disease susceptibility (Marinari et al. 2024; Novak et al. 2024). By utilizing preserved genetic material, cloning can "rescue" lost alleles and reintegrate them into living populations, providing a high-tech safety net for species on the brink of extinction (Corey 2021; Fritts 2022; Novak et al. 2024).

ii. Successful cloning for conservation (The Ferret Model)

The black-footed ferret (BFF) was the first successfully cloned native US endangered species (Cowl et al. 2024). Their survival is jeopardized by low genetic variability, making them more susceptible to disease and fertility issues as a result of inbreeding (Marinari et al. 2024). To address this, cloned embryos of a deceased female, Willa, were implanted into surrogates and several genetic replicas were born (Novak et al., 2024). This established Willa as a key contributor to the

available gene pool, with her DNA carrying 10 times more unique alleles than those previously available in the captive population, providing crucial genetic variation (Fritts 2022).

Success was recently confirmed when one of Willa's three clones, Antonia, successfully reproduced, actively adding genetic variability to the existing population and demonstrating the viability of cloned animals for species recovery (Marinari et al. 2024; Novak et al. 2024; Turner et al. 2025). These biotechnologies also pave the way for future interventions, such as utilizing gene editing to immunize BFFs to sylvatic plague, a pathogen that is often deadly to the species (Tibbetts 2022; Turner et al. 2025).

iii. Current regulatory landscape for animal cloning

The current legal framework governing animal cloning in the United States is characterized as a "patchwork of vague and ill-fitting regulations" (Magoffie 2023). While regulatory oversight exists for the cloning of domestic livestock and pets, the specific sector of wild animal cloning currently lacks a dedicated federal regulatory framework (Corey 2021; Magoffie 2023). The primary mechanism for evaluating the risks of introducing new biotechnology into the environment is the Coordinated Framework for the Regulation of Biotechnology (CFRB) (Corey 2021; Magoffie 2023). Under the CFRB, regulatory responsibility is shared among the Food and Drug Administration (FDA), the US Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) (Corey 2021; Magoffie 2023).

Currently, the FDA regulates bioengineered animals as a "new animal drug" under the Federal Food, Drug, and Cosmetic Act (FFDCA) (Erwin 2023; Magoffie 2023). This "new animal drug" classification is ill-suited for conservation contexts because it evaluates wild animals as commercial products designed for sale rather than as living components of an ecosystem (Erwin 2023). Furthermore, the FDA often waives formal requirements for non-food species, leaving environmental risk assessments to agency "discretion" rather than the mandatory oversight of the National Environmental Policy Act (NEPA) (Erwin 2023).

For species already listed under the Endangered Species Act (ESA), the USFWS manages cloning and reintroduction projects through a rule called a Section 10(j) designation. This rule allows cloned individuals to be classified as an "experimental population," which provides the government with "additional flexibility" in how those specific projects are overseen. However, relying on these existing administrative tools creates significant legal voids regarding which projects are allowed to proceed and for what purpose:

- **Gap for extinct species**: Section 10(j) only applies to species currently listed as "threatened" or "endangered" (Magoffie 2023). This leaves a legal gap for "de-extinction" projects involving species that cannot be formally listed because they no longer exist (Corey 2021; Magoffie 2023).
- **Lack of a conservation mandate**: Because 10(j) is primarily a management tool for where animals are released rather than a filter for why they are created, there is no specific mandate to prioritize projects based on verified conservation value (Magoffie 2023).
- **Absence of ethical and technical filters**: Current policies fail to outline strict restrictions for the potential misuse of cloning or provide clear, standardized allowances for its use in dire, "last resort" situations (Corey 2021; Erwin 2023).
- **Enabling non-recovery projects**: The current regulatory void allows private biotech firms to initiate speculative projects that may not focus on necessary or meaningful species recovery (Pilcher 2025; Turner et al. 2025).

iv. Speculative experiments

In contrast to using cloning strictly for conservation purposes, such as with the BFF, projects like the engineered "dire wolf" prioritize public relations over ecological health (Beier 2023; Looby 2022; Pilcher 2025; Turner et al. 2025). In this case, Colossal Biosciences, a biotech company, claimed to resurrect the dire wolf; however, the project actually edited grey wolf DNA to mimic the physical traits of the extinct species rather than using real dire wolf DNA (Pilcher 2025).

Furthermore, Colossal Biosciences has hesitated to publish their scientific methods and analysis for the project. Instead, they gave exclusive access to Time magazine and ABC, released videos of the "first dire wolf howls heard in over 10,000 years," and posted photos and interviews with celebrities associated with Game of Thrones, a popular fantasy series that brought dire wolves into the spotlight (Colossal Biosciences, n.d.-b; Pilcher 2025). While Colossal has the potential to contribute to conservation efforts, they have misled the public with a highly publicized project that appears to hold little actual conservation value (Pilcher 2025; Turner et al. 2025).

These speculative cloning activities highlight specific legal voids in the current regulatory landscape:

- **The "extinct species gap"**: Because the dire wolf is extinct and cannot be formally listed under the ESA, Colossal's project operates in a regulatory vacuum where no federal oversight exists to verify scientific claims or safety (Corey 2021; Magoffie 2023).
- **Failure of the CFRB "product" lens**: Under the CFRB, these wolves would be regulated as "products" or "new animal drugs" (Corey 2021; Erwin 2023; Magoffie 2023). This allows the company to focus on the final output rather than the scientific intent, as there is no conservation-based filter to determine if the project is a "scientific necessity" or a public relations venture (Magoffie 2023).
- **Misleading "rightful place" claims**: While the company claims to return these animals to their "rightful place in the ecosystem," they remain in captivity with no known ecological introduction plans (Colossal Biosciences, n.d.-b). However, this highlights the dangers of a lack of necessity-based cloning in current policy: the reintroduction of a long-extinct predator could have catastrophic effects on modern ecosystems that have developed without it for thousands of years (Turner et al. 2025).

Such projects, alongside separate efforts such as those seeking to bioengineer "glow-in-the-dark" rabbits for art and deer with unnaturally large antlers for hunters, utilize genetic modification for spectacle rather than prioritizing what may be valuable to existing environments (Fiester 2005). These experiments represent the absence of ethical and technical filters in current policy, allowing private firms to divert time and resources, which could otherwise support more urgent efforts (Fiester 2005). Furthermore, these misleading experiments can cause public distrust in biotechnology by drawing attention to its misuse, overshadowing genuine genetic rescue efforts that support conservation (Fiester 2005; Magoffie 2023; Pilcher 2025).

II. Policy options and analysis

To close the current regulatory gap and assert federal control over wild animal cloning, the USFWS must clarify its role in the regulatory landscape (Magoffie 2023). The options outlined below leverage the broad authority already embedded within the ESA and existing administrative powers (Corey 2021).

i. Option 1: Negotiate Cross-Agency Agreements

Work with the FDA, USDA, and EPA to establish a unified policy for wild species under the existing CFRB (Corey 2021; Magoffie 2023). The CFRB is a collaborative effort designed to assess the risks of introducing new biotechnology into the environment (Corey 2021; Magoffie 2023). Currently, the CFRB operates on the principle that the intended use of the product, rather than the process used to create it, determines which agency has jurisdiction. Under this framework, cloning is largely viewed through a commercial or agricultural lens (Corey 2021; Erwin 2023; Magoffie 2023).

- **Advantages**: Achieves interagency consistency for assessing risks and tracking organisms across different legal domains (Corey 2021; Magoffie 2023). The combined expertise of the EPA, FDA, and USDA is advantageous because it allows for a multi-disciplinary review of complex environmental and health impacts that a single agency might lack the specialized ability to evaluate alone (Corey 2021; Magoffie 2023).
- **Disadvantages**: Continues to rely on a patchwork of regulations originally designed for commercial products, which are a poor fit for conservation goals (Corey 2021; Erwin 2023). For example, bioengineered animals being regulated as a "new animal drug" is an

oversimplified classification incompatible with a living, wild animal (Erwin 2023). This framework does not allow prioritization based on conservation value; rather, it only ensures cloning projects are technically "safe" as "products" (Magoffie 2023). Furthermore, there are major concerns that this cooperative framework would lead to significant regulatory gaps in application, such as how to address species that are not "endangered" due to already being extinct (Corey 2021; Magoffie 2023).

ii. Option 2: Conservation-mandated framework

Adopt formal ESA rulemaking to require that all genetic interventions involving wild animals, including cloning, genetic engineering, and de-extinction proxies, undergo federal review by the USFWS. This can be achieved by amending the existing Controlled Propagation regulations of the ESA to incorporate a Recovery-Based Necessity Test for USFWS approval (Erwin 2023; US Fish and Wildlife Service 2018a). Under this framework, authorization would be granted only when the proposed intervention demonstrates measurable benefits to species recovery and long-term conservation outcomes (Erwin 2023). To distinguish between academic study and project implementation, this test would be triggered once research transitions from non-invasive genomic sequencing to the actual creation of living clones or proxies (Corey 2021; Erwin 2023). This would help ensure that cloning efforts are being performed for verified and beneficial purposes.

- **Advantages**: This approach closes the current regulatory gap by ensuring that USFWS exercises its authority over the purpose of any animal cloning or genetic intervention project (Corey 2021; Erwin 2023). It directs resources toward genuine species recovery efforts rather than experimental or publicity uses (Corey 2021; Erwin 2023; Pilcher 2025). The framework is grounded in the principle that conservation interventions should promote wildness and move species away from a "conservation-reliant" existence, fostering conditions for true recovery rather than perpetual management (Erwin 2023; Turner et al. 2025). It also prioritizes ecological integrity and conservation goals over the spectacle of technological innovation (Erwin 2023; Pilcher 2025).
- **Disadvantages**: The primary concerns surrounding the allowance of wild animal cloning are its high cost and potential animal welfare risks (Corey 2021; Erwin 2023; Magoffie 2023).
- **Counterargument**: While cloning involves high costs and welfare risks, the ESA charges the USFWS with employing all necessary measures, including innovative strategies like cloning, to recover species (Corey 2021; Erwin 2023; Magoffie 2023). The proposed Recovery-Based Necessity Test ensures that funding and research are directed exclusively toward legitimate conservation, justifying welfare risks only when the project directly contributes to species survival (Corey 2021; Erwin 2023). By establishing these clear criteria, the framework ensures that biotechnologies are applied responsibly and in strict alignment with federal recovery goals (Erwin 2023; Novak et al. 2024).

III. Recommendation and implementation plan

I recommend the immediate adoption of The Recovery-Based Necessity Test, as described in Option 2, by utilizing the full legal abilities of the ESA to govern the intent of wild animal cloning and filter out non-conservation-based projects (Erwin 2023).

i. Action 1: Define "Conservation Necessity"

In the next six months, the USFWS should initiate formal rulemaking to amend the existing Controlled Propagation regulations (Erwin 2023). This amendment must define a Recovery-Based Necessity Test which makes a permit for cloning projects conditional on proof that the technology is required to mitigate an "intractable threat" that traditional methods cannot overcome (Erwin 2023; Turner et al. 2025). This may include genetic bottlenecks that threaten health and reproduction such as with the BFFs (Marinari et al. 2024).

- **Prohibit Non-Recovery Projects**: Under this revised rule, the USFWS gains the necessary authority to deny permits for cloning or genetically modifying wild animals solely for novelty or to create proxies of extinct species that serve no ecological recovery function (Beier 2023; Corey 2021; Erwin 2023).

ii. Action 2: Mandate adaptive risk assessment and transparency (ongoing)

All permitted projects must be reviewed under the ESA and NEPA mandates, requiring a comprehensive ethical and ecological impact assessment (Corey 2021). This must cover:

- **Animal welfare and monitoring**: Permits must mandate a high level of animal monitoring, acknowledging that genetic manipulation is a procedure with the potential to cause moderate to severe pain and distress, due to the unpredictable physiological and welfare outcomes inherent in the process (Erwin 2023; Ormandy et al. 2011; Turner et al. 2025). This effort should be guided by a formal framework for ethical analysis to determine when the procedures are justified (Corey 2021; Erwin 2023).
- **Resource diversion and ethical review**: The review must address resource diversion, acknowledging concerns that genetic initiatives could divert limited resources from traditional, more certain conservation and biodiversity initiatives (Corey 2021). The rationale must be subjected to a case-by-case ethical analysis, ensuring the welfare costs of cloning are justified by the conservation benefits (Biasetti et al. 2022; Erwin 2023; Fiester 2005).

iii. Action 3: Assert ESA authority for wild species (immediate)

Issue a policy directive clarifying that the ESA and USFWS have exclusive authority in the USA for governing the genetic intervention of any wild species (Corey 2021). This action asserts federal control, replacing the uncoordinated and narrow mandates of commercial regulatory bodies for this specific conservation purpose (Corey 2021; Erwin 2023).

IV. Conclusion

The current regulatory gap allows private companies to define the future of wild animal biotechnology, posing risks to public trust, resource allocation, and animal welfare. The USFWS possesses the clear authority under the Endangered Species Act to fill this gap (Corey 2021; Erwin 2023; Magoffie 2023). By establishing the Recovery-Based Necessity Test, the USFWS will ensure that the high monetary and welfare costs of complex genetic interventions are only undertaken when they meet the demonstrable necessity of true species recovery (Brister et al. 2021; Corey 2021; Erwin 2023; Magoffie 2023). By establishing this framework, the US Fish and Wildlife Service will protect the long-term viability of biotechnologies for conservation and improve public trust. Ultimately, this secures a future where biotechnology serves as a tool for ecological restoration rather than a vehicle for experimentation, ensuring the integrity of the natural world remains protected for generations to come.

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