CITIZEN PETITION

October 14, 2025

The undersigned submit this petition under 21 C.F.R. § 10.30, Section 505 of the Food Drug and Cosmetic Act (21 U.S.C. § 355), 21 C.F.R. § 10.25(a)[1], Section 7 of the Endangered Species Act of 1973 (16 U.S.C. § 1531 *et seq.*) (hereinafter, "ESA") to request that the Commissioner of the Food and Drug Administration ("FDA") revisit the approval of the Abbreviated New Drug Application 216616, a generic version of Mifepristone, (hereinafter, "Mifepristone") because of the FDA's continued failure to comply with the requirements of the CWA and ESA. Moreover, we request a requirement be in place that prescribers include a Medical Waste bag and Catch-Kit with all Mifepristone prescriptions.

Students for Life of America ("SFLA") is the nation's largest pro-life youth organization that uniquely represents the generation most targeted for abortion. SFLA, a 501(c)(3) charity, exists to recruit, train, and mobilize the Pro-Life Generation to abolish abortion and provide policy, legal, and community support for women and their children, born and preborn. SFLA and its members care about the environment, and its members nationwide have a vested interest in protecting the environment from pollution, protecting endangered species and habitats from destruction, and preserving these species and habitats for future generations to see and experience. SFLA seeks to prevent the dumping of Mifepristone into the waterways of the United States and the inevitable harm that has and will continue to result to endangered species.

A. Action Requested

This Petition makes one request: that the FDA revoke its actions to approve the Abbreviate New Drug Application 216616, a generic version of Mifepristone, and modify the associated regimen (including the REMS) until the agency conducts the required consultation with the United States Fish and Wildlife Service ("FWS") and National Marine Fisheries Service ("NMFS") (collectively, "the Services") as compelled by the ESA. Before allowing Mifepristone for human consumption, use outside of a medical setting, and disposal into the environment, the FDA must first consult with the Services to determine the extent and the effects that its Mifepristone actions have on listed endangered or threatened species or designated critical habitats in the FDA's action area (i.e., the entire United States and its territories).

B. Statement of Grounds

The FDA has a legal obligation to comply with the ESA. As set forth in this citizen petition, the FDA's actions on Mifepristone have failed to meet the requirements of the ESA and, therefore, must be revoked until the agency can implement measures to ensure that its actions do not adversely affect listed endangered or threatened species or designated critical habitats. Failure to do so could lead to the extinction of these species.

[1] "Citizen petitions may be filed with the FDA by those with rights to or scientific knowledge of a brand name drug. These petitions request that the FDA take or refrain from certain administrative action. *See* 21 C.F.R. §§ 10.25(a), 10.30(e)." *Hill Dermaceuticals, Inc. v. U.S. Food & Drug Admin.*, 524 F. Supp. 2d 5, 8 (D.D.C. 2007) (emphasis added).

1. The FDA's Actions on Mifepristone and Failure to Comply with the ESA

a. The 2000 Approval of Mifepristone

When the FDA approved Mifepristone in 2000 to be used for chemical abortions, the agency did not consult the Services to determine the effects of Mifepristone on listed endangered or threatened species of designated critical habitats. The FDA merely relied on an environmental assessment that the Population Council performed under the National Environmental Policy Act.

In a document entitled, "ENVIRONMENTAL ASSESSMENT AND FINDING OF NOT SIGNIFICANT IMPACT FOR NDA 20-687 MIFEPRISTONE TABLETS," the FDA stated without further explanation that "[a]dverse effects are not anticipated upon endangered or threatened species." This conclusion runs afoul of the requirements of the ESA.

This conclusion also made numerous incorrect assumptions about how Mifepristone could enter the environment. Indeed, the FDA did not conduct an environmental study regarding the potential impact Mifepristone could have on the nation's wastewater. The problem with the FDA's assessment is that it only reviewed the impact that packaging, partially empty packaging, production waste, and pharmaceutical waste would have on the environment, and underestimated the impact the excretion of Mifepristone would have on the environment.[2] Further, it underestimated the number of chemical abortions, which are abortions committed through use of Mifepristone.

b. The 2016, 2019, 2021, and 2023 Changes to the Mifepristone Regimen and REMS

When the FDA made significant changes to the Mifepristone regimen and REMS in 2016, 2019, 2021, and 2023, the agency simply failed to conduct any ESA consultation or environmental assessment. This failure flies in the face of the ESA and must be corrected immediately—especially in light of the FDA's removal of the in-person dispensing requirement, which opened up the floodgates to do-it-yourself abortions at home and disposal of Mifepristone directly into our nation's water supply.

2. The Legally Necessary Consultation with the Services Regarding the Impact of Mifepristone on Listed Endangered or Threatened Species or Designated Critical Habitats

The purpose of the ESA is to provide a means to conserve the ecosystems upon which endangered and threatened species depend and provide a program for the conservation of such species. Section 7 of the ESA, codified at 16 U.S.C. § 1536 ("Section 7"), directs all Federal agencies to participate in conserving these species. Specifically, Section 7(a)(1) of the ESA charges Federal agencies to aid in the conservation of listed species, and Section 7(a)(2) requires all federal agencies cooperate and consult with the Services to aid in the conservation of listed

[2] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 1 of Cover Letter.

species and ensure that their activities are not likely to jeopardize the continued existence of federally listed species or destroy or adversely modify designed critical habitats.

First, in order to ensure compliance with the ESA, before taking action such as approving a drug or medication, a federal agency such as the FDA must first define the action area and submit a proposed list of impacted species or request from the Services a list of impacted species. The purpose of this is to encompass all listed species that may be impacted by the proposed agency action. The species list must include all listed and proposed species and designated critical habitats that may be present in the action area. The action area must not neglect indirect effects, such as stormwater run-off, or the effect felt in wastewater or wastewater effluent and the route it takes to public waterways. And because there are no geographical limitations to the FDA's approval of mifepristone, the relevant action area is the entire United States and its territories.

Second, the FDA must determine whether the proposed action *may affect* a Section 7 resource, or a species on the aforementioned list. This is done through assessments of the direct or indirect effects mentioned previously.[3] Every listed species or habitat must be analyzed through this lens. As discussed below, the "may affect" designation is a low bar. And given the nationwide action area and known potential effects of Mifepristone, a "no effect" determination cannot apply to the FDA's actions on Mifepristone. The "no effect" determination applies only in very limited circumstances, such as when the species ranges and critical habitat do not overlap with the action area.

Third, if the proposed action *may affect* a Section 7 resource, the FDA must enter into "information consultation" with the Services to analyze the aforementioned potential direct and indirect, adverse, and beneficial effects of the action on the Section 7 resources that may be affected. The ESA requires clear documentation (i.e., a Biological Assessment or Biological Evaluation) that there is a determination being made, regardless of the effect itself. And the Services must expressly concur in writing with any determination that the action is not likely to adversely affect any Section 7 resources.

Finally, in instances where an adverse effect is *likely*, the ESA requires a "formal consultation" between the FDA and the Services wherein the FDA would submit further documentation to the Services and provide a full Biological Opinion on the impact, in this case of Mifepristone, would have on any listed species or habitats. Beyond this, the FDA would be required to show Mifepristone would not jeopardize, destroy, or adversely affect listed species or habitats, and if it does, then either seek an exemption or provide for reasonable and prudent alternatives.

3. The Section 7 Regulations and Federal Case Law on ESA Consultations

Section 7 consultation requirements apply to federal agency actions, including actions on federal land and actions on private land with a federal nexus. The Services' joint regulations[4] on Section 7 consultations define an agency action as all activities or programs of any kind authorized,

[3] Direct effects are those that are caused by the action, while indirect effects are those that are caused by the action and are later in time, but still are reasonably certain to occur.
[4] 50 C.F.R. § 402 *et seq*.

funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. Examples include, but are not limited to:

> (a) actions intended to conserve listed species or their habitat;
> (b) **the promulgation of regulations**;
> (c) **the granting of licenses**, contracts, leases, easements, rights-of-way, **permits**, or grants-in-aid; or
> (d) actions directly or indirectly causing modifications to the land, water, or air.

50 C.F.R. § 402.02 defines an "action" as anything that "includes any activity authorized, funded, or carried out by a federal agency, including permits and licenses." Federal courts have interpreted an agency action requiring consultation in the context of the ESA to be a low threshold, lower than that of other Federal environmental protection statutes, including the National Environmental Policy Act (NEPA):

> It is instructive to compare the requirements under the ESA to those under NEPA. Whereas NEPA asks the agency to identify and prepare an environmental impact report for "significant" impacts on any aspect of the environment, the ESA requirements are triggered by a lower threshold, but for a narrower set of impacts. The agency must identify *any* potential effect, however small, on listed species and consult with the relevant agencies about the proposed action. *See Karuk Tribe of California v. U.S. Forest Service*, 681 F.3d 1006, 1027 (9th Cir. 2012).

Inst. for Fisheries Res. v. United States Food & Drug Admin., 499 F. Supp. 3d 657, 668 (N.D. Cal. 2020). Similarly, the D.C. Circuit found in 2021 that:

> Implementing regulations promulgated pursuant to the Endangered Species Act require an agency to "determine whether any action **may affect** listed species or critical habitat," and, if so, to **consult with the Services**. 50 C.F.R. § 402.14(a); *see* 16 U.S.C. § 1536(a)(2). Only if an agency determines that its action will have no effect on listed species or critical habitat can it dispense with consultation. *Ctr. for Biological Diversity v. U.S. Dep't of Interior*, 563 F.3d 466, 475 (D.C. Cir. 2009). "May affect" purposefully sets a low bar: **"Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement."** *Interagency Cooperation—Endangered Species of 1973, as Amended*, 51 Fed. Reg. 19,926, 19,949 (June 3, 1986). "Thus, actions that have any chance of affecting listed species or critical habitat — even if it is later determined that the actions are 'not likely' to do so — require at least some consultation under the ESA." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012).

Growth Energy v. Env't Prot. Agency, 5 F.4th 1, 30 (D.C. Cir. 2021) (emphasis added). Likewise, the ESA broadly defines "take" to include a wide range of actions, such as to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect an endangered wildlife species, or any attempt to engage in such conduct. 16 U.S.C. § 1532(19). The Northern District of California has stated that "mere harm" to a listed species can constitute a take for the purposes of the Act. What this means

is that an action Agency proceeding without guidance from the Services puts itself at great risk for the substantial civil or criminal liabilities enumerated in the Act in the event their action harms an endangered species or listed habitat. *See Pacificans for a Scenic Coast v. California Dep't of Transportation*, 204 F. Supp. 3d 1075 (N.D. Cal. 2016). In the above referenced *Karuk* case, the Ninth Circuit in explaining that the definition of agency "action" can cover a variety of activities found that:

> [t]here is "little doubt" that Congress intended agency action to have a broad definition in the ESA, and we have followed the Supreme Court's lead by interpreting its plain meaning "in conformance with Congress's clear intent." *Pac. Rivers Council v. Thomas,* 30 F.3d 1050, 1054–55 (9th Cir.1994) (citing *Tenn. Valley Auth.,* 437 U.S. at 173, 98 S.Ct. 2279).
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> The ESA implementing regulations limit Section 7's application to "'actions in which there is discretionary Federal involvement or control.'" *Nat'l Ass'n of Home Builders v. Defenders of Wildlife,* 551 U.S. 644, 666, 127 S.Ct. 2518, 168 L.Ed.2d 467 (2007) (quoting 50 C.F.R. § 402.03). The Supreme Court explained that this limitation harmonizes the ESA consultation requirement with other statutory mandates that leave an agency no discretion to consider the protection of listed species. *Home Builders,* 551 U.S. at 665–66, 127 S.Ct. 2518.

Karuk at 1020–21 (9th Cir. 2012). It is clear that many courts have established that under the ESA, "agency action" is both a low bar that an agency will very likely cross but also a broad one. "Any possible effect" triggers the FDA's duty to consult with the Services; and there is no doubt that Mifepristone has "any possible effect" on an endangered species.

Federal courts define the requirements of Section 7 as a two-fold burden. The first is a procedural burden: the action agency is to engage in consultation with the Services as the experts in the field, and the second is a more substantive requirement: to ensure that the proposed action will not jeopardize a listed species or its critical habitat.

At the onset, the action agency and Services engage in "informal consultation." Informal consultation is a wide-ranging term, and generally covers the conversations, correspondence, and discussions between the Services and action agency at the early stages to see whether or not the next step is necessary – formal consultation, as oftentimes the two parties can determine then and there that there will be no impact on a listed species or habitat. In the event the proposed action requires "formal" consultation, the first step in this process is to form a "biological assessment" followed by a biological opinion from the Services. This opinion summarizes the information needed to show the potential impact the agency action might have. Only at this point, if the action will not jeopardize an endangered species or habitat, may the action agency proceed. If there is a chance of endangerment, the Services will provide "reasonable and prudent" alternatives, and the action agency is encouraged to adopt those alternatives, or risk civil and criminal penalties for failing to comply with the ESA. *See Pacificans* generally, 204 F. Supp. 3d 1075 (N.D. Cal. 2016).

The purpose of Section 7's consultation provision is to determine if any agency may adversely affect an endangered species or habitat. By failing to conduct even an informal consultation, the FDA did not ensure that the approval of Mifepristone would not harm potential listed species.

> The purpose of the consultations is to "draw on the expertise of 'wildlife agencies to determine whether [an] action is likely to jeopardize a listed species' or its habitat, and 'to identify reasonable and prudent alternatives' to avoid those harmful impacts." *Ctr. for Biological Diversity*, 847 F.3d at 1075 (quoting *Karuk Tribe*, 681 F.3d at 1020). NMFS provides consultation on actions involving marine and anadromous species and habitats, and FWS for all other species and habitats.

Ecological Rts. Found. v. Fed. Emergency Mgmt. Agency, 384 F. Supp. 3d 1111, 1115 (N.D. Cal. 2019). The consultation process need not proceed to the formal stage, if as in the case of *Shafer*, the action agency and the wildlife agency agree it is not necessary:

> While the consultation process can take a variety of forms, the action agency often performs a preliminary review to determine whether the proposed action could affect any listed species. *See* 50 C.F.R. § 402.14(a); *see also* 16 U.S.C. § 1536(c); 50 C.F.R. §§ 402.10–402.13. If the action agency determines—and the wildlife agency concurs—that no listed species or critical habitats are likely to be adversely affected, then no formal consultation is required. 50 C.F.R. § 402.14(b)(1). But if either the action agency or the wildlife agency concludes that the proposed action "may affect" a listed species or its critical habitat, then a formal consultation begins. *Id.* § 402.14(a).

Shafer & Freeman Lakes Env't Conservation Corp. v. FERC, 992 F.3d 1071, 1079 (D.C. Cir. 2021). The case law is clear that not every time there is an agency action will there be even a formal consultation, but in failing to even begin the informal process, the FDA failed to comply with a Congressional mandate placed upon all federal agencies.

Federal courts have interpreted the triggering of ESA's Section 7 protections to be a low bar, lower than similar federal statutory constructs, but that the Act's mandate to protect endangered species and threatened habitats do require action agencies that propose new actions to consult in some degree with the relevant Service. In approving Mifepristone, the FDA bypassed this requirement. This citizen petition requests that the FDA comply with the ESA and conduct the appropriate consultation with the Services.

4. Examples of Endangered Species Potentially Affected by the FDA's Actions

The current list of endangered species recognized by the Services contains nearly 1,500 different species and can be found at https://ecos.fws.gov/ecp0/reports/ad-hoc-species-report?kingdom=V&kingdom=I&status=E&status=T&status=EmE&status=EmT&status=EXPE&status=EXPN&status=SAE&status=SAT&mapstatus=3&fcrithab=on&fstatus=on&fspecrule=on&finvpop=on&fgroup=on&header=Listed+Animals.

By way of some specific examples, *Canis rufus*[5] (more commonly known as the red wolf) is a canine native to the Southeastern United States, intermediate in size between the grey wolf and coyote. Originally listed in 1967 under the Endangered Species Preservation Act of 1966 (the predecessor act to the ESA) the red wolf is critically endangered with fewer than 50 currently in the wild, and around 200 in captivity. The red wolf is gradually being reintroduced into the Southeastern United States, and often inhabits wetlands, forest, and some agricultural lands. The red wolf is at one of the more sensitive stages of reintroduction into these ecosystems. Similarly, *Lepidochelys kempii*[6], or Kemp's ridley sea turtle, listed since 1970, is the world's rarest and most endangered species of sea turtle, finds its range along the Gulf Coast region of the Southeastern United States, and often employs the coasts of Texas as a primary nesting range. The Kemp's ridley sea turtle numbers fewer than 10,000 and faces critical habitat loss from human impact on the Gulf of Mexico. *Percina pantherine*[7], or leopard darter, is a freshwater fish originally found throughout Oklahoma and Arkansas, and listed as an endangered species since 1978. The leopard darter's habitat throughout these states is often connected to outflows from sewage processing

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plants and other human elements that can cause disruption. *Gymnogyps californianus*[8], the California condor, is another listed species within the United States that has a long history of conservation having being listed since 1967 (similar to the red wolf above). According to the Fish and Wildlife Service, over $35 million has been spent on California condor conversation efforts, making it one of the most expensive conservation projects in American history.[9] With fewer than 600 living, in captivity and the wild, it remains one of the world's rarest bird species. Originally inhabiting locations across North America, today in the wild they can only be found in small portions of Southern California. California condor feed off of a variety of carrion across their habitat in Southern California, and will consume nearly any non-bird carcass they come across, including aquatic creatures. *Crocodylus acutus*[10], the American crocodile, inhabits portions of southern Florida as well as locations across the Caribbean and parts of South America. Its status as a member of the endangered species list is owed to 20th Century over-hunting and destruction of their habitats by human actions. There are fewer than 2,000 members living in Florida; they feed on many aquatic creatures and can inhabit nearly any fresh or salt-water environment within

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9 https://web.archive.org/web/20070808215527/http://www.fws.gov/hoppermountain/cacondor/FAQ.html#money

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the southern portion of that state. Finally, *Oncorhynchus nerka*[11], the sockeye salmon, is one of the most popular salmon used for food, and is a listed species in locations within the United States. Compared to soho salmon, steelhead trout, and Chinook salmon, populations of sockeye in the Pacific Northwest are not experiencing a resurgence in population.[12] In fact, populations in Idaho and Oregon have become completely extinct. In recent years populations across North America have come under their spawning estimates and are at 50-year lows in some places. Sockeye inhabit many fresh and saltwater locations across the Pacific Northwest and Alaska and are heavily impacted by human activity in those waters.

All of these listed species depend on a variety of ecosystems within the United States that are often impacted by human activity. SFLA and its members are concerned that the failure of the FDA to conduct consultation with the Services has led to irreparable harm to many listed species and habitats and will likely lead to the destruction of some of these species. When federal agencies propose actions that could impact these ecosystems, they are required to consult with the Services to determine if these actions will harm these three species, among the list of nearly 1,500 individual species. FDA did not do this when approving Mifepristone in 2000 and changing the regimen in 2016, 2019, 2021, and 2023.

The FDA Did Not Conduct Sufficient Advanced Studies on the Impact Mifepristone Could Have on the Nation's Water Supply at Any Point Before or Since Formal Approval of Mifepristone for Women and Girls in 2000. This Can Have a Negative Impact on Endangered Species and Threatened Habitats.

The FDA did not conduct sufficient advanced studies on the impact Mifepristone could have on the nation's water supply when the Mifepristone regimen was approved for women and girls in 2000. In the lead up to 2000 approval, the FDA reported that there would be high standards for disposal related to Mifepristone.[13] This has not been the case.

Mifepristone and fetal remains in wastewater have impacts beyond humans and onto animals and plants. Mifepristone usage results in the generation of Medical Waste[14] and must be treated as such. The residual effects of exposure to Mifepristone in the nation's waterways can impact animals, causing teratologic repercussions or congenital anomalies like birth defects to

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[12] https://www.wsj.com/articles/SB10001424052748703657604575005562712284770

[13] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 02.

[14] Medical waste, as defined by the EPA: "Generally, medical waste is healthcare waste that [] may be contaminated by blood, body fluids or other potentially infectious materials and is often referred to as regulated medical waste."

animals.[15] Proper control of drugs, hormones, and chemicals in wastewater is vital to human health and the health of other life exposed.

a. The FDA did not conduct sufficient advanced studies on the impact Mifepristone could have on the nation's water supply when the Mifepristone regimen was approved for women and girls in 2000.

The FDA did not conduct sufficient advanced studies on the impact Mifepristone could have on the nation's water supply when the Mifepristone regimen was approved for women and girls in 2000. This has resulted in an incalculable amount of human remains and drug residue entering our nation's water supply following the usage of Mifepristone. This has not been analyzed from the perspective of the Endangered Species Act and the effect of Mifepristone on listed species or habitats. From the 1996 report that the FDA prepared for Mifepristone's approval:

> The Food and Drug Administration, Center for Drug Evaluation and Research (CDER) has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared. In support of their new drug application for Mifepristone Tablets, The Population Council has prepared an environmental assessment in accordance with 21 CFR 25.3a (attached) which evaluates the potential environmental impacts of the manufacturer, use and disposal of the product. Mifepristone is a synthetic drug which will be administered orally to provide a medical approach to the termination of early pregnancy. Mifepristone may enter the environment from the excretion by patients, from disposal of pharmaceutical waste or from emissions from manufacturing sites. . . . The Center for Drug Evaluation and Research has concluded that the product can be manufactured, used, and disposed of without any expected adverse environmental effects.[16]

By their own admission, the FDA failed to study or assess the environmental impact of Mifepristone itself, but also the natural "by-product" of Mifepristone use: medical and pathological waste. The study only evaluated the impact of "manufacturer, use and disposal of the product," i.e., the impact of trash from the packaging. There was not any evaluation of Mifepristone's effect on the water supply or pollution for the people or animals who consume that water.

i. In the lead up to 2000 approval, the FDA reported that there would be high standards for disposal related to Mifepristone. This has not been the case.

The 1996 Environmental Assessment stated that there would be high standards for disposal; however, the focus was primarily on the drug itself and its associated packaging, not the chemical remnants, human remains, and other tissues which are a natural result of Mifepristone

[15] Gonsioroski A, Mourikes VE, Flaws JA. *Endocrine Disruptors in Water and Their Effects on the Reproductive System.* Int J Mol Sci. 2020 Mar 12;21(6):1929. doi: 10.3390/ijms21061929. PMID: 32178293; PMCID: PMC7139484.

[16] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 1 of Cover Letter.

usage. This waste is generally flushed into the wastewater system. Proliferation of Mifepristone usage is only increasing with the 2016 changes to the REMS, the 2021 removal of the in-person dispensing requirement, and the authorization of mail-order pills; thus, the associated pollution into the waterways is growing.

When Mifepristone was first approved by the FDA in 2000, the Environmental Assessment prepared for the FDA included specific provisions for disposal locations. That assessment required that clinics or healthcare providers prescribing Mifepristone to follow the Center for Disease Control guidelines for handling hazardous waste. Specifically, it stated that "the applicant will use a licensed incineration or grinding and landfill facility to dispose of this type of material."[17] However, considering the purported "convenience" afforded by the usage of Mifepristone (compared to the clinical setting), the majority of abortions via Mifepristone are occurring in the home. In fact, it is often touted as one of the main benefits of Mifepristone, as explained by the Guttmacher Institute: "[m]edication abortion can be completed outside of a medical setting—for example, in the comfort and privacy of one's home."[18]

More than sixty percent of all abortions (63%) are committed with Mifepristone.[19] This figure is an estimate, as the actual percentage of abortions as committed by Mifepristone is unknown as there is no national abortion reporting law.[20] States don't report uniformly, and some report nothing at all. This is exacerbated by the chaos of online purchases, and the fact that many Mifepristone[21] pill vendors are located internationally. Given current trends, Mifepristone may soon cause more than 90% of all abortions. Three-quarters of abortions in Europe are committed with Mifepristone pills, according to *the New York Times*.[22] And it can be more, as an NIH report notes that countries like Finland use Mifepristone pills 97.7% of the time, and in Sweden, the pills are used more than 96.4%.[23] The number of fetal remains flushed into the wastewater system is only increasing and it is likely that the United State will be following Europe's lead in light of the United States Supreme Court's overturning of *Roe v. Wade* and increasing restrictions on chemical abortions in many states.

The industry's practice to date is to allow the byproducts of Mifepristone usage to be flushed into the patient's toilet, as is FDA's; but everything that is flushed goes into America's wastewater system.[24] Most Americans know that the only things you can safely flush are the "three Ps": Pee, Poo, Paper.[25] In fact, "the U.S. Environmental Protection Agency is encouraging all Americans to only flush toilet paper."[26] The EPA is very direct on how to "protect local

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[17] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 3.
[18] *Jones, Rachel K, and Amy Friedrich-Karnic*, "Medication Abortion Accounted for 63% of All US Abortions in 2023—an increase from 53% in 2020," *Guttmacher Institute*, (March 19, 2024), available at https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.
[19] *Id*.
[20] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2306667
[21] Some studies refer to Mifepristone and misoprostol usage generally as "Chemical Abortion."
[22] https://www.nytimes.com/2022/05/09/upshot/abortion-pills-medication-roe-v-wade.html
[23] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8567957/
[24] https://cwhccolorado.com/services/medication-abortion/aftercare-medication-abortion/index.html
[25] https://www.portland.gov/bes/safe-flush
[26] https://www.epa.gov/newsreleases/epa-encourages-americans-only-flush-toilet-paper

waterways" by not flushing the wrong things.[27] Treated wastewater is released into local waterways where it's used again for any number of purposes, such as supplying drinking water, irrigating crops, and sustaining aquatic life.[28]

The route by which human waste travels from bathrooms and into the waterways is an important reference point to highlight the route by which pharmaceuticals follow the same path, and namely the manner by which Mifepristone remnants can harm endangered species. Oftentimes what is in human waste and uterine content contains specific chemical compounds that find their way back into water; whether that be drinking water, groundwater, or surface water. Those compounds break down into their various member parts, either through human filtering, or through chemical processes. These "metabolites", can be either "active" or "inactive." Active pharmaceutical metabolites can still carry out the intention of the original drug or chemical compound they were a part of, even after consumption by humans. Thus, in cases where metabolites of the drug or compound are active, once it cycles through the liver it can still work in the body (or other bodies) to facilitate the action the chemical or drug was designed to do. Mifepristone itself has several active metabolites that are still functioning as intended even after filtration by the human body and expulsion from the uterus.[29] These metabolites can be found in uterine contents like placenta and fetal remains, as well as urine or feces; these naturally find their way into the wastewater system. In fact, the directly expelled uterine contents are far more chemically tainted than waste would be, as those materials are directly passed into the water system because of Mifepristone and are not just byproducts passed off in waste.

Many studies have been conducted on the effects pharmaceutical metabolites can have after they are secreted by the body and end up in water, or in agricultural and industrial settings where metabolites end up in runoff, to see to what extent and degree their original purpose still survives. [30] Pharmaceutical metabolites of chemicals can end up in a wide range of water sources, after either human consumption or other human activities such as the application of herbicides, pesticides, and fungicides. In more recent studies of the impact pharmaceuticals have had on the environment shows that wastewater treatment plants (WWTPs) are unable to entirely treat the water and remove the active metabolites from human waste and by extension human uterine content that ends up in the water. What this in turn means is that through human consumption and transmission into waste, many potentially harmful pharmaceuticals are finding their way into our waterways. Wastewater, once it is treated at the WWTP and sent back into the environment in the form of effluent, could very likely still contain the active metabolites of whatever drugs were filtered into it by humans along the way. The FDA and EPA do not attach other regulation on the amount of potentially harmful chemicals that enter our waterways. The FDA in approving Mifepristone did not determine whether the amount of that drug that enters our waterways was enough to harm endangered species. The FDA failed to comply with Section 7 by approving Mifepristone despite not knowing the full impact of its active metabolites. These same metabolites

[27] https://www3.epa.gov/npdes/pubs/centralized_brochure.pdf
[28] https://www.cwea.org/news/epa-bans-flushing-all-drugs-including-hazardous-waste-drugs/
[29] https://pubmed.ncbi.nlm.nih.gov/14698071/#:~:text=The%20three%20most%20proximal%20metabolites,human%20progesterone%20and%20glucocorticoid%20receptors
[30] https://setac.onlinelibrary.wiley.com/doi/pdf/10.1897/09-173.1

that enter the wastewater system and eventually the environment where it likely effects endangered species.

Medications and chemicals flushed into the wastewater system cause particular problems.[31] Yet this is permissible because of the FDA's failure to comply with Section 7 of the ESA. There has been no comprehensive review of the effect this widespread proliferation of Mifepristone, and its consequences, could have on American water, and thereafter plants and animal life. The 1996 Environmental Assessment laid out specific instructions for the proper disposal methods to be used with Mifepristone packaging, but the study failed to consider how to properly dispose of the results of Mifepristone use itself.

Surgically extracted fetal remains, and chemically expelled fetal remains, tissues, and fluids are treated differently; including how they are disposed of. Many state laws exist that elucidate the proper disposal method for fetal and human remains in the context of surgical abortion in order to protect public health.[32] Many of these state laws provide that fetal remains are to be cremated or properly buried, and in fact Vermont's law states:

> Fetal remains shall be disposed of by burial or cremation unless released to an educational institution for scientific purposes or disposed of by the hospital or as directed by the attending physician in a manner which will not create a public health hazard. Permission shall be obtained from one of the parents, if competent, for disposition in all cases where a funeral director is not involved. One copy of the fetal death report shall be printed in such manner that completion and signing by the physician or medical examiner shall constitute permission to make final disposition of the fetal remains.[33]

These laws contemplate surgical abortion only, and have not kept up with the pace of Mifepristone usage. It's clear the same concern applies in the case of chemical abortion. It is antithetical to the passage of these laws or similar laws to allow the products of Mifepristone usage to be transmitted into the waterways when surgically aborted fetuses are properly disposed of through cremation or burial.

Unfortunately, this same level of concern has not been extended to usage of Mifepristone, despite the fact that chemical abortion caused by Mifepristone creates more harmful byproducts, along with the expected fetal remains, because it includes the remains of Mifepristone itself. Other state laws provide that citizens have a right to know what, if any, contaminants are in their water. Plus, a state's waterways are highly regulated in general.[34] This same level of regulation should be extended to chemical pollutants in our waterways. Further, the FDA must comply with Section 7's requirements of consultation with the Services to determine the effects of this medical waste on listed species or habitats in our nation's waters.

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[31] https://www.epa.gov/sites/default/files/2015-06/documents/how-to-dispose-medicines.pdf
[32] See Fla Admin. Code 59A-9.030, Ga Code Ann. § 16-12-141.1(a)(1), Miss Code Ann. § 41-39-1, Or Rev. Stat. § 432.317(3), Ohio Admin. Code § 3701-47-05(A), Ariz Rev. Stat. 36-331, and Tenn Code Ann. § 68-3-506.
[33] 18 VT Stat. Ann. § 5224(a).
[34] See Fla Stat 403.021(2), (10).

b. Mifepristone remains and fetal remains in wastewater have impacts beyond humans and onto animals and plants. Mifepristone usage results in the generation of Medical Waste and must be treated as such.

Mifepristone and fetal remains in wastewater have impacts beyond humans and onto animals and plants. The EPA acknowledges that pharmaceuticals and human remains can impact the fertility of animals and fish.[35] Mifepristone in wastewater is distinct from a natural spontaneous miscarriage, as the products of Mifepristone are chemically tainted with this drug. As Students for Life of America President Kristan Hawkins noted in a 2020 letter to then FDA Commissioner Stephen Hahn, a re-evaluation of the environmental impact of the volume of human remains is needed, given the current status. Hawkins wrote:

> During the approval process for RU-486, an environmental impact study for the drugs focused on the impact of packaging for the drugs, rather than on the impact of human remains in our wastewater system and ground water. Today, with so many lives ending by such chemical abortion pills, it's vital to reopen an inquiry into the environmental impact on our water and land as so many human beings are being flushed away. When you consider that the Environmental Protection Agency recommends against flushing tampons to preserve the environment and water safety, how much more significant is disposing of human remains through the wastewater systems across America?[36]

The need to protect and preserve endangered species and habitats, among other environmental priorities, impacts everyone. This led the Federal Government to create agencies such as the EPA and the Services and to pass legislation such as the Endangered Species Act and Clean Water Act. However, as the EPA notes, states lead the way and there is not much that the EPA can do in the realm of Medical Waste. The "EPA has not had authority, specifically [to regulate] medical waste, since the Medical Waste Tracking Act (MWTA) of 1988 expired in 1991."[37] In fact, the EPA encourages citizens "to contact your state environmental program first when disposing of medical waste" and "[c]ontact your state environmental protection agency and your state health agency for more information regarding your state's regulations on medical waste."[38] Rather than tackle the byproducts of Mifepristone after they have already entered our waterways, this Citizen Petition suggests to the FDA that they must handle the problem at the beginning. The FDA must determine the impact that Mifepristone may have on listed species or habitats through consultation with the Services, and thus learn of the impact of these chemical byproducts on our ecosystems and waterways.

Given that no complete Environmental Impact Study took place in 1996, the true impact of Mifepristone, human tissues, and human remains on our nation's wastewater system is largely unknown. It is likely that the nation's drinking water is contaminated in some appreciable amount by the increasing abundance of Mifepristone and human remains – as of March 2024, 63% of all abortions were performed via Mifepristone usage, up from 53% in 2020 – being flushed into the

[35] https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=312892&Lab=NHEERL
[36] https://www.epa.gov/newsreleases/epa-encourages-americans-only-flush-toilet-paper
[37] https://www.epa.gov/rcra/medical-waste#who%20regulates%20medical%20waste
[38] https://www.epa.gov/rcra/medical-waste#who%20regulates%20medical%20waste

system.[39] [40] This can have detrimental effects on the fertility of animals, as well as having unknown detrimental effects on plant life and ecosystems. As was stated above, this is only going to increase in the coming months and years as Mifepristone use becomes the primary method of abortion in the United States.

Human remains are considered "pathological waste," which the World Health Organization (WHO) recommends being carefully treated by incineration or other special handling.[41] Mishandling human remains and Medical Waste can lead to severe consequences. Those negative consequences can impact animals, plants, and people. As the WHO notes: "[t]he disposal of untreated health care wastes in landfills can lead to the contamination of drinking, surface, and ground waters if those landfills are not properly constructed."[42] The American Academy of Family Physicians, in discussing Medical Waste disposal in non-medical locations, notes:

> [h]ome based health care can create medical waste which can be hazardous if not disposed properly. Inappropriate medical waste disposal can pose harmful environmental concerns and significant health risks to the public, which include but are not limited to, potential water contamination, … and toxic exposure to pharmaceutical products. The AAFP encourages practices to keep all medical and non-medical waste separate to avoid contamination and to facilitate safe disposal of all medical waste. The importance of routine medical waste disposal and destruction practices should be stressed at all city and county levels of collection.[43]

Due to the FDA's failure to conduct proper consultation with the Services in the context of the Endangered Species Act, it is unknowable the impact of this pathological waste may have on listed species or habitats. Even if unknowable, it is very likely to cross the low threshold for agency actions enumerated above by federal courts to constitute a take against the ESA. This must be remedied through FDA complying with Section 7's requirements and consultation with the Services.

i. The residual effects of exposure to Mifepristone in the nation's waterways can impact animals, causing teratologic repercussions and congenital anomalies like birth defects, to animals.

In the FDA's 1996 Environmental Assessment, the Teratogenicity realities of Mifepristone pills were shown to impact rats, mice, and rabbits in testing. As a Harvard University paper, *The Life of the Abortion Pill in the United States*, states, initial studies of the drugs included requirements that the women agree to a surgical abortion if Mifepristone failed because of the risk of birth defects.[44] This way, the products of surgical abortion would be disposed through healthcare facility disposal systems, rather than getting flushed into waterways.

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[39] https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020
[40] https://all.org/abortion/abortion-statistics
[41] https://www.who.int/news-room/fact-sheets/detail/health-care-waste
[42] https://www.who.int/news-room/fact-sheets/detail/health-care-waste
[43] https://www.aafp.org/about/policies/all/medical-waste-disposal.html
[44] *The Life of the Abortion Pill in the United States* (2000 Harvard Library, Office for Scholarly Communication.) https://dash.harvard.edu/bitstream/handle/1/8852153/Hogan%2C_Julie.pdf?sequence=1&isAllowed=y

The report noted:

> [a]nimal toxicology on both mifepristone and misoprostol show teratologic effects in animals, and usually such teratologic effects in animals will translate or have a high possibility of translating to teratologic effects in humans. Dr. Bardin, an endocrinologist and independent consultant for the Population Council, reported at a 1996 FDA Advisory Committee meeting, that 21 children have been born to women who changed their minds, after mifepristone-misoprostol administration, and three of these children have had congenital anomalies. The congenital anomalies were club foot, abnormal fingernails, and an immune disease that led to death.[45]

The creator of the drug, Roussel-Uclaf and later Hoechst, was reluctant to engage in the U.S. Market because of concerns over lawsuits if birth defects or injury resulted because of Mifepristone. From the Harvard Report:

> "The company's biggest worry may have been the fact that mifepristone and misoprostol have been shown to have teratologic effects. If a woman is administered both mifepristone and misoprostol and carries her pregnancy to term, her fetus is at risk. A child with birth defects is one of the most sympathetic plaintiffs."[46]

More studies, culminating in consultation with the Services, should be conducted to alleviate, if possible, such concerns surrounding the usage of Mifepristone and the potential for teratological defects in endangered animals and listed habitats exposed to the drug through environmental contamination.

In fact, many studies and organizations have already found that Mifepristone and other pharmaceuticals have an adverse effect on animal and aquatic life:

- "Effects of long term antiprogestine mifepristone (RU486) exposure on sexually dimorphic lncRNA expression and gonadal masculinization in Nile tilapia (Oreochromis niloticus)," https://pubmed.ncbi.nlm.nih.gov/31491707/#:~:text=A%20long%2Dterm%20exposure%20of,and%20germline%20stem%20cell%20survival;
- "Drugs flushed into the environment could be cause of wildlife decline," https://www.theguardian.com/environment/2014/oct/13/drugs-flushed-into-the-environment-could-be-cause-of-wildlife-decline;
- "Medicating the environment: assessing risks of pharmaceuticals to wildlife and ecosystems," https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4213582/;
- "For pharmaceuticals fouling wastewater and wildlife, solutions exist (commentary)," https://news.mongabay.com/2022/01/for-pharmaceuticals-fouling-wastewater-and-wildlife-solutions-exist-commentary/;

[45] *Id*.
[46] *Id.* at page 45.

- "Impact of Pharmaceutical Waste on Biodiversity," https://www.researchgate.net/publication/322127132_Impact_of_Pharmaceutical_Waste_on_Biodiversity;
- "Endocrine Disruptors," https://www.biologicaldiversity.org/campaigns/pesticides_reduction/endocrine_disruptors/index.html;
- "Two synthetic progestins and natural progesterone are responsible for most of the progestagenic activities in municipal wastewater treatment plant effluents in the Czech and Slovak republics," https://www.sciencedirect.com/science/article/abs/pii/S0043135418301787;
- "Determination of Hormone Antagonists in Waste-Water Samples by Micellar Electrokinetic Chromatography," https://link.springer.com/article/10.1007/s10337-018-3631-0;
- "Detection of Pharmaceutical Residues in Surface Waters of the Eastern Cape Province," https://pubmed.ncbi.nlm.nih.gov/32517338/;
- "Mapping multiple endocrine disrupting activities in Virginia rivers using effect-based assays," https://pubmed.ncbi.nlm.nih.gov/33592464/;
- "Exposure to environmental endocrine disrupting compounds and men's health," https://pubmed.ncbi.nlm.nih.gov/20347536/;
- "Pharmaceuticals and Endocrine Disrupting Compounds in U.S. Drinking Water," https://pubs.acs.org/doi/10.1021/es801845a;
- "Pharmaceuticals of Emerging Concern in Aquatic Systems: Chemistry, Occurrence, Effects, and Removal Methods," https://pubs.acs.org/doi/10.1021/acs.chemrev.8b00299;
- "The pharmacokinetics of mifepristone in humans reveal insights into differential mechanisms of antiprogestin action," https://pubmed.ncbi.nlm.nih.gov/14698071/;
- "Impacts of endocrine disrupting chemicals on reproduction in wildlife and humans," https://www.sciencedirect.com/science/article/pii/S0013935121018855;
- "Endocrine Disruptors in Domestic Animal Reproduction: A Clinical Issue?," https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4584497/; and
- "Endocrine Disruptors in Water and Their Effects on the Reproductive System," https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7139484/.

Presently the Medical Waste from Mifepristone usage is transmitted directly into the wastewater system when the patient completes the Mifepristone and associated misoprostol regimen. This is harmful to drinking water sources, groundwater sources, and any other sources of water that are touched by wastewater. This water does come into contact with endangered species and was not accounted for when the FDA approve Mifepristone for consumer use in 2000.

a. The generator of Medical Waste is responsible for disposal of that Medical Waste.

The generator of Medical Waste is responsible for disposal of human tissue or remains. This rule should be extended to the prescribers of Mifepristone as generators of Medical Waste. Consider that if a limb were amputated, one isn't sent home with it in a bag to dispose of elsewhere.

The medical practitioner that began the chain of events leading to the creation of this "waste" is responsible for its proper disposal.

According to the EPA:

> Medical waste is a subset of wastes generated at health care facilities, such as hospitals, physicians' offices, dental practices, blood banks, and veterinary hospitals/clinics, as well as medical research facilities and laboratories. Generally, medical waste is healthcare waste that that [sic] may be contaminated by blood, body fluids or other potentially infectious materials and is often referred to as regulated medical waste.[47]

Accordingly, the physician or other medical practitioner that prescribes Mifepristone is thus the generator of Medical Waste – without their involvement, the prescription would never be issued or consumed, leading to the production of Medical Waste. The EPA notes in model guidelines that the generator of Medical Waste has responsibility for its disposal. Blood and human remains would usually be handled by incineration or a process of cleansing the material before disposal.[48]

According to Waste Today Magazine, nearly all 50 states have enacted Medical Waste regulations to some extent. However, unlike state hazardous waste regulations, which are all compliant with the federal Resource Conservation and Recovery Act (RCRA) standards, state Medical Waste standards vary significantly. Some state Medical Waste rules are fashioned after the Medical Waste Tracking Act of 1988, while others bear little to no resemblance to that historical law. In most places, the state EPA equivalent is primarily responsible for developing and enforcing regulations for Medical Waste management and disposal. Although in some states, the department of health may play a leading role (e.g., Missouri and Oklahoma) or even serve as the primary regulatory agency, such as the case in Colorado. Where both agencies are involved, like in Louisiana and Missouri, typically the department of health is responsible for on-site management and the environmental agency is responsible for transportation and disposal.[49]

There is no generalized nationwide direction from states or the federal government for the proper disposal of fetal remains, a problem that plagues the entirety of the abortion industry. The FDA, through a modification of the Mifepristone REMS, can begin to alleviate this problem and establish a national disposal standard. Most states' laws are too broad in this context to truly encapsulate what is necessary for the safe disposition of fetal remains or, by extension, the chemical remains from Mifepristone.

CONCLUSION

This Petition requests that the FDA conduct on Abbreviated New Drug Application 216616 the appropriate consultation under Section 7 of the Endangered Species Act with the United States Fish and Wildlife Service and National Marine Fisheries Service in light of the unknown affect

[47] https://www.epa.gov/rcra/medical-waste
[48] https://www.epa.gov/sites/default/files/2016-02/documents/model_guidelines_for_state_medical_waste_management.pdf
[49] https://www.wastetodaymagazine.com/article/medical-waste-regulation-processing/

that Mifepristone could have on all listed endangered or threatened species or designated critical habitats in the FDA's approval jurisdiction.

The Endangered Species Act requires federal agencies to consult with the Services to ensure that the actions they fund, authorize, permit, or otherwise carry out will not jeopardize the continued existence of any listed species or adversely modify designed critical habitats. When approving this new generic version of Mifepristone for human consumption, the FDA did not do this.

The purpose of the Endangered Species Act is to provide a means to conserve the ecosystems upon which endangered and threatened species depend and provide a program for the conservation of such species. The Section 7 consultation requirements apply to all federal agency actions.

Because FDA did not perform the proper consultation under the Act, it is unknowable the impact Mifepristone and its by-products may have on the nation's waterways and ecosystems, and more specifically the impact the same has had and will have on endangered species or listed habitats. The approval of Mifepristone should be halted to allow for a full investigation into its harms to humans, the environment, and endangered species, as required by law.

C. ENVIRONMENTAL IMPACT

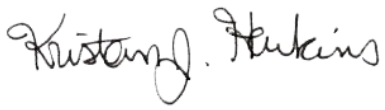
Petitioner is categorically excluded from conducting an environmental impact statement under 21 C.F.R. § 25.30, 25.31, 25.32, 25.33, or § 25.34 or an environmental assessment under 21 C.F.R. § 25.40.

D. ECONOMIC IMPACT

Petitioner will submit information upon request of the Commissioner following review of this petition.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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