CITIZEN PETITION

December 18, 2024

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 313 of the Clean Water Act of 1972 (33 U.S.C. §1251 *et seq.*) (hereinafter, "CWA"), and 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") refrain from modifying the approved use of Mifepristone to include miscarriage care because of the FDA's continued failure to comply with the requirements of the CWA and ESA when it proposed to take the original action, and this new action. 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 the nation's waterways from destruction, and preserving waters of the United States 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 these waters and all their applications.

A. Action Requested

This Petition makes two requests:

1) that the FDA refrain from modifying the approved usage of Mifepristone to include miscarriage care until the agency determines that it:

a. Has complied with the various states' water quality standards as compelled by the CWA. Before allowing Mifepristone for human consumption, use outside of a medical setting, and disposal into the environment, the FDA must first determine the extent and the effects that its actions regarding Mifepristone have on waters of the United States in the FDA's action area (i.e., the entire United States and its territories).
b. Has conducted 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

[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).

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).

2) that the FDA refrain from modifying the approved usage of Mifepristone to include miscarriage care until the agency requires the inclusion of a provision in all Prescriber Requirements that a Catch-Kit and Red Medical Waste Bag be included with Mifepristone Prescriptions

B. Statement of Grounds

The FDA has a legal obligation to comply with the CWA. As set forth in this citizen petition, the FDA's proposed actions on Mifepristone have failed to meet the requirements of the CWA and, therefore, must be revoked until the agency can implement measures to ensure that its actions do not adversely affect waters of the United States. Failure to do so could lead to the permanent contamination of these waters.

I. Under the CWA

1. The FDA's Proposed Actions on Mifepristone and How the Failure to Comply with the CWA will Continue

a. The 2000 Approval of Mifepristone

When the FDA approved Mifepristone in 2000 to be used for chemical abortions, the agency did not determine the effects of Mifepristone on waters of the United States; specifically, the FDA did not determine that permitting the approval of Mifepristone would not violate the water quality standards of the various states as delegated to them by the CWA under Section 313(a) of the Act. The FDA merely relied on an earlier environmental assessment that the Population Council performed under the National Environmental Policy Act ("NEPA").

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 "[t]he product can be manufactured, used and disposed of without any expected adverse environmental effects."[2] This conclusion runs afoul of the requirements of the CWA.

This conclusion also made numerous unverified 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, and production waste would have on the environment, and did not examine the impact the

[2] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 2 of Cover Letter. Available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_EA.pdf.

excretion of Mifepristone would have on the environment.[3] Further, it underestimated the number of chemical abortions, which are abortions committed through use of Mifepristone. No consideration was given in the assessment to the effects of the drug itself, and how Mifepristone might affect the water supply.

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 CWA review or NEPA environmental assessment. This failure flies in the face of the CWA 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 Compliance with State Water Quality Standards Regarding the Impact of Mifepristone on Waters of the United States

The Clean Water Act was passed by Congress in 1972[4] to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." 33 U.S.C. § 1251(a). The Clean Water Act, and the various definitions of "waters of the United States" ("WOTUS"), has spawned a vast array of regulations that define the extent to which the United States Environmental Protection Agency and the United States Army Corps of Engineers (hereinafter referred to collectively as the "EPA") possess regulatory jurisdiction over the Clean Water Act. Congress has authorized the EPA to administer the Clean Water Act, 33 U.S.C. § 1251(d), and the United States Army Corps of Engineers to issue permits for projects on land or water under the Act's jurisdiction. Congress has attempted to craft the Clean Water Act "to recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution [and] to plan the development and use (including restoration, preservation, and enhancement) of land and water resources." 33 U.S.C. § 1251(b).

Further, the purpose of the CWA is to provide a means to conserve the WOTUS and to bring these waters to certain fishable and swimmable standards; more specifically "to prevent, reduce, and eliminate pollution in the nation's water." 33 U.S.C. § 1251(a). The states are directed under Section 303 to adopt water quality criteria and standards. 33 U.S.C. § 1313. Section 313 of the CWA, codified at 33 U.S.C. § 1323 ("Section 313"), directs all Federal agencies to comply with these state water quality standards if they are engaged in any activity that results in or may result in the discharge or runoff of pollutants. More specifically, Section 313(a) states in relevant part that any agency of the federal government that is:

[3] In the 1996 Environmental Assessment, the impact of pharmaceutical waste is only mentioned in context of disposal and would be done "by the manufacturer" and "the Population Council at licensed disposal facilities." This has not occurred.

[4] Congress amended and reorganized the 1948 Federal Water Pollution Control Act in 1972 to such a significant degree that it became known as the Clean Water Act for the first time that year.

> engaged in any activity resulting, or which may result, in the discharge or runoff of pollutants, and each officer, agent, or employee thereof in the performance of his official duties, shall be subject to, and comply with, all Federal, State, interstate, and local requirements, administrative authority, and process and sanctions respecting the control and abatement of water pollution in the same manner, and to the same extent as any nongovernmental entity.

Id. Federal courts have interpreted this to mean a variety of activities, but importantly in the case of FDA and Mifepristone, simple licensing or permitting has been determined to be activity that results in or may result in the discharge or runoff of pollutants. *See Hells Canyon Pres. Council v. Haines,* No. CV 05-1057-PK, 2006 WL 2252554, at *4 (D. Or. Aug. 4, 2006) (Under CWA Section 313, "Federal agencies must ensure that any authorized activity on federal lands complies with all applicable water quality standards."); *Save Our Cabinets v. U. S. Dep't of Agric.*, 254 F.Supp.3d 1241, 1249 (D. Mont. 2017) ("Under the Clean Water Act Section 313, the Forest Service cannot authorize mining operations that do not comply with state and federal water quality regulations"). In *Cent. Sierra Env't Res. Ctr. v. Stanislaus Nat'l Forest*, the Court determined that the Forest Service was subject to and was required to comply with all state and local regulations concerning water pollution because the Forest Service:

> "(1) ha[s] jurisdiction over any property," in this case, the BEH allotments in Stanislaus National Forest. It also is "(2) engaged in any activity resulting, or which may result, in the discharge or runoff of pollutants." 33 U.S.C. § 1323(a). There is no requirement that the government itself be the discharger, only that it undertake an activity that "may result" in the discharge or runoff of pollutants. Issuing a permit to allow cattle grazing is an activity that may result in the discharge or runoff of pollutants, as Plaintiffs allege it did here.

Cent. Sierra Env't Res. Ctr. v. Stanislaus Nat'l Forest, 304 F. Supp. 3d 916, 936–37 (E.D. Cal. 2018). The Ninth Circuit determined that "[t]he CWA requires federal agencies to determine that approved actions do not result in pollution in violation of state water quality standards." *Greater Yellowstone Coalition v. Lewis*, 628 F.3d 1143, 1146 (9th Cir. 2010). Congress crafted the Clean Water Act to restore and maintain the country's water, but it also recognized that the States have primary responsibility and rights over their land and resources. 33 U.S.C. § 1251(b).

The United States Supreme Court has stated that the requirements that can be enforced against federal agencies under Section 313(a) are limited to objective state standards of control, such as effluent limitations in permits, compliance schedules and other controls on pollution applicable to dischargers. *See EPA v. California*, 426 U.S. 200, 215 (1976). Most Clean Water Act requirements ultimately arise from the foundational requirement to obtain a permit before discharging any pollutant into waters of the United States. 33 U.S.C. § 1311(a). Each permit must include effluent limitations and other requirements sufficient to protect water

quality standards. *See* 33 U.S.C. § 1311(b)(1)(C). *In re ACF Basin Water Litig.*, 467 F. Supp. 3d 1323, 1337 (N.D. Ga. 2020).

But that is not all that CWA requires. Indeed, FDA's approval of Mifepristone has naturally led to what the Act defines as "nonpoint source pollution."

> We recognize that nonpoint sources of pollution constitute a major source of pollution in the nation's waters. . . . When Congress established the National Pollutant Discharge Elimination System (NPDES) in 1972 and concomitantly created a new approach to regulating and abating water pollution, it drew a distinct line between point and nonpoint pollution sources. Point sources are subject to direct federal regulation and enforcement under the Act. *See* 33 U.S.C. § 1342. Nonpoint sources, because of their very nature, are not regulated under the NPDES. Instead, Congress addressed nonpoint sources of pollution in a separate portion of the Act which encourages states to develop areawide waste treatment management plans.

Oregon Nat. Res. Council v. U.S. Forest Serv., 834 F.2d 842, 849 (9th Cir. 1987). Nonpoint sources are "diffuse sources of pollution, like farms or roadways, from which runoff drains into a watershed." *Am. Farm Bureau Fed'n v. U.S. E.P.A.*, 792 F.3d 281, 289 (3d Cir. 2015). Nonpoint source pollution is what is contemplated when, as the Supreme Court elucidated in *EPA v. California*, the federal government is subject to state standards.

The CWA establishes a mandate that states create their own water quality standards, reviewable by the EPA, and courts have consistently held that under Section 313 federal agencies are to comply with those standards. "Under the Clean Water Act, all federal agencies must comply with state water quality standards. . . . 33 U.S.C. § 1323(a). Judicial review of this requirement is available under the Administrative Procedure Act." *Oregon Natural Resources Council* at 852; *see also National Wildlife Federation v. U.S. Army Corps of Engineers*, 132 F. Supp 2d 876, 878 (D. Or. 2001) (finding that the court had jurisdiction to review claims that the Corps was "violating the Clean Water Act by not complying with the water quality standards of the State of Washington") and *North Dakota v. U.S. Army Corps of Engineers*, 270 F. Supp. 2d 1115, 1120–21 (D. N.D. 2003) ("[t]hus, it appears the Corps' compliance with the Clean Water Act is subject to judicial review [under the APA]").

Courts have continuously interpreted Section 313 to refer to state standards of control, and that federal agency liability with regards to the CWA and nonpoint sources may be litigated under those standards only as written. In *Center for Native Ecosystems v. Cables*, the plaintiffs challenged the Forest Service's decision to authorize livestock grazing in two national forests. The nonpoint source run-off from livestock grazing had caused the water quality standard for fecal coliform to be exceeded. *Center for Native Ecosystems v. Cables*, 509 F.3d 1310, 1332 (10th Cir. 2007). But the Tenth Circuit held that the plaintiffs did not have a claim under Section 313(a) because the Forest Service had not violated any applicable requirement imposed by the state. *Id.* As the court explained, "Wyoming law does not make a nonpoint-source polluter a guarantor of water-quality compliance." *Id.* at 1331. Instead, Wyoming law required only that certain nonpoint sources implement Best Management Practices (BMPs) to control runoff. Since

the Forest Service had satisfied this obligation, it had met all applicable requirements "in the same manner, and to the same extent as any nongovernmental entity." *Id.* at 1333 (quoting 33 U.S.C. § 1323(a)). *See*, e.g., *Kelley for & on Behalf of Michigan v. United States*, 618 F. Supp. 1103, 1107-08 (W.D. Mich. 1985) (holding that the plaintiffs failed to identify a "requirement" under Section 313(a) because the United States Supreme Court held that the requirements language of Section 313(a) … referred only to "objective state standards of control" in *EPA v. California*). In other words, FDA must comply with only those "objective state standards of control" that may apply to the nonpoint source pollution that may result from Mifepristone prescription.

While it was initially true that Agencies could maintain compliance with Section 313 while technically being in violation of state water quality standards, Courts have found those cases to be specifically tailored to situations where the Agency has undertaken ongoing work to comply:

> The lesson of these cases (*Center for Biological Diversity v. Wagner*, No. CIV. 08-302-CL, 2009 WL 2176049 (D. Or. June 29, 2009), *Northwest Indian Cemetery Protective Association v. Peterson*, 795 F.2d 688, 697 (9th Cir. 1986), and *Oregon Wild v. U.S. Forest Serv.*, 193 F. Supp. 3d 1156 (D. Or. 2016)) is even when an agency might be shown to otherwise technically violate a state water quality standard, compliance can be achieved in a number of indirect ways, including through the implementation of BMPs serving as an acknowledged alternative to direct compliance; or through the existence of other mechanisms, including a combination of BMPs, memoranda of understanding with the state regulators, and other efforts designed to achieve compliance with water quality standards.

Cent. Sierra Env't Res. Ctr. v. Stanislaus Nat'l Forest, No. 117CV00441LJOSAB, 2019 WL 3564155, at *15 (E.D. Cal. Aug. 6, 2019), aff'd, 30 F.4th 929 (9th Cir. 2022). Courts have subsequently applied a "strict compliance standard." For example, Courts have grappled with situations where states modified their water quality standards after previously the state, or another plaintiff, failed in its challenge to the action being undertaken by the federal agency:

> Sometime between *Wagner* and the present action, Oregon DEQ removed the regulatory provision equating agencies' implementation of BMPs to compliance. Due to this revision, Plaintiffs argue the Forest Service can no longer rely on its BMPs and, instead, must "strictly comply" with state water quality standards. The Court disagrees. By deleting the provision, DEQ merely eliminated agencies' ability to *automatically* qualify as compliant by implementing BMPs. It did not prohibit agencies from utilizing BMPs to comply with water quality standards on a case-by-case basis. Here, DEQ has certified that the Forest Service's WQRP "contains the elements necessary to address" its responsibilities and, therefore, that the federal agency "is in compliance with the [state's] requirements" so long as it implements the plan's approved restoration goals and protective measures. SECOND SUPP POL 42. In doing so, DEQ recognized violations may occur while the Forest Service works to achieve long-term goals. It noted "some time will be required for the actions identified in the WQRP to realize full water quality benefits," but found these actions will eventually "result in improved water quality and better overall environmental conditions." SECOND SUPP POL 42. Though

> Plaintiffs speculate that the Forest Service has not fully implemented its BMPs, there is no evidence that the agency has failed to undertake any specific commitment or otherwise acted in bad faith.

Oregon Wild v. U.S. Forest Serv., 193 F. Supp. 3d 1156, 1170–71 (D. Or. 2016) (emphasis added). The important distinction to be made is that an Agency may, in some narrow circumstances, maintain compliance with Section 313 even if they are in technical violation of a state's water quality standards. However, in this case, FDA has not even attempted to comply with the various states' requirements; the states cannot "recogniz[e] [that] violations may occur while the [FDA] works to achieve long-term goals" because there was no planning on FDA's part regarding the impact of Mifepristone on WOTUS and the mandates issued under the CWA.

Though the CWA does not itself regulate nonpoint pollution sources, it provides that federal agencies are required to comply with state and local water quality requirements to the same extent as nongovernmental actors that regulate nonpoint pollution sources. The CWA "provides no direct mechanism to control nonpoint source pollution." *O.N.D.A. v. Dombeck*, 172 F.3d 1092, 1097 (9th Cir. 1998). Instead, the CWA "uses the 'threat and promise' of federal grants to the states to accomplish this task" through federal grants for state wastewater treatment plans, 33 U.S.C. § 1288(b)(2), and a requirement that states prepare nonpoint source management programs, 33 U.S.C. § 1329. *Nat. Res. Def. Council v. E.P.A.*, 915 F.2d 1314, 1318 (9th Cir. 1990). Most importantly, there is no requirement that the government itself be the discharger, only that it undertake an activity that "may result" in the discharge or runoff of pollutants. Issuing a permit to allow cattle grazing is an activity that may result in the discharge or runoff of pollutants.

> Federal Defendants' argument that the waiver in Section 313 was intended only to apply where the government is acting in a nongovernmental capacity is at odds with the plain language of the text, which is worded broadly to cover activities that may result in the discharge or runoff of pollutants without regard for the nature of the activity. Rather than exempting certain activities because of its status as a government actor, the waiver in Section 313 does the opposite—it ensures that an agency's status as a governmental actor does *not* exempt it from complying with otherwise applicable water regulations. "Congress intended this section to ensure that federal agencies were required to 'meet all [water pollution] control requirements as if they were private citizens,'" not to exempt them because they are not.

Ctr. For Native Ecosystems v. Cables, 509 F.3d 1310, 1332 (10th Cir. 2007) (quoting S. Rep. No. 92–414 (1971), *as reprinted in* 1972 U.S.C.C.A.N. 3668, 3734). *Cent. Sierra Env't Res. Ctr. v. Stanislaus Nat'l Forest*, 304 F. Supp. 3d 916, 936–37 (E.D. Cal. 2018).

Indeed, under many state water quality standards the FDA violated a mandate that they—as the federal agency proliferating Mifepristone through their [FDA's] approval process which is not unlike the *Stanislaus Nat'l Forest* Court's finding regarding the issuance of cattle grazing permits being an act that could reasonably lead to pollution—protect the usability of those states' waters.

The Missouri Code of State Regulations Water Quality Standards states in part:

> (4) General Criteria - The following water quality criteria shall be applicable to all waters of the state at all times including mixing zones. No water contaminant, by itself or in combination with other substances, shall prevent the waters of the state from meeting the following conditions:
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> …
>
> (D) Waters shall be free from substances or conditions in sufficient amounts to result in toxicity to human, animal, or aquatic life. However, acute toxicity criteria may be exceeded by permit in zones of initial dilution, and chronic toxicity criteria may be exceeded by permit in mixing zones;
>
> …
>
> (H) Waters shall be free from physical, chemical, or hydrologic changes that would impair the natural biological community;

Missouri Code of State Regulations 10 CSR 20-7.031. Like the WQS in play in *Stanislaus*, Missouri's standards require prospective polluters to determine whether their pollution will "impair the natural biological community." Mifepristone by its very nature as an abortifacient with active metabolites is very likely to "impair the natural biological community" in some appreciable magnitude, but without further investigation by the FDA this is unknowable. Other states have water quality standards not unlike Missouri.

> In Idaho, the Idaho Department of Environmental Quality states that:
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> The following general water quality criteria apply to all surface waters of the state, in addition to the water quality criteria set forth for specifically designated waters.
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> 01. Hazardous Materials. Surface waters of the state shall be free from hazardous materials in concentrations found to be of public health significance or to impair designated beneficial uses. These materials do not include suspended sediment produced as a result of nonpoint source activities.
>
> 02. Toxic Substances. Surface waters of the state shall be free from toxic substances in concentrations that impair designated beneficial uses. These substances do not include suspended sediment produced as a result of nonpoint source activities.
>
> 03. Deleterious Materials. Surface waters of the state shall be free from deleterious materials in concentrations that impair designated beneficial uses. These materials do not include suspended sediment produced as a result of nonpoint source activities.

ID ADC 58.01.02.200 - General Surface Water Quality Criteria. These are further defined in ID ADC 58.01.02.010:

> 21. Deleterious Material. Any nontoxic substance which may cause the tainting of edible species of fish, taste and odors in drinking water supplies, or the reduction of the usability of water without causing physical injury to water users or aquatic and terrestrial organisms.
>
> 47. Hazardous Material. A material or combination of materials which, when discharged in any quantity into state waters, presents a substantial present or potential hazard to human health, the public health, or the environment.
>
> 67. Nuisance. Anything which is injurious to the public health or an obstruction to the free use, in the customary manner, of any waters of the state.
>
> 79. Pollutant. Dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical waste, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, silt, cellar dirt; and industrial, municipal and agricultural waste, gases entrained in water; or other materials which, when discharged to water in excessive quantities, cause or contribute to water pollution. Provided however, biological materials do not include live or occasional dead fish that may accidentally escape into the waters of the state from aquaculture facilities.
>
> 101. Toxic Substance. Any substance, material or disease-causing agent, or a combination thereof, which after discharge to waters of the State and upon exposure, ingestion, inhalation or assimilation into any organism (including humans), either directly from the environment or indirectly by ingestion through food chains, will cause death, disease, behavioral abnormalities, malignancy, genetic mutation, physiological abnormalities (including malfunctions in reproduction) or physical deformations in affected organisms or their offspring. Toxic substances include, but are not limited to, the one hundred twenty-six (126) priority pollutants identified by EPA pursuant to Section 307(a) of the federal Clean Water Act.
>
> 110. Water Pollution. Any alteration of the physical, thermal, chemical, biological, or radioactive properties of any waters of the state, or the discharge of any pollutant into the waters of the state, which will or is likely to create a nuisance or to render such waters harmful, detrimental or injurious to public health, safety or welfare, or to fish and wildlife, or to domestic, commercial, industrial, recreational, aesthetic, or other beneficial uses.

ID ADC 58.01.02.010. Certainly, further investigation into whether Mifepristone qualifies as a toxic substance, pollutant, or hazardous material under Idaho's water quality standards is warranted in light of the CWA's mandate that all federal agencies maintain compliance with the various states' standards.

Idaho and Missouri are not alone in their regulatory structures calling for specific maintenance of their waters. Indeed, in Colorado, the state legislature has proclaimed that "state

water shall be free from substances attributable to human-caused point source or nonpoint source discharge in amounts, concentrations or combinations which are harmful to the beneficial uses or toxic to humans, animals, plants or aquatic life." 5 CCR 1002-31.11(1)(a)(iv).

In Florida the legislature crafted the Florida Air and Water Pollution Control Act (FAWPCA) as a means to tackle their mandate under the CWA that "in recognition that pollution of Florida's air and water is a menace to public health and welfare; is harmful to wildlife; and impairs domestic, agricultural, industrial, and other uses of air and water."[5] Specifically under the FAWPCA:

> a "Contaminant" is any substance which is harmful to plant, animal, or human life and "Pollution" is the presence in the outdoor atmosphere or waters of the state of any substances, contaminants, noise, or manmade or human-induced impairment of air or waters or alteration of the chemical, physical, biological, or radiological integrity of air or water in quantities or at levels which are or may be potentially harmful or injurious to human health or welfare, animal or plant life, or property or which unreasonably interfere with the enjoyment of life or property, including outdoor recreation unless authorized by applicable law.

FL ST § 403.031. This mandate is further extrapolated upon in the Florida Administrative Code section related to Surface Waters wherein the Florida Department of Environmental Management established water quality standards pursuant to the CWA that elucidate a minimum quality standard:

> (1) Minimum Criteria. All surface waters of the State shall at all places and at all times be free from:
>
> (a) Domestic, industrial, agricultural, or other man-induced non-thermal components of discharges which, alone or in combination with other substances or in combination with other components of discharges (whether thermal or non-thermal):
>
> 1. Settle to form putrescent deposits or otherwise create a nuisance, or
> 2. Float as debris, scum, oil, or other matter in such amounts as to form nuisances, or
> 3. Produce color, odor, taste, turbidity, or other conditions in such degree as to create a nuisance, or
> 4. Are acutely toxic, or
> 5. Are present in concentrations which are carcinogenic, mutagenic, or teratogenic to human beings or to significant, locally occurring, wildlife or aquatic species, unless specific standards are established for such components in subsection 62-302.500(2) or rule 62-302.530, F.A.C., or
> 6. Pose a serious danger to the public health, safety, or welfare.

FL ADC 62-302.500. Florida therefore has established a concerted effort to combat water pollution

[5] 2021 Handbook of Florida Water Regulation: Florida Air and Water Pollution Control Act; https://edis.ifas.ufl.edu/publication/FE607.

under their CWA mandate, and the proliferation of Mifepristone within its boundaries has the potential to run cotnrary to this directive. It is incumbent on the FDA to determine whether there is an appreciable amount of Mifepristone, or its metabolites, within the WOTUS contained within Florida's borders to aboid a violation of the relevant Florida statutes and adminsitrative code.

Certainly, there are other states with language similar to these, as again all states are given the charge under the CWA to maintain WOTUS to a specific healthy standard aside from the point-source derived NPDES program.[6] FDA as a federal agency must then comply with the states' WQS if the CWA is to have any meaning and effect. The (1) 2000 approval of the Population Council's new drug application for mifepristone (Mifeprex® or RU-486), (2) the 2019 approval of GenBioPro, Inc.'s generic 200mg mifepristone tablet (collectively, "Mifepristone"), (3) the 2016 changes to the Mifepristone regimen and associated Risk Evaluation and Mitigation Strategy ("REMS"), (4) the 2021 changes to the Mifepristone REMS, and (5) the 2023 changes to the Mifepristone REMS all constituted moments that federal case law could define as reasonably leading to pollution in violation of the express provisions of the CWA, not unlike the proposed modification of the Mifepristone regimen. Therefore, we call on FDA to refrain from modifying the Mifepristone regimen until such an investigation can be launched and conducted considering the specific impact of Mifepristone on WOTUS as it relates to the various states' WQS and the mandates of the CWA.

II. <u>Under the ESA.</u>

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

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.[7] Further, it

[6] For example: CA Water Code § 13160 and Mich. Admin. Code R. 323.1041.
[7] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 1 of Cover Letter.

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 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.[8] 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.

[8] 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.

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[9] on Section 7 consultations define an agency action as all activities or programs of any kind authorized, 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).

[9] 50 C.F.R. § 402 *et seq.*

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 and will continue to do so through this proposed modification of the regimen. 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*[10] (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,

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Lepidochelys kempii[11], 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*[12], 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 plants and other human elements that can cause disruption. *Gymnogyps californianus*[13], 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.[14] With fewer than

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

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*[15], 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 the southern portion of that state. Finally, *Oncorhynchus nerka*[16], 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.[17] 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 six species, among the list of nearly 1,500 individual species. FDA did not do this when approving Mifepristone in 2000, changing the regimen in 2016, 2019, 2021, and 2023, and now with this proposed modification of the prescribing regimen.

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17 https://www.wsj.com/articles/SB10001424052748703657604575005562712284770

III. Effect on the Water and Implementation of Medical Waste Bags

The FDA Did Not Conduct Sufficient Advanced Studies on the Impact That 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 Waters of the United States.

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.[18] This has not been the case. Moreover, this has not been the case as the FDA prepares to modify the prescribing regimen.

Mifepristone and fetal remains in wastewater have impacts beyond humans and onto animals and plants. Mifepristone usage results in the generation of Medical Waste[19] 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 animals.[20] 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 Clean Water Act and the effect of Mifepristone on waters of the United States. 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

[18] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 02; see fn. 4 above.
[19] 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."
[20] 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.

> 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.[21]

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. No other possible effects were analyzed.

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 disposal of the drug itself, the chemical remnants, human remains, and other tissues which are a natural result of Mifepristone 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."[22] 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."[23]

More than half of all abortions (54%) are committed with Mifepristone.[24] This figure is an estimate, as the actual percentage of abortions as committed by Mifepristone is unknown as there

[21] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 1 of Cover Letter; see fn. 4 above.
[22] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 3; see fn. 4 above.
[23] *Jones, Nash, Cross, Philbin, and Kirstein*, "Medication Abortion Now Accounts for More Than Half of All US Abortions," *Guttmacher Institute*, (February 24, 2022), available at https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.
[24] *Id*.

is no national abortion reporting law.[25] States don't report uniformly, and some report nothing at all. This lack of data is exacerbated by the chaos of online purchases, and the fact that many Mifepristone[26] 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*.[27] 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 in more than 96.4% abortions.[28] The number of fetal remains flushed into the wastewater system is only increasing.

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.[29] Most Americans know that the only things you can safely flush are the "three Ps": Pee, Poo, Paper.[30] In fact, "the U.S. Environmental Protection Agency is encouraging all Americans to only flush toilet paper."[31] The EPA is very direct on how to "protect local waterways" by not flushing the wrong things.[32] 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.[33]

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 enter waters of the United States. 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

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[25] *Charlotte Lozier Institute*, "Fact Sheet: National Abortion Reporting, It Is Time to Upgrade," *Charlotte Lozier Institute*, (March 10, 2023), available at https://lozierinstitute.org/fact-sheet-national-abortion-reporting-it-is-time-to-upgrade/.

[26] Some studies refer to Mifepristone and misoprostol usage generally as "Chemical Abortion."

[27] *Claire Cain Miller and Margot Sangor-Katz*, "Medication Abortions Are Increasing: What They Are and Where Women Get Them," *New York Times*, (May 9, 2022), available at https://www.nytimes.com/2022/05/09/upshot/abortion-pills-medication-roe-v-wade.html.

[28] *Celine Miani*, "Medical abortion ratios and gender equality in Europe: an ecological correlation study," *Sexual and Reproductive Health Matters*, (2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8567957/.

[29] *Colorado Comprehensive Women's Health Center*, "Aftercare Instructions: Medication Abortion," *CWHC Colorado*, (2019), available at https://cwhccolorado.com/services/medication-abortion/aftercare-medication-abortion/index.html.

[30] *Portland Environmental Services*, "What You Can (and Can't) Flush," *City of Portland*, (2020), available at https://www.portland.gov/bes/safe-flush.

[31] *EPA Press Office*, "EPA Encourages Americans to Only Flush Toilet Paper," *U.S. Environmental Protection Agency*, (March 30, 2020), available at https://www.epa.gov/newsreleases/epa-encourages-americans-only-flush-toilet-paper.

[32] *EPA Press Office*, "What Can You Do to Protect Local Waterways?," *U.S. Environmental Protection Agency*, (December 2002), available at https://www3.epa.gov/npdes/pubs/centralized_brochure.pdf.

[33] *California Water Environmental Association*, "EPA Bans Flushing All Drugs, Including Hazardous Waste Drugs," *CWEA*, (2019), available at https://www.cwea.org/news/epa-bans-flushing-all-drugs-including-hazardous-waste-drugs/.

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.[34] 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 natural human 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.[35] 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. More recent studies of the impact pharmaceuticals have had on the environment shown that wastewater treatment plants (WWTPs) are unable to entirely treat the water and remove the active metabolites from human waste, and by extension are unable to remove all human uterine contents 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 pollute waters of the United States. The FDA failed to comply with Section 313's mandate that agencies comply with state water quality standards by approving Mifepristone; despite not knowing the full impact of its active metabolites—the same metabolites that the wastewater system, and eventually the environment, where it likely pollutes every type of water it touches.

Medications and chemicals flushed into the wastewater system cause particular problems.[36] Yet such flushing of waste is permissible because of the FDA's failure to comply with Section 313 of the CWA. 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.

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[34] *Heikinheimo, Kekkonen, and Lähteenmäki*, "The pharmacokinetics of mifepristone in humans reveal insights into differential mechanisms of antiprogestin action," *Contraception*, (December 2003), available at https://pubmed.ncbi.nlm.nih.gov/14698071/#:~:text=The%20three%20most%20proximal%20metabolites,human%20progesterone%20and%20glucocorticoid%20receptors.

[35] *Celiz, Tso, and Aga*, "Pharmaceutical Metabolites In The Environment: Analytical Challenges And Ecological Risks," *Environmental Toxicology and Chemistry*, (June 12, 2009), available at https://setac.onlinelibrary.wiley.com/doi/pdf/10.1897/09-173.1.

[36] *EPA Office of Water*, "How to Dispose of Medicines Properly," *U.S. Environmental Protection Agency*, (April 2011), available at https://www.epa.gov/sites/default/files/2015-06/documents/how-to-dispose-medicines.pdf.

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.[37] 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.[38]

These laws contemplate surgical abortion only, and they have not kept up with the pace of Mifepristone usage. It is clear that 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.[39] This same level of regulation should be extended to chemical pollutants in our waterways. Further, the FDA must comply with Section 313's requirements of compliance with the states' water quality standards to determine the effects of this medical waste on our nation's waters.

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.[40] 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

[37] 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.
[38] 18 VT Stat. Ann. § 5224(a).
[39] See Fla Stat 403.021(2), (10).
[40] *EPA Center for Environmental Measurement and Modeling*, "Don't Flush! Why Your Drug Disposal Method Matters," *U.S. Environmental Protection Agency*, (April 29, 2016), available at https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=312892&Lab=NHEERL.

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?[41]

The need to protect and preserve waters of the United States, among other environmental priorities, impacts everyone. This led the Federal Government to create agencies such as the EPA and the United States Fish and Wildlife Service and to pass legislation such as the Clean Water Act and the Safe Drinking 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."[42] 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."[43] 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 waters of the United States through a review of Mifepristone on state water quality standards, 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 February 2022, 54% of all abortions were performed via Mifepristone usage, up from 39% in 2017 – being flushed into the system.[44] [45] 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

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[41] *EPA Press Office*, "EPA Encourages Americans to Only Flush Toilet Paper," *U.S. Environmental Protection Agency*, (March 30, 2020), available at https://www.epa.gov/newsreleases/epa-encourages-americans-only-flush-toilet-paper.
[42] *EPA*, "Medical Waste," *U.S. Environmental Protection Agency*, (May 5, 2023), available at https://www.epa.gov/rcra/medical-waste#who%20regulates%20medical%20waste.
[43] *Id*.
[44] *Jones, Nash, Cross, Philbin, and Kirstein*, "Medication Abortion Now Accounts for More Than Half of All US Abortions," *Guttmacher Institute*, (February 24, 2022), available at https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.
[45] *American Life League*, "Abortion Statistics," *American Life League*, (August 1, 2021), available at https://all.org/abortion/abortion-statistics.

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.[46] 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."[47] 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.[48]

Due to the FDA's failure to conduct proper consultation with the Services in the context of the Clean Water 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.[49] 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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[46] *WHO Newsroom*, "Health-care waste," *World Health Organization*, (February 8, 2018), available at https://www.who.int/news-room/fact-sheets/detail/health-care-waste.
[47] *Id*.
[48] *AAFP Policies*, "Medical Waste Disposal in Non-Medical Locations," *American Academy of Family Physicians*, (2020), available at https://www.aafp.org/about/policies/all/medical-waste-disposal.html.
[49] *Julie A. Hogan*, "The Life of the Abortion Pill in the United States," Harvard Library, Office for Scholarly Communication, (2000), available at 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.[50]

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.[51]

More studies, culminating in analysis of the pharmaceutical impact of Mifepristone on waters of the United States, 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, including the following:

- "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/;

[50] *Id*.
[51] *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 pollution of waters of the United States 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, a patient isn't sent home with that limb 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.[52]

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.[53]

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.[54]

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

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[52] *EPA*, "Medical Waste," *U.S. Environmental Protection Agency*, (May 5, 2023), available at https://www.epa.gov/rcra/medical-waste#who%20regulates%20medical%20waste.

[53] *Council of State Governments*, "Model Guidelines for State Medical Waste Management," *Center For Environment*, (1992), available at https://www.epa.gov/sites/default/files/2016-02/documents/model_guidelines_for_state_medical_waste_management.pdf.

[54] *Tom Dumez*, "Understanding medical waste regulations," *Waste Today Magazine*, (January 18, 2019), available at https://www.wastetodaymagazine.com/article/medical-waste-regulation-processing/.

establish a national disposal standard. Even having failed to do so over the past 24 years, through this proposed modification of the Mifepristone prescribing regimen, the FDA can fix the problem rather than make it worse. 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 refrain from modifying the prescribing regimen for Mifepristone in light of the unknown affect that Mifepristone could have on Waters of the United States that may be in violation of the various states' Water Quality Standards as promulgated under the Clean Water Act and that the FDA conduct 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 that Mifepristone could have on all listed endangered or threatened species or designated critical habitats in the FDA's approval jurisdiction.

The Clean Water Act requires federal agencies to comply with the states' Water Quality Standards to ensure that their actions would not violate the specific regulations put forth by the states in compliance with their mandate under the Clean Water Act. When approving Mifepristone for human consumption, the FDA did not do this.

The purpose of the Clean Water Act is to provide a means to conserve Waters of the United States upon which the nation depends and to maintain these waters to specific fishable, swimmable, and recreatable standards. The Clean Water Act requirements apply to all federal agencies and facilities they control.

Because FDA did not approve Mifepristone in context with 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 the regulated Waters of the United States. Now, the modification of the Mifepristone prescribing regimen should be halted to allow for a full investigation into its harms to humans, the environment, and Waters of the United States, as required by law.

Likewise, 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 Mifepristone for human consumption, the FDA did not do this and has not done this now in relation to this proposed modification of the prescribing regimen.

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

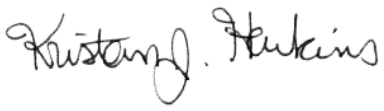
Petitioner is categorically excluded from conducting an environmental impact statement under 21 C.F.R. § 25.30, 25.31, 25.32, 25.33, or § 25.34 or an environmental assessment under 21 C.F.R. § 25.40.

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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