

CITIZEN PETITION

August 6, 2026

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 to request that the Commissioner of the Food and Drug Administration (“FDA”) revoke (1) the 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, to require the inclusion of a provision in all Prescriber Requirements that a Catch-Kit and Red Medical Waste Bag be included with Mifepristone Prescriptions. This petition adds new data and information that was not previously included with the petition under Docket No. FDA-2022-P-2872.

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 the following requests:

that the FDA revoke (1) the 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, to require 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

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).

I. 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.² 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 Waste³ 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.⁴ 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

² 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 02; see fn. 4 above.

³ 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."

⁴ 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.⁵

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.”⁶ 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.”⁷

More than sixty percent of all abortions (63%) are committed with Mifepristone.⁸ This figure is an estimate, as the actual percentage of abortions as committed by Mifepristone is

⁵ 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 1 of Cover Letter; see fn. 4 above.

⁶ 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 3; see fn. 4 above.

⁷ 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>.

⁸ *Id.*

unknown as there is no national abortion reporting law.⁹ 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 Mifepristone¹⁰ 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*.¹¹ 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.¹² 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.¹³ Most Americans know that the only things you can safely flush are the "three Ps": Pee, Poo, Paper.¹⁴ In fact, "the U.S. Environmental Protection Agency is encouraging all Americans to only flush toilet paper."¹⁵ The EPA is very direct on how to "protect local waterways" by not flushing the wrong things.¹⁶ 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.¹⁷

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

⁹ *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/>.

¹⁰ Some studies refer to Mifepristone and misoprostol usage generally as "Chemical Abortion."

¹¹ *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>.

¹² *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/>.

¹³ *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>.

¹⁴ *Portland Environmental Services*, "What You Can (and Can't) Flush," *City of Portland*, (2020), available at <https://www.portland.gov/bes/safe-flush>.

¹⁵ *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>.

¹⁶ *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.

¹⁷ *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.¹⁸ 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.¹⁹ 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.

Past research has shown that steroid hormones and other endocrine-disrupting compounds (EDCs) are present in environmental water, with implications for human and wildlife health. Abortion providers have shifted a large part of their practice to medication-induced abortion, using the anti-progesterone synthetic steroid hormone mifepristone. In a recent study, significant levels of mifepristone (up to 0.041 µgram/l) were found in the water of all but one of the nine sampling classes. Because of the plethora of effects of progesterone, this contaminant could affect the physiology of aquatic animals; and human health, including fertility, pregnancy and fetal development. The findings indicate the necessity for significant additional investigation into the

¹⁸ Heikinheimo, Kekkonen, and Lähteenmäki, "The pharmacokinetics of mifepristone in humans reveal insights into differential mechanisms of antiprogesterin action," *Contraception*, (December 2003), available at <https://pubmed.ncbi.nlm.nih.gov/14698071/#:~:text=The%20three%20most%20proximal%20metabolites,human%20progesterone%20and%20glucocorticoid%20receptors>.

¹⁹ 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>.

levels of various hormones and endocrine disrupting compounds, including mifepristone, in water sources.²⁰

Medications and chemicals flushed into the wastewater system cause particular problems.²¹ 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.

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.²² 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.²³

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.²⁴ This same level of regulation should be extended to chemical pollutants in our waterways. Further, the FDA must comply with Section

²⁰ Rose, Elise and Varveris, Michael, "Anti-Progesterone in Environmental Water," *Issues in Law & Medicine A Journal of the Alliance for Hippocratic Medicine*, (July 2026), available at <https://issuesinlawandmedicine.com/articles/anti-progesterone-in-environmental-water/>.

²¹ 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>.

²² 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.

²³ 18 VT Stat. Ann. § 5224(a).

²⁴ See Fla Stat 403.021(2), (10).

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.²⁵ 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?²⁶

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."²⁷ 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."²⁸ 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

²⁵ 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.

²⁶ 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>.

²⁷ EPA, "Medical Waste," U.S. Environmental Protection Agency, (May 5, 2023), available at <https://www.epa.gov/rcra/medical-waste#who%20regulates%20medical%20waste>.

²⁸ *Id.*

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 March 2024, 63% of all abortions were performed via Mifepristone usage, up from 53% in 2020 – being flushed into the system.^{29 30} 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.³¹ 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.”³² 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.³³

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.

²⁹ 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>.

³⁰ *American Life League*, “Abortion Statistics,” *American Life League*, (August 1, 2021), available at <https://all.org/abortion/abortion-statistics>.

³¹ *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>.

³² *Id.*

³³ *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>.

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.³⁴ This way, the products of surgical abortion would be disposed through healthcare facility disposal systems, rather than getting flushed into waterways.

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.³⁵

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.³⁶

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:

³⁴ 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.

³⁵ *Id.*

³⁶ *Id.* at page 45.

- “Effects of long term antiprogesterone 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](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/>;
- “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 antiprogesterone 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.³⁷

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.³⁸

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

³⁷ EPA, "Medical Waste," *U.S. Environmental Protection Agency*, (May 5, 2023), available at <https://www.epa.gov/rcra/medical-waste#who%20regulates%20medical%20waste>.

³⁸ *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.

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.³⁹

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 can begin to alleviate this problem and establish a national disposal standard. Even having failed to do so over the past 25 years, 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

Most states have regulations covering packaging, storage, and transportation of Medical Waste. Some states require health care facilities to register and/or obtain a permit for their waste. State rules may also cover the development of contingency plans, on-site treatment, training, waste tracking, recordkeeping, and reporting. Irrespective of the failure of EPA to review the environmental impact associated with the results of Mifepristone use and the creation of Medical Waste, the fact remains that Medical Waste is a serious matter that is controlled by strict standards promulgated by both the EPA and most states. Mifepristone usage by its very purpose creates Medical Waste. To date there is no advanced guideline requiring proper disposal of that particular Medical Waste. This can be alleviated by the inclusion of a Medical Waste bag and Catch-Kit with all Mifepristone prescriber requirements.

C. ENVIRONMENTAL IMPACT

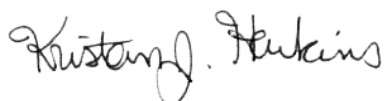
Petitioner is categorically excluded from conducting an environmental impact statement under 21 C.F.R. § 25.30, 25.31, 25.32, 25.33, or § 25.34 or an environmental assessment under 21 C.F.R. § 25.40.

D. ECONOMIC IMPACT

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

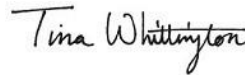
E. CERTIFICATION

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.


/s/ _____
Kristan Hawkins

³⁹ Tom Dumez, "Understanding medical waste regulations," *Waste Today Magazine*, (January 18, 2019), available at <https://www.wastetodaymagazine.com/article/medical-waste-regulation-processing/>.

President
STUDENTS FOR LIFE OF AMERICA
1000 Winchester Street, Suite 301
Fredericksburg, VA 22401
(540) 834-4600


/s/ _____
Tina Whittington
Executive Vice President
STUDENTS FOR LIFE OF AMERICA


/s/ _____
Kristi Hamrick
Vice President of Media and Policy
STUDENTS FOR LIFE OF AMERICA