November 15, 2022

**Citizen Petition**

The undersigned submits this petition under 21 C.F.R. § 10.30 and Section 505-1 of the Food Drug and Cosmetic Act (21 U.S.C. § 355-1) to request the Commissioner of the Food and Drug Administration (FDA) to modify the Risk Evaluation and Mitigation Strategy (REMS) regarding mifepristone (Mifeprex® or RU-486) (hereinafter, "Mifepristone") to require prescribers to include a Medical Waste bag and Catch-Kit with all Mifepristone prescriptions.

## A. ACTION REQUESTED

**Require that the FDA Include a Provision in all Prescriber Requirements that a Catch-Kit[1] and Red Medical Waste Bag[2] be Included with Mifepristone Prescriptions**

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.

When approving Mifepristone for consumer use in 2000, the FDA did not conduct an environmental study regarding the potential impact Mifepristone could have on the nation's wastewater, nor was a study conducted when REMS were adopted in 2011 or when the REMS were modified in 2016, supplemented in 2019, and modified again in 2021. The 1996 Environmental Assessment provided by the Population Council to Environmental Protection Agency (EPA) reported a Finding of No Significant Impact (FONSI) to the environment. The problem with this 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.[3] Further,

[1] A Catch-Kit is similarly to a sharps disposal container, as approved by the FDA. It would include a plastic container for the Medical Waste bag to be placed for proper and safe disposal by the prescriber of Mifepristone. See example below.

[2] A red Medical Waste bag is a biohazard bag most often associated with the disposal and removal of medical or pathological waste. See example below.

[3] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 1 of Cover Letter.

it underestimated the number of chemical abortions, which are abortions committed through use of Mifepristone.

Requiring that a Catch-Kit and Medical Waste[4] bag be included with all prescriber requirements for Mifepristone would alleviate some amount of human remains (this includes fetal remains)[5] and Mifepristone contaminants in the nation's water supply. This would allow the produced Medical Waste to be appropriately handled as any other Medical Waste would be.

## B. STATEMENT OF GROUNDS

**The FDA Did Not Conduct Sufficient Advanced Studies on the Impact Mifepristone Could Have on the Nation's Water Supply at Any Point Before or Since Formal Approval of Mifepristone for Consumers 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 consumers in 2000. In the lead up to 2000 approval, the FDA reported that there would be high standards for disposal related to Mifepristone.[6] This has not been the case.

Mifepristone and fetal remains in wastewater have impacts beyond humans and onto animals and plants. Mifepristone usage results in the generation of Medical Waste 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.[7] Proper control of drugs, hormones, and chemicals in wastewater is vital to human health and the health of other life exposed.

In medical settings, the generator of Medical Waste is responsible for disposal of human remains and other tissue. This must be extended to prescribers of Mifepristone. We encourage the FDA to update the REMS for Mifepristone to include a requirement of a Catch-Kit and Medical Waste bag.

### 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 consumers 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 consumers 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 can be mediated by the inclusion

[4] 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."
[5] "Human Remain contaminants" or "Human Remains" includes fetal remains, placenta, body fluids, and any other byproducts of Mifepristone usage aside from Mifepristone itself.
[6] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 02.
[7] 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.

within the prescriber requirement of a Catch-Kit or Medical Waste bag. From the 1996 report that the FDA prepared for Mifepristone's approval:

> The Food and Drug Administration, Center for Drug Evaluation and Research (CDER) has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment and that an environmental impact statement therefore will not be prepared. In support of their new drug application for Mifepristone Tablets, The Population Council has prepared an environmental assessment in accordance with 21 CFR 25.3a (attached) which evaluates the potential environmental impacts of the manufacturer, use and disposal of the product. Mifepristone is a synthetic drug which will be administered orally to provide a medical approach to the termination of early pregnancy. Mifepristone may enter the environment from the excretion by patients, from disposal of pharmaceutical waste or from emissions from manufacturing sites. . . . The Center for Drug Evaluation and Research has concluded that the product can be manufactured, used, and disposed of without any expected adverse environmental effects.[8]

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

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

The 1996 Environmental Assessment stated that there would be high standards for disposal; however, the focus was primarily on the drug itself and its associated packaging, not the 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 and thus the associated pollution into the waterways is increasing.

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."[9] However, considering the 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:

[8] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 1 of Cover Letter.
[9] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 3.

"[m]edication abortion can be completed outside of a medical setting—for example, in the comfort and privacy of one's home."[10]

More than half of all abortions (54%) are committed with Mifepristone.[11] This figure is an estimate, as the actual percentage of abortions as committed by Mifepristone is unknown as there is no national abortion reporting law.[12] States don't report uniformly, and some report nothing at all. This is exacerbated by the chaos of online purchases, and the fact that many Mifepristone[13] 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*.[14] And it can be more, as an NIH report notes that countries like Finland use Mifepristone pills 97.7% of the time, and in Sweden, the pills are used more than 96.4%.[15] The number of fetal remains flushed into the wastewater system is only increasing and it is likely that the United State will be following Europe's lead in light of the United States Supreme Court's overturning of *Roe v. Wade* and increasing restrictions on medical abortions in many states.

The industry's practice to date is to allow the byproducts of Mifepristone usage to be flushed into the patient's toilet, as is FDA's; but everything that is flushed goes into America's wastewater system.[16] Most Americans know that the only things you can safely flush are the three Ps: Pee, Poo, Paper.[17] In fact, "the U.S. Environmental Protection Agency is encouraging all Americans to only flush toilet paper."[18] The EPA is very direct on how to "protect local waterways" by not flushing the wrong things.[19] 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.[20]

Medications and chemicals flushed into the wastewater system cause particular problems.[21] Yet this is permissible under the current REMS for Mifepristone. There has been no comprehensive review of the effect this widespread proliferation of Mifepristone, and its consequences, could have on American water. 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

[10] https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions
[11] *Id.*
[12] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2306667
[13] Some studies refer to Mifepristone and misoprostol usage generally as "Chemical Abortion."
[14] https://www.nytimes.com/2022/05/09/upshot/abortion-pills-medication-roe-v-wade.html
[15] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8567957/
[16] https://cwhccolorado.com/services/medication-abortion/aftercare-medication-abortion/index.html
[17] https://www.portland.gov/bes/safe-flush
[18] https://www.epa.gov/newsreleases/epa-encourages-americans-only-flush-toilet-paper
[19] https://www3.epa.gov/npdes/pubs/centralized_brochure.pdf
[20] https://www.cwea.org/news/epa-bans-flushing-all-drugs-including-hazardous-waste-drugs/
[21] https://www.epa.gov/sites/default/files/2015-06/documents/how-to-dispose-medicines.pdf

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

Unfortunately, this same level of concern has not been extended to usage of Mifepristone, despite the fact that chemical abortion caused by Mifepristone creates more harmful byproducts, along with the expected fetal remains, because it includes the remains of Mifepristone itself. Other state laws provide that citizens have a right to know what, if any, contaminants are in their water. Plus, a state's waterways are highly regulated in general.[24] This same level of regulation should be extended to chemical pollutants in our waterways.

**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. Mifepristone usage results in the generation of Medical Waste and must be treated as such. 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

[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).
[25] https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=312892&Lab=NHEERL

> 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 for safe drinking water, among other environmental priorities, impacts everyone. This led the Federal Government to create agencies such as the EPA and the FDA and to pass legislation such as the Clean Water Act. However, as the EPA notes, states lead the way and there is not much that the EPA can do in the realm of Medical Waste. The "EPA has not had authority, specifically [to regulate] medical waste, since the Medical Waste Tracking Act (MWTA) of 1988 expired in 1991."[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] Revisiting the REMS to require the inclusion of a Catch-Kit and Medical Waste bag in the prescriber requirements is one way to combat the inability of the EPA or FDA to control Medical Waste.

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.[29] [30] This can have detrimental effects on the fertility of both animals and humans, 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

[26] https://www.epa.gov/newsreleases/epa-encourages-americans-only-flush-toilet-paper
[27] https://www.epa.gov/rcra/medical-waste#who%20regulates%20medical%20waste
[28] https://www.epa.gov/rcra/medical-waste#who%20regulates%20medical%20waste
[29] https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions
[30] https://all.org/abortion/abortion-statistics
[31] https://www.who.int/news-room/fact-sheets/detail/health-care-waste
[32] https://www.who.int/news-room/fact-sheets/detail/health-care-waste

> 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]

**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 should be conducted to alleviate, if possible, such concerns surrounding the usage of Mifepristone and the potential for teratological defects in humans or animals exposed to the drug through environmental contamination.

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[33] https://www.aafp.org/about/policies/all/medical-waste-disposal.html
[34] https://dash.harvard.edu/bitstream/handle/1/8852153/Hogan%2C_Julie.pdf?sequence=1&isAllowed=y
[35] *Id*.
[36] *The Life of the Abortion Pill in the United States* (2000 Harvard Library, Office for Scholarly Communication, page 45.)

### ii. Proper control of drugs, hormones, and chemicals in wastewater is vital to our health and the health of other life exposed.

Proper control of drugs, hormones, and chemicals in wastewater is vital to human health and the health of other life exposed. Drugs and chemicals that impact human biology and reproductive cycles can have the same impact on fish and animals exposed in the nation's waterways. There is a long track record of noticeable impact upon animals with human contraceptives and similar drugs. It is widely known that birth control hormones in water can disrupt fish reproduction. A European Commission study notes:

> [s]ewage effluent contains a complex mixture of chemicals, including pharmaceuticals, which are not completely removed during treatment. Among these are steroidal oestrogens, such as 17α-ethinylestradiol (EE2), from human birth control pills, that have been shown to negatively affect fish reproduction. However, oestrogens may also influence populations of fish through mechanisms other than reproduction, such as reducing survival, and have cumulative effects only seen over multiple generations.[37]

Mifepristone is far more damaging to the environment than hormones. Importantly, the difference between natural hormones, such as estrogen, and Mifepristone is that hormones are naturally occurring. Mifepristone would not exist but for the pharmaceutical company that initially created it and sold it to the marketplace. There is no way for Mifepristone to enter our waterways except for in the wastewater system after being flushed down the toilet. Mifepristone is a chemical designed to induce an abortion, significantly more powerful on its own than a hormone or a natural miscarriage that occurs spontaneously.

According to the National Institute of Health, contraceptives in fish can be passed back to people.[38] In the United States, around 15 million women regularly take birth-control pills, which typically rely on a synthetic form of estrogen known as EE2.[39] Since it's an endocrine disruptor, EE2 can interfere with reproductive hormones and development if consumed in excess or by vulnerable individuals like infants.[40] Birth-control pills add more than 10 million doses of synthetic estrogen to America's wastewater every day. That estimate is based the number of women who take oral contraceptives in the United States, and assumes those women take the pill 21 days of the month and excrete around 90% of the dose into wastewater. [41]

A 2010 study determined that birth-control pills account for less than 1% of the total amount of estrogen found in America's drinking water.[42] But since local water systems don't test for the synthetic estrogen EE2, the study's authors noted, it's hard to determine how much of the hormone is in our water. In the northeastern United States, scientists have discovered that

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[37] https://environment.ec.europa.eu/research-and-innovation/science-environment-policy_en
[38] https://pubmed.ncbi.nlm.nih.gov/16312978/
[39] https://www.cdc.gov/nchs/data/hus/hus16.pdf
[40] https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/mestraethinyleinfo.pdf
[41] Seth M. Siegel, *Troubled Water What's Wrong with What We Drink* (2019).
[42] *Environ. Sci. Technol.* 2011, 45, 1, 51–60, Publication Date: October 26, 2010, https://doi.org/10.1021/es1014482

estrogen in rivers and lakes can cause male fish to develop female biomarkers like ovaries.[43] Other studies have shown that exposure to EE2 has led fish to become less fertile across generations.[44] There is reason enough to believe that estrogen and the pharmaceutical compounds that are being ingested in micro-quantities across the nation are having a detrimental effect.[45] The EPA has also cautioned about the impact of hormones on the reproductive lives of animals and fish.[46] This is likely not an isolated occurrence, nor limited just to contraceptives.

The United States Geological Survey (USGS) has also conducted similar studies with similar results:

> Another source of pharmaceuticals in stream water is you and me. Essentially, drugs that people take internally are not all metabolized in the body, and the excess ends up in our wastewater leaving homes and entering the sewage-treatment plants. It might sound surprising that these drugs could be detected in streams miles downstream from wastewater-treatment plants, but many plants do not routinely remove pharmaceuticals from water.[47]

Multiple agencies across multiple divisions of the federal government, and some international bodies, are finding similar results: human consumed pharmaceuticals and pharmaceuticals consumed by industry can find their way into the wastewater system or even the water table. There is ample evidence to suggest that remnants of Mifepristone are in the nation's water system, causing unknown harm to citizens and animals alike. This can be alleviated by the inclusion of a Medical Waste bag and Catch-Kit with all Mifepristone prescriptions.

**c. The generator of Medical Waste is responsible for disposal of that Medical Waste.**

The generator of Medical Waste is responsible for disposal of human tissue or remains. This rule should be extended to the prescribers of Mifepristone as generators of Medical Waste. Consider that if a limb were amputated, one isn't sent home with it in a bag to dispose of elsewhere. The medical practitioner that began the chain of events leading to the creation of this "waste" is responsible for its proper disposal.

According to the EPA:

> Medical waste is a subset of wastes generated at health care facilities, such as hospitals, physicians' offices, dental practices, blood banks, and veterinary hospitals/clinics, as well as medical research facilities and laboratories. Generally, medical waste is healthcare waste that that [sic] may be contaminated

[43] Iwanowicz, L. R., et al. *Evidence of estrogenic endocrine disruption in smallmouth and largemouth bass inhabiting Northeast U.S. national wildlife refuge waters: A reconnaissance study.* Ecotoxicology and environmental safety vol. 124 (2016): 50-59. doi:10.1016/j.ecoenv.2015.09.035.
[44] Bhandari, R., et al. *Transgenerational effects from early developmental exposures to bisphenol A or 17α-ethinylestradiol in medaka, Oryzias latipes.* Sci Rep 5, 9303 (2015). https://doi.org/10.1038/srep09303
[45] Siegel, *supra*.
[46] https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=312892&Lab=NHEERL
[47] https://www.usgs.gov/special-topics/water-science-school/science/pharmaceuticals-water

> by blood, body fluids or other potentially infectious materials and is often referred to as regulated medical waste.[48]

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.[49] At the very least in the instance of Mifepristone, the human remains and tissue should be collected in a Catch-Kit or Medical Waste bag, to be returned to the Mifepristone prescriber for disposal, as the prescribing of Mifepristone is the event that led to the human remains and tainted tissue.

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.[50]

There is no generalized nationwide direction from states or the federal government for the proper disposal of fetal remains, a problem that plagues the entirety of the abortion industry. The FDA, through a modification of the Mifepristone REMS, can begin to alleviate this problem and establish a national disposal standard. Most states' laws are too broad in this context to truly encapsulate what is necessary for the safe disposition of fetal remains or, by extension, the chemical remains from Mifepristone. A way to combat these issues – the transmission of fetal remains and chemical remains from Mifepristone into the wastewater systems and eventually the drinking water system – is to put in place a requirement from the FDA that all prescriptions of Mifepristone be accompanied by a Catch-Kit and Medical Waste Bag so that the "natural" products of usage be deposited in a Medical Waste bag and Catch-Kit and returned to the institution that provided the 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

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

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.

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