Abortion in Our Water:
A Special Report

Chemical Home Abortions
& the Disposition of Aborted Fetal Remains

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"Environmental protection efforts are necessary to counter the potential harm that chemical abortion drugs are creating for our people, wildlife, and ecosystems. ***The American people deserve to know the negative effects caused by chemical abortion drugs.****"*

> —Letter from former U.S. Senator Marco Rubio and Representative Josh Brecheen, et al., to former EPA Administrator Michael Regan, May 29, 2024

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Executive Summary

"Crystal-clean water" has been a priority of President Donald J. Trump since day one of his first administration.[1] As recently as April 2025, his administration announced it is "leveraging environmental policies . . . to promote economic growth while maintaining the standards that have afforded Americans the **cleanest air and water** in the world for generations."[2]

Yet daily, our waterways are being contaminated by chemical abortion drugs and human remains as American women—left alone at home to endure the agonizing process of expelling their pregnancy—are often instructed by abortion providers to dispose of their aborted child's remains down the toilet.

Original and Subsequent Approvals of the Abortion Pill Fail to Consider Disposal of Fetal Remains

In 2000, the Food and Drug Administration (FDA) approved the use of the chemical abortion pill, Mifeprex (mifepristone). As part of the application in which said approval was sought, the Population Council submitted an Environmental Assessment (EA) that concluded, in part based on the estimated "Expected Introduction Concentration from Use" in the environment, that the impact of the drug on our environment would be minimal; hence, no further study was completed.[3] The same assessment failed to address the issue of how the fetal remains would be disposed of, essentially ignoring the reality that in many cases, said remains would enter U.S. water systems in violation of various fetal disposal and medical waste laws. Though the Clean Water Act (CWA) requires compliance with all such laws for any drug approval, these and state and local laws on water quality were clearly overlooked. The FDA's subsequent approval of the generic version of Mifeprex (mifepristone) and its periodic approvals for changes to the drug's safety protocols likewise failed to consider how the disposal of aborted fetal remains would be handled.

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[1] "Remarks by President Trump on America's Environmental Leadership," The White House, July 8, 2019, https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-americas-environmental-leadership/.

[2] "On Earth Day, We Finally Have a President Who Follows Science," The White House, April 22, 2025, https://www.whitehouse.gov/articles/2025/04/on-earth-day-we-finally-have-a-president-who-follows-science/.

[3] Food and Drug Administration Center for Drug Evaluation and Research, "Environmental Assessment and Finding of No Significant Impact for NDA 20-687—Mifepristone Tablets," July 1996, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_EA.pdf. More specifically, after the drug is used by women, it is excreted; the amount of the drug excreted is then "introduced" into the environment (first by entering the sewer system). The EA calculated mifepristone's "Expected Introduction Concentration from Use" at less than 1 part per billion and outlined a few other possible environmental impacts related to manufacture and disposal of the drug / drug packaging; no further environmental information was sought or provided.

These oversights, among others, by both the FDA and the Environmental Protection Agency (EPA), amount to violations of both the CWA and the National Environmental Policy Act (NEPA).

Increasing Use of the Abortion Pill Increases Environmental Concern

Furthermore, over the last two decades-plus, the use of the chemical abortion pill has increased dramatically, such that now the vast majority of the approximately one million annual abortions that occur in the U.S. are performed outside of a clinical setting (at least 63% in 2023, though this percentage is likely much higher, given both the lack of formal nationwide reporting requirements and access to pills via online purchases).[4] This increase has not only led to further harm for women, who are often directed to flush their babies' remains and then are traumatized by "seeing their fully formed babies in a glob of blood floating in the toilet," but has also increased the level of abortion pill contaminants and the amount of fetal remains entering our water systems.[5]

As it relates to the harm for women, like other pharmaceuticals known to cause adverse effects on our ecosystem,[6] mifepristone forms active metabolites.[7] These metabolites may retain the therapeutic effects[8] of mifepristone even after being excreted by humans and passing into wastewater treatment plants (WWTP), most of which are not designed to remove them.[9] Unfortunately, having passed through WWTP, some pharmaceuticals

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[4] Isaac Maddow-Zimet and Candace Gibson, "Despite Bans, Number of Abortions in the United States Increased in 2023," Guttmacher Institute, March 19, 2024; Last modified May 10, 2024, https://www.guttmacher.org/2024/03/despite-bans-number-abortions-united-states-increased-2023; Rachel K. Jones and Amy Friedrich-Karnik, "Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020," Guttmacher Institute, March 2024, https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020. See also, "Abortion pills by mail in every state," Plan-C, 2025, https://www.plancpills.org/.

[5] Lisa Bast, "Helpline founder sees spike in women 'seeing their fully formed babies' after abortion pill," Live Action, February 20, 2024, https://www.liveaction.org/news/national-helpline-calls-chemical-abortions/. See also: "I Saw My Baby," Live Action, accessed April 15, 2025, https://www.liveaction.org/i-saw-my-baby/, and "Aftercare Instructions: Medication Abortion," Comprehensive Women's Health Center, accessed April 7, 2025, https://cwhccolorado.com/services/medication-abortion/aftercare-medication-abortion/index.html.

[6] Maite Ortúzar, Maranda Esterhuizen, Darío Rafael Olicón-Hernández, Jesús González-López, Elisabet Aranda, "Pharmaceutical Pollution in Aquatic Environments: A Concise Review of Environmental Impacts and Bioremediation Systems," *Frontiers in Microbiology,* April 26, 2022, https://pmc.ncbi.nlm.nih.gov/articles/PMC9087044/.

[7] Blake M. Autry and Roopma Wadhwa, "Mifepristone," National Library of Medicine, February 28, 2024, https://www.ncbi.nlm.nih.gov/books/NBK557612/.

[8] "Overview of Active Metabolites," Creative Proteomics, accessed April 8, 2025, https://www.creative-proteomics.com/resource/overview-of-active-metabolites.htm.

[9] "How Pharmaceuticals Enter the Environment," United States Environmental Protection Agency, Last modified February 11, 2025, https://www.epa.gov/household-medication-disposal/how-pharmaceuticals-enter-environment. The EPA specifically states, "[W]hile POTWs may remove some pharmaceuticals incidentally, many pass through and enter the environment because POTWs are not designed to remove pharmaceuticals. While some POTWs [Publicly Owned Treatment Works] may have

have been found in America's drinking water.[10] Given that research on mifepristone metabolites in our environment is lacking, their possible adverse effects on our ecosystem and on the humans who may be drinking them are unknown.

What we do know, however, is cause for concern: Mifepristone acts as an endocrine disruptor by blocking progesterone, a vital fertility hormone.[11] Relatedly, infertility rates are on the rise and now affect 1 in 6 individuals.[12] While there is a clear correlation between the increase in chemical abortions and increased rate of infertility, further study is sorely needed to establish whether there is causation.

Furthermore, according to one estimate, as much as "40+ tons of chemically-tainted medical waste—human tissue, placenta, and blood" (aborted babies and related byproducts) are flushed into our waterways.[13] Wastewater treatment plants should not be processing these human remains. Even so—they (ineffectively) end up serving in that capacity, in part because the myriad state laws that regulate the handling of human remains often—illogically—are not applied to aborted babies, *who are also humans*.[14] While a few states separately impose burial or cremation requirements for aborted children, "most states do not specifically regulate" aborted fetal remains disposal.[15] Though in states without such laws medical waste laws should still apply, these laws can

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implemented advanced treatment technologies, even these technologies are not specifically designed to remove pharmaceuticals." While referring to medications that are flushed and a couple other sources, the EPA also acknowledges that human excretion *is* a source of pharmaceuticals in the environment. See also the EPA's 2019 rule on pharmaceuticals, which acknowledges that "pharmaceuticals are thought to be primarily entering the environment through excretion," further noting "reducing intentional sewer disposal" will "help reduce the environmental loading of pharmaceuticals into our Nation's Waters." Environmental Protection Agency, "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine | Final rule," Federal Register, Vol. 84, No. 36, February 22, 2019, https://www.govinfo.gov/content/pkg/FR-2019-02-22/pdf/2019-01298.pdf.

[10] "Study Finds Drugs Seeping Into Drinking Water," National Public Radio, March 10, 2008, https://www.npr.org/2008/03/10/88062858/study-finds-drugs-seeping-into-drinking-water.

[11] Mayo Clinic Staff, "Medical Abortion," Mayo Clinic, June 28, 2024, https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687; "Progesterone," You and Your Hormones, March 2021, https://www.yourhormones.info/hormones/progesterone/.

[12] "1 in 6 people globally affected by infertility: WHO," World Health Organization, April 4, 2023, https://www.who.int/news/item/04-04-2023-1-in-6-people-globally-affected-by-infertility.

[13] "Stop Chemical Abortion," This is Chemical Abortion, accessed May 20, 2025, https://thisischemicalabortion.com/. *NB: Estimating the amount of medical and pathological waste generated is complicated as it relies on a variety of factors; for example, the number of chemical abortions performed annually, which is likely much higher than reported, and estimates of fetal and placenta mass in the first trimester, which vary widely.*

[14] Moreover, laws governing human remains vary widely; see: "Rights and Obligations As To Human Remains and Burial," Stimmel, Stimmel & Roeser, accessed June 4, 2024, https://www.stimmel-law.com/en/articles/rights-and-obligations-human-remains-and-burial. The reality that numerous separate laws exist in several states to govern the disposal of fetal remains from both abortions and miscarriages/stillbirths suggest general laws on human remains tend not to apply to aborted or miscarried children. For example, see: "Information on Miscarriage and Stillbirth by State," Heaven's Gain Ministries, June 1, 2023, https://heavensgain.org/state-laws/ and "Fetal Burial Requirements," *Law Atlas,* November 1, 2022, https://lawatlas.org/datasets/fetal-burial-requirements.

[15] "Fetal Burial Requirements," *Law Atlas* . . .

lack proper enforcement, as is the case in Florida where chemical abortion providers appear to disregard medical waste disposal laws. In other words, abortion providers issuing chemical abortion pills have been able to use wastewater treatment plants as their de-facto medical waste facilities for decades. Numerous babies have been found in wastewater treatment plants.[16]

Urgent "Gold-Standard" Action Required

Both the dramatic increase in chemical abortions and lack of humane fetal disposition laws requires action. To the first point, further study is needed to understand the impact the abortion pill—unique to all other pharmaceuticals, given its lethal nature and the fact that it generates "medical waste"—has on our water supply. Notably, such action aligns with the priorities of the current administration: In addition to desiring "crystal clean water," in May 2025 President Trump signed an executive order restoring "Gold Standard Science"—that is, science that is "subject to unbiased peer review," among other things.[17] Said order seeks to ensure all federal agencies adhere to the principles outlined in the order "in the conduct and management of their respective scientific activities."[18] A report released by the Make America Healthy Again Commission in the same month likewise emphatically declared that the "government is committed to fostering radical transparency and **gold-standard science** to better understand the potential cumulative impacts of environmental exposures."[19]

As one such "environmental exposure," mifepristone is in dire need of "gold-standard" scientific research. Indeed, this was outlined by Representative Josh Brecheen and (former) Senator Marco Rubio, alongside other members of Congress, in a letter to the former administrator of the EPA:

> *The full impact of mifepristone has never been sufficiently studied. When the FDA approved the drug in 2000, it relied on a 1996 environmental assessment that*

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[16] There are numerous examples of wastewater treatment plants discovering babies in their systems; for example, in a South Carolina wastewater treatment plant two babies were recovered from the wastewater; authorities said, "it's impossible to tell how long they were in the water." See also: "2 fetuses found at wastewater treatment plant," The Associated Press, August 16, 2016, https://apnews.com/article/16fb077a579d483da1343bd547bb9f33; "Fetus found in sewage at wastewater plant," The Associated Press, May 31, 2022, https://apnews.com/article/mississippi-wastewater-natchez-8021c8d89b77a8f82716ec3b2d8b78e1; Bonnie Campo, "Fetus Found By Deer Creek Waste Water Treatment Facility Workers," March 16, 2018, https://www.newson6.com/story/5e3490e2527dcf49dad7d914/fetus-found-by-deer-creek-waste-water-treatment-facility-workers; Jessica Schmidt, "Human fetus discovered inside Cincinnati wastewater treatment plant," Fox19 Now, February 14, 2017, https://www.fox19.com/story/34495350/human-fetus-discovered-inside-cincinnati-wastewater-treatment-plant/.

[17] "Restoring Gold Standard Science," The White House Executive Orders, May 23, 2025, https://www.whitehouse.gov/presidential-actions/2025/05/restoring-gold-standard-science/.

[18] Ibid.

[19] "The MAHA Report | Make Our Children Healthy Again Assessment," The White House, accessed May 23, 2025, https://www.whitehouse.gov/wp-content/uploads/2025/05/WH-The-MAHA-Report-Assessment.pdf.

> *failed to consider that human fetal remains and the drug's active metabolites would be making their way into wastewater systems across the U.S. Any studies that have been conducted in the past should be repeated and updated to reflect the fact that the drug is far more prevalent today than it was three decades ago. In addition, the EPA should study the impact of the "byproducts" of mifepristone, such as the placental tissue, fetal remains, and active metabolites that are being flushed into our nation's wastewater system.*[20]

Liberty Counsel Action agrees that not only is further study needed, so also is dignified disposition of human remains. Specifically, Congress should hold hearings and require updated research on our oceans, lakes, and rivers, seeking concrete information on whether and how chemical abortion pills and related byproducts (developing skulls, placentas, other fetal remains, etc.) are impacting the environment, particularly to determine whether they are adversely affecting human and animal health and vitality via possible emerging diseases or anomalies (or have the potential to). Similarly, the EPA should require testing and monitoring of our water supply for the presence of mifepristone metabolites, similar to how it does for "forever chemicals."[21]

Related, at a minimum, fetal disposition laws at the state and national level should be updated to ensure all deceased unborn children, whether as a result of miscarriage or elective abortion, have the opportunity to receive dignified disposition via interment (burial), cremation, or otherwise. For miscarried children, this would require ensuring parents are provided with and informed of their options, which is currently only explicitly required in certain states.[22] It would also require new protocols for chemical abortion, either establishing that they can only be performed in a clinic (preferable); or, if at-

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[20] U.S. Senator Marco Rubio and Representative Josh Brecheen, et. al., "Members of Congress to the Honorable Michael Regan, Administrator, U.S. Environmental Protection Agency," May 29, 2024, https://static.foxnews.com/foxnews.com/content/uploads/2024/05/05.29.24-Rubio-Brecheen-et-al-Letter-to-EPA-re-Mifepristones-Effect-on-Environemnet.pdf.

[21] Michael Phillis, "Why is the EPA regulating PFAS and what are these 'forever chemicals'?" Associated Press, April 10, 2024, https://apnews.com/article/forever-chemicals-pfas-pollution-epa-drinking-water-517ce0049ffbd2931157da4970992f05.

[22] "Information on Miscarriage and Stillbirth by State," Heaven's Gain Ministries, June 1, 2023, https://heavensgain.org/state-laws/; "Parental rights after a miscarriage or stillbirth," Heritage Defense, October 23, 2024, https://heritagedefense.org/parental-rights-after-a-miscarriage-or-stillbirth/. Note: Many expectant moms suffering the loss of their baby will go to the hospital, and even for those who do not, not all will willingly flush their baby down the toilet. To be clear, Liberty Counsel Action specifically promotes information on options for fetal disposition after a miscarriage be provided to those families who seek medical care and wish to receive said information; however, there should be no requirements imposed (e.g. issuing "mis-kits"), given such an event is unplanned. Conversely, as an abortion is planned, it would be possible to require "catch kits;" indeed, it is irresponsible not to, given the harmful impact aborted babies may have on our water supply. See: Patrick Adams, "Many ERs offer minimal care for miscarriage. One group wants that to change," NPR, January 4, 2023, https://www.npr.org/sections/health-shots/2023/01/04/1146801914/many-ers-offer-minimal-care-for-miscarriage-one-group-wants-that-to-change. See also: "After a miscarriage," Miscarriage Association, accessed May 6, 2025, https://www.miscarriageassociation.org.uk/information/miscarriage/after-a-miscarriage/.

home abortions continue, ensuring abortion providers issue a "catch kit" and red medical waste bag to women (as proposed by Students for Life of America [SFLA][23]) so they can collect the fetal remains of their pregnancy for proper disposal.

Addressing this issue should unite all Americans. Clean drinking water and human dignity should not be controversial.

Background

Lack of Proper Regulatory Structure

Across the United States, women are being shipped the abortion pill drugs—mifepristone and misoprostol—to induce abortions at home. These pills and the mail-order process by which women obtain them are the subject of one of the greatest controversies in modern U.S. politics, given the danger these drugs pose to women and the fact that shipping abortion pills through the mail violates federal law.[24] Even so, this access to the pills continues, and women performing "at-home" abortions are left to dispose of their aborted child's remains on their own—unless they are rushed to the emergency room because they are unable to expel the pregnancy.[25] Those remaining at home often flush their baby down the toilet—and often, it is only then that they come face to face with the harsh reality that abortion ends a human life.[26]

On its face, this undignified disposition of fetal remains runs afoul of various state and federal fetal disposal and medical waste regulations. While some states require fetal remains to be disposed of similar to other human remains (interment or cremation), at the least, aborted babies fall into the category of "medical waste"[27],[28] (itself a vague term

[23] Kristan Hawkins, Kristi Hamrick, et. al., "Citizen Petition (to the Food and Drug Administration)," November 15, 2022, https://thisischemicalabortion.com/wp-content/uploads/2023/02/FDA-2022-P-2872-0001_attachment_1.pdf.
[24] Brianna Herlihy, "19 state AGs warn Costco, Kroger, other retailers against mailing abortion pills to customers," Fox Business, February 27, 2023, https://www.foxbusiness.com/politics/state-ags-warn-costco-kroger-retailers-mailing-abortion-pills-customers; see also Mabel Felix, Laurie Sobel, and Alina Salganicoff, "The Comstock Act: Implications for Abortion Care Nationwide," KFF, April 15, 2024, https://www.kff.org/womens-health-policy/issue-brief/the-comstock-act-implications-for-abortion-care-nationwide/.
[25] **"**Public Health Threat: Chemical Abortion Leads to Significantly Higher Rate of ER Visits," Charlotte Lozier Institute, November 16, 2021, https://lozierinstitute.org/public-health-threat-chemical-abortion-leads-to-significantly-higher-rate-of-er-visits/.
[26] "Aftercare Instructions: Medication Abortion," Comprehensive Women's Health Center …
[27] "Infection Control, Regulated Medical Waste," CDC, 2003, https://www.cdc.gov/infection-control/hcp/environmental-control/regulated-medical-waste.html. Among other things, the CDC states, "Precisely defining medical waste on the basis of quantity and type of etiologic agents present is virtually impossible."
[28] Catherine Glenn Foster, "Abortionists' Disposal of Fetal Remains," Americans United For Life, July 18, 2022, https://aul.org/2022/07/18/aborted-fetus-used-for-energy/.

with no uniform definition).[29] And, while numerous federal agencies have some limited regulatory authority over medical waste today, the primary level of regulation for medical waste remains with the states.[30] For babies aborted in clinics, providers tend to dispose of them as medical waste, even at times via "waste-to-energy" initiatives, which incinerate them alongside other "infectious/biomedical waste and non-hazardous pharmaceuticals" for conversion into energy.[31] Again, while there are a few state laws requiring aborted children be interred or cremated,[32] the vast majority are subject to the indifferent, callous attitude of the industry that took these lives.

In this patchwork regulatory context (limited fetal disposition laws and allowing mail-order access to the abortion pill), it seems the abortion industry has essentially been given a free pass to not only traumatize women but also to contaminate (pollute, poison) our water with chemically aborted fetal remains.

Increasing Use of the Abortion Pill Amidst Decreasing Health and Safety Standards

What the Pill Does & Increased Usage Over Time

Most surgical abortions in a clinical setting use a fatal injection and/or dismemberment[33] to end the baby's life. In contrast, with a chemical abortion, the deadly drugs mifepristone and misoprostol work separately or together to end the baby's life and expel him or her from the mother's womb, often in the mother's home. The first set of pills, mifepristone (originally approved as Mifeprex/RU-486), blocks progesterone.[34] Without this essential hormone, the woman's uterine lining will loosen and shed, causing the baby to detach and starve to death.[35] If this does not cause a complete abortion, the second drug, misoprostol, can be taken 24-48 hours later, essentially inducing labor and

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[29] Elizabeth Kimball Key, "The Forced Choice of Dignified Disposal: Government Mandate of Interment or Cremation of Fetal Remains," University of California, 2017, https://lawreview.law.ucdavis.edu/sites/g/files/dgvnsk15026/files/media/documents/51-1_Key.pdf.
[30] Elizabeth Kimball Key, "The Forced Choice of Dignified Disposal…" See also: "Medical Waste," United States Environmental Protection Agency, May 5, 2025, https://www.epa.gov/rcra/medical-waste.
[31] Catherine Glenn Foster, "Abortionists' Disposal of Fetal Remains…"
[32] Kristi Burton Brown, "Fetal Disposition: The Abuses and The Law," The Charlotte Lozier Institute, December 2016, https://lozierinstitute.org/wp-content/uploads/2016/12/ARS_FetalDisposition_final.pdf. Of note, the article outlines, "a basic examination will show that fetal disposal laws are not universally predictable across the nation, and need individual evaluation." See also: Catherine Glenn Foster, "Abortionists' Disposal of Fetal Remains…"
[33] "Fact Sheet: Dismemberment Abortion," Charlotte Lozier Institute, January 28, 2025, https://lozierinstitute.org/fact-sheet-dismemberment-abortion/.
[34] Mayo Clinic Staff, "Medical Abortion," Mayo Clinic, June 28, 2024, https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687; "Progesterone," You and Your Hormones, March 2021, https://www.yourhormones.info/hormones/progesterone/.
[35] Ibid.

forcing the woman's body to expel her deceased child.[36] (Of note, though, Planned Parenthood instructs women they can have an abortion without the use of mifepristone.[37])

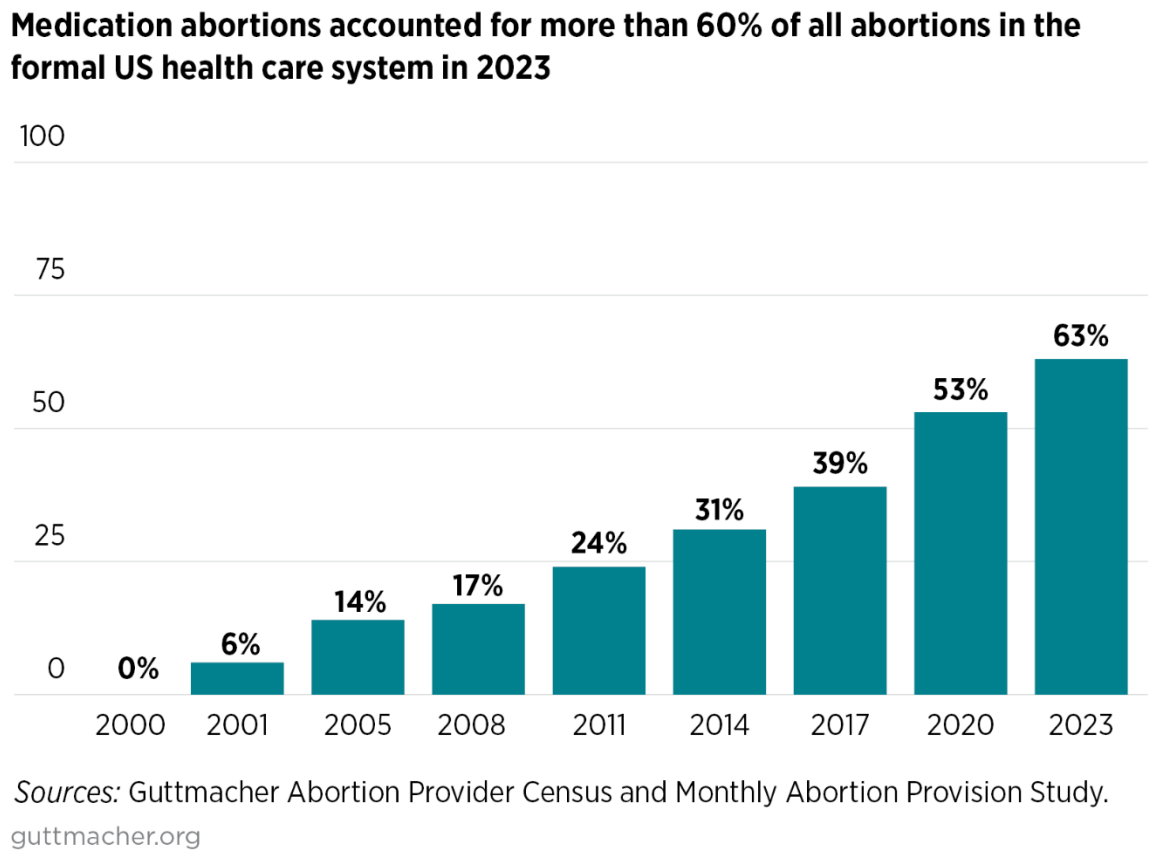

Figure 1; Rachel K. Jones and Amy Friedrich-Karnik, "Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020," Guttmacher Institute, March 2024, https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.

Historically, surgical abortions were responsible for most abortion deaths. Over time, however, chemical abortions—that is, those utilizing the abortion drugs mifepristone and misoprostol—have grown such that they now account for the majority of abortions: In 2001, chemical abortions were responsible for 6% of all abortions; in 2008, 17%; in 2014, 31%; in 2017, 39%,[38] and in 2022, the CDC reported that a majority (58%) of reported abortions were chemical abortions (though the percentage is likely higher given

[36] Ibid.; see also: Kirstie Piper, "The Abortion Pill: How Does it Work?," Focus on the Family, November 22, 2024, https://www.focusonthefamily.com/pro-life/abortion/the-abortion-pill-how-does-it-work/.
[37] "How do I have an abortion using only misoprostol?" Planned Parenthood, accessed April 7, 2025, https://www.plannedparenthood.org/learn/abortion/the-abortion-pill/how-do-i-have-an-abortion-using-only-misoprostol.
[38] Ingrid Skop, "The 'No-Test Medication Abortion' Protocol: Experimenting with Women's Health," Charlotte Lozier Institute, July 30, 2020, https://lozierinstitute.org/the-no-test-medication-abortion-protocol-experimenting-with-womens-health/#_edn21.

certain jurisdictions do not report to the CDC).[39] As highlighted above, this (the majority of abortions being non-surgical) remained the case in 2023, with 63% of all abortions performed with pills.[40] Furthermore, it seems likely this rise will continue, given "chemical abortion's lucrative nature, the dwindling numbers of physicians willing to carry out surgical abortions, the closure of many financially precarious abortion facilities, and the rise of laws placing restrictions on surgical abortions."[41] Consider as well in Europe that three-quarters of abortions are performed via the pill; in Finland and Sweden, almost all abortions are chemical abortions.[42]

Original Approval Followed by Dangerous Deregulation

Mifepristone was first approved by the FDA in 2000, at which time semi-strict protocols were outlined for its use. Specifically, the New Drug Application (NDA) for Mifeprex proposed that the administration of the drug would be three tablets taken orally; then, if the termination did not occur (since termination can happen with mifepristone only),[43] the patient would take a single oral dose of misoprostol two days post-Mifeprex ingestion.[44] In 2000, it was approved "for use as recommend[ed] in the agreed upon labelling text,"[45] with the caveat that it must be administered by a physician.[46] While three in-person visits were required, given that a woman was allowed to go home after being administered the first pill and then required to return on day three for a second pill that could complete the abortion *if it was not already complete,* by implication, some

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[39] Centers for Disease Control and Prevention, "Abortion Surveillance—United States, 2022," *Morbidity and Mortality Weekly Report,* Vol. 73, No. 7, November 28, 2024, https://www.cdc.gov/mmwr/volumes/73/ss/pdfs/ss7307a1-H.pdf. In addition to the fact that some jurisdictions do not report abortion data to the CDC, women can now obtain abortion pills via the mail from (at times illegal) providers online, which would also increase the overall percentage of chemical abortions (verses surgical abortions).

[40] Rachel K. Jones and Amy Friedrich-Karnik, "Medication Abortion Accounted for 63% of All US Abortions in 2023 …"

[41] Ingrid Skop, "The 'No-Test Medication Abortion' Protocol: Experimenting with Women's Health …"

[42] Claire Cain Miller and Margot Sanger-Katz, "What Is Mifepristone and How Is It Used?" The New York Times, June 13, 2024, https://www.nytimes.com/2024/06/13/us/politics/what-is-mifepristone.html; "Nine out of 10 abortions done before 12 weeks in many high-income countries," BMJ Group, May 9, 2019, https://bmjgroup.com/nine-out-of-10-abortions-done-before-12-weeks-in-many-high-income-countries/.

[43] Center for Drug Evaluation and Research, "Medical Review(s)," November 22, 1999, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf.

[44] "Center for Drug Evaluation and Research, "Clinical Pharmacology and Biopharmaceutics Review(s)," July 8, 1996, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_clinphrmr_P1.pdf.

[45] The text states "Patients taking Mifeprex must take 400 µg of misoprostol two days after taking mifepristone **unless a complete abortion has already been confirmed before that time** (see DOSAGE AND ADMINISTRATION). After being provided the second pill, she is given a phone number to call if she has questions, again implying she would not remain in the clinic." See: MIFEPREX™ (mifepristone) Tablets, 200 mg For Oral Administration Only," accessed May 8, 2025, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

[46] Center for Drug Evaluation and Research, Letter to the Population Council, September 28, 2000, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf.

abortions would already have been completed. In other words, women were permitted to be at home (or anywhere else) when the pregnancy was expelled (for further details, see Appendix I below, "FDA abortion pill approvals disregard the FDA's own safety protocols and standards").

Most notably, during the original approval process for Mifeprex (the brand-name abortion pill originally used for chemical abortions, now in competition with its generic counterpart, mifepristone[47]), the FDA failed to adequately complete the legally required environmental assessment. Likewise, the EPA appears to have overlooked its ability to pressure the FDA to act, per its role to enforce "environmental protection standards consistent with national environmental goals."[48]

Eleven years later, the FDA approved and implemented a Risk Evaluation and Mitigation Strategy (REMS), a safety plan "designed to minimize complications" and "applied to medications that have a known or potential serious risk associated with them."[49] Eventually, this "Mitigation Strategy" was weakened to the degree that it essentially became superfluous. Under the Biden administration during the COVID-19 pandemic in 2021, the FDA stopped enforcing the requirement that women be seen in person prior to obtaining the abortion pill, ushering in mail-order abortion.[50] (A few months later, they announced the change allowing at-home abortion would be permanent, though it was not officially reflected in the mifepristone REMS until 2023.[51]) Ironically, just two years prior to the initial change in 2021, the FDA had "issued warning letters to two companies illegally distributing mifepristone online, Aid Access and Rablon. Because of safety concerns, the FDA warned the companies were in violation of the Federal Food, Drug, and Cosmetic Act by 'introducing into interstate commerce misbranded and unapproved new drugs' and requested a response within 15 days."[52]

After the 2021 approval removing safety measures, a lawsuit was brought forward seeking to challenge the FDA's decision to remove "commonsense safety standards for

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[47] "Abortion Drug Facts," Charlotte Lozier Institute, accessed April 7, 2025, https://lozierinstitute.org/abortion-drug-facts/#federal-action.

[48] Office of the Law Revision Counsel, 42 U.S.C. §4321, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim. See also §4332, which states all federal agencies "identify and develop methods and procedures, in consultation with the Council on Environmental Quality established by subchapter II of this chapter, which will ensure that presently unquantified environmental amenities and values may be given appropriate consideration in decisionmaking along with economic and technical considerations." Clearly this is an "environmental protection standard" the EPA would have authority to enforce, and which would have required the FDA to consider the "unquantified value" of an environment free from fetal remains.

[49] Ingrid Skop, "The 'No-Test Medication Abortion' Protocol: Experimenting with Women's Health . . ."

[50] "The Availability and Use of Medication Abortion," KFF, March 20, 2024. Last modified March 10, 2025, https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/.

[51] "Abortion Drug Facts," Charlotte Lozier Institute ...

[52] Ibid.

abortion drugs."[53] For example, a press release on the case highlights "that the FDA's own label says that roughly one in 25 women who take chemical abortion drugs will end up in the emergency room."[54] Also of note as it pertains to women's health and safety, a recent study on serious adverse events found that "[t]he real-world rate" of said events post-use of mifepristone for abortion "is at least 22 times as high as the summary figure of less than 0.5 percent in clinical trials reported on the drug label."[55]

Loosening safety protocols to allow home abortions (among other things) by nature leads to an increase in home abortions, which, in turn, increases the amount of human fetal tissues and abortion pill contaminants entering our waterways. This increased contamination should have triggered further environmental review; yet, as it did in the first instance, the FDA failed to consider the environmental impact of the decision to ease access to these pills. Apart from the risks that eased access poses to women, this also poses a significant risk to the environment, given traditional wastewater treatment plants are not designed to process these contaminants (for more on this, see section 3).

Thankfully, the recently appointed Secretary of Health and Human Services, Robert F. Kennedy (an environmental attorney), "pledged during his confirmation hearing . . . to investigate the safety of abortion pills."[56] Likewise, the EPA, FDA, and Congress should also act, not only to promote human dignity but also to mitigate the possible harmful effects chemical abortion pills and fetal remains have on our water supply (see Recommendations section).

Why Current Policy Is Problematic: The FDA's Flawed Environmental Review Process

The FDA's abortion pill approval process skirted the law as well as (during later updated approvals) numerous of its own health and safety protocols. Research highlighting the

[53] "FDA Avoids Accountability After Supreme Court Ruling," Alliance Defending Freedom, November 18, 2022. Last modified June 24, 2024, https://adflegal.org/article/fda-avoids-accountability-after-supreme-court-ruling/; For details on the FDA's lawless actions see: "Alliance for Hippocratic Medicine et. al., v. the U.S. Food and Drug Administration, et. al.," Complaint, November 18, 2022, https://adflegal.org/wp-content/uploads/2022/11/Alliance-for-Hippocratic-Medicine-v-FDA-2022-11-18-Complaint.pdf.
[54] "FDA's recklessness continues for now," Alliance Defending Freedom, June 13, 2024, https://adflegal.org/press-release/fdas-recklessness-continues-now/.
[55] Jamie Bryan Hall and Ryan T. Anderson, "The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event," Ethics & Public Policy Center, April 28, 2025, https://eppc.org/stop-harming-women/.
[56] Ariel Wittenberg and Alice Miranda Ollstein, "'Using the devil's own tools against them': Abortion opponents turn to environmental laws," Politico, January 30, 2025, https://www.politico.com/news/2025/01/30/abortion-opponents-environmental-laws-00201423.

legal and health flaws in said approval process abounds.[57] The following will therefore focus on the approval process as it relates to the nation's water supply.

1. Relevant Laws: The Clean Water Act, National Environmental Protection Act, and State Laws on Clean Water & Fetal Disposal

While the FDA may argue that it followed the law as it pertains to environmental assessments (in 2000, it contests the 1996 Environmental Assessment provided by those seeking the drug's approval was adequate, and in 2019, it argues it was not required based on a categorical exclusion[58]), there is evidence to suggest that the FDA, in fact, overlooked (and likely violated) the laws outlined below. Such negligent action would justify an immediate pause in the use of the abortion pill, especially for home use, until a proper environmental analysis can be completed.

A. The Clean Water Act (CWA): The FDA's Failure to Consider State & Local Medical Waste and Water Quality Laws

The CWA states, "It is the policy of the Congress to recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution, to plan the development and use (including restoration, preservation, and enhancement) of land and water resources, and to consult with the Administrator in the exercise of his authority under this chapter."[59] Going on, it underscores that federal agencies are required to abide by state and local laws pertaining to water quality:

> *Each department,* ***agency,*** [e.g., the FDA] *or instrumentality of the executive, legislative, and judicial branches of the Federal Government . . . engaged in any activity* [e.g., drug approvals] *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 including the payment of reasonable service charges.* ***The preceding sentence shall apply (A) to any requirement whether substantive or procedural*** *(including any recordkeeping or reporting requirement, any requirement respecting permits and any other*

[57] See, for example, Alliance for Hippocratic Medicine et. al., v. the U.S. Food and Drug Administration, et. al., Complaint . . .
[58] Patrizia A. Cavazzoni, "U.S. Food and Drug Administration to Kristan Hawkins, President and Kristi Hamrick, Chief Media & Policy Strategist, Students for Life of America,". . .
[59] "Clean Water Act Section 401: Overview and Recent Developments," Congress.gov, February 7, 2025, https://www.congress.gov/crs-product/R46615. See also: Office of the Law Revision Counsel, 33 U.S.C. §1251, accessed April 16, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim.

requirement, whatsoever), (B) to the exercise of any Federal, State, or local administrative authority, and (C) ***to any process and sanction, whether enforced in Federal, State, or local courts or in any other manner.***

Various legal cases uphold the interpretation that agencies issuing licenses or permits fall under this statute.[60]

Furthermore, based on the above text from the CWA, the FDA should have considered that its action to approve mifepristone would result in the generation of "medical waste" as defined by the CWA, which, if disposed of improperly, can result "in the discharge . . . of pollutants."[61] Excretion of active mifepristone metabolites[62] likewise may result in pollution.

Specifically, according to the following relevant definitions under the CWA:

- "Pollutant" is defined as "dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, **chemical wastes, biological materials** . . . discharged into water." [63] Fetal remains are biological materials that may be discharged into the water as a result of chemical abortion. Mifepristone metabolites are chemical wastes that may be discharged into the water as a result of chemical abortion.
- "Pollution" is defined as "man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water."[64] Placing fetal remains in the water supply (via the toilet) and excreting active mifepristone metabolites could alter the biological integrity of the water,[65] constituting pollution.
- "Medical waste" includes (among other things) "infectious agents; **human blood and blood products; pathological wastes" and "body parts"** [66] (emphasis added).

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[60] Kristan Hawkins, Tina Whittington, and Kristi Hamrick, "Citizen Petition (to the Food and Drug Administration)," December 18, 2024, https://thisischemicalabortion.com/wp-content/uploads/2024/12/Citizen-Petition-5.pdf.

[61] Office of the Law Revision Counsel, 33 U.S.C. § 1323(a), accessed May 30, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim

[62] Metabolites are formed after a drug is broken down in the body; if they have "therapeutic effects," they are known as active metabolites. Mifepristone forms active metabolites; see section 4 for details. Also see: "Overview of Active Metabolites," Creative Proteomics, accessed April 8, 2025, https://www.creative-proteomics.com/resource/overview-of-active-metabolites.htm.

[63] Office of the Law Revision Counsel, 33 U.S.C. § 1362(6), accessed May 30, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim

[64] Office of the Law Revision Counsel, 33 U.S.C. §1362(19), accessed May 30, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim.

[65] Defined by the EPA as "the condition of the aquatic community inhabiting unimpaired waterbodies of a specified habitat as measured by community structure and function." See: United State Environmental Protect Agency, "Biological Criteria,"1990, https://www.epa.gov/sites/default/files/2018-10/documents/national-program-guidance-surface_waters.pdf.

[66] Office of the Law Revision Counsel, 33 U.S.C. §1362(20), accessed May 30, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim.

According to this language, fetal remains would (at the least) be considered medical waste.

Based on these definitions, disposal of fetal remains and excretion of mifepristone metabolites into our waterways (via the sewer system) may constitute pollution; hence all state and local laws related to water quality should have been considered. They were not.

Finally, the CWA also established the National Pollutant Discharge Elimination System (NPDES). Specifically, an NPDES permit is required for anyone discharging "pollutants" via a "point source."[67] Said permit contains limits on what one may discharge, as well as "monitoring and reporting requirements, and other provisions to ensure that the discharge does not hurt water quality or people's health."[68] The permits may be issued by both the Environmental Protection Agency (EPA) and states (those "with authorized NPDES programs").[69] This is relevant given the EPA could require wastewater treatment plants to monitor mifepristone metabolites present in the water as a condition of their permit (detailed in the Recommendations section).

The FDA's Acceptance of a 1996 Environmental Analysis by the Population Council Violated the CWA

In response to a citizen's petition filed by SFLA, the FDA outlines the following:

- In 1996, an Environmental Assessment (EA) for mifepristone (Mifeprex® or RU-486) was submitted to the FDA by the Population Council as part of the application for the drug's overall approval. According to said assessment, "[t]he product can be manufactured, used and disposed of without any expected adverse environmental effects."[70]
- Based on the EA, the FDA issued a "finding of no significant impact" (FONSI) rather than requiring further environmental analysis (via an Environmental Impact

[67] "National Pollutant Discharge Elimination System (NPDES)," United States Environmental Protection Agency, January 10, 2025, https://www.epa.gov/npdes/npdes-program-management-and-oversight.
[68] Ibid.
[69] Ibid. See also: Office of the Law Revision Counsel, 33 U.S.C. §1251, accessed April 16, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim, which defines "pollutant" as "dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water."
[70] Food and Drug Administration Center for Drug Evaluation and Research, "Environmental Assessment and Finding of No Significant Impact for NDA 20-687—Mifepristone Tablets . . ."

Statement [EIS]).[71] More specifically, they "determined that there would be no significant effects on the quality of the human environment," and "there was no information that indicated that extraordinary circumstances existed that would warrant the submission of additional environmental information,"[72] though there are clearly extraordinary circumstances, as this was the first time a pill was introduced with the intention of forcing a woman to expel the contents of her uterus (see below for further information).

The FDA should never have issued a FONSI.[73] By failing to consider the "extraordinary circumstance" of fetal remains being expelled and therefore needing to be properly disposed of (at the very least a gross oversight if not negligence), the FDA failed to ensure that "biological pollution" would be prevented and that all state laws related to medical waste disposal would be adhered to (detailed in section 5).

In addition to its oversight of medical waste laws, as per SFLA, 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"[74] (emphasis added).

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[71] Patrizia A. Cavazzoni, "U.S. Food and Drug Administration to Kristan Hawkins, President and Kristi Hamrick, Chief Media & Policy Strategist, Students for Life of America," Letter, January 15, 2025, https://downloads.regulations.gov/FDA-2023-P-1528-0005/attachment_1.pdf. NB: This letter clarifies a FONSI is "a determination by a Federal agency that a proposed agency action does not require the issuance of an environmental impact statement."

[72] Ibid.

[73] NEPA also suggests that the FDA should not have issued a FONSI; see point B.

[74] Note: The FDA did, however, make conservative estimates of the amount of mifepristone that could be leaving a WWTP; specifically the estimates assumed, "every molecule of the pharmaceutical produced enters the WWTP in influent (water entering the treatment plant) without being metabolized by the patient, is discharged in effluent without being degraded or removed, and is not diluted upon release into the receiving water." They further stated, "the Material Safety Data Sheet in the 1996 EA noted that mifepristone is "[b]iodegradable in natural media," and ". . . mifepristone is not *expected* to accumulate in the environment because it will break down through the action of microorganisms" (emphasis added). See: Patrizia A. Cavazzoni, "U.S. Food and Drug Administration to Kristan Hawkins, President and Kristi Hamrick, Chief Media & Policy Strategist, Students for Life of America," Letter, January 15, 2025, https://downloads.regulations.gov/FDA-2023-P-1528-0005/attachment_1.pdf. However, according to the Compound Summary for mifepristone published by PubChem, "Biodegradation data were not available. If released into water, mifepristone is expected to adsorb to suspended solids and sediment based upon the estimated Koc. An estimated BCF of 2,800 suggests potential for bioconcentration in aquatic organisms is very high." See: National Center for Biotechnology Information, "PubChem Compound Summary for CID 55245, Mifepristone," *PubChem,* Retrieved June 2, 2025 from https://pubchem.ncbi.nlm.nih.gov/compound/Mifepristone. Likewise, a study on mifepristone in the environment specifically highlights that "In an aerobic biodegradation study (28 days) in water Mifepristone was not considered as readily biodegradable." See: Nordic Drugs, "Mifepristone Linepharma," *Environmental impact Mifepristone,* accessed June 2, 2025, https://www.fass.se/LIF/product?userType=0&nplId=19920904000068&docType=78 (NB: To translate text from Swedish to English, use Google translate) https://www.fass.se/LIF/product?-1.-documentTabPanel-tabs-panel-article~tools~bottom-articletools-printbiglink&userType=0&nplId=20100302000013&docType=78. Furthermore, expectations are not

On this point, it is important to note that mifepristone may enter our waterways via excretion[75] or women disposing of unwanted or leftover pills down the toilet. The FDA failed to ensure these potential forms of pollution would not violate state laws on water quality.[76] In response to this specific critique, the FDA states:

- "Excretion by patients is addressed in section 6.e.i 'Expected Introduction Concentration from Use,'" [EIC] of the 1996 EA, which notes expected concentration from use is less than 1 part per billion (ppb).[77]
- Adding to this point, the FDA outlines:

> *The 1995 and 1998 EA Guidances recommend a default calculation to use for estimating the EIC of pharmaceuticals at the point of entry into the aquatic environment when information is unavailable regarding metabolism and environmental depletion mechanisms that occur in the wastewater treatment process. This default calculation is scientifically appropriate to use for purposes of determining whether the 1 ppb categorical exclusion would apply. The 1995 and 1998 EA Guidances recommend that the default calculation be made using certain assumptions to provide for a conservative estimate. As such, factors such as the metabolism of the drug by the human body, the anticipated dilution of the drug, and the ability of WWTP to remove pharmaceuticals from wastewater generally are not considered when calculating the estimated EIC of a pharmaceutical at its entry into the environment.*

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always the same as the reality, and as noted by the Minnesota Department of Health in relation to different drugs (synthetic estrogens), although one (EE2) "*can* degrade in the environment, *there is a constant replenishment from wastewater treatment plants*" (emphasis added); given they have been detected in drinking water sources and may be present in drinking water, there is a risk of harmful health impacts. See: "17α-Ethinylestradioland Mestranol and Drinking Water," Minnesota Department of Health, September 2016, https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/mestraethinyleinfo.pdf. Finally, another study on the wider matter of endocrine disrupting chemicals (EDCs; mifepristone can be classified as an endocrine disruptor) found "many EDCs are not degraded enough by the available microorganisms [to remove them from the water]," so "biodegradation must be associated with other methods . . . to improve removal percentages." Concetta Pironti, Maria Ricciardi, Antonio Proto, Pietro Massimiliano Bianco, Luigi Montano, Oriana Motta, "Endocrine-Disrupting Compounds: An Overview on Their Occurrence in the Aquatic Environment and Human Exposure," *Water,* May 2021, https://www.mdpi.com/2073-4441/13/10/1347.

[75] Excretion of active drug metabolites after human use could have an impact on the environment; see section 4 for further details.

[76] Kristan Hawkins, Tina Whittington, and Kristi Hamrick, "Citizen Petition (to the Food and Drug Administration)," December 18, 2024, https://thisischemicalabortion.com/wp-content/uploads/2024/12/Citizen-Petition-5.pdf.

[77] Patrizia A. Cavazzoni, "U.S. Food and Drug Administration to Kristan Hawkins, President and Kristi Hamrick, Chief Media & Policy Strategist, Students for Life of America,". . .

The EA itself further notes the calculations are small "even without consideration of metabolism," and based on the estimate—again, a concentration of less than 1 ppb—it seems no further study or testing was required.[78]

- Also, as per the FDA, "The assumptions underlying the 1996 EA are conservative because, among other reasons, they do not account for any treatment at a WWTP, which is designed to reduce or remove pollutants from wastewater."[79]

It should first be noted that while WWTP are designed to reduce *pollutants,* most are not designed to, nor do they, remove all *pharmaceutical* pollutants.[80] Furthermore, while one could argue the assumptions underlying the estimates made in the 1996 EA *may* have sufficed for the FDA's purposes in 2000 (they did not), even if that were the case, the FDA should have at least considered the various state laws on water quality, and it does not appear it did. Rather, the FDA states the EA was submitted "in accordance with CDER [Center for Drug Evaluation and Research] guidance,"[81] which "normally" relieves the applicant from providing information on "Environmental effects of released substances" (along with other further information) if the EIC is below a certain threshold.[82]

Arguably, guidance that allows the FDA to avoid complying with states' laws related to clean water, as is required by the CWA, should be considered invalid. For example, Missouri's law requires "prospective polluters to determine whether their pollution will 'impair the natural biological community.'"[83] Having not studied mifepristone's possible "environment effects," the FDA would have no way of knowing whether mifepristone would "impair the biological community." Furthermore, evidence today shows that even in trace amounts, contamination from pharmaceutical pollutants can be detrimental to wildlife,[84] suggesting even if it was not done originally, further study is more than warranted today (see section 4 for further details).

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[78] Food and Drug Administration Center for Drug Evaluation and Research, "Environmental Assessment and Finding of No Significant Impact for NDA 20-687—Mifepristone Tablets . . ."
[79] Patrizia A. Cavazzoni, "U.S. Food and Drug Administration to Kristan Hawkins, President and Kristi Hamrick, Chief Media & Policy Strategist, Students for Life of America,". . .
[80] "How Pharmaceuticals Enter the Environment," United States Environmental Protection Agency, Last modified February 11, 2025, https://www.epa.gov/household-medication-disposal/how-pharmaceuticals-enter-environment.
[81] Food and Drug Administration Center for Drug Evaluation and Research, "Environmental Assessment and Finding of No Significant Impact for NDA 20-687—Mifepristone Tablets . . ."
Specific guidance: "Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements (November 1995)."
[82] Ibid.
[83] Kristan Hawkins, Tina Whittington, and Kristi Hamrick, "Citizen Petition . . ." For examples of other state laws see section 1.(C) below and the section entitled "*Case Study: Florida*."
[84] Water Science School, "Pharmaceuticals in Water," U.S. Geological Survey, June 6, 2018, https://www.usgs.gov/special-topics/water-science-school/science/pharmaceuticals-water#overview.

B. National Environmental Policy Act (NEPA): The FDA's Failure to Consider Disposal of Aborted Fetal Remains

Congress' purpose in passing the National Environmental Policy Act (NEPA) included (among other things) "[t]o declare a national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man."[85] Alongside this statute, numerous federal regulations and guidance have been developed and periodically updated.

Arguably, several of the law's provisions, as well as provisions in said regulations and guidance were overlooked or blatantly violated by the FDA (and EPA) in the original approval of and subsequent expansions for use of mifepristone.

1. **Based on the plain meaning of the NEPA, the FDA should have given "appropriate consideration" to "unquantified environmental values" during its original approval of Mifeprex, 2019 ANDA approval for generic mifepristone, and the 2011, 2016, 2021 and 2023 approvals related to the REMS.**
   a. Section 4332 of the NEPA states:

> *To the fullest extent possible . . . the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in this chapter, and (2) "all agencies of the Federal Government shall—(A) utilize a systematic, interdisciplinary approach which will ensure the integrated use of the natural and* ***social sciences*** *and the environmental design arts in planning* ***and in decision making*** *which may have an impact on man's environment.* [86]

Use of "social sciences" in decision making should include consideration of humanity's relationship to and perception of their environment, which would be tainted by the notion that aborted babies are being disposed of into the sewer system and potentially making their way into the ecosystem.[87]

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[85] Office of the Law Revision Counsel, 42 U.S.C. §4321, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.
[86] Office of the Law Revision Counsel, 42 U.S.C. §4332, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.
[87] "What Can You Do to Protect Local Waterways?", Environmental Protection Agency, December 2002, https://www3.epa.gov/npdes/pubs/centralized_brochure.pdf; "Wastewater Technology Fact Sheet Screening and Grit Removal," United States Environmental Protection Agency, June 2003, https://www3.epa.gov/npdes/pubs/final_sgrit_removal.pdf; "How Wastewater Treatment Works… The Basics," United States Environmental Protection Agency, May 1998, https://www3.epa.gov/npdes/pubs/bastre.pdf.

b. According to the NEPA, agencies shall also *"identify and develop methods and procedures, in consultation with the Council on Environmental Quality established by subchapter II of this chapter, which will ensure that presently* ***unquantified environmental amenities and values may be given appropriate consideration in decision making*** *along with economic and technical considerations."*[88] Arguably in violation of this requirement, the FDA failed to consider the **unquantified value** of an environment free of fetal remains.

2. **Based on the plain meaning of the NEPA, the FDA failed to conduct a proper Environmental Assessment (EA) or Environmental Impact Statement (EIS), which is required for any "major federal action" unless an exclusion applies.**
   a. As outlined in section 4332 of the NEPA, ***"every*** *recommendation or report on proposals for legislation and other* ***major Federal actions significantly affecting the quality of the human environment,"*** is to include *"a detailed statement by the responsible official on—(i) reasonably foreseeable environmental effects of the proposed agency action"* and *"(ii) any reasonably foreseeable adverse environmental effects which cannot be avoided should the proposal be implemented,"* among other things.
   b. Section 4336 of the NEPA provides further clarity on the matter of environmental documents, stating:

> *An agency* [e.g., the FDA] *shall issue an environmental impact statement with respect to a proposed agency action* [e.g. a drug approval] *requiring an environmental document that has a* ***reasonably foreseeable significant effect on the quality of the human environment***.

If the significance of the effect of said action[89] is **unknown,** at the least, "*an agency shall prepare an environmental assessment,"* unless an exclusion applies (note, an environmental assessment is used to determine whether

[88] Office of the Law Revision Counsel, 42 U.S.C. §4332, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.

[89] Note: According to NEPA, "The term 'major Federal action' means an action that the agency carrying out such action determines is subject to substantial Federal control and responsibility." Ibid., §4336. By definition, the New Drug Application (NDA), as was used for the original application and 2000 approval for Mifeprex, supplemental New Drug Application (sNDA) and Abbreviated New Drug Application (ANDA), as was used in the 2016 REMS changes and 2019 generic mifepristone approval (respectively) as well as changes to the 2021 and 2023 REMS, are considered "major federal actions" that may impact the quality of the human environment, warranting at the least, a consideration of an EA.

to issue a Finding of No Significant Impact (FONSI) or require a further environmental analysis in an Environmental Impact Statement [90]).

c. According to the 1995 Code of Federal Regulations (CFR) (upon which original approval was based),[91] the human environment is to be interpreted as including:

> ***The natural and physical environment and the relationship of people with that environment*** *. . . This means that economic or social effects are not intended by themselves to require preparation of an environmental impact statement. When an environmental impact statement is prepared and economic or social and natural or physical environmental effects are interrelated, then the environmental impact statement will discuss all of these effects on the human environment.*[92]

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[90] Food and Drug Administration | Department of Health and Human Services, "Final Rule" | National Environmental Policy Act; Revision of Policies and Procedures, July 29, 1997, https://www.govinfo.gov/content/pkg/FR-1997-07-29/pdf/97-19566.pdf; see also: Code of Federal Regulations, Title 21, Chapter I, § 25.20, April 1998, https://www.govinfo.gov/content/pkg/CFR-1998-title21-vol1/pdf/CFR-1998-title21-vol1-chap-id2.pdf.

[91] Note: Title 21 §25.states"[a]ll agency actions are subject to environmental consideration. Actions are individually examined for potential environmental impact unless excluded as a class by categorical exclusion under s 25.24." None of the exclusions apply to new drug applications, hence, an EA was required—yet as has been demonstrated, it was not properly completed. Exclusions outlined include: "*(1) Action on an ANDA if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the agency do not establish that, at the expected level of exposure, the substance may be toxic to organisms in the environment. (2) Action on an amendment or supplement to an NDA of the following types if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the agency do not establish that, at the expected levels of exposure, the substance may be toxic to organisms in the environment. (i) Changes specified in s 314.70 (c) or (d); or (ii) Any other type of amendment or supplement to an NDA which meets the above criteria for exclusion. (3) Withdrawal of approval of an NDA or ANDA when the drug is no longer being marketed or at the request of the application holder. (4) Action on a investigational new drug application (IND), if the drug shipped under such notice is intended to be used for clinical studies or research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic. (5) Testing and certification of batches of an antibiotic or insulin. (6) Promulgation, revocation, or amendment of a monograph for a drug that is not a new drug, for an antibiotic drug, or for an over-the-counter (OTC) drug, if the drug is already marketed for the proposed use and data available to the agency do not establish that, at the expected levels of exposure, the drug may be toxic to organisms in the environment. (7) Establishment of bioequivalence requirements for a marketed drug product if there is no change in the existing levels of use or intended uses of the product. (8) Action on changes in a biological product license or an establishment license reported under s 601.12 of this chapter. (9) Revocation of a license for a biological product when it is no longer being marketed, or revocation of a biological product or establishment license at the request of the license holder. (10) Promulgation, amendment, or revocation of a standard for a licensed biological product or amendment of the license for a biological product if there is no change in the existing levels of use or intended uses of the product. (11) Action on a license application for transfusable blood or blood products."* See: Code of Federal Regulations, Title 21, Chapter I, § 25.24, 1995.

[92] Code of Federal Regulations, Title 40, Chapter 5, §1508.14, 1995.

d. The need to dispose of fetal remains and the likelihood they would be disposed of down the toilet is a "**reasonably foreseeable effect"** of approving mifepristone that is also **significant** according to the 1995 CFR, which outline that "significantly" includes consideration of several factors, among them, "*The degree to which the effects on the quality of the human environment are likely to be highly controversial*" and "*the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks*."[93] Indeed, fetal remains being flushed into the sewer system would, in the eyes of many, be highly controversial and create a unique and unknown risk related to the "quality of the human environment" (even if unquantified).
e. A proper EA should have therefore included consideration of fetal remains disposal, which should have then led the FDA to perform an EIS (or perhaps ensure proper mitigation requirements were put in place), depending on how fetal remains would be disposed of. Instead of considering the need to dispose of fetal remains, the FDA accepted the 1996 EA submitted by the Population Council and issued a FONSI.
f. Given there is an "unquantified" value in keeping our ecosystem free from the flushed remains of aborted pregnancies, and, per the definition outlined above, that there is an irrefutable "significant" environmental impact that may be caused by approval of the abortion pill (pending on how the fetal remains generated would be disposed of, which was not addressed), issuing a FONSI was a clear violation of the NEPA and its related regulations.
g. The FDA defended its decision in 2000 by stating it is unaware "of any evidence suggesting that products of conception pose an environmental hazard to the water supply."[94] This makes sense given that that the FDA has not done any studies on the matter. The one "study" the FDA acknowledged having reviewed, the 1996 EA submitted by the Population Council, states the following:

> *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.*

[93] Code of Federal Regulations, Title 40, Chapter 5, §1508.27, 1995.
[94] Kristan Hawkins, Tina Whittington, and Kristi Hamrick, "Citizen Petition . . ."

> *. . . 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 excretion by patients, from disposal of pharmaceutical waste or from emissions from manufacturing sites.*[95]

In other words, the assessment notes that the drug itself may enter the water via urine/fecal matter ("excretion by patients"), disposing of any unused pills or packaging (presumably) ("disposal of pharmaceutical waste"[96]), and manufacturing plant emissions. **The assessment did not touch on the impact of the aborted fetuses themselves, nor the possibility they may enter the water supply**.[97]

h. In summary, by failing to conduct a proper study of the possible effects of aborted fetal remains and mifepristone metabolites entering the water, the FDA failed to comply with a host of measures as outlined by the NEPA, which require the FDA head to release a "detailed statement" on:
   - "[R]easonably foreseeable environmental effects of the proposed agency action" [disposal of fetal remains];
   - "[A]ny reasonably foreseeable adverse environmental effects which cannot be avoided should the proposal be implemented" [affects individual's relationship with the environment];
   - "[A]reasonable range of alternatives to the proposed agency action, including an analysis of any negative environmental impacts of not implementing the proposed agency action in the case of a no action alternative, that are technically and economically feasible, and meet the purpose and need of the proposal," [it does not appear this was done];
   - "the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity."[98]

   Moreover, prior to making a "detailed statement," the head of the FDA was required to "consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any

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[95] Food and Drug Administration Center for Drug Evaluation and Research, "Environmental Assessment and Finding of No Significant Impact for NDA 20-687—Mifepristone Tablets . . ."
[96] "Pharmaceutical Waste," Science Direct, accessed May 5, 2025, https://www.sciencedirect.com/topics/earth-and-planetary-sciences/pharmaceutical-waste. Note the distinction from medical waste.
[97] The 1996 EA also refers to "waste drug products"; again, while somewhat unclear, this does not adequately address the issue of "medical waste" from use of the drug product, which would need to be disposed of. Whether that is an environmental hazard would depend on how said medical waste is disposed of, which likewise was not addressed.
[98] Office of the Law Revision Counsel, 42 U.S.C. §4332(C)(i-iv), accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.

environmental impact involved." The statute goes on to note, "Copies of such statement and the comments and views of the appropriate Federal, State, and local agencies, which are authorized to develop and enforce environmental standards, shall be made available to the President . . . and to the public as provided by section 552 of title 5, and shall accompany the proposal through the existing agency review processes."[99] The EPA certainly has special expertise, yet the FDA in failing to issue a detailed statement likewise failed to consult with them on the same. [100]

3. **Exclusions allowing the FDA to bypass the requirement of an EIS or EA should not have applied to "major actions" related to the abortion pill in 2011, 2016, 2019, 2021 and 2023, given the existence of "extraordinary circumstances."**
    a. As has been demonstrated, in 2000, the FDA approved mifepristone based on a flawed EA that failed to consider fetal remains disposal. All subsequent "major federal actions" by the FDA to control access to and expand use of the abortion pill likewise failed to consider how fetal remains (medical waste) would be disposed of in an EA, as no EAs were conducted.
    b. Specifically: In 2019, the FDA approved used of generic mifepristone, and in 2011, 2016, 2021, and 2023, the FDA approved various supplemental drug applications that, among other things, loosened the safety protocols related to mifepristone.[101] For example, in 2016, the FDA approved a supplemental New Drug Application (sNDA) from Danco Laboratories, LLC, that (in addition to other changes) sought an "increase in the maximum gestational age from 49 days to 70 days."[102] By default, this would increase the amount of fetal remains entering the water supply (rather than limiting

[99] Office of the Law Revision Counsel, 42 U.S.C. §4332(C), accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.
[100] Code of Federal Regulations, Title 21, Chapter I, §25.5, April 1996, https://www.govinfo.gov/content/pkg/CFR-1996-title21-vol1/pdf/CFR-1996-title21-vol1.pdf.
[101] The 2011 "major action" implemented the REMS protocol. See: Letter to Danco Laboratories, LLC, from the Food and Drug Administration, "SUPPLEMENT APPROVAL," June 8, 2011, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020687s014ltr.pdf. See also: Letter to Danco Laboratories, LLC, from the Food and Drug Administration, "SUPPLEMENT APPROVAL," March 29, 2016, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020687Orig1s020ltr.pdf; Letter to GenBioPro, Inc.,, from the Food and Drug Administration, "ANDA APPROVAL," April 11, 2019; https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf; Letter to Danco Laboratories, LLC, from the Food and Drug Administration, "SUPPLEMENT APPROVAL," May 14, 2021,https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/020687Orig1s024ltr.pdf, and Letter to Danco Laboratories, LLC, from the Food and Drug Administration, "SUPPLEMENT APPROVAL," January 3, 2023, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/020687Orig1s025ltr.pdf.
[102] "APPLICATION NUMBER: 020687Orig1s020 | Summary Review," Center for Drug Evaluation and Research, March 29, 2016, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf.

abortions to babies at 7 weeks gestational age, now, they would allow babies as old as 10 weeks to be aborted and then flushed into the water supply, increasing both the frequency and amount of fetal remains being expelled).[103]

c. Each of these "major actions" should have required its own EA based on the NEPA, as outlined above.
d. While exclusions *can* apply,[104] and the FDA may argue exclusions did apply in each year a major decision was made following the drug's original approval,[105] the 1998 CFR (which remained in similar form in the 2014 CFR[106]) outline that **even in cases where an exclusion applies**, the "FDA will require at least an EA for any specific action [e.g. approving a drug] that ordinarily would be excluded **if extraordinary circumstances indicate** that the specific proposed action may significantly affect the quality of the human environment."[107]
e. **To clarify what is included in extraordinary circumstances:**
    - The 1998 guidance on the rule at hand states, "[e]xtraordinary **circumstance** can be shown by data available either to the Agency or

[103] Of note, the application supplement states one of the changes would be to "the labeled time for expected expulsion of pregnancy from 4-24 hours to 2-24 hours post misoprostol administration." Given misoprostol could be administered at home, they clearly anticipated fetal remains being disposed of by the pregnant woman at home. Ibid.

[104] A "categorical exclusion" is "a category of actions that a Federal agency has determined normally does not significantly affect the quality of the human environment within the meaning of section 4332(2)(C) of this title." Office of the Law Revision Counsel, 42 U.S.C. §4336, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim. See also Code of Federal Regulations, Title 21, Chapter I, § 25.20, April 1998, https://www.govinfo.gov/content/pkg/CFR-1998-title21-vol1/pdf/CFR-1998-title21-vol1-chap-id2.pdf. Said section states "[a]ny proposed action of a type specified in this section ordinarily requires at least the preparation of an EA, unless it is an action in a specific class that qualifies for exclusion," and outlines several types of actions, including "[a]pproval of NDA's, **abbreviated applications,** applications for marketing approval of a biologic product, **supplements** to such applications, and actions on IND's."

[105] If a drug's "estimated concentration . . . at the point of entry into the aquatic environment will be below 1 part per billion (ppb)"—in this case, it was—the drug qualifies for a "categorical exception,"—unless there is an "extraordinary circumstance." See: "Environmental Assessment of Human Drug and Biologics Applications | Guidance for Industry," U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research Center for Biologics Evaluation and Research, July 1998, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/environmental-assessment-human-drug-and-biologics-applications.

[106] Code of Federal Regulations, Title 21, Chapter 1, §25.21, 2014, https://www.govinfo.gov/content/pkg/CFR-2014-title21-vol1/pdf/CFR-2014-title21-vol1.pdf.

[107] Food and Drug Administration | Department of Health and Human Services, "Final Rule" | National Environmental Policy Act; Revision of Policies and Procedures, July 29, 1997, https://www.govinfo.gov/content/pkg/FR-1997-07-29/pdf/97-19566.pdf; see also: Code of Federal Regulations, Title 21, Chapter I, §25.21, April 1998, https://www.govinfo.gov/content/pkg/CFR-1998-title21-vol1/pdf/CFR-1998-title21-vol1-chap-id2.pdf.

the applicant and can be based on the production, use, **or disposal <u>from use</u> of the FDA-regulated article**." [108]

- In the case of Mifeprex, a **"disposal <u>from use</u>"** of the FDA-regulated article would be necessary after the drug is used as intended (to end a pregnancy). Specifically, it **requires the disposal (from use of the drug) of human remains from a pregnancy**. This is, by definition, an "extraordinary circumstance" that should have been considered.
- Given fetal remains disposal was not properly considered in 2000 (though, again, it should have been), this now very explicit requirement makes it inescapable that the FDA should have considered disposal **from use.** Any exclusions allowing an exemption for an EA in the 2011, 2016, 2019, 2021, and 2023 approvals should not have applied.

f. **To clarify what is included in the "human environment":**
   - After the original approval of mifepristone, federal regulations continued to define the human environment broadly, outlining for several years that "the relationship of people with that environment" should be a consideration in an EIS (though may not be the sole means for requiring an EIS). [109] An individual's relationship with [110] the environment may be damaged upon learning that aborted babies are "processed" at wastewater treatment facilities; for example, they may be reticent to swim in local lakes, streams, and rivers, or drink local water.

g. **To clarify what is meant by "significantly":** Post the original approval of mifepristone, federal regulations continued to outline that "significantly as used in the NEPA" required consideration of "context and intensity," with

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[108] Environmental Assessment of Human Drug and Biologics Applications | Guidance for Industry," U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research Center for Biologics Evaluation and Research, July 1998, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/environmental-assessment-human-drug-and-biologics-applications. This document goes into yet greater detail, reiterating the rule: "The Food and Drug Administration (FDA) is required under the NEPA to consider the environmental impacts of approving drug and biologics applications as an integral part of its regulatory process."

[109] Code of Federal Regulations, Title 40, Chapter V, § 1508.14, 1996, https://www.govinfo.gov/content/pkg/CFR-1996-title40-vol18/pdf/CFR-1996-title40-vol18-chapV.pdf; Code of Federal Regulations, Title 40, Chapter V, § 1508.14, July 1, 2014, https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol33/pdf/CFR-2014-title40-vol33.pdf; in 2023, the definition again remained similar, and reads, "Human environment means comprehensively the natural and physical environment and the relationship of present and future generations of Americans with that environment. (See also the definition of ''effects'' in paragraph (g) of this section.)" See: Code of Federal Regulations, Title 40, Chapter V, § 1508.1, 2023, https://www.govinfo.gov/content/pkg/CFR-2023-title40-vol37/pdf/CFR-2023-title40-vol37.pdf.

[110] According to the Cambridge Dictionary, "relationship" means "the way in which things are connected or work together . . . A relationship is the way two or more people are connected, or the way they behave toward each other." See: "Relationship," Cambridge University Press and Assessment, accessed June 11, 2025, https://dictionary.cambridge.org/us/dictionary/english/relationship.

intensity referring to "severity of impact."[111] In evaluating intensity of an action, several factors "should be considered," the most relevant of which include:

- *"(4) The degree to which the effects on the quality of the human environment are likely to be highly controversial."* Disposing of aborted babies into our water supply is unequivocally highly controversial.
- *"(5) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks."* Given the effect of human remains and mifepristone metabolites in the waterways was not studied, the risks are undoubtably unique and may include unknown harms.
- *"(7) Whether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts."* The action taken by the FDA permits a woman to flush her aborted baby down the toilet, which one could argue has a negligible impact on its own; however, considering the increased use of chemical abortion pills, the cumulative impact now amounts to an estimated 40+ tons of blood, tissues, placentas, etc., being flushed into our waterways.[112] Clearly that is a significant amount of what at the least constitutes medical waste (much of it constitutes human remains that should be interred or cremated as per point 6 below). WWTP are not meant to handle this waste. If a hospital decided to dispose of 40 tons of medical waste into our wastewater systems, public outcry would inevitably follow.
- *"(10) Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment."* The action to permit women to dispose of aborted fetal remains at home "threatens a violation of" several state and local laws related to proper disposal of medical waste (as outlined in point 1).

4. **Not only should an EA have been completed in 2011, 2016, 2019, 2021 and 2023 that addressed the issue of fetal remains, *it also should have made disposal of them a focus of its analysis*.**

[111] Code of Federal Regulations, Title 40, Chapter V, § 1508.27, 1995; relevant quotes remained identical in April 1996,1998, 2016, 2019. See: https://www.govinfo.gov/content/pkg/CFR-1996-title40-vol18/pdf/CFR-1996-title40-vol18-chapV.pdf. As of 2020 this section of the code is no longer publicly available.
[112] See footnote 11.

a. Per the 1998 Code of Federal Regulations, should an EA be required (as it should have been in the years listed) then, **"[t]he <u>EA shall focus on</u> relevant environmental issues relating to the use and disposal <u>from use</u> of FDA-regulated articles** [not merely disposal of the product] and shall be a concise, objective, and well balanced document that allows the public to understand the agency's decision."[113] The NEPA itself likewise states that agencies shall "ensure the professional integrity, including scientific integrity, of the discussion and analysis in an environmental document."[114]
b. Again, while the 1996 EA should have addressed disposal from use as demonstrated above, it failed to do so. Rather, the EA stated, "[t]he **product** can be manufactured, **used and disposed of** without any expected adverse environmental effects." Specifically, the FDA evaluated:
    - The potential environmental impacts of the manufacture of the drug (they would take precaution at the manufacturing sites, which was expected "to minimize occupational exposures and environmental release"),
    - Use of the drug (based on excretion from use, with an anticipated concentration of less than 1 ppb),
    - Disposal of the drug (which can result from "production waste such as out of specification lots, returned goods and user disposal of empty or partly used product and packaging;" further stating "disposal methods are expected to minimize . . . environmental release").

    Clearly the EA did not address disposal **<u>from</u>** use—that is, the fetal remains. Hence, the FDA cannot logically argue the 1996 EA (that failed to consider fetal remains) was sufficient to forgo environmental assessments in 2011, 2016, 2019, 2021, and 2023 that not only should have considered fetal remains, but should have **<u>focused</u>** on the relevant environmental issues related to disposal of said fetal remains.
c. By not requiring an EA in the years mentioned, the FDA likewise failed to do its duty to ensure an objective, integrous EA was conducted.

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[113] Food and Drug Administration | Department of Health and Human Services, "Final Rule" | National Environmental Policy Act; Revision of Policies and Procedures, July 29, 1997, https://www.govinfo.gov/content/pkg/FR-1997-07-29/pdf/97-19566.pdf; Code of Federal Regulations, Title 21, Chapter I, § 25.40, April 1998, https://www.govinfo.gov/content/pkg/CFR-1998-title21-vol1/pdf/CFR-1998-title21-vol1-chap-id2.pdf. (See also the rule in 2014, as that would have applied in the 2016 approval to changes to the mifepristone REMs; Code of Federal Regulations, Title 21, Chapter 1, §25.40, 2014, https://www.govinfo.gov/content/pkg/CFR-2014-title21-vol1/pdf/CFR-2014-title21-vol1.pdf.)

[114] Office of the Law Revision Counsel, 42 U.S.C. §4332, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.

5. **Ultimately, the Population Council and FDA's failure to ensure proper disposal of human remains/medical waste amounts to negligence.**
    a. The "intended use" of Mifeprex, a novel drug when introduced in 2000, was the "termination of an early pregnancy." The successful action of the drug was to be measured by the complete expulsion of the entire contents of a pregnant uterus, resulting in the need to dispose of fetal human remains, placental tissue, and other potentially infectious material.
    b. The FDA and Population Council were well aware of this fact and should know that at the least it constitutes Regulated Medical Wastes (RMW) (see section 5 for further details on medical waste).
    c. By way of comparison, during a surgical abortion, guidance from the World Health Organization (WHO) recommends providers verify completion by checking for all fetal parts.[115] The removed fetal parts should then be disposed of according to state fetal remains or medical waste regulations.
    d. By way of the FDA's oversights, at-home abortion providers have evaded this requirement (which is also a danger to the woman, who may have fetal remains left in her uterus), off-loading the proper collection and containment of potentially infectious[116] medical waste to the woman (patient) herself.
    e. As outlined previously, various states have specific requirements for sanitary and appropriate fetal remains disposition, and all states have regulated medical waste requirements.
    f. If, somehow, consideration of aborted babies being flushed into the water supply qualified for an exclusion in 1996, those making said exclusions were negligent. Not only does it disregard medical waste disposal laws (which are in place for a reason), it ignores the disturbing reality that babies are being flushed into the water—a reality "significant" (controversial) to many that may adversely impact their relationship to the environment.

6. **An EA should have been completed by the FDA.**
    a. In addition to the above issues, the NEPA states, "[s]uch environmental assessment shall be a concise public document **prepared by a Federal agency** to set forth the basis of such agency's finding of no significant impact or determination that an environmental impact statement is

[115] "Clinical Practice Handbook for Safe Abortion," World Health Organization, 2014, https://www.ncbi.nlm.nih.gov/books/NBK190095/.
[116] The "Universal Precautions" approach suggests that if it can be infectious, it should be treated as if it is infectious. See: "Bloodborne Pathogens," OSHA, https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030/.

necessary."[117] However, the EA in the case of mifepristone was prepared by the Population Council. The FDA failed to do its own assessment.

b. While there is a portion of the law that states "[i]n making a determination under this subsection, an agency—(A) may make use of any reliable data source; and (B) is not required to undertake new scientific or technical research unless the new scientific or technical research is essential to a reasoned choice among alternatives, and the overall costs and time frame of obtaining it are not unreasonable,"
   - The Population Council is not a reliable source (it is a biased source).
   - The terms used here are subjective. Arguably, research on aborted babies and abortion pill metabolites entering the water should have been "essential" to making "a reasoned choice"; hence, the overall costs and time frame for obtaining said research would, therefore, not be unreasonable.

7. **The EPA should have pressed the FDA to complete the required environmental analysis.**
   a. After the NEPA's passage, the EPA was formed with the following primary functions in mind: "The establishment and **enforcement** of environmental protection standards consistent with national environmental goals" (among others).[118]
   b. Based on its authority to enforce environmental standards, the EPA has purview over chemical abortion pills and fetal remains entering our waterways.
   c. More specifically, the appropriate consideration of "unquantified environmental amenities and values" in decision making is an "**environmental protection standard**" the EPA would arguably have authority to enforce, and which should have required the FDA to consider the "unquantified value" of an environment free of fetal remains.

8. **The FDA cannot claim ignorance on the matter of fetal disposition.**
   a. While failure to consider the reality that aborted babies would end up in our waterways may have been due to the fact that the original application

[117] Office of the Law Revision Counsel, 42 U.S.C. §4336, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.
[118] Office of the Law Revision Counsel, 42 U.S.C. §4321, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim..

and EA for the drug limited its *administration* to clinical settings,[119] the pregnancy *expulsion* could occur at home, or anywhere else.[120]

b. Furthermore, guidance provided by the American Civil Liberties Union (ACLU) at the time on how state abortion restrictions would apply to the abortion pill make it abundantly clear that the ACLU (and arguably the abortion providers they wrote to) understood that while in many cases, state disposal laws appear to "permit a doctor to instruct a patient to flush the products of conception down the toilet,"[121] by implication, certain other states would not permit flushing "products of conception."
c. The FDA should certainly have understood (and almost certainly did) and addressed this reality (medical waste being disposed of down the toilet, as well as the fact that this would violate various states' laws), given its environmental impacts.

In summary, by the plain reading of these statutes, it appears the FDA failed to perform its duty to consider fetal remains in its decision-making process, and the EPA failed to perform its duty to uphold "environmental protection standards consistent with national environmental goals."[122] Furthermore, while the FDA may claim the EA and EIS requirements are not applicable based on a 1995 guidance and later exclusions, guidance and regulations should not lead to violations of the law they are created to implement.

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[119] Note: It seems a label submitted to the FDA prior to the drug's approval may have outlined women are to stay in a clinical setting for 3-4 hours after use of mifepristone and/or misoprostol; however, that requirement was based on a study which used another drug with mifepristone and had some risks associated. Given that drug is *not used* in the U.S. and the risks associated with it appear to be a primary reason for the observation period, the 3–4-hour observation period was rendered moot. Women were thus allowed to simply leave clinical settings after being administered mifepristone and (3 days latter) misoprostol. See: "Memorandum K" from the Department of Health and Human Services, Public Health Service, Food and Drug Administration to the Population Council; September 28, 2000.

[120] "Drug Approval Package," Mifeprex (Mifepristone) Tablet, FDA, September 28, 2000, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_mifepristone.cfm. See specifically the Approval Letter, 9/28/2000, and Approved Labeling Text, 9/28/00. Specifically, the original drug approval letter outlined the drug could be used "for use as recommended in the agreed upon labeling text." Said labelling text outlined there were to be three visits, two wherein the chemical abortion pills are provided and taken. Based on the fact that she is allowed to go home after pill administration, which is indicated by the text stating that she is to return to the clinic after taking Mifeprex to take misoprostol if the abortion did not already occur with Mifeprex only, as well as text stating that after taking misoprostol, she is to be "given instructions on what to do if significant discomfort, excessive bleeding or other adverse reactions occur and should be given a phone number to call if she has questions following the administration of the misoprostol," (presumably, if she were in the clinic, she would not need a phone number), the expulsion could occur anywhere.

[121] ACLU, "Do Existing State Abortion Laws Apply to Mifepristone (RU-486)?" February 21, 2000, https://www.aclu.org/documents/do-existing-state-abortion-laws-apply-mifepristone-ru-486.

[122] In addition to the statute, see "Basic Information on Enforcement," United States Environmental Protection Agency, February 26, 2025, https://www.epa.gov/enforcement/basic-information-enforcement.

Further addressing the FDA's acceptance of the 1996 EA (2000 approval of Mifeprex) and its (supposed) adherence to the NEPA

The FDA (in its response to the SFLA petition) states that "[t]he applicant [Population Council] submitted a Tier 0 EA in accordance with Agency regulations and consistent with guidance that existed at that time (specifically the *Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements* (November 1995))."[123] Presumably, though the drug was not approved until 2000, they are (at least in part) relying on this 1995 Guidance as the legal basis for the original approval of Mifeprex.

There are a few issues with this reasoning: First, the law itself, which allows agencies to create exclusions,[124] arguably would not allow an agency to create guidance or an exclusion that violates other aspects of law, in this case the NEPA and CWA (as outlined in point A). Excluding environmental analysis of fetal remains and the likelihood they will be flushed down the toilet, as well as excluding further analysis of the drug's metabolites because the expected introduction concentration of mifepristone use in the environment is low, does the following:

- (As per the above) ignores the section of the NEPA that states all major federal actions (e.g., drug approval) that significantly affect "the quality of the human environment" (e.g., human's relationship with it, as per the 1995 and later CFR) require "a detailed statement by the responsible official on . . . any reasonably foreseeable adverse

[123] Patrizia A. Cavazzoni, "U.S. Food and Drug Administration to Kristan Hawkins, President and Kristi Hamrick, Chief Media & Policy Strategist, Students for Life of America,". . .

[124] Section 4336e specifically states: "*The term 'categorical exclusion' means a category of actions that a Federal agency has determined normally does not significantly affect the quality of the human environment within the meaning of section 4332(2)(C) of this title*." 4332(2)(C) states, "*(C) consistent with the provisions of this chapter and except where compliance would be inconsistent with other statutory requirements, include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on—*
(i) reasonably foreseeable environmental effects of the proposed agency action;
(ii) any reasonably foreseeable adverse environmental effects which cannot be avoided should the proposal be implemented;
(iii) a reasonable range of alternatives to the proposed agency action, including an analysis of any negative environmental impacts of not implementing the proposed agency action in the case of a no action alternative, that are technically and economically feasible, and meet the purpose and need of the proposal;
(iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity; and
(v) any irreversible and irretrievable commitments of Federal resources which would be involved in the proposed agency action should it be implemented." Office of the Law Revision Counsel, 42 U.S.C., accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.

environmental effects which cannot be avoided should the proposal be implemented."[125]

- Violates the CWA's provision that requires agencies to adhere to all state laws "respecting the control and abatement of water pollution."[126]

Second, three years elapsed between the new rule (July 1997[127]) and the approval of mifepristone (September 2000[128]). In approving food or drugs for human use, any reasonable person would hope the FDA follows the most up-to-date guidance and regulations available, a point underscored by Title 21 of the Code of Federal Regulations: *"All FDA policies and programs will be planned, developed, and implemented so as to achieve the policies declared by NEPA and required by the CEQ regulations* ***to ensure responsible stewardship of the environment*** *for present and future generations"* (emphasis added).[129] *Responsible* implementation surely requires considerations of updated best practices. Furthermore, three years would have been enough time to redo the EA in accordance with the new rule. Such effort should be standard practice for an agency **responsible** for the health and safety of U.S. citizens.

Further addressing the FDA's acceptance of the 2019 ANDA (2019 approval of generic mifepristone) and its (supposed) adherence to the NEPA

In reference to the 2019 approval of generic mifepristone, the FDA states that "the applicant for ANDA 091178 claimed a categorical exclusion under 21 CFR 25.31(a) because action on the ANDA did not increase use of the active moiety (i.e., mifepristone). FDA reviewed the application and approved ANDA 091178 in 2019."[130]

[125] Office of the Law Revision Counsel, 42 U.S.C. §4332, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.
[126] Office of the Law Revision Counsel, 33 U.S.C. §1251, accessed April 16, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim.
[127] Food and Drug Administration | Department of Health and Human Services, "Final Rule" | National Environmental Policy Act; Revision of Policies and Procedures, July 29, 1997, https://www.govinfo.gov/content/pkg/FR-1997-07-29/pdf/97-19566.pdf; see also: Code of Federal Regulations, Title 21, Chapter I, § 25.20, April 1998, https://www.govinfo.gov/content/pkg/CFR-1998-title21-vol1/pdf/CFR-1998-title21-vol1-chap-id2.pdf.
[128] Center for Drug Evaluation and Research, Letter to the Population Council, September 28, 2000, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf.
[129] Code of Federal Regulations, Title 21, Chapter I, §25.5, April 1996, https://www.govinfo.gov/content/pkg/CFR-1996-title21-vol1/pdf/CFR-1996-title21-vol1.pdf.
[130] Patrizia A. Cavazzoni, "U.S. Food and Drug Administration to Kristan Hawkins, President and Kristi Hamrick, Chief Media & Policy Strategist, Students for Life of America," Letter, January 15, 2025, https://downloads.regulations.gov/FDA-2023-P-1528-0005/attachment_1.pdf.

- Approval of the generic version of the drug via an ANDA submitted in 2009[131] should have adhered to the same rules referred to above,[132] which, as outlined, precluded exclusions in the case of "extraordinary circumstances."
- More specifically, the exclusion the FDA cites should not have applied, given that not only did the original NDA fail to consider the extraordinary circumstances of fetal remains entering the water supply—hence, that "extraordinary circumstance" still required addressing—but after over a decade, the amount of fetal remains entering our water systems had substantially increased and would likely further increase after approval of a generic version of the parent drug, amounting to a second extraordinary circumstance.

Call for further study is more than justified

The increase of at-home abortion has more than likely resulted in large amounts of human remains entering the water supply, which has still not been analyzed as the NEPA requires, nor has it "been analyzed from the perspective of the Clean Water Act and the effect of Mifepristone on waters of the United States."[133] Yet, lack of information does not equate to a lack of harm.

As the above outlines:

1. The Population Council's EA (intentionally or not) gave no consideration to fetal remains and their disposal, misrepresenting the possible environmental impact of this drug. Given that "extraordinary circumstances" (expulsion of babies that will require disposition) "indicate that the specific proposed action" (approving Mifeprex) "may significantly affect the quality of the human environment" (individuals' relationship to it and violation of state laws on proper fetal disposition), the EA should have focused on where the expulsion of the pregnancy would occur and how the disposal from use would be contained and controlled for proper disposal.
2. The FDA violated the NEPA and related regulations by granting the FONSI. Notably, requiring an EIS (as it should have) may have inhibited approval of mifepristone or at the very least, required the expulsion to be completed in a clinical setting.
3. The subsequent approvals for expanding use of mifepristone and easing access to it should have also required an EA or EIS—the extraordinary circumstances being the increase of aborted fetal remains entering the water and failure to consider disposal of said remains in the original NDA.

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[131] Letter to GenBioProInc. from the Center for Drug Evaluation and Research, "ANDA APPROVAL," April 11, 2019, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf. Note, the use of the chemical abortion pill was increasing.
[132] Code of Federal Regulations, Title 21, Chapter 1, §25.21, 2014, https://www.govinfo.gov/content/pkg/CFR-2014-title21-vol1/pdf/CFR-2014-title21-vol1.pdf.
[133] Kristan Hawkins, Tina Whittington, and Kristi Hamrick, "Citizen Petition . . ."

4. It was the FDA's responsibility at time of approvals to **objectively** consider whether the proper "use" of this drug would have a "significant effect" (effects can be direct or indirect) on society, or threaten a violation of Federal, State, or local law or requirements imposed for the protection of the environment.[134] Instead, the FDA relied on an EA completed by those seeking the drug's approval.

Underscoring this obvious lack of objectivity, a recently released "Make America Healthy Again" report found, "[p]harmaceutical companies often craft studies and papers designed to favor their products. **Evidence shows industry studies are much more likely to report favorable outcomes, exaggerating benefits and underreporting harms**" (emphasis added).[135] In the case of mifepristone, it seems clear the Population Council crafted its EA to be favorable to approval of its product.

In short, an unbiased, comprehensive environmental assessment that studies both the effect of fetal remains and mifepristone metabolites entering our waterways is sorely needed.

C. State Water Quality Laws

As it relates to the Clean Water Act, as outlined above, the FDA did not ensure it adhered to all state and local laws related to "abatement of water pollution" during its approval of Mifepristone.[136] These state water quality standards can be extensive; consider, for example, that Minnesota has "general standards for waters of the state," alongside seven classes of water with their own specific water quality standards.[137] There is no indication the FDA considered these standards. By way of another example, Florida's water quality standards include, per the Department of Environmental Protection,

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[134] See: Code of Federal Regulations, Title 40, Chapter V, §1508.8 and 1508.27, 2014, https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol33/pdf/CFR-2014-title40-vol33.pdf. NB: §1508.8 specifically states, "[E]ffects include: (a) Direct effects, which are caused by the action and occur at the same time and place. (b) Indirect effects, which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable. Indirect effects may include growth inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems. Effects and impacts as used in these regulations are synonymous. Effects includes ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health, whether direct, indirect, or cumulative. Effects may also include those resulting from actions which may have both beneficial and detrimental effects, even if on balance the agency believes that the effect will be beneficial."

[135] "The MAHA Report | Make Our Children Healthy Again Assessment," The White House, accessed May 23, 2025, https://www.whitehouse.gov/wp-content/uploads/2025/05/WH-The-MAHA-Report-Assessment.pdf.

[136] Office of the Law Revision Counsel, 33 U.S.C. § 1323(a), accessed April 16, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim.

[137] Minnesota Administrative Rules, "CHAPTER 7050, WATERS OF THE STATE," accessed May 22, 2025, https://www.revisor.mn.gov/rules/7050/.

minimum criteria for "all surface waters of the State," which outline they shall be kept free from:

> *"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."*[138]

Although this rule became effective after the original 2000 approval of Mifeprex, when the FDA approved the generic form of mifepristone in 2019 and eased REMS protocols in other years, it should have conducted a proper environmental analysis to ensure said actions would *not* "pose a serious danger to the public health, safety, and welfare" of Floridians. Yet, again, the FDA failed to—clearly skirting its duty under the Clean Water Act.

D. State Fetal Disposition Laws

As it pertains to fetal disposal laws, a few states (like Indiana) have statutes requiring aborted children to be interred or cremated.[139] In other states, the absence of such laws essentially means fetal remains can be disposed of as medical waste.[140] Even so, violations of these laws are not uncommon: A 2016 paper on this subject found myriad issues and violations related to fetal disposition in several states, among them "Indiana, Michigan, Pennsylvania, South Carolina, Texas and Utah."[141] Examples of said issues include the following:

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[138] Also cited by SFLA; see: "Rule: 62-302.500 | Surface Waters: Minimum Criteria, General Criteria," Florida Administrative Code & Florida Administrative Register, August 1, 2013, https://flrules.org/gateway/RuleNo.asp?title=SURFACE%20WATER%20QUALITY%20STANDARDS&ID=62-302.500.

[139] "Fetal Burial Requirements," Law Atlas, accessed April 16, 2025, https://lawatlas.org/datasets/fetal-burial-requirements; see also: "Procedures for disposal of fetal remains amended, advanced after cloture vote," Unicameral Update, April 15, 2025, https://update.legislature.ne.gov/?p=38505.

[140] "Procedures for disposal of fetal remains amended, advanced after cloture vote," Unicameral Update . . .

[141] Kirsti Burton Brown, "Fetal Disposition: The Abuses and The Law," …

- In 2005, the license of a New Jersey abortionist was revoked due to medical waste "being improperly disposed of down the sanitary sewer at that location."[142]
- Almost 45 abortion facilities in Detroit, Michigan, "routinely flushed baby parts into garbage disposals and out into the sewer system because it was cheap and legal, according to an archaic law."[143] The law was subsequently amended.[144]
- In Ohio, babies aborted by Planned Parenthood would be dumped at a Kentucky landfill after being "steam-cooked."[145]

While fetal disposal laws often only directly apply to surgical abortions (those performed in a clinical setting), the issues these laws address, for example, ensuring fetal remains are disposed of in a "manner that will not create a public health hazard,"[146] are just as relevant to chemical abortions, given both surgical and chemical abortions result in the need to dispose of fetal remains. Such a discrepancy sets an illogical double standard.

Finally, fetal disposal laws are "often archaic and scattered throughout a variety of state codes, regulations, and statutes," meaning "a dedicated effort must be made to find each related state law."[147] As the above demonstrates, this lack of regulatory structure means abortion providers are often allowed to practice harmful disposal procedures (requiring the women to dispose of fetal remains) that benefit their industry by reducing overhead costs (as internment and cremation cost money).[148]

These disturbing practices highlight the need for proper regulation, both for the protection of our environment and for the sake of human dignity.

E. Federal and State Medical Waste Regulations

As alluded to, in states without fetal disposal laws, human remains from abortions should be still disposed of according to applicable medical waste regulations, as all states have regulations on "proper medical waste disposal."[149] Various federal agencies, including the Centers for Disease Control (CDC), Occupational Safety and Health

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[142] Ibid.
[143] Ibid.
[144] Senate Substitute for House Bill No. 5711, Michigan Legislature, December 14, 2012, https://www.legislature.mi.gov/documents/2011-2012/billconcurred/House/pdf/2012-HCB-5711.pdf. Specifically, the "law requires burial, cremation, or incineration, 'unless the mother has provided written consent for research on the fetal remains.'" See: Kirsti Burton Brown, "Fetal Disposition: The Abuses and The Law," ...
[145] Jeremy Pelzer, "Aborted fetal remains from Ohio Planned Parenthood ended up in landfills, incinerators, attorney general says," Cleveland.com, December 11, 2015, https://www.cleveland.com/open/2015/12/aborted_fetal_remains_from_ohi.html; see also: Kirsti Burton Brown, "Fetal Disposition: The Abuses and The Law," ...
[146] The Vermont Statutes Online, 18 V.S.A. § 5224, accessed April 16, 2025, https://legislature.vermont.gov/statutes/section/18/107/05224.
[147] Kirsti Burton Brown, "Fetal Disposition: The Abuses and The Law . . ."
[148] Ibid.
[149] "Federal Laws Regarding Medical Waste Regulations," MCF environmental Services, Oct 18, 2023, https://mcfenvironmental.com/federal-laws-regarding-medical-waste-regulations/.

Administration (OSHA), and U.S. Food and Drug Administration (FDA) (and possibly others), also have regulations on medical waste, though as the noted by the EPA, it is primarily regulated by the states.[150] (See section 5 for further information.)

Recommended Action Based on Relevant Statutes

Regardless of whether violations of these laws occurred, with increasing amounts of chemical abortions and other pollutants being monitored at less than 1 pbb, the EPA and FDA should reconsider the original and subsequent approvals of the abortion pill, study and monitor metabolites in our water, and (ideally) pull the abortion pill from the market until said study is complete. At the least, they should change the protocol for the pill to either require women to expel the baby in a clinical setting or issue a "catch kit" if they allow them to exit the clinic. As said study is underway, they should also issue warnings to the general public as it pertains to fetal remains entering our waterways. (Detailed recommendations can be found in the Recommendations section.)

2. Lack of Comprehensive Environmental Analysis (Evidence) on Abortion Pill Metabolites Impact on Our Water Does Not Equate to Lack of a Problem

In the same response to the aforementioned citizen's petition, the FDA highlights several references SFLA made to mifepristone or its metabolites and concludes: "Although some of these references speak to overarching concerns about environmental contaminants, none of these references establishes that the concern in the Petition that mifepristone or its metabolites are in the United States' water causing harm is anything other than theoretical."[151] As alluded to above, the FDA also "reviewed publicly available data on current usage rates of mifepristone in consideration of the Petition's concern about increasing rates of use of the drug and the asserted potential negative environmental impact of any such increase" and "applied the default environmental calculations described in our current environmental guidance . . . to estimates of current use rates in order to characterize the current expected level of exposure of mifepristone and potential for effects on the environment." [152] The calculations—like the 2000 approval—show an exposure level that is so low for mifepristone "it is predicted to have no effect on the environment."[153] However:

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[150] "Medical Waste," United States Environmental Protection Agency . . .
Of note, the Resource Conservation and Recovery Act (RCRA), while not an agency, also "provides regulatory guidelines of the EPA when it comes to hazardous medical waste." See: "Federal Laws Regarding Medical Waste Regulations," MCF environmental Services . . .
[151] Ibid.
[152] Ibid.
[153] Ibid.

- These are projections based on calculations—they don't appear to be *actually studying or testing* U.S. waterways to determine if they may be contaminated or if said contamination may be causing harm.
- The lack of a direct link showing that abortion pill metabolites are causing harm does not mean that said link doesn't exist. Rather, given that as of today, there is scant research on the effect of abortion pill metabolites in our water, it means that further testing and study are required.

Notably, such research is more than warranted given what we do know, both based on the impact of other pharmaceuticals contaminating our water that have been found to be detrimental to the environment[154] (see section 4) and given, as outlined by an attorney advising SFLA on this matter, the pill is synthetic, potent, and designed to end pregnancies (distinguishing it from all other pharmaceuticals); in other words, it "stop[s] biological processes."[155]

In short, the FDA approved the use of the chemical abortion pill "despite not knowing the full impact of its active metabolites," and then eased access to it multiple times.[156] This lack of knowledge should compel national, state, and local governments to initiate comprehensive study on the matter.

3. Wastewater Treatment and Water Filtration Processes Incapable of Removing All Contaminants

According to the EPA, pharmaceutical contaminants can enter our environment in a variety of ways, including via human excretion. The latter is, in fact, thought to be one of the primary ways pharmaceuticals enter the environment, as noted in a study referenced by the EPA in a final rule on managing hazardous waste pharmaceuticals.[157]

Wastewater Treatment Plants Do Not Remove All Pharmaceutical Contaminants and Are Not Meant to Process Fetal Remains

After being excreted (prior to entering the environment), pharmaceutical contaminants become part of wastewater. In households connected to public sewer systems, this

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[154] Water Science School, "Pharmaceuticals in Water," U.S. Geological Survey, June 6, 2018, https://www.usgs.gov/special-topics/water-science-school/science/pharmaceuticals-water#overview; Teresa A. Donovan, "Musing Aloud," *Research Gate,* August 2015, https://www.researchgate.net/publication/281101224 ; Richard A. Lovett, "Human drugs make fish flounder," *Nature,* November 16, 2012, https://www.nature.com/articles/nature.2012.11843.

[155] Ariel Wittenberg and Alice Miranda Ollstein, "'Using the devil's own tools against them' …"

[156] Kristan Hawkins, Tina Whittington, and Kristi Hamrick, "Citizen Petition (to the Food and Drug Administration)," . . .

[157] Environmental Protection Agency, "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine | Final rule," Federal Register, Vol. 84, No. 36, February 22, 2019, https://www.govinfo.gov/content/pkg/FR-2019-02-22/pdf/2019-01298.pdf.

water then enters Publicly Owned Treatment Works (POTW, also referred to as wastewater treatment plants[158]). However, traditional wastewater treatment facilities "**are not designed to remove pharmaceuticals**"[159] (emphasis added). Indeed, while some wastewater treatment facilities "may remove some pharmaceuticals incidentally," many others "pass through and enter the environment."[160] This has become a major environmental concern, as there is a wide range of evidence demonstrating that the pharmaceutical contaminants entering our water supply via wastewater effluent are adversely affecting various forms of wildlife (see section 4 for details).

Related, wastewater treatment plants are not intended to process fetal remains (medical waste facilities exist for this purpose), though they end up serving in this capacity as fetal remains from chemical abortions are often flushed into the sewer system.

Specifically, conventional wastewater treatment plants involve two or three levels of treatment:

1. Primary treatment involves removing solids. In this step, any solids that passed through the screening process are allowed to settle.[161] Specifically, "when the wastewater enters a sedimentation tank, it slows down and the suspended solids gradually sink to the bottom."[162]

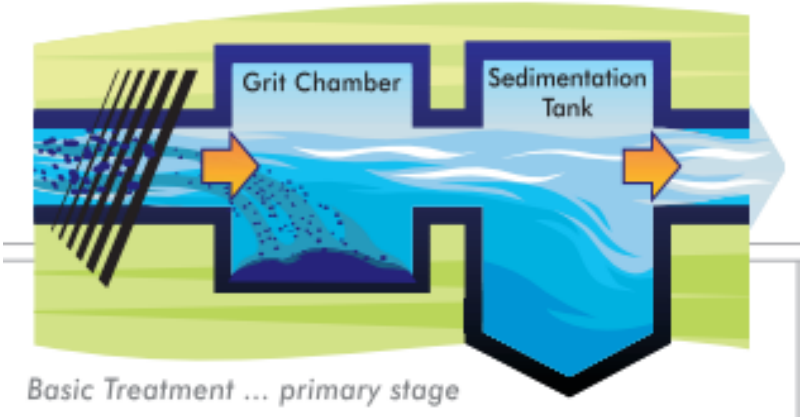

Figure 2; "Primer for Municipal Wastewater Treatment Systems," United States Environmental Protection Agency, September 2024, https://www3.epa.gov/npdes/pubs/primer.pdf.

2. By inference, fetal remains that don't "settle" in primary treatment enter secondary treatment. Secondary treatment involves using "biological

[158] A POTW is a sewage treatment plant owned by the government. "United States Environmental Protection Agency (EPA) Publicly Owned Treatment Works (POTW) Influent Per- and Polyfluoroalkyl Substance (PFAS) Study," United States Environmental Protection Agency, March 2024, https://www.epa.gov/system/files/documents/2024-03/potw-influent-study-icr-supporting-statement-part-b_508.pdf.

[159] "How Pharmaceuticals Enter the Environment . . ." See also: Environmental Protection Agency, "Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine | Final rule," . . .; as outlined in section XIII, ". . . comments supporting the prohibition against sewering came from states, regional, and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not eliminate many of the drugs that are flushed into the sewers."

[160] Ibid.

[161] "Primer for Municipal Wastewater Treatment Systems," United States Environmental Protection Agency, September 2024, https://www3.epa.gov/npdes/pubs/primer.pdf.

[162] Ibid.

processes to degrade organic pollutants."[163] In this step, "aerobic bacteria digest organic matter."[164]

The amount of matter the bacteria can oxidize is indicated by "Biochemical Oxygen Demand [BOD]."[165] More specifically, the BOD represents "the amount of dissolved oxygen required by aerobic microorganisms, specifically aerobic bacteria, to decompose organic matter present in water. **High BOD levels indicate a significant presence of organic pollutants,** which can lead to oxygen depletion in water bodies, adversely affecting aquatic life and overall water quality."[166] The EPA's standards for secondary treatment usually require at least an 85 percent reduction of BOD.[167]

In other words, WWTP are not required to remove all organic matter, nor do they. As outlined by a primer on wastewater treatment by the EPA, "[s]econdary treatment processes can remove up to 90 percent of the organic matter in wastewater by using biological treatment processes" (emphasis added).[168] By implication, approximately 10 percent of the organic matter in wastewater—which may include fetal biomass (including the mifepristone metabolites that caused the chemical abortion)—is not removed (consider, for example, microscopic fragments of skin or other organic fetal remains).

3. After secondary treatment, the effluent (in this case, treated wastewater) is then either discharged and enters our water bodies[169] or, in some cases, is treated in a tertiary treatment process. This process seeks "to remove nutrients and further disinfect the water with methods such as filtration and chlorination."[170]

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[163] "Effluent Discharge Regulations in Wastewater: Understanding Compliance and Impact," Waterandwastewater.com, 2024, https://www.waterandwastewater.com/effluent-discharge-regulations-understanding-compliance-and-impact/.
[164] "Secondary Treatment in Wastewater: Understanding the Biological Process," Wasteandwaster.com, 2024, https://www.waterandwastewater.com/secondary-treatment-in-wastewater-understanding-the-biological-process/.
[165] Ibid.
[166] "How to Effectively Reduce BOD in Wastewater," Bioprocess H2O, May 23, 2024, https://www.bioprocessh2o.com/blog/how-to-remove-bod-from-wastewater-a-comprehensive-guide.
[167] "Secondary Treatment in Wastewater: Understanding the Biological Process," Wasteandwaster.com. . . See also: "U.S. Environmental Protection Agency NDPES Permit Writers' Manual," U.S. United States Environmental Protection Agency, September 2010, https://www.epa.gov/sites/default/files/2015-09/documents/pwm_2010.pdf.
[168] "Primer for Municipal Wastewater Treatment Systems," United States Environmental Protection Agency, September 2024, https://www3.epa.gov/npdes/pubs/primer.pdf.
[169] The water may also be reused; see: "Municipal Wastewater," United States Environmental Protection Agency, March 31, 2025, https://www.epa.gov/npdes/municipal-wastewater.
[170] "Effluent Discharge Regulations in Wastewater: Understanding Compliance and Impact," Waterandwastewater.com . . .

Based on the above, it is possible that organic material from fetal remains may be found among the overall organic material in the raw drinking water supply on a higher molecular level. Even if the water is disinfected, the fact that human remains are being disposed of in this manner raises ethically complex questions that cannot be fully addressed by "disinfecting" our water. At the very least, as outlined in section 1, the knowledge that fetal remains are disposed of into the sewer system and may reach our lakes and streams can be damaging to one's relationship with the environment.

Conventional Drinking Water Filtration Processes Do Not Remove All Pharmaceutical Contaminants

Figure 3; "Primer for Municipal Wastewater Treatment Systems," United States Environmental Protection Agency, September 2024, https://www3.epa.gov/npdes/pubs/primer.pdf.

Unfortunately, pharmaceutical contaminants that remain in the water supply after wastewater treatment can then make their way into our tap water as, according to recent research, conventional drinking water treatment processes are likewise "ineffective in removing pharmaceuticals."[171] For example, a joint, two-phase U.S. Geological Survey-U.S. Environmental Protection Agency study found several pharmaceuticals contaminants present in treated water; Phase II specifically detected 26 different pharmaceuticals across 25 drinking water treatment plants.[172] A separate paper providing an overview of this two-phase national study further outlines that while the amount of pharmaceuticals

[171] Saleh Taghvaeian, "Pharmaceuticals in Drinking Water," OKState.edu, March 2017, https://extension.okstate.edu/fact-sheets/pharmaceuticals-in-drinking-water.html. Note: Some advanced methods "can remove more than 99 percent of targeted pharmaceuticals."

[172] Edward T Furlong, Angela L Batt, Susan T Glassmeyer, Mary C Noriega, Dana W Kolpin, Heath Mash, Kathleen M Schenck, **"**Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States: Pharmaceuticals," *Sci Total Environ*, February 2017, https://www.sciencedirect.com/science/article/abs/pii/S0048969716305551?via%3Dihub.

present is typically reduced after treatment, some nevertheless remain present at low levels, including an antibiotic, hormone, and antidepressant.[173]

This "persistent presence" of pharmaceuticals "suggests that there is exposure via water consumption," which, in turn, suggests further study is needed.[174] Indeed, as a 2019 study on pharmaceuticals of emerging concern explicitly outlines, the "long-term effects of [daily low doses consumed in drinking water] are still unknown," which is itself cause for concern.[175] A 2025 study corroborates this, outlining, "While the direct implications of exposure to low doses of pharmaceutical pollutants in humans have not been firmly established, the presence of multiple pharmaceutically active compounds in a single sample suggests a high potential for aggregation and compounding effects, **particularly with long-term exposure**" (emphasis added).[176]

4. Impact of Emerging Contaminants: Pharmaceuticals and "Forever Chemicals" in Our Environment Suggest Mifepristone Contamination Deserves Strict Scrutiny

Overview: Mifepristone's Active Metabolites and the Potential for Harm

Metabolites are formed after a drug is broken down in the body (metabolized).[177] If they retain "therapeutic effects," they are known as active metabolites.[178] As it pertains to the abortion pill, mifepristone forms active metabolites that retain therapeutic effects similar to mifepristone itself, which may enter our water via excretion, as outlined above.[179]

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[173] Susan T. Glassmeyer et. al., "Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States," Science of the Total Environment, December 2016, https://www.sciencedirect.com/science/article/pii/S0048969716326894?ref=pdf_download&fr=RR-2&rr=946880df1e0ddd19.

[174] Ibid.

[175] Manvendra Patel, Rahul Kumar, Kamal Kishor, Todd Mlsna, Charles U. Pittman Jr., Dinesh Mohan, "Pharmaceuticals of Emerging Concern in Aquatic Systems: Chemistry, Occurrence, Effects, and Removal Methods," *Chemical Reviews,* Vol. 119, No. 6, March 4, 2019, https://pubs.acs.org/doi/10.1021/acs.chemrev.8b00299.

[176] Ojima Zechariah Wada and David Bamidele Olawade, "Recent occurrence of pharmaceuticals in freshwater, emerging treatment technologies, and future considerations: A review," *Chemosphere,* Vol. 374, April 2025, https://www.sciencedirect.com/science/article/pii/S0045653525000955.

[177] "Overview of Active Metabolites," Creative Proteomics, accessed April 8, 2025, https://www.creative-proteomics.com/resource/overview-of-active-metabolites.htm.

[178] While the therapeutic effects can be similar to or distinct from the parent drug, in the case of mifepristone, they are similar (see the following footnote). Ibid.

[179] N. N. Sarkar, "Mifepristone: bioavailability, pharmacokinetics and use-effectiveness," *European journal of obstetrics, gynecology, and reproductive biology*, Vol. 101, No. 2, March 10, 2002, https://www.ejog.org/article/S0301-2115(01)00522-X/fulltext. Specifically, this article states: "Three

As it relates to potential for harm, mifepristone acts as an endocrine disruptor—that is, it "disrupts" natural hormonal processes.[180] PFAS, a subset of pollutants that have recently come under extreme scrutiny for their adverse effects on human health, are also potential endocrine disruptors[181] (detailed further below). Evidence today shows that even in low concentrations in the environment, contamination from these endocrine-disrupting pollutants, as well as various other pharmaceutical pollutants, can be harmful to human and animal health.[182]

Even so, to date, the federal government has not studied the extent to which active abortion pill metabolites may be entering the environment, nor the possibility they may be adversely impacting animal or human health.

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metabolites of mifepristone have been identified. This compound undergoes demethylation to produce mono-demethylated (RU42633) and di-demethylated (RU42848) derivatives as well as hydroxylation of the propynyl group to yield hydroxylated metabolite (RU42698) . . . Like mifepristone, these metabolites are immunologically and biologically active and retain anti-progestational and anti-glucocorticoid properties. Elimination of mifepristone and its metabolites from the body is mainly through feces (83%) and urine (8.8%) within 6–7 days after administration of a single oral dose." Another source states, "[t]he major route of excretion of Mifepristone and metabolites is via the faeces (83%) with 9% being excreted in the urine," though there is "uncertainty about the amounts metabolites excreted." See: "Mifepristone Linepharma," *Environmental impact Mifepristone*. . . Finally, as per a 2003 study: "The three most proximal metabolites, namely, monodemethylated, didemethylated and hydroxylated metabolites of mifepristone, all retain considerable affinity toward human progesterone and glucocorticoid receptors. Also, the serum levels of these three metabolites are in ranges similar to those of the parent mifepristone." See: Oskari Heikinheimo, Raimo Kekkonen, and Pekka Lähteenmäki, "The pharmacokinetics of mifepristone in humans reveal insights into differential mechanisms of antiprogestin action," *Contraception*, December 2003, https://pubmed.ncbi.nlm.nih.gov/14698071/. See also: Blake M. Autry and Roopma Wadhwa, "Mifepristone," National Library of Medicine, February 28, 2024, https://www.ncbi.nlm.nih.gov/books/NBK557612/.

[180] "Endocrine Disruptors and Your Health," National Institute of Environmental Health Sciences, March 2023, https://www.niehs.nih.gov/sites/default/files/health/materials/endocrine_disruptors_508.pdf.

[181] Ibid., see also: Scott Belcher, "PFAS Chemicals: EDCs Contaminating Our Water and Food Supply," Endocrine Society, accessed May 9, 2025, https://www.endocrine.org/topics/edc/what-edcs-are/common-edcs/pfas, and Katarzyna Mokra, "Endocrine Disruptor Potential of Short- and Long-Chain Perfluoroalkyl Substances (PFASs)—A Synthesis of Current Knowledge with Proposal of Molecular Mechanism," *International Journal of Molecular Sciences,* Vol. 22, No. 4, February 21, 2021, https://pmc.ncbi.nlm.nih.gov/articles/PMC7926449/.

[182] Water Science School, "Pharmaceuticals in Water," U.S. Geological Survey, June 6, 2018, https://www.usgs.gov/special-topics/water-science-school/science/pharmaceuticals-water#overview; Teresa A. Donovan, "Musing Aloud," *Research Gate,* August 2015, https://www.researchgate.net/publication/281101224; Michael Phillis, "Why is the EPA regulating PFAS and what are these 'forever chemicals'?" Associated Press, April 10, 2024, https://apnews.com/article/forever-chemicals-pfas-pollution-epa-drinking-water-517ce0049ffbd2931157da4970992f05.

Known & Suspected Harms of Various Pharmaceuticals

As summarized above, there is a potential that either on its own or in combination with other contaminants, mifepristone is harming our waterways. Consider the following evidence:

- A study on the effects of long-term exposure to mifepristone on Nile tilapia found strong indication that "long-term exposure of RU486 [mifepristone] resulted in sex reversal of XX female fish."[183] This same study also highlights that mifepristone has been detected in the water supply in China.
- Addressing the issue of medications being flushed into our waterways more broadly, Richard A. Lovett, writing for *Nature,* outlines, "[s]cientists have known for years that human medications, from anti-inflammatories to the hormones in birth-control pills, are ending up in waterways and affecting fish and other organisms."[184] Indeed, in developed nations like the U.S. and countries in Europe, "fish and other aquatic organisms may be exposed to a *variety* of hormonally active compounds and their metabolites or conjugates,"[185] leading to adverse health impacts. In short, there is "mounting evidence that excretion of hormonal contraceptives and their metabolites have immediate and long-term effects on our aquatic and human ecosystems."[186]
- A 2014 article on drugs being flushed into our environment highlights research that "an anti-depressant reduces feeding in starlings" and "a contraceptive drug slashes fish populations in lakes."[187]

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[183] Jing Cai, Lu Li, Lingyun Song, Lang Xie, Feng Luo, Shaohua Sun, Tapas Chakraborty, Linyan Zhou, and Deshou Wang, "Effects of long term antiprogestine mifepristone (RU486) exposure on sexually dimorphic lncRNA expression and gonadal masculinization in Nile tilapia (*Oreochromis niloticus*)," *Aquatic Toxicology,* Vol. 215, October 2019, https://www.sciencedirect.com/science/article/abs/pii/S0166445X19305004?via%3Dihub. Note: While it is unclear if the exposure levels used in the study are similar to those expected in the environment, the study demonstrates mifepristone exposure may cause harm to wildlife over time, suggesting further research is warranted.

[184] Teresa A. Donovan, "Musing Aloud," *Research Gate,* August 2015, https://www.researchgate.net/publication/281101224_Musing_aloud; Richard A. Lovett, "Human drugs make fish flounder," *Nature,* November 16, 2012, https://www.nature.com/articles/nature.2012.11843. The former article references other studies highlighting the adverse impacts of various estrogens; for example, "Bhandari and colleagues (2015) found that exposure to environmentally relevant quantities of ethinyl estradiol—commonly contained in most oral contraceptive regimens—led to reduced fertility rates and increased embryo mortality in a model fish population. Moreover, adverse impacts on population health persisted in offspring three generations later."

[185] Teresa A. Donovan, "Musing Aloud."

[186] Ibid.

[187] Damian Carrington, "Drugs flushed into the environment could be cause of wildlife decline," The Guardian, October 12, 2014, https://www.theguardian.com/environment/2014/oct/13/drugs-flushed-into-the-environment-could-be-cause-of-wildlife-decline; see also the following article cited by the aforementioned source: Tom G. Bean, Alistair B. A. Boxall, Julie Lane, Katherine A. Herborn, Stéphane Pietravalle and Kathryn E. Arnold, "Behavioural and physiological responses of birds to environmentally relevant concentrations of an antidepressant," Philosophical Transactions of the Royal Society B,

- Likewise in 2013, publishing in the journal Environmental Pollution, scientists outlined the "'presence of the synthetic estrogen 17α-ethinylestradiol (EE2) [used widely in contraceptives[188]] in the environment is of increasing concern due to the endocrine disruption of aquatic organisms. Incomplete removal from wastewater (WW) is one of the main sources of EE2 in aquatic ecosystems, thus improving processes like biological WW treatment/activated sludge (AS) is becoming significantly important."[189]
- A 2021 study utilizing "a series of comprehensive literature surveys" corroborates the above, noting, for example, that the "feminization" effect on fish populations from the use of contraceptives is well documented.[190]
- The U.S. Geological Survey acknowledges of the over 4,000 human and animal prescription medications, many "ultimately find their way into the environment," polluting either "directly from pharmaceutical manufacturing plants or from humans and animals." [191] This "pollution" from humans includes some pharmaceutical drugs that are "excreted essentially unchanged" after passing through the body. [192] Once these chemicals enter the environment, they unsurprisingly can affect the behaviour and health of different forms of wildlife.[193]
- An interview conducted by the U.S. Geological Survey further highlights that, as noted above, it has long been suspected that a variety of "emerging contaminants" are entering the environment, though they have only recently been "verified due to improvements in analytical techniques." [194] These contaminants include pharmaceuticals, endocrine-disrupting compounds, and numerous others. Again,

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November 19, 2014, https://royalsocietypublishing.org/doi/10.1098/rstb.2013.0575. This study states, "[M]any wildlife species forage on sewage-contaminated food, for example, at wastewater treatment plants and on fields fertilized with sewage sludge. The resultant exposure to human pharmaceuticals remains poorly studied for terrestrial species." To study this, the researchers "administered the common antidepressant fluoxetine (FLUOX) or control treatment via prey to wild-caught starlings," using as a basis "predicted exposure levels in the wild." Their results "suggest that fluoxetine at environmentally relevant concentrations can significantly alter behaviour and physiology." See also: Karen A. Kidd, Michael J. Paterson, Michael D. Rennie, Cheryl L. Podemski, Dave L. Findlay, Paul J. Blanchfield and Karsten Liber, "Direct and indirect responses of a freshwater food web to a potent synthetic oestrogen," Philosophical Transactions of the Royal Society B, November 19, 2014, https://royalsocietypublishing.org/doi/full/10.1098/rstb.2013.0578.

[188] "17α-Ethinylestradioland Mestranol and Drinking Water . . ."

[189] Simone Larcher and Viviane Yargeau, "Biodegradation of 17α-ethinylestradiol by heterotrophic bacteria," *Environmental Pollution,* Vol. 173, February 2013, https://www.sciencedirect.com/science/article/abs/pii/S0269749112004678.

[190] William V Williams et. al., "Hormonally Active Contraceptives, Part II: Sociological, Environmental, and Economic Impact," *The Linacre Quarterly*, Vol. 88, No. 3, April 21, 2021, https://journals.sagepub.com/doi/10.1177/00243639211005121.

[191] Water Science School, "Pharmaceuticals move throughout the aquatic environment," U.S. Geological Survey, accessed April 8, 2025, https://www.usgs.gov/media/images/pharmaceuticals-move-throughout-aquatic-environment.

[192] Ibid.

[193] Ibid.

[194] Water Science School, "Pharmaceuticals in Water," . . .

wastewater treatment plants do not remove all the contaminants, and as outlined in the interview, "[i]t turns out that there is evidence **that even at these really low concentrations some of these emerging contaminants are actually harmful to the environment**" (emphasis added).[195] By way of example, the interviewee highlights a study that found largemouth and smallmouth bass "are exhibiting female characteristics even in the male fish, and this phenomenon appears to be widespread in rivers and streams across the U.S."[196]

- Similarly, a 2022 research analysis on emerging contaminants (EC) in water and wastewater found "[a]ll ECs are potential hazardous materials of ecosystem affecting the quality of freshwater . . . Exposure of such contaminants and its bioaccumulation can induce endocrine disruption, congenital disorders, mutagenesis and carcinogenesis, etc. on human health."[197] These EC "involve a wide variety of compounds **including pharmaceuticals** (veterinary and human drugs) . . . etc." (emphasis added) and enter the aquatic ecosystem (where water is drawn from to supply drinking water, irrigate crops, and more) principally via "municipal and industrial Wastewater Treatment Plants (WWTP) that treat domestic sewage, wastewater from hospital, chemical manufacturing plants, livestock and agriculture."[198]

Notably, the EPA keeps a list of possible harmful water contaminants for periodic review (based on authority given to the agency under the Safe Drinking Water Act),[199] which has historically included certain pharmaceuticals.[200] Given the above, at the very least, mifepristone should be considered for such a list.

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[195] Ibid.
[196] Ibid.
[197] Lata Ramrakhiani, Sourja Ghosh, & Swachchha Majumdar, "Emerging Contaminants in Water and Wastewater: Remediation Perspectives and Innovations in Treatment Technologies," *Springer Nature,* May 25, 2022, https://www.researchgate.net/publication/360849479_Emerging_Contaminants_in_Water_and_Wastewater_Remediation_Perspectives_and_Innovations_in_Treatment_Technologies.
[198] Ibid.
[199] Contaminant Candidate List (CCL) and Regulatory Determination," Environmental Protection Agency, January 30, 2025, https://www.epa.gov/ccl/basic-information-ccl-and-regulatory-determination; "Drinking Water Contaminant Candidate List (CCL) and Regulatory Determination," United States Environmental Protection Agency, March 27, 2025 https://www.epa.gov/ccl.
[200] "Contaminant Candidate List 4—CCL 4," United States Environmental Protection Agency, Last modified November 27, 2024, https://www.epa.gov/ccl/contaminant-candidate-list-4-ccl-4-0 ;"Drinking Water Contaminant Candidate List (CCL) and Regulatory Determination," United States Environmental Protection Agency, March 27, 2025 https://www.epa.gov/ccl; "Contaminants to Monitor in Fish and Shellfish Advisory Programs: Compilation of Peer Review-Related Information," United States Environmental Protection Agency | Office of Water, July 2024, https://www.epa.gov/system/files/documents/2024-06/contaminants-monitor-fish-peer-review-package.pdf.

Endocrine Disrupting Chemicals: Abortion Pill Metabolites Are Potential Endocrine Disruptors

Some pharmaceuticals found in the environment are part of a wider class of contaminants known as endocrine-disrupting chemicals (EDC) (this includes, for example, a synthetic estrogen).[201] Specifically, these chemicals "are natural or human-made chemicals that may mimic, block, or interfere with the body's hormones."[202] Similar to the increasing concerns related to pharmaceuticals, there is mounting evidence that EDCs are entering our waterways, harming humans and animals. Notably:

- By blocking the natural hormone progesterone (as outlined previously), mifepristone acts as an endocrine disruptor.[203]
- As per the National Institute of Environmental Health Sciences, endocrine-disrupting chemicals "are associated with a wide array of health issues."[204]
    - Various scientific studies demonstrate the risks and detrimental impacts these "disruptors" can have on the environment.[205]

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[201] To be clear, not all pharmaceuticals are EDCs, and not all EDCs are pharmaceuticals—but some compounds are both, like mifepristone and synthetic estrogen. See for example: Maite Ortúzar, Maranda Esterhuizen, Darío Rafael Olicón-Hernández, Jesús González-López, Elisabet Aranda, "Pharmaceutical Pollution in Aquatic Environments: A Concise Review of Environmental Impacts and Bioremediation Systems," *Frontiers in Microbiology,* April 26, 2022, https://pmc.ncbi.nlm.nih.gov/articles/PMC9087044/. See also: "17α-Ethinylestradioland Mestranol and Drinking Water," Minnesota Department of Health, September 2016, https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/mestraethinyleinfo.pdf and Karen A. Kidd, Michael J. Paterson, Michael D. Rennie, Cheryl L. Podemski, Dave L. Findlay, Paul J. Blanchfield and Karsten Liber, "Direct and indirect responses of a freshwater food web to a potent synthetic oestrogen," Philosophical Transactions of the Royal Society B, November 19, 2014, https://royalsocietypublishing.org/doi/full/10.1098/rstb.2013.0578.

[202] "Endocrine Disruptors and Your Health," National Institute of Environmental Health Sciences, March 2023, https://www.niehs.nih.gov/sites/default/files/health/materials/endocrine_disruptors_508.pdf. Similarly, as per the Endocrine Society, "Endocrine-disrupting chemicals (EDCs) are substances in the environment (air, soil, or water supply), food sources, personal care products, and manufactured products that interfere with the normal function of your body's endocrine system. Since EDCs come from many different sources, people are exposed in several ways, including the air we breathe, the food we eat, and the water we drink. EDCs also can enter the body through the skin." See: Daniel Ruiz and Heather Patisaul, "Endocrine-Disrupting Chemicals (EDCs)," Endocrine Society, January 24, 2022, https://www.endocrine.org/patient-engagement/endocrine-library/edcs.

[203] "Compound Summary | Mifepristone," *Pub Chem,* accessed April 23, 2025, https://pubchem.ncbi.nlm.nih.gov/compound/RU486#section=Human-Drugs. See also "Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation," FDA, February 11, 2025, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[204] "Endocrine Disruptors and Your Health," National Institute of Environmental Health Sciences . . .

[205] See for example: Andressa Gonsioroski, Vasiliki E. Mourikes, Jodi A. Flaws, "Endocrine Disruptors in Water and Their Effects on the Reproductive System," *International Journal of Molecular Sciences,* 2020, https://www.mdpi.com/1422-0067/21/6/1929; Concetta Pironti, Maria Ricciardi, Antonio Proto, Pietro Massimiliano Bianco, Luigi Montano, Oriana Motta, "Endocrine-Disrupting Compounds: An Overview on Their Occurrence in the Aquatic Environment and Human Exposure," . . . (this study notes as well contaminants may not be totally removed by wastewater treatment); Aswin Thacharodi, Saqib Hassan,

    - According to one of said studies, EDCs are "some of the major chemicals that are known as water contaminants" and exposure to them "is associated with adverse health and reproductive outcomes in non-human animals and humans; thus, the presence of these chemicals in water has become a public health concern."[206]
    - While the sources of this chemical contamination in water are diverse, they include "byproducts formed during water disinfection processes," as well as "release from industry and livestock activity, or **therapeutic drugs released into sewage**."[207]
- The EPA, acknowledging the research that has accumulated on the subject of endocrine disruptors, states, **"there has been a growing awareness of the possible adverse effects in humans and wildlife from exposure to chemicals that can interfere with the endocrine system.** These effects can include:
    - developmental malformations;
    - interference with reproduction;
    - increased cancer risk; and
    - disturbances in the immune and nervous system function."[208]
- Individuals working within the EPA further outlined that "drugs that our *[sic]* designed to disrupt our endocrine system, like oral contraceptives and hormone replacement therapies, also disrupt the endocrine system of fish and other aquatic organisms when they get into our waterways."[209]

Amid the growing awareness, according to the EPA, "very few chemicals have been tested for their potential to interfere with the endocrine system. Current standard test methods do not provide adequate data to identify potential endocrine disruptors (EDs) or to assess their risks to humans and wildlife."[210] Still, based on what is known, the EPA concludes that "**there is little doubt that small disturbances in endocrine function, particularly during certain highly sensitive stages of the lifecycle (e.g., development,**

Thanushree A. Hegde, Dhanya Dilip Thacharodi, Kathirvel Brindhadevi, Arivalagan Pugazhendhi, "Water a major source of endocrine-disrupting chemicals: An overview on the occurrence, implications on human health and bioremediation strategies," *Environmental Research*, Vol. 231, August 15, 2023, https://www.sciencedirect.com/science/article/abs/pii/S0013935123008897; Diana A Stavreva et. al., "Mapping multiple endocrine disrupting activities in Virginia rivers using effect-based assays," *National Library of Medicine*, June 15, 2021, https://pubmed.ncbi.nlm.nih.gov/33592464/; Teresa A. Donovan, "Musing Aloud," among others.

[206] Andressa Gonsioroski, Vasiliki E. Mourikes, Jodi A. Flaws, "Endocrine Disruptors in Water and Their Effects on the Reproductive System," . . .

[207] Ibid.

[208] "Overview of Endocrine Disruption," Environmental Protection Agency, December 19, 2024, https://www.epa.gov/endocrine-disruption/overview-endocrine-disruption.

[209] S. Ernst, "Don't Flush! Why Your Drug Disposal Method Matters," It All Starts With Science, U.S. EPA Office of Research and Development, 2016, https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=312892&Lab=NHEERL.

[210] "Overview of Endocrine Disruption," Environmental Protection Agency, . . .

pregnancy, lactation) can lead to profound and lasting effects"[211] (emphasis added). Given "small disturbances" of endocrine function can have "profound" effects, even if its impact as a potential endocrine disruptor is minimal, further study and monitoring of mifepristone is sorely needed.

Especially Harmful Endocrine Disruptors: "Forever Chemicals" and Their Parallel to Mifepristone

Notably, a subset of these possible endocrine disrupting chemicals is currently receiving heightened scrutiny from the EPA: perfluoroalkyl and polyfluoroalkyl substances (PFAS), commonly referred to as "forever chemicals."[212] PFAS are a "category of chemicals used since the 1940s," certain ones of which science has shown "can cause cancer and other illnesses" after long-term exposure.[213] Similarly, an EPA "Action Plan" published during the first Trump administration notes that, "[d]epending on the PFAS, increased risks observed in some animal studies include developmental effects to fetuses during pregnancy and infants . . . cancer . . . immune effects" and more.[214]

- Numerous steps are being taken to combat PFAS contamination given the harm they can cause by entering our water supply—even though the amount of the substances in the water is minimal (measured in parts per trillion [ppt])[215]: In 2024, the EPA issued requirements for monitoring certain PFAS substances, addressing a decades-long oversight related to its failure to properly regulate PFAS.[216]

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[211] Ibid.

[212] Michael Phillis, "Why is the EPA regulating PFAS and what are these 'forever chemicals'?" Associated Press, April 10, 2024, https://apnews.com/article/forever-chemicals-pfas-pollution-epa-drinking-water-517ce0049ffbd2931157da4970992f05. See also: "Endocrine Disruptors and Your Health," National Institute of Environmental Health Sciences . . .

[213] "Biden-Harris Administration Finalizes First-Ever National Drinking Water Standard to Protect 100M People from PFAS Pollution," United States Environmental Protection Agency, April 10, 2024, https://www.epa.gov/newsreleases/biden-harris-administration-finalizes-first-ever-national-drinking-water-standard.

[214] EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan, United States Environmental Protection Agency, February 2019, https://www.epa.gov/sites/default/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.

[215] Ibid.

[216] "EPA's Final PFAS National Primary Drinking Water Regulation: Monitoring and Reporting," United States Environmental Protection Agency, April 2024, https://www.epa.gov/system/files/documents/2024-04/pfas-npdwr_fact-sheet_monitoring_4.8.24_0.pdf. Of note, in 2025 the EPA published "Frequent Questions about PFAS Methods for NPDES Permits," which states, "National Pollutant Discharge Elimination System (NPDES) permitting authorities and pretreatment control authorities implement effluent monitoring conditions in NPDES permits and Industrial User permits for the discharge of per- and polyfluoroalkyl substances (PFAS) in wastewater." See: "Frequent Questions about PFAS Methods for NPDES Permits," United States Environmental Protection Agency, January 2025, https://www.epa.gov/cwa-methods/frequent-questions-about-pfas-methods-npdes-permits.

- In May of 2025, the EPA announced that though it intends to reconsider the monitoring requirements for some PFAS, it will maintain the requirements for monitoring two of the aforementioned PFAS chemicals.[217]
- Newly appointed EPA Administrator Lee Zeldin has likewise outlined agency actions to address PFAS pollution, including (among other things) designating "an agency lead for PFAS," creating "effluent limitations guidelines (ELGs) for certain PFAS to stop these forever chemicals from entering drinking water systems," and launching "initiatives to engage with Congress and industry to establish a clear liability framework that ensures the polluter pays and passive receivers are protected."[218]
- Finally, as previously outlined by the EPA, while "[c]urrent scientific research suggests that exposure to certain PFAS may lead to adverse health outcomes," **research is still needed and is underway** to "better understand the health effects associated with low levels of exposure to PFAS over long periods of time."[219]

Given that current evidence suggests mifepristone metabolites may also adversely affect human and animal health, further research is likewise needed to better understand the possible health impacts from "low levels of exposure" to them. Considering the known impact of mifepristone on women (ending a pregnancy) alongside the known, detrimental impact similar pharmaceutical drugs can have even on aquatic wildlife even at low concentration levels—this is a matter of utmost concern. Should said abortion pill contaminants continue to accumulate, it is possible that animals and humans may experience detrimental impacts.

Mounting Evidence a Cause for Action

The evidence outlined above clearly demonstrates the abortion pill is part of a larger picture that involves a wide range of diverse, harmful contaminants entering our waterways—a picture well painted in the "Make America Healthy Again" Report released in May 2025.[220]

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[217] "EPA Announces It Will Keep Maximum Contaminant Levels for PFOA, PFOS," United States Environmental Protection Agency, May 14, 2025, https://www.epa.gov/newsreleases/epa-announces-it-will-keep-maximum-contaminant-levels-pfoa-pfos. See also: "Per- and Polyfluoroalkyl Substances (PFAS)," United States Environmental Protection Agency, May 16, 2025, https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.

[218] EPA Press Office, "Administrator Zeldin Announces Major EPA Actions to Combat PFAS Contamination," United States Environmental Protection Agency, April 28, 2025, https://www.epa.gov/newsreleases/administrator-zeldin-announces-major-epa-actions-combat-pfas-contamination.

[219] "Our Current Understanding of the Human Health and Environmental Risks of PFAS," The United States Environmental Protection Agency, November 26, 2024, https://www.epa.gov/pfas/our-current-understanding-human-health-and-environmental-risks-pfas.

[220] The MAHA Report | Make Our Children Healthy Again Assessment," The White House, accessed May 23, 2025, https://www.whitehouse.gov/wp-content/uploads/2025/05/WH-The-MAHA-Report-Assessment.pdf. For example, the report states, "The cumulative load of thousands of synthetic

Yet even in the face of mounting evidence that this is the case, skeptics suggest the abortion pill remains perfectly safe. One such skeptic, Tracey Woodruff, an environmental health professor at the University of California San Francisco, has done studies that found "when traces of hormonal birth control medications make it into rivers and streams, they enter the environment from industrial farms that don't treat their wastewater, not via human consumption."[221] This conclusion is not only contradicted by other sources [222] (noting hormonal birth control does enter our water from human excretion) but fails to address the fact that, as outlined by the EPA, numerous other pharmaceuticals *also enter our waterways via human consumption* (excretion), and most wastewater treatment plants are *not designed to remove them*.[223]

Woodruff also notes that "*[a]ll kinds of pharmaceuticals are in the drinking water supply, so the fact that this group [Students for Life of America] is making this argument is not actually about drinking water . . . They are doing this to control women's bodies.*"[224] While again it is true that all kinds of pharmaceutical drugs are entering our water, and they are, in fact, cause for concern (indeed, all pharmaceuticals should be proven safe before entering our waterways), no other pill is uniquely designed to end life in the womb and leads to human remains entering the water supply. Given these distinctions, heightened scrutiny is called for. Until then, the core issue remains: The overall environmental impact mifepristone may have on our water supply (either on its own, based on the drug's lethal nature, or in tandem with other pollutants) and its potential to cause harm by entering our tap water is unknown and should have been studied prior to its approval. Further testing and study are more than justified.

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chemicals that our children are exposed to through the food they eat, the water they drink, and the air they breathe may pose risks to their long-term health, including neurodevelopmental and endocrine effects," and "The cumulative effect of multiple chemical exposures and impact on children over time is not fully understood."

[221] Ariel Wittenberg and Alice Miranda Ollstein, "'Using the devil's own tools against them' . . . ".

[222] While hormonal birth control can enter the water via "industrial farms that don't treat their wastewater," it can also enter "via human consumption," and via "city wastewater treatment plants;" see, for example: William V. Williams et. al., and "Hormonally Active Contraceptives, Part II: Sociological, Environmental, and Economic Impact . . . "; Aria Bendix, "Birth-control pills could add 10 million doses of hormones to our wastewater every day. Some of that estrogen may wind up in our taps," Business Insider, October 24, 2019, https://www.businessinsider.com/birth-control-pills-hormones-estrogen-drinking-water-health-effects-2019-10; and "17α-Ethinylestradioland Mestranol and Drinking Water," Minnesota Department of Health . . ., which states "EE2 and MeEE2 enter the environment through human excretion and through the disposal of unused medications into toilets, sink, and landfills. EE2and MeEE2 pass through the body and are excreted in urine and feces. Wastewater treatment removes some of the EE2, but some passes through into the environment."

[223] See footnote 8.

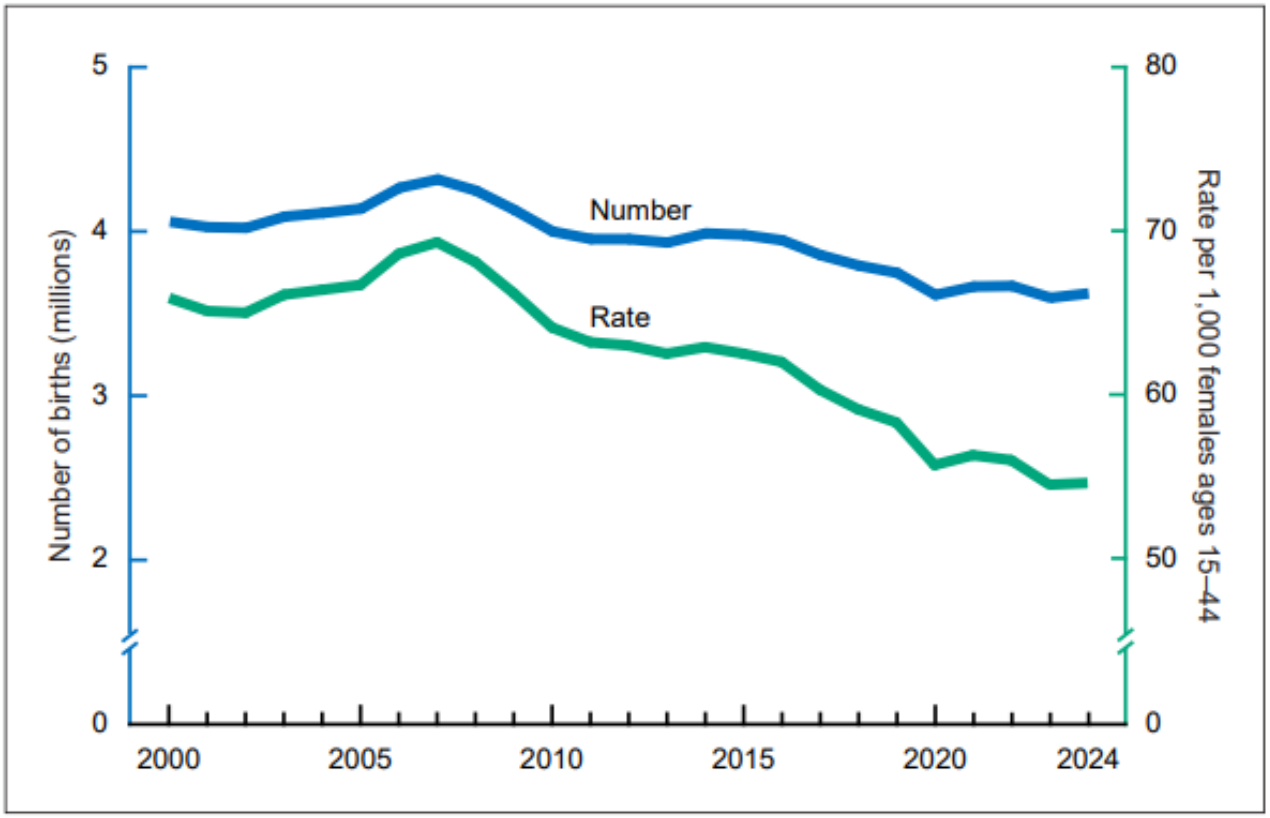
[224] Ariel Wittenberg and Alice Miranda Ollstein, "'Using the devil's own tools against them' . . ."

Further Food for Thought

Recall that mifepristone acts as an endocrine disruptor that blocks progesterone, a vital fertility hormone.[225] Its metabolites may remain active after excretion and passing through wastewater treatment plants. That wastewater enters the streams and lakes that supply water for our taps, and conventional drinking water treatments do not fully remove all pharmaceutical contaminants.

Now consider that infertility globally affects 1 in 6 individuals, and the U.S. is not exempt from this trend - as demonstrated by the declining fertility rates shown in Figure 4.[226]

Number of live births and general fertility rate: United States, final 2000-2023 and provisional 2024



SOURCE: National Center for Health Statistics, National Vital Statistics System, natality data file.

Figure 4; Brady E. Hamilton, Ph.D., Joyce A. Martin, M.P.H., and Michelle J.K. Osterman, M.H.S., "Vital Statistics Rapid Release | Births: Provisional Data for 2024," National Vital Statistics System, No. 38, April 2025, https://www.cdc.gov/nchs/data/vsrr/vsrr038.pdf.

Consider as well that endometriosis is present in up to 63% of unexplained infertility

[225] Mayo Clinic Staff, "Medical Abortion," Mayo Clinic, June 28, 2024, https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687.

[226] "1 in 6 people globally affected by infertility: WHO," World Health Organization, April 4, 2023, https://www.who.int/news/item/04-04-2023-1-in-6-people-globally-affected-by-infertility. The CDC reports that "1 in 5 (19%) of married women aged 15 to 49 with no prior births are unable to get pregnant after 1 year of trying," see: "Infertility: Frequently Asked Questions," U.S. Centers for Disease Control and Prevention, accessed May 23, 2205, https://www.cdc.gov/reproductive-health/infertility-faq/index.html.

cases[227] for women and can be treated in some with synthetic progesterone[228]—*the hormone that is blocked by mifepristone*. Furthermore, a 2023 study highlights that "[e]ndometriosis has been potentially linked to exposure to [endocrine disrupting chemicals]."[229]

It bears asking whether mifepristone's metabolites are playing a part in our nation's fertility crisis, given that if they are, addressing it is a matter of urgency.

5. Lack of Environmental Analysis on the Effect of Fetal Remains in our Water Supply May Have Exacerbated Evasion of Medical Waste Disposal Laws

Just as concerning if not more so than the possible adverse effects of active abortion pill metabolites that may be in our water supply is the issue of aborted babies (fetal remains) being disposed of into our water systems. Indeed, as has been outlined, the FDA's approval of Mifeprex/mifepristone in 2000 failed to consider (or intentionally overlooked) how disposal would be done. The result: Women performing abortions on themselves at home are not only left to suffer through the pain and trauma of expelling their dead unborn child, but they must also then decide what to do with the fetal remains of their abortions.

Fetal Remains Lack Dignified Disposal; Classification as Medical Waste Is Merely a Step Above Flushing

At the most basic level, fetal remains expelled after an abortion should be buried or cremated *as they are humans*.[230] Indeed, it is common knowledge that one does not dispose of deceased human beings (that is, those who pass away *outside* the womb) via dumping them into our waterways. Laws exist to ensure proper disposition of human

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[227] Camran Nezhat, Farrah Khoyloo, Angie Tsuei, Ellie Armani, Barbara Page, Thomas Rduch, Ceana Nezhat, "The Prevalence of Endometriosis in Patients with Unexplained Infertility," *Journal of Clinical Medicine,* Vol, 13, No. 2, January 13, 2024, https://www.mdpi.com/2077-0383/13/2/444.

[228] "Progesterone Resistance in Endometriosis," *American Medical Journal,* August 16, 2022, https://www.emjreviews.com/en-us/amj/reproductive-health/article/progesterone-resistance-in-endometriosis-j150122/. See also: "Progestin," Cleveland Clinic, March 21, 2023, https://my.clevelandclinic.org/health/treatments/24838-progestin.

[229] Sudipta Dutta, Sakhila K Banu, Joe A Arosh, "Endocrine disruptors and endometriosis," *Reproductive Toxicology,* Vol. 115, January 2023, https://www.sciencedirect.com/science/article/abs/pii/S0890623822001691.

[230] Note: While babies should not be aborted in the first place, given they are human beings and deserve the basic, foundational right to life, this paper is addressing the reality that abortion occur, and therefore dual tracks are needed in policy making—in addition to seeking an end to abortion, while it is allowed, fetal remains must be disposed of properly.

remains,[231] not only because we inherently believe human bodies should be treated with dignity, but also because they present a health and safety risk if not disposed of properly.

Sadly, this is often not the case when it comes to aborted babies. Even so, ***at the very least*, it is important to note that the outcome of an abortion consists of what the EPA would define as medical waste,**[232] specifically, "healthcare waste that may be contaminated by blood, body fluids or other potentially infectious materials."[233] The WHO expands further, noting that health care waste includes "pathological waste," which (among other things) consists of "human tissues, organs or fluids, body parts" and "foetuses."[234]

Backdrop: A Broken Patchwork of State Regulations on Fetal Disposition Post-Abortion and Varied Medical Waste Laws

State fetal disposition laws have failed to keep up with the increased use of abortion pills. Indeed, there are no standard procedures or regulations regarding the proper means by which to dispose of fetal remains after an at-home abortion, and state laws vary widely on this subject. While some states have laws regarding fetal disposition generally, as noted in point 1, they "are often archaic and scattered throughout a variety of state codes, regulations, and statutes."[235]

Yet, even for those states that fail to regulate the disposal of fetal remains post-abortion, all states have Regulated Medical Waste (RMW) regulations, as shown in Figure 5, which should have been considered in the abortion pill's approval process (outlined in section 1).

[231] "Rights and Obligations As To Human Remains and Burial," Stimmel, Stimmel & Roeser, accessed June 4, 2024, https://www.stimmel-law.com/en/articles/rights-and-obligations-human-remains-and-burial.
[232] To be clear, babies are by no means medical waste. They all—whether miscarried or aborted—deserve dignity; and at the very least, they should be disposed of via respectful, sanitary means.
[233] "Medical Waste," United States Environmental Protection Agency, May 17, 2024, https://www.epa.gov/rcra/medical-waste.
[234] "Health-care waste," World Health Organization, October 24, 2024, https://www.who.int/news-room/fact-sheets/detail/health-care-waste.
[235] Kristi Burton Brown, "Fetal Disposition: The Abuses and The Law . . ."

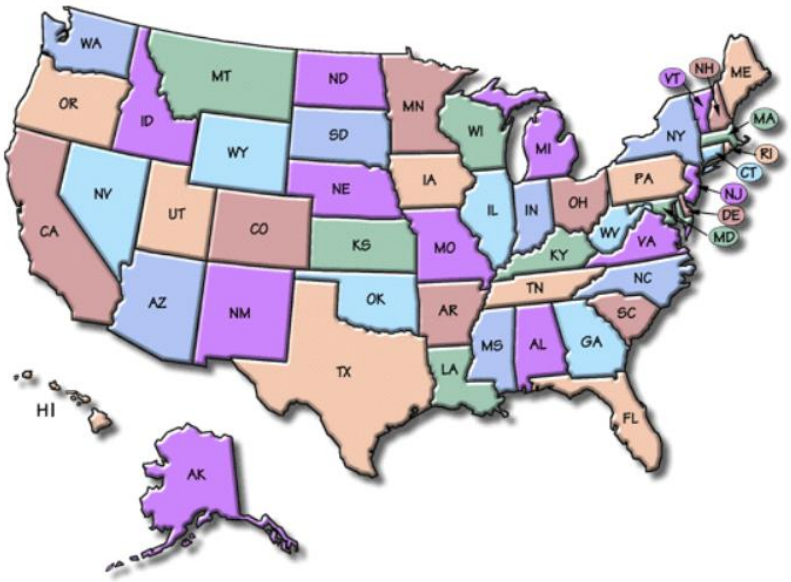

Figure 5; "State-by-state Regulated Medical Waste Resource Locator," Pollution Prevention and Compliance Assistance Information for the Healthcare Industry, Healthcare Environmental Resource Center, 2015, https://www.hercenter.org/rmw/rmwlocator.php.

Though the terminology among states for RMW varies, including "regulated medical waste, biohazardous waste or infectious medical waste," the terms used usually "refer to the same thing: that portion of the medical waste stream that may be contaminated by blood, body fluids or other potentially infectious materials, thus ***posing a significant risk of transmitting infection***."[236] In order to ensure such waste is properly handled, most state regulations cover "packaging, storage, and transportation of medical waste."[237] State rules may further include "on-site treatment, training, waste tracking, recordkeeping, and reporting."[238] (For an example of state regulations pertaining to medical waste, see section entitled "Case Study: Florida" below.) In short, while abortion providers must adhere to their states' RMW standards for abortions performed in a clinic, somehow, at-home abortions have evaded these requirements.

Federal Guidelines: Generators (Abortion Providers) of Medical Waste are Meant to Dispose of Medical Waste

Though medical waste is primarily regulated by the states, various federal agencies have created regulatory standards for disposing of medical and pathological waste. These regulations underscore the reality that fetal remains are, in fact, medical waste and should be subject to proper disposal.

[236] Regulated Medical Waste State Resource Locator | Georgia, 2018, https://www.envcap.org/srl/rmw/ga-rmw.html.
[237] Ibid.
[238] Ibid.

- The EPA houses model guidelines for State Medical Waste Management on its website. According to these guidelines, this sort of waste—that is, all human "medical waste" (though again, babies are by no means waste)—is meant to be sterilized, disinfected, or decontaminated, which can be done via incineration, chemical disinfection, thermal inactivation, or other means.[239] Instead, with at-home abortions, fetal remains are flushed down the toilet.
- These guidelines further outline that "[e]ach medical waste generator [which include but are not limited to hospitals, care facilities, clinics, physician offices, dental offices, etc.] should prepare a written management and operations plan outlining policies and procedures for the safe and effective management of medical waste."[240] In other words, the *generator* of the medical waste, not the patient, should be responsible for "policies and procedures" that lead to the safe management of medical waste.
    - While guidelines are, by nature, unenforceable, they set out principles and standards of best practice that merit attention. In at-home abortions, the generators of medical waste are (arguably) the abortion providers sending women abortion pills. By these standards, they should be ensuring the safe and effective management of the waste that is generated yet are failing to do so.
    - In a parallel example, consider that when a limb is amputated, medical doctors do not give individuals their "leg in a bag to take care of elsewhere."[241] Rather, "the medical practitioner that began the chain of events leading to the tissue is responsible for its proper disposal."[242]
- Likewise, according to the CDC, "[m]edical wastes require careful disposal and containment before collection and consolidation for treatment. OSHA has dictated initial measures for discarding regulated medical-waste items . . . Any facility that generates regulated medical wastes should have a regulated medical waste management plan to ensure health and environmental safety as per federal, state, and local regulations." [243] In a similar vein, the American Academy of Family

[239] R. Steven Brown et. al, "Model Guidelines for State Medical Waste Management," The Council of State Governments, 1992, https://www.epa.gov/sites/default/files/2016-02/documents/model_guidelines_for_state_medical_waste_management.pdf.
[240] "Model Guidelines for State Medical Waste Management," United States Environmental Protection Agency, September 26, 2024, https://www.epa.gov/rcra/model-guidelines-state-medical-waste-management. Note: While "self care" is included in the list of generators, a woman cannot prescribe herself the abortion pill; hence, the "care" comes from the abortion provider issuing the pills. Therefore, they should be responsible for the waste generated.
[241] Kristi Hamrick, "Thank you PolitiFact for Making Our Case About the Potential Harms of Chemical Abortion Pills to America's Water Safety . . ."
[242] Ibid.
[243] "Regulated Medical Waste | Guidelines for Environmental Infection Control in Health-Care Facilities," U.S. Centers for Disease Control and Prevention, January 8, 2024, https://www.cdc.gov/infection-control/hcp/environmental-control/regulated-medical-waste.html.

Physicians states that medical waste not disposed of appropriately "can pose harmful environmental concerns and significant health risks to the public," including "potential water contamination."[244] They, therefore, encourage practices that "keep all medical and non-medical waste separate to avoid contamination and to facilitate safe disposal of all medical waste," noting that "the importance of routine medical waste disposal and destruction practices should be stressed at all city and county levels of collection."[245]

    - Again illogically, it seems unless an abortion is performed in an abortion "facility," abortion providers have been permitted to ignore these standard practices.

- While waste treatment options vary, the CDC's website states, "Historically, treatment methods involved steam-sterilization (i.e., autoclaving), incineration, or interment (for anatomy wastes). Alternative treatment methods developed in recent years include chemical disinfection, grinding/shredding/disinfection methods, energy-based technologies (e.g., microwave or radio wave treatments), and disinfection/encapsulation methods."[246]
    - Disposing of human body parts in the sewer system or other U.S. waterways is conspicuously absent as a waste treatment option. [247]

Like their evasion of state RMW regulations, abortion providers have likewise failed to adhere to federal guidelines outlining the need to ensure medical waste is properly disposed of. While they may argue the home setting relieves them of this responsibility, as noted in section one, regulations that require abortion providers to properly dispose of fetal remains after a surgical abortion but not after abortions performed at home create an illogical double standard. This double standard has led to massive amounts of medical waste entering our sewer systems, which in any other context would be a national scandal. This discrepancy *(medical waste laws applying to and being enforced for abortions done in clinic vs. outside the clinic)* urgently needs addressing.

If We Are Not Meant to Flush Baby Wipes, We Should Not Be Flushing Babies

As the above demonstrates, our water systems (wastewater treatment plants) are not meant to be treating pathological waste,[248] which is typically subject to a more intense

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[244] "Medical Waste Disposal in Non-Medical Locations," American Academy of Family Physicians, December 2024, https://www.aafp.org/about/policies/all/medical-waste-disposal.html.
[245] Ibid.
[246] "Regulated Medical Waste | Guidelines for Environmental Infection Control in Health-Care Facilities," U.S. Centers for Disease Control and Prevention . . .
[247] Ibid. While the CDC's webpage goes on to note: "*Small amounts of blood and other body fluids should not affect the functioning of a municipal sewer system. However, large quantities of these fluids, with their high protein content, might interfere with the biological oxygen demand (BOD) of the [municipal sewer] system*," this only refers to fluids—aborted fetal remains include body parts, not just fluids.
[248] Indeed, they are not set up to do so. Furthermore, and even if the remains are "disinfected" so to speak, allowing fetal remains to enter the environment—as detailed in section 1—affects the "*quality of*

treatment process.[249] To underscore this point, consider that the EPA recommends against flushing anything but toilet paper to help ensure "that the toilets, plumbing, sewer systems and septic systems will continue working properly to safely manage our nation's wastewater."[250] The EPA specifically states, "[p]reventable toilet and sewer backups can pose a threat to human health and present an extra challenge to our water utilities and their workforce. **Flushing anything other than toilet paper** [wipes, tampons, etc.] . . . **can damage internal plumbing, local sewer systems and septic systems."**[251]

And indeed, this has happened as a result of flushing a fetus: The tenant of an apartment complex in Texas was "working to unclog a pipe" and found fetal remains inside.[252] Similarly, wastewater treatment facility employees have uncovered numerous babies within wastewater treatment plants.[253]

Overall, as SFLA points out, the disposal of human remains through wastewater systems across America are likely causing a much more significant impact on the "environment and water safety" than, for example, flushing tampons (or wipes, etc.).[254] Indeed, the pro-abortion organization Guttmacher Institute reported that approximately 1,037,000 abortions occurred in 2023, with approximately 642,700 of those performed as chemical abortions (when one considers the number of unreported abortions, this number is likely

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the human environment," that is, individuals' relationship with it, by decreasing their enjoyment of it. See also: "What Can You Do to Protect Local Waterways?", Environmental Protection Agency, December 2002, https://www3.epa.gov/npdes/pubs/centralized_brochure.pdf.

[249] As stated by one waste management company, "Disposing of pathological waste requires strict safety procedures to comply with state and federal regulations. Improper disposal can lead to hefty fines, severe penalties, and an increased risk of illness or injury." See: "What Is Pathological Waste and How Should It Be Disposed Of?," In genium, accessed April 15, 2025, https://www.pureingenium.com/regulatory-updates/what-is-pathological-waste/. See also: Hernan G. Mazzei and Stefania Specchia, "Latest insights on technologies for the treatment of solid medical waste: A review," *Science Direct,* Vol. 11, No. 2, April 2023, https://www.sciencedirect.com/science/article/pii/S2213343723000489.

[250] "EPA Encourages Americans to Only Flush Toilet Paper," United States Environmental Protection Agency, March 30, 2020, https://www.epa.gov/newsreleases/epa-encourages-americans-only-flush-toilet-paper.

[251] Ibid.

[252] Alejandra Yañez, "Update: Tenant finds fetus while working on apartment plumbing in Mission," January 31, 2023, ValleyCentral.com, https://www.valleycentral.com/news/local-news/plumber-finds-fetus-in-mission-pipes-sources-say/.

[253] See footnote 12.

[254] Kristan Hawkins, Tina Whittington, and Kristi Hamrick, "Citizen Petition . . ." Also, please note: The same FDA response to the SFLA petition discussed previously states they are not "aware of any evidence suggesting that products of conception from induced abortions differ from the naturally occurring products of conception from spontaneous abortions (commonly known as miscarriages)." We would argue that in the case of induced abortion, as it is planned, the possible effect of the outcome (an expelling of human tissue) on our water can be mitigated. Furthermore, as outlined in the recommendations section, we propose women should have the option to bury or inter fetal remains whether from abortion or miscarriage.

far greater).[255] These abortions constitute a large amount of pathological waste (placenta, blood, fluid, and body parts) and should by no means be disposed of into the sewer system via flushing or other means. Rather, given the unknown effect of fetal remains being disposed of in our water systems, at a minimum, fetal remains should be disposed of according to the same regulatory requirements to which all other pathological waste is subject.

In short: While it undermines the dignity of aborted babies to classify them as medical waste (indeed, the better option is to ensure dignified disposition[256]), said classification would at the very least help ensure they do not enter our waterways.

Case Study: Florida

As previously outlined, several states have fetal disposition laws as well as specific laws pertaining to clean water that could better serve to mitigate the possible negative impacts of the use of the abortion pill. Research by one activist on this subject highlights that fetal remains may contribute to toilet clogs and city sewer pipe clogs, possibly leading to system backups and overflows, given that human fetal remains do not break down like human excrement. Even so, fetal remains are still being flushed into POTW collection systems.[257]

In part or at times, this may be due to a lack of proper enforcement of the law. For example, Florida's current statutes and regulations already suffice in terms of the legal language required to protect Florida's waterways and mitigate the potential harmful impacts aborted fetal remains may have on sewer utilities and the water supply. Unfortunately, abortion providers appear to be evading these laws (detailed below) on a regular basis, when they instruct women to flush their pregnancy remains down the toilet—without consequence.

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[255] Isaac Maddow-Zimet and Candace Gibson, "Despite Bans, Number of Abortions in the United States Increased in 2023 . . ."; Rachel K. Jones and Amy Friedrich-Karnik, "Medication Abortion Accounted for 63% of All US Abortions in 2023 …"; also as highlighted above, the CDC reported that in 2022, 58% of abortions (for which the method was reported) were chemical abortions (315,392 total); though of note these numbers exclude California, Maryland, New Hampshire, and New Jersey. See: Stephanie Ramer et. al., "Abortion Surveillance—United States, 2022 . . ."

[256] The best option is prohibiting abortion. In the current cultural context, that is unlikely.

[257] POTWs "collect wastewater from homes, commercial buildings, and industrial facilities and transport it via a series of pipes, known as a collection system, to the treatment plant." See: "POTW Operation," FedCenter.gov, July 28, 2017, https://www.fedcenter.gov/assistance/facilitytour/wastewater/operations/index.cfm.

Relevant Statutes & Regulations

Several laws and administrative codes combine to provide the legal framework that sets out how fetal remains from aborted babies must be managed in Florida.

1. Right to Know & Clean Water

Under Florida's Air and Water Pollution Control Act of 1967, individuals have a legal right to know if offensive contaminants are in their water.[258] Aborted fetal remains are undoubtedly an offensive contaminant.

2. Fetal Remains

According to Florida's Administrative Code section 59A-9.030, "Fetal remains shall be disposed of in a sanitary and appropriate manner and in accordance with standard health practices and Chapters 381 [Public Health: General Provisions] and 390 [Termination of Pregnancies], F.S., and Chapter 64E-16, F.A.C. [Chapter on Biomedical Waste]."[259]

- F.S. Chapter 381 outlines the treatment of biomedical waste, which is defined as "any solid or liquid waste which may present a threat of infection to humans," including "nonliquid human tissue and body parts . . . human blood, blood products, and body fluids."[260]
- F.S. Chapter 390 outlines, "[o]nly a physician may perform or induce a termination of pregnancy. A physician may not use telehealth as defined in s. 456.47 to perform an abortion, including, but not limited to, medical abortions. Any medications intended for use in a medical abortion must be dispensed in person by a physician and may not be dispensed through the United States Postal Service or by any other courier or shipping service."[261] Essentially, any abortion provider who provides pills to women to take at home without seeing them in person is violating the law.

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[258] Michael T. Olexa, Tatiana Borisova, and Jana Caracciolo, "2021 Handbook of Florida Water Regulation: Florida Air and Water Pollution Control Act," University of Florida, June 22, 2021, https://edis.ifas.ufl.edu/publication/FE607; specifically, this notes that Florida Department of Environmental Protection (FDEP) must, "Compile, correlate, and disseminate available information on any contaminant which endangers or may endanger existing or potential drinking water resources."

[259] "Rule: 59:1-9.030 | Disposal of Fetal Remains," Florida Administrative Code & Florida Administrative Register, April 5, 2017, https://flrules.org/Gateway/View_notice.asp?id=18753221.

[260] "The 2024 Florida Statutes (including 2025 Special Session C) | Title XXIX, Public Health," Chapter 381, Public Health: General Provisions, Online Sunshine, accessed April 9, 2025, http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=0300-0399/0381/0381.html.

[261] "The 2024 Florida Statutes (including 2025 Special Session C) | Title XXIX, Public Health," Chapter 390, Termination of Pregnancies, Online Sunshine, accessed April 9, 2025, http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=0300-0399/0390/0390.html.

- This same provision also provides for revocation or suspension of a clinic's license, "[i]f an owner or employee of an abortion clinic fails to dispose of fetal remains and tissue in a sanitary manner pursuant to s.381.0098 [Chapter on Biomedical Waste]."[262]
- Proper disposal of "Biomedical waste" as defined in Florida's administrative code first requires treatment "by steam, incineration, or an alternative process approved by the department as described in Section 64E-16.007(4), F.A.C.," which "shall occur within 30 days of collection from the generator."[263]

3. Home Health Care

While Florida law requires women to take the first abortion pill in person with a provider, the second pill may be taken at home.[264] According to Florida's Administrative Code, there are specific requirements for "home users" of health care that require providers of in-home medical services to "remove or have removed by a registered biomedical waste transporter all biomedical waste generated during the performance of these services."[265] The law further outlines:[266]

- "Health Care Provider" means "any person who provides medical care or personal services. . . "
- "Health care providers shall inform their home user clients verbally and in writing of the recommended method for handling biomedical waste generated in the home setting."
- "Home User" is "an individual who generates biomedical waste as a result of self-care or care by a family member or other non health care provider."
- "Home users should segregate and package their biomedical waste in a manner that reduces the chance of exposure to the public."
- "Biomedical waste" includes "[a]ny solid or liquid waste which may present a threat of infection to humans, including nonliquid tissue, body parts, blood, blood products, and body fluids from humans."
- The section titled "Storage and Containment" outlines that "[B]iomedical waste . . . shall be packaged and sealed at the point of origin in impermeable, red plastic bags or, at the discretion of the generator, into sharps containers. The

[262] Ibid.
[263] "Rule: 64E-16.007 | Treatment," Florida Administrative Code & Florida Administrative Register, June 3, 1997, https://flrules.org/gateway/ruleno.asp?id=59A-9.030 and https://flrules.org/gateway/RuleNo.asp?title=BIOMEDICAL%20WASTE&ID=64E-16.007.
[264] Stephanie Colombini, "As Florida's 6-week abortion law begins, here are 7 things to know," WUSF, April 30, 2024, https://health.wusf.usf.edu/health-news-florida/2024-04-30/florida-six-week-abortion-ban-may-1-7-things-to-know.
[265] "Rule Chapter: 64E-16, Florida Administrative Code & Florida Administrative Register," accessed April 9, 2025, https://flrules.org/gateway/ChapterHome.asp?Chapter=64E-16.
[266] Ibid. *Information on each of the bullet points can be found by clicking on "View Chapter."*

international biological hazard symbol shall be at least six inches in diameter on bags 19" × 14'' or larger, and at least one inch in diameter on bags smaller than 19'' × 14''."

- Point of origin: "The room or area where the biomedical waste is generated."

Per the above requirements, all abortion providers should be informing women of the "recommended method for handling biomedical waste generated in the home setting," which, as detailed above, includes tissue, body parts, and blood. Arguably, the provider should also let them know how to obtain a red plastic bag, so they can collect the fetal remains "at the point of origin."

In clear violation of this provision, former abortion facility workers and traumatized post-abortive women report that they were instructed to flush "products of conception."

4. Municipal Code Examples

- The City of Davie prohibits users from introducing or causing to be introduced the following into wastewater facilities (among other things): "*Solid or viscous substances in amounts which may cause obstruction of the flow in the WWF resulting in interference, but in no case solids greater than one-half (½) inch in any dimension, such as, but not limited to, grease, garbage, ashes, sand, straws, rags, waste paper, towels, wipes, diapers, hygiene products, fabric and other,*" specifically noting, "*The POTW are designated and designed to treat domestic waste and no user shall introduce into the POTW anything other than normal wastewater.*"[267]
    - Aborted babies could very well fall into this category as a 10-week-old fetus is on average at least one inch.[268]

[267] "Chapter 25 | Utilities," Davie, FL, Municode Codification, March 25, 2025, https://library.municode.com/fl/davie/codes/code_of_ordinances?nodeId=PTIICOOR_CH26FIPESPPR.
[268] While estimates vary, multiple sources suggest a 10-week fetus is at least one inch; see: Karen Miles, "How fast is your baby growing? See how fetal weight and height change by week during pregnancy," *Baby Center,* May 30, 2025, https://www.babycenter.com/pregnancy/your-body/growth-chart-fetal-length-and-weight-week-by-week_1290794; "Measurements of the fetus at 10 weeks of pregnancy," Invitra, September 28, 2023, https://www.invitra.com/en/10-weeks-pregnant/foetus-week-10-strawberry/; "Better Health | Start For Life, Week 10," National Health Service, accessed June 2, 2025, https://www.nhs.uk/start-for-life/pregnancy/week-by-week-guide-to-pregnancy/1st-trimester/week-10/. Note: While in FL chemical abortion is only allowed until 6 weeks, this limitation did not come into effect until May 1, 2024; prior to this, abortions were allowed up to 15 weeks. See: Stephanie Colombini, "Florida's 6-week abortion ban is now in effect, curbing access across the South," NPR, May 1, 2024, https://www.npr.org/2024/05/01/1247990353/florida-6-week-abortion-ban-south. Furthermore, even under the current limit, it is likely abortions are happening much later, given the availability of abortion pills online. See: Stephanie Colombini, "As Florida's 6-week abortion law begins, here are 7 things to know" . . .

- Similarly, the City of Melbourne has regulations that state, "*No user shall introduce or cause to be introduced into the WWF the following pollutants, substances, or wastewater . . . Solid or viscous substances in amounts which will cause obstruction of the flow in the WWF resulting in interference, but in no case solids greater than one-half inch in any dimension*."[269]
    - Again, aborted babies meet this criteria.

5. Relevant Enforcement Authority

- F.S. 390.012(6) states the Agency for Health Care Administration "may adopt and enforce rules, in the interest of protecting the public health, to ensure the prompt and proper disposal of fetal remains and tissue resulting from pregnancy termination."[270] Such rules could include requiring abortion providers to issue "catch kits" for women to use at the "point of origin" and then return to the provider (after their at-home abortion) for proper disposal, or, alternatively, prohibiting providers from dispensing medical abortion pills, requiring women to remain in the clinic during their medical abortion. Given that the women would remain under the direct supervision of a provider in case of complications, the latter option is preferable.
- An executive order signed by Governor Ron DeSantis in 2019 outlines that the Department of Environmental Protection (DEP) is required to take over the Environmental Crimes Enforcement Unit to "ensure strong enforcement of Florida's environmental laws."[271] Similarly, a 2022 Administrative Directive for Florida's DEP makes clear that it is within the DEP's authority to impose civil or administrative penalties they deem "appropriate" for regulated persons who violate regulatory requirements, outlining that "a penalty may be entirely appropriate for a first-time violator [e.g., an abortion clinic] who knew or had reason to know that the actions were illegal."[272] Abortion providers had reason to know they were in violation of the regulations regarding fetal remains disposal detailed previously. Given they are not ensuring fetal remains are disposed of

[269] "Article IV | Wastewater Treatment," Melbourne , FL, Municode Codification, January 3, 2025, https://library.municode.com/fl/melbourne/codes/code_of_ordinances?nodeId=PTIICICO_CH58UT_ARTIVWATR_DIV2WARACH_S58-242SEIMFECOEX.
[270] "The 2024 Florida Statutes (including 2025 Special Session C) | Title XXIX, Public Health," Chapter 390, Termination of Pregnancies . . .
[271] Executive Order, "State of Florida, Office of the Governor Executive Order Number 19-12," January 10, 2019, https://www.flgov.com/eog/sites/default/files/executive-orders/2024/EO_19-12.pdf.
[272] "Settlement Guidelines for Civil and Administrative Penalties," State of Florida Department of Environmental Protection, Jun 10, 2022, https://floridadep.gov/sites/default/files/DEP_923.pdf. NB: "With the enactment of the Environmental Litigation Reform Act (ELRA), Section 403.121, Florida Statutes (2001), the Department has administrative penalty authority for most regulatory programs."

properly, instead allowing them to contaminate the waterways of Florida by being processed at POTW, the DEP should issue proper penalties.

Based on these directives, Florida's Agency for Health Care Administration and the DEP have the authority required to enforce Florida's fetal disposition and biomedical waste laws. They simply need to do so.

Florida's Gestational Limit Law Also Needs Enforcement

It is worth noting that while Florida's abortion law is one of the strictest in the nation—only permitting abortion up to six weeks of pregnancy with certain exceptions—"thousands of Americans in states with abortion restrictions are taking matters into their own hands . . . ordering pills from online services and taking them at home without the supervision of a doctor or nurse . . . the World Health Organizations *[sic]* has recommendations on it."[273] Furthermore, there are groups in states with "shield laws" (that is, laws seeking to "protect providers should Florida or another state take action against them"), as well as international groups, that would likely provide women with access to abortion pills.[274] Hence, though it is illegal in Florida to do so, women are very likely able to access abortion pills to perform at-home abortions beyond six weeks. How to prevent this in some ways becomes a federal matter.

Recommendations

Neither "crystal clean water" nor "gold-standard science"—priorities of the current administration—were given proper consideration when the government approved use of the chemical abortion pill. Prioritization of both is needed now.

Furthermore, in considering the following recommendations, it is vital to note that some solutions are meant to be temporary. Laws requiring proper disposition of aborted babies *still permit aborting babies*. However, they draw attention to the humanity of preborn children and serve as an incremental, crucial step toward a world in which all unborn lives are cherished, and mothers and fathers are provided the support they need to nurture another life. Indeed, while it would be ideal given the numerous issues surrounding the abortion pill to simply ban its use (as per legislation introduced by Representative Andy Ogles, the Ending Chemical Abortions Act of 2025),[275] or prohibit abortion altogether (as per the Life at Conception Act, which explicitly extends 14th

[273] Stephanie Colombini, "As Florida's 6-week abortion law begins, here are 7 things to know . . ."; exceptions include the life of the mother, rape, and incest, among a few others.
[274] Ibid.
[275] Congressman Andy Ogles, "Rep. Ogles Reintroduces Bill to Federally Ban Chemical Abortions," Press Release, January 24, 2025, https://ogles.house.gov/media/press-releases/rep-ogles-reintroduces-bill-federally-ban-chemical-abortions.

Amendment protections to preborn humans),[276]—and Liberty Counsel Action fully supports these efforts—they are unlikely to gain traction.[277]

A next-best option is to require comprehensive research and environmental analysis on the possible adverse effects of the chemical abortion pill and its byproducts (as should have legally been completed prior to its original approval in 2000). Such research is needed in order to determine whether and how clean our water is and will assist in determining the harmful impact fetal remains disposal has on women undergoing at-home abortions. Alongside this, Congress should advance fetal disposition laws that promote human dignity, akin to Indiana's fetal disposition law.[278]

1. Hold Congressional Hearings and Solicit Independent Research

In short, the lack of information related to the possible environmental impact of abortion pill metabolites being excreted through women alongside the possible environmental impact of expelled fetal remains makes effectively legislating on this topic challenging, if not impossible. Liberty Counsel Action specifically recommends the following:

A) Hold a series of Congressional hearings

We propose Congress hold hearings on this subject, both to solicit expert analysis and insight on the extent to which mifepristone and its byproducts may be harming our waterways, as well as educate the wider public on the dangers posed by the chemical abortion pill. Said hearings would also serve to provide the oversight of the FDA and EPA that was lacking during the original and subsequent approvals for use of mifepristone, particularly given their failure to consider how fetal remains from chemical abortions would be disposed of (which was, at best, an oversight, at worst, negligence, given those seeking the drug's approval and those providing said approval should have been well aware that aborted babies would be disposed of via toilets apart from explicit requirements to the contrary).[279] Both the FDA and EPA appear to have (intentionally or not) avoided their respective duties as outlined in the NEPA and should be held accountable now.

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[276] "H.R.722—Life at Conception Act," Congrses.gov, January 24, 2025, https://www.congress.gov/bill/119th-congress/house-bill/722/text.

[277] There are several other bills in Congress that would mitigate the harm cause by the abortion pill; for example, see "H.R.679—To nullify the modifications made by the Food and Drug Administration in January 2023 to the risk evaluation and mitigation strategy for the abortion pill mifepristone, and for other purposes," Congrses.gov, January 23, 2025, https://www.congress.gov/bill/119th-congress/house-bill/679.

[278] Please note: While all actions are ideal and complement one another, we recognize some may face more opposition than others. Even so, each on its own merits would serve to advance the cause of protecting life and health.

[279] Center for Drug Evaluation and Research, Letter to the Population Council, September 28, 2000, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf. See also MIFEPREX™ (mifepristone) Tablets, 200 mg For Oral Administration Only," accessed May 8, 2025, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

Ultimately, the hearings would underscore the need for agencies to properly adhere to federal law and serve as a call to action, which could include several items outlined below.

B) Introduce legislation to require updated, comprehensive "Gold Standard"[280] (objectively peer-reviewed) research on the possible adverse effects of mifepristone and fetal remains in our water supply and drinking water

As highlighted above, scientific study on the specific issue of chemical abortion pills and their effect on our water supply is scarce yet entirely warranted, given current research demonstrates other pharmaceuticals, as well as potential endocrine disrupting substances, have an adverse impact on wildlife and humans.[281] To address this gap, legislation should be introduced soliciting independent "gold standard" scientific study ("subject to unbiased peer-review") on pharmaceutical contaminants in our water supply with a special focus on mifepristone metabolites (given the drug is uniquely designed to end a life) and fetal remains. This should include but is not limited to:

- Research on how **long-term exposure** to mifepristone in the **drinking water supply** may adversely affect aquatic and related ecosystems, particularly focusing on human and animal health.
- Research on whether mifepristone is present in our **drinking water** and whether **long-term exposure** to low doses of it may adversely affect human health—especially fertility.
- Research on the **potential synergistic effects** of mifepristone combined with (potential and known) endocrine-disrupting chemicals and pollutants in our water supply, given—as a recent report from the MAHA Commission outlines—"*No country in the world has fully accounted for the fact that children are often exposed to* [via drinking water and other means] *complex mixtures of chemicals.*"[282]
- Studying and **surveying individual's reactions** to the reality that human remains are regularly being disposed of into the sewer system and may be in our lakes, streams, and rivers.

[280] "Restoring Gold Standard Science," The White House | Executive Orders, May 23, 2025, https://www.whitehouse.gov/presidential-actions/2025/05/restoring-gold-standard-science/.
[281] See section 4.
[282] "The MAHA Report | Make Our Children Healthy Again Assessment," The White House, accessed May 23, 2025, https://www.whitehouse.gov/wp-content/uploads/2025/05/WH-The-MAHA-Report-Assessment.pdf.

2. Request (or Require) the EPA to Investigate and Track the Effect of Abortion Pill Metabolites and Fetal Remains in Our Water

The EPA's primary functions include *"[t]he conduct of research on the adverse effects of pollution and on methods and equipment for controlling it, the gathering of information on pollution, and the use of this information in strengthening environmental protection programs and recommending policy changes."*[283] Furthermore, the EPA is well equipped to monitor possible harmful contaminants in our water. For example, as it pertains to possible endocrine disrupting pollutants and PFAS (which may also act as endocrine disruptors):

- The EPA was previously tasked with, via the EPA's Endocrine Disruptor Screening Program, "prioritizing and testing chemicals for potential endocrine disruption."[284] Though this testing relates to pesticides and other chemicals, the risk of endocrine disruption posed by pharmaceuticals, including mifepristone, may be similar.[285]
- The EPA has stated that it is "leading the national effort" both to *understand* PFAS and *reduce the risk they pose the public*.[286] As outlined previously, the EPA is committed to regulating two PFAS at 4 ppt.

This laudable commitment by the EPA to monitor a substance present in trace amounts, *even though research is still underway to better understand the harm it poses to the public*, presents a perfect model for mifepristone monitoring. Liberty Counsel Action therefore proposes the EPA also "lead the national effort" in seeking to understand and reduce the risk mifepristone poses to the public. This could be achieved through the following actions:

A) Members of Congress sending a follow-up letter to the EPA requesting immediate action

In 2024, members of Congress sought information on this matter in a letter (led by [former] Senator Marco Rubio and Representative Josh Brecheen) to the former EPA administrator. As outlined in the Executive Summary, the specific request was that

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[283] Office of the Law Revision Counsel, 42 U.S.C. §4321, accessed May 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.
[284] "Chemicals and Materials We Are Researching," The United States Environmental Protection Agency, May 16, 2024, https://www.epa.gov/chemical-research/chemicals-and-materials-we-are-researching.
[285] "EPA Rebuilds Endocrine Disruptor Screening Program to Better Assess Human Endocrine Effects of Pesticides," The United States Environmental Protection Agency, October 26, 2023, https://www.epa.gov/newsreleases/epa-rebuilds-endocrine-disruptor-screening-program-better-assess-human-endocrine; "Endocrine Disruptors and Your Health," National Institute of Environmental Health Sciences . . . See also: "Endocrine Disruptor Screening Program (EDSP); Near-Term Strategies for Implementation; Notice of Availability and Request for Comment," The Federal Register, October 27, 2023, https://www.federalregister.gov/documents/2023/10/27/2023-23721/endocrine-disruptor-screening-program-edsp-near-term-strategies-for-implementation-notice-of; "Endocrine Disruptors and Your Health," National Institute of Environmental Health Sciences . . .
[286] "Chemicals and Materials We Are Researching," Environmental Protection Agency, May 9, 2025, https://www.epa.gov/chemical-research/chemicals-and-materials-we-are-researching.

the EPA re-do and update "[a]ny studies that have been conducted in the past . . . to reflect the fact that the drug is far more prevalent today than it was three decades ago. In addition, the EPA should study the impact of the 'byproducts' of mifepristone, such as the placental tissue, fetal remains, and active metabolites that are being flushed into our nation's wastewater system."[287] Similarly, a letter to members of Congress signed by prominent pro-life organizations makes the case that environmental testing for the presence of abortion pill mifepristone should be conducted the same way the EPA tests for the presence of "forever chemicals."[288] The results would allow for assessment of "potential environmental harms from exposing aquatic animal and plant life and the people relying on them to mifepristone."[289]

Given the EPA is under new leadership, there is a new opportunity for action. We therefore propose that members of Congress send the EPA a letter similar to that which was written in 2024 requesting the EPA initiate research into this matter and that the EPA immediately implement requirements for testing and monitoring mifepristone similar to how it does for "forever chemicals" (PFAS).

B) Introducing legislation to require the EPA to monitor and research abortion pill contaminants and fetal remains in our waterways

The constant stream of mifepristone metabolites and fetal remains entering our water, even if in trace amounts, similar to PFAS entering our water in trace amounts, deserves heightened scrutiny and monitoring from the EPA. As needed (if the EPA delays or declines to act), legislation should be introduced to require said monitoring and research.

3. Request (or Require) the FDA to Complete an EA/EIS on Abortion Pill Metabolites and Fetal Remains in Our Water Supply; Revoke Approval of Mifepristone Until It Is Complete

Given that the FDA's original approval of the abortion pill relied on a 1996 EA that only estimated the impact of the abortion pill (versus actually studying it), as well as its failure to consider the issue of fetal remains disposal, use of the abortion pill should be immediately suspended. Liberty Counsel Action specifically recommends the following administrative and congressional actions:

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[287] U.S. Senator Marco Rubio and Representative Josh Brecheen, et. al., "Members of Congress to the Honorable Michael Regan, Administrator, U.S. Environmental Protection Agency . . ."
[288] Kristan Hawkins, Marjorie Dannenfelser, et. al., "To Members of Congress," Letter, February 26, 2024, https://www.studentsforlifeaction.org/wp-content/uploads/2024/02/SFLACTION-EPA-SBANamesaddedFinalLetter02-2024.pdf.
[289] Ibid.

A) Members of Congress send a letter to the FDA requesting immediate action

Like the EPA, the FDA is now under new leadership, presenting a new opportunity to call for a thorough environmental analysis (ideally an Environmental Impact Statement) of mifepristone and its impact on our waterways. Said analysis should (as per requirements under the Clean Water Act) consider all relevant state and local water quality standard laws. As the analysis is being completed, the FDA should revoke the current approval of mifepristone/Mifeprex. We propose members of Congress send a letter on this matter to the FDA in conjunction with the letter sent to the EPA.

B) Introduce legislation rendering the original and subsequent approvals of chemical abortion pills null and void until legally required research and analysis is complete and the original application is reevaluated in light of said research

Again, given the evidence demonstrating the FDA failed to properly adhere to the environmental standards in place when the agency originally approved the abortion pill in 2000, pending the above recommendation (or in addition to it), Congress should pass legislation to require the FDA immediately withdraw approval of the abortion pill (suspend its use) until a thorough environmental analysis can be completed (see also recommendation 2 above). Said analysis should then be used to reevaluate the initial approval of Mifeprex and the subsequent major federal actions (in 2011, 2016, 2019, 2021, and 2023) related to expanding its use.*

**If the pill obtains reapproval, a requirement that women remain in a clinic during expulsion or that prescribers issue a "catch kit" should be included.*

4. Advance Legislation in Congress to Protect the Dignity of Unborn Children

Two bills introduced in the 119th Congress address the issue of dignified disposal for deceased unborn children: the Dignity for Aborted Children Act and the Protecting the Dignity of Unborn Children Act. Both would serve to bring uniformity to the current regulatory patchwork of various states' fetal remains laws.

A) Dignity for Aborted Children Act

As highlighted above, fetal tissue remains resulting from induced abortion are most likely flushed or drained into our water supply. Not only is this unsanitary, but it demeans humanity to treat deceased preborn humans in such a callous manner. While a few states have enacted laws similar to Indiana's, to "ensure abortion

businesses cannot treat human remains like garbage,"[290] much more needs to be done. Indeed, even in states with dignified fetal disposal laws, they do not always apply to abortions performed at home.

The aforementioned legislation, most recently introduced by Sen. Ricketts (R-NE) and Rep. Mary Miller (R-IL), requires abortion providers to offer patients an informed consent form that gives the patient two primary options for disposal of the baby after an abortion:

- "The patient may take possession of the human fetal tissue and may choose to transfer the tissue to an entity providing interment or cremation services."
- "The patient may elect to release the human fetal tissue to the abortion provider," who must also dispose of the baby via either interment or cremation.[291]

As outlined in the bill, "the term 'abortion' means the use or prescription of any instrument, medicine, drug, or any other substance or device—(A) to intentionally kill the unborn child of a woman known to be pregnant; or (B) to intentionally terminate the pregnancy of a woman known to be pregnant," unless done so after viability "to produce a live birth and preserve the life and health of the child" or "to remove a dead unborn child."[292]

To strengthen this act and directly address the matter of aborted children's remains entering our water, Liberty Counsel Action recommends language be added explicitly outlining that chemical abortions are to be subject to the same fetal disposition requirements as surgical abortions, and that either of these occur:

- Women remain in an abortion facility post use of the abortion pills until they expel the entire contents of their uterus in the immediate presence of a physician within the confines of a licensed facility.
- The abortion provider give women "catch kits" with the abortion pill, instructing them to collect the fetal remains with said kit, and, per the bill's language, either "transfer the tissue to an entity providing interment or cremation services" after they expel their baby or to return all fetal remains to the abortion provider for interment or cremation post-use of the abortion pill.

This legislation serves a twofold purpose by (first) ensuring women are informed of the reality that their baby is human, not mere tissue that can be disposed of as other medical waste, and by (second) protecting our waterways from contamination from aborted children's remains. To the first point, such information would undoubtedly

[290] Catherine Glenn Foster "How Abortionists Dispose of Their Victims," First Things, July 18, 2022, https://firstthings.com/how-abortionists-dispose-of-their-victims/.
[291] "H.R.798—Dignity for Aborted Children Act," Congress.gov, January 28, 2025, https://www.congress.gov/bill/119th-congress/house-bill/798/text.
[292] Ibid.

have benefited numerous women who were unaware that taking the abortion pill would result in the trauma of witnessing their fully formed baby floating in a toilet—these women, "scared, because they've passed a tiny but recognizable fetus" often end up calling an abortion hotline "'completely freaked out, crying, sobbing' . . . because they were not expecting to see recognizable human fetuses."[293] Their regret[294] is impossible to overstate, and a primary failing of the abortion industry.

Notably, similar legislation was introduced in a prior Congress,[295] in part as a response to the egregious revelation that "the remains of over 2,200 aborted babies were discovered at an Indiana abortionists' home."[296] Speaking to a news outlet on the subject, Sen. Ricketts is clear: "It's horrifying that human remains would be treated like common medical waste," underscoring the importance of this or similar legislation.[297]

B) Protecting the Dignity of Unborn Children Act

As per the press release on this bill, it would make the disposing of aborted babies "in landfills or in any navigable waters of the United States" a federal crime.[298] Though it appears to target abortion providers that callously place aborted children in landfills

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[293] "I Saw My Baby," Live Action, accessed April 15, 2025, https://www.liveaction.org/wp-content/uploads/2023/06/LA23ISMB-WhitePaper.pdf. See also: Carole Novielli, "'They never told me': Women testify of being deceived by the abortion industry," Live Action, January 5, 2018, https://www.liveaction.org/news/women-testify-deceived-abortion-industry/.

[294] Ibid. For example, after taking the abortion pill and developing contractions, along with heavy bleeding, Heather shares: "I was scared and my friend took me to the ER, told them I thought I was having a miscarriage because I was too ashamed to admit I took a[n abortion] pill my friend sent me in the mail. I gave birth to an 11 wk, 5 day old fetus in the toilet of the ER. The baby was kicking inside the sac as it was basically drowning in cold toilet water. This [is] probably the most traumatic thing I have ever seen or been through in my life . . . and **this is the single greatest regret of my entire 37 years on this earth**. I will never forget what I saw and **I still cry about it to this day . . . I am not sure if I will ever forgive myself for this."** This same report goes on to conclude, "As long as the abortion industry is allowed to distribute this lethal drug, essentially without oversight, hundreds of thousands of American preborn children will continue to die annually in the most undignified manner—their bodies treated as sewage to be flushed down the toilet—and mothers will continue to experience life-altering trauma."

[295] Writing at the time, Heritage Action notes that "unfortunately, Illinois and numerous other states have no laws against such practices." See: "Heritage Action Supports Senator Mike Braun's Dignity for Aborted Children Act," Heritage Action for America, October 1, 2019, https://heritageaction.com/blog/heritage-action-supports-senator-mike-brauns-dignity-for-aborted-children-act.

[296] Elizabeth Troutman Mitchell, "Exclusive: Sen. Ricketts to Introduce Bill to Protect Dignity of Aborted Unborn Babies," The Daily Signal, January 24, 2025, https://www.dailysignal.com/2025/01/24/exclusive-sen-ricketts-introduces-bill-protect-dignity-aborted-unborn-babies/, and Ibid.

[297] Ibid.

[298] "Latta Attends March for Life, Reintroduces Pro-Life Bills," Bob Latta | Press Releases, January 24, 2025, https://latta.house.gov/news/documentsingle.aspx?DocumentID=405513. See also: "H.R.686—Protecting the Dignity of Unborn Children Act of 2025," Congress.gov, January 23, 2025, https://www.congress.gov/bill/119th-congress/house-bill/686.

or in our water supply,[299] it serves to acknowledge the issue at hand and presents an opportunity to strengthen laws related to human dignity.

Like the above legislation, Liberty Counsel Action would propose an amendment to likewise prohibit disposal of fetal remains into wastewater systems, and to ensure the abortion providers are held accountable under this language for the disposal of fetal remains resulting from chemical abortion pills they issued.

5. All States Should Review and Enforce, or Strengthen, Their Medical Waste and Fetal Disposition Laws or Lack Thereof

While conscientious legislators and taxpaying citizens have been investing hundreds of millions of dollars to create intricate reusable wastewater systems to safely serve community needs and protect delicate ecosystems, chemical abortion providers have been using America's sewer systems as their own covert medical waste facilities. Pro-life lawmakers and advocates should review their states' laws to determine whether current medical waste or fetal disposal laws explicitly cover fetal remains from at-home abortions and are being enforced (as outlined above, Florida presents a perfect case study regarding laws in place that regulate fetal disposition yet lack enforcement). If not, legislation on the same should be introduced.

Specific considerations should include the following, at a minimum:

- **Review of medical waste regulations.** As outlined above, all states have regulations on medical waste. These, like Florida's, may already prohibit disposing of fetal remains down the toilet.
- **Amending current statutes related to miscarriage.** Notably, several states have laws regarding the fetal disposition of miscarried children, who often may be buried or cremated per their parents' wishes. Such laws could be amended to ensure proper procedures for interring or cremating aborted babies as well.[300]
- **Amend current statutes related to human disposition.** As proposed by the Charlotte Lozier Institute, states may be able to amend current disposition statutes "that apply to other deceased human beings" to ensure that, rather than "being considered medical or pathological waste," aborted children are explicitly included in the definition of "human beings" or "human bodies."[301]

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[299] Bob Latta, "Latta Introduces Pro-Life Legislation to Prohibit the Disposal of Fetal Body Parts in Landfills," Press Releases, April 27, 2018, https://latta.house.gov/news/documentsingle.aspx?DocumentID=398665.
[300] "Information on Miscarriage and Stillbirth by State," Heaven's Gain Ministries, June 1, 2023, https://heavensgain.org/state-laws/; "Parental rights after a miscarriage or stillbirth," Heritage Defense, October 23, 2024, https://heritagedefense.org/parental-rights-after-a-miscarriage-or-stillbirth/.
[301] Kristi Burton Brown, "Fetal Disposition: The Abuses and The Law . . ."

- **Ensure proper regulation of abortion clinics.** Likewise, states can enact or strengthen regulations related to the disposition of aborted babies by passing legislation to require regular inspections of abortion clinics that includes enforceable penalties (for example, suspension of the clinics' operations, fines, etc., instead of warnings) for violations of fetal disposal laws.[302]

6. All States Should Review and Enforce or Strengthen Their Wastewater Treatment Standards

As outlined in the Case Study on Florida, certain municipalities in the state have wastewater treatment regulations that clearly prohibit disposing of fetal remains down the drain, though the enforcement opportunities have yet to be fully utilized. As per recommendation 5, pro-life lawmakers and advocates should review their states' regulations to determine whether similar prohibitions apply in their localities and either (1) promote regulations to address any gaps permitting fetal disposal via the sewer system or (2) seek enforcement. Litigation could be required to achieve the latter.

Protect Women and Promote Clean Water

While these recommendations are merely stopgap measures, they serve to highlight the need for further research and accountability regarding chemical abortions, not only to ensure the FDA upholds proper health and safety protocols for women undergoing chemical abortions and to ensure the EPA upholds clean water standards, but to demonstrate that all humans—including those who are aborted—deserve dignity.

[302] Ibid.

Appendix I: FDA Abortion Pill Approvals Disregard the FDA's Own Safety Protocols and Standards

In addition to flouting the Clean Water Act (CWA) and the National Environmental Policy Act (NEPA), the FDA's approval process for the use of the abortion pill violated federal law and was based on faulty reasoning, which included deeming pregnancy an "illness."[303] Yet rather than reverse course, the FDA simply "doubled down on its actions and removed the few safeguards that were in place."[304] To highlight a few specifics as it pertains to environmental impact and women's safety:[305]

- In its original though ultimately lawless[306] 2000 approval for use of the pill, the FDA outlined (at least somewhat) strict requirements for its use. Most notably, it was only approved for up to 49 days of pregnancy and needed to be administered by a "certified provider" in person.[307] In total, three in-person visits to an abortion provider were required,[308] which provided an opportunity for women to be examined to check for the following:
    - Gestational age, given that taking the pill at later stages carries increased risks of complications, not to mention a more traumatic experience for women who, depending on their gestation, may end up essentially giving birth to a stillborn infant.[309]
    - Ectopic pregnancies, given failure to detect one can lead to life-threatening complications.[310]

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[303] Alliance for Hippocratic Medicine et. al., v. the U.S. Food and Drug Administration, et. al., "Complaint," November 18, 2022, https://adflegal.org/wp-content/uploads/2022/11/Alliance-for-Hippocratic-Medicine-v-FDA-2022-11-18-Complaint.pdf.

[304] Ibid.

[305] See background section for further details.

[306] Alliance for Hippocratic Medicine et. al., v. the U.S. Food and Drug Administration, et. al., "Complaint . . ." This lawsuit also outlines that "the FDA never studied the safety of the drugs under the labeled conditions of use despite being required to do so by the Federal Food, Drug, and Cosmetic Act (FFDCA)" and that they "ignored the potential impacts of the hormone-blocking regimen on the developing bodies of adolescent girls in violation of the Pediatric Research and Equity Act (PREA) . . . disregarded the substantial evidence that chemical abortion drugs cause more complications than even surgical abortions."

[307] "Abortion Drug Facts," Charlotte Lozier Institute, accessed April 7, 2025, https://lozierinstitute.org/abortion-drug-facts/#federal-action.

[308] "Abortion Pill Petition," Americans United For Life, accessed April 8, 2025, https://aul.org/abortion-pill/petition/.

[309] For example, an abortionist at Planned Parenthood allegedly failed to verify gestational age via ultrasound or physical exam and dated a woman's baby to be six weeks gestation; she was provided abortion pills and subsequently delivered a 30–36-week-old "lifeless, fully-formed baby in the toilet" at home. Per the complaint on this matter, the woman "endured significant stress, trauma, emotional anguish, physical pain, including laceration and an accelerated labor and delivery unaided by medication, lactation, soreness, and bleeding." She would not have had an abortion had she known how far along she was. See: Jane Doe v. Meera Shah, M.D., Abigail Mensah, N.P., Planned Parenthood Hudson Peconic, Inc., "Complaint," January 20, 2021, https://www.liveaction.org/news/wp-content/uploads/2022/10/Kings-Co-501531_2021_JANE_DOE_v_MEERA_SHAH.pdf.

[310] "Abortion Pill Petition . . ."

- Confirmation the now-deceased child was completely expelled and the woman was not suffering from life-threatening or other complications.[311]
- Whether the woman is a victim of sex trafficking or is otherwise being coerced to have an abortion (tragically, many women in trafficking situations have experienced multiple forced abortions;[312] ensuring women seeking abortion saw a provider first was a way to mitigate forced and coerced abortion by abusers and sex traffickers, as "interaction with the medical system is an opportunity for these women to be identified and helped."[313] Now, as "these drugs can be easily obtained by anyone," traffickers are "left free to subject women and girls in their thrall to induced abortions in order to extend their servitude."[314])

- This original approval also required reporting serious adverse events, which included the deaths of four women between 2000 and 2005.[315]
- Subsequent updates post these fatalities were numerous: Following the passage of legislation requiring that "all drugs with existing restricted-distribution programs . . . including mifepristone" have an REMS,[316] the FDA approved the Mifeprex REMS, which incorporated the restrictions already in place "into the new, formal 2011 REMS."[317] In 2011, the FDA also made changes to its guidelines on how to distribute the drug and on how to report complications.[318]
- Later in 2016, the FDA significantly weakened its safety protocols. For example, the approved use was extended from 7 to 10 weeks (70 days), and

[311] Ibid.
[312] Ingrid Skop, "Chemical Abortion: Risks Posed by Changes in Supervision," *Journal of American Physicians and Surgeons*, Vol 27, No. 2, 2022, https://www.jpands.org/vol27no2/skop.pdf.
[313] Ibid. In short, the FDA appears to be ignoring the fact that they have made it easier for other individuals with malintent—those seeking to surreptitiously slip abortion pills into women's food or drink— to perform said criminal acts. Indeed, "[U]nmonitored distribution of abortion-inducing drugs puts vulnerable populations, such as pregnant women who are not seeking abortion, at risk." See: Hannah Howard, "Medical and Social Risks Associated with Unmitigated Distribution of Mifepristone: A Primer," Charlotte Lozier Institute, October 1, 2020, https://lozierinstitute.org/medical-and-social-risks-associated-with-unmitigated-distribution-of-mifepristone-a-primer/.
[314] Ibid.; "CLI Fact Sheet: An Abundance of Neglect | FDA's Suspension of Medical Management of Abortion complications related to the drug. Pills," Charlotte Lozier Institute, accessed April 9, 2025, https://sbaprolife.org/wp-content/uploads/2021/04/An-Abundance-of-Neglect_clean.pdf.
[315] "Abortion Drug Facts . . ."
[316] Laurie Sobel, Alina Salganicoff, and Mabel Felix, "Legal Challenges to the FDA Approval of Medication Abortion Pills," KFF, March 13, 2023, https://www.kff.org/womens-health-policy/issue-brief/legal-challenges-to-the-fda-approval-of-medication-abortion-pills/.
[317] "Abortion Drug Facts . . ."
[318] Ibid.

they no longer required reporting serious adverse advents, apart from deaths.[319]

- In 2019, the FDA approved the generic version of Mifeprex, mifepristone.[320] At this time, no environmental analysis was completed, given (it seems) that the drug was approved via an abbreviated new drug application (ANDA).[321] Such applications may rely on previous findings "that the reference listed drug (RLD) is safe and effective," though to do so, they "must provide sufficient information to show . . . that its drug product has the same active ingredient(s), conditions of use, route of administration, dosage form, strength, and, with certain permissible differences, labeling as the RLD."[322]
    - Arguably, generic mifepristone is similar to Mifeprex; however, in both cases, the FDA failed to adequately adhere to the CWA and NEPA (as outlined above). Furthermore, the original approval of Mifeprex in 2000 disavowed "science and law" in other ways, given the FDA disregarded extensive evidence demonstrating that the abortion pill was more harmful than surgical abortions (among other things).[323]
    - Relying on an RLD to approve a similar drug that should not have been approved in the first place is irresponsible, to say the least, and ultimately increased the danger women face when taking this drug.
- A year later, in 2020, a set of recommendations was produced on "increasing access" to chemical abortion during the COVID-19 pandemic (and beyond) without the use of the previous safeguards the FDA required. Notably, these recommendations directly contradict "the results of a 2017 survey of abortion-providing members of the Society of Family Planning, which found that one-third had seen complications as a result of 'self-managed' abortion, and only half felt it was safe."[324]

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[319] Ibid.

[320] "Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation," The U.S. Food and Drug Administration, January 17, 2025, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[321] Kristan Hawkins, Tina Whittington, and Kristi Hamrick, "Citizen Petition . . ." See also: Alliance for Hippocratic Medicine et. al., v. the U.S. Food and Drug Administration, et. al., "Complaint . . ."

[322] Ibid.

[323] Alliance for Hippocratic Medicine et. al., v. the U.S. Food and Drug Administration, et. al., "Complaint . . ."

[324] Ingrid Skop, "The 'No-Test Medication Abortion' Protocol: Experimenting with Women's Health," Charlotte Lozier Institute, July 30, 2020, https://lozierinstitute.org/the-no-test-medication-abortion-protocol-experimenting-with-womens-health/#_edn21; Courtney A Kerestes, Colleen K Stockdale, M Bridget Zimmerman, Abbey J Hardy-Fairbanks, "Abortion providers' experiences and views on self-managed medication abortion: an exploratory study," *Contraception,* Vol.100, No. 2, August 2019, https://www.sciencedirect.com/science/article/abs/pii/S001078241930143X.

- Indeed, it is telling that adverse events post a chemical abortion are four times more likely than post a surgical abortion and will be experienced by 20 percent of women.[325] Known chemical abortion harms and complications include (but are not limited to):[326]
    - Death
    - Septic infection
    - Excessive bleeding
    - Incomplete abortions

  Furthermore, women who have had chemical abortions at home can remain traumatized by bathrooms,[327] as that is where they saw their baby expelled from their body. Bloodied eyeballs, arms, legs, and little hands and feet are often easily recognizable; for example, one woman undergoing a chemical abortion "screamed" when she saw that her aborted baby "had a head, hands, and legs" and "[d]efined fingers and toes."[328] Mental and emotional trauma, while in some ways impossible to measure (particularly given its nature—many women are reticent to speak out on their experiences), is rampant.[329]
- Even so, in 2021, the FDA approved home use of abortion without a single doctor visit, dramatically changing the conditions for using the pills[330]—again doubling down on its original lawless approval of the abortion pill. Furthermore, even if the original approval had been legal, the FDA chose to ignore its own safety standards, as outlined in the 2011 REMS and 2016 REMS (which weakened the 2011 REMS but still maintained an in-person visit to obtain pills).
- In 2023, this change was finally reflected in the mifepristone REMS, which was officially updated with the "elimination of the in-person dispensing

[325] Alliance for Hippocratic Medicine et. al., v. the U.S. Food and Drug Administration, et. al., "Complaint . . ."
[326] "Abortion Pill Petition . . ."
[327] Maria Wiering, "Women traumatized by abortion pill experience feel 'solely responsible for what happened,'" The Catholic Virginian, May 25, 2023, https://catholicvirginian.org/news/national/women-traumatized-by-abortion-pill-experience-feel-solely-responsible-for-what-happened/.
[328] Maria Wiering, "Women traumatized by abortion pill experience feel 'solely responsible for what happened' . . ."; See also, Alliance for Hippocratic Medicine et. al., v. the U.S. Food and Drug Administration, et. al., "Complaint . . ."
[329] Ibid.
[330] Though the condition changed was not an indication—that is, the purpose for which it is to be use—insofar as the phrase "conditions of use" is understood according to it plainest meaning, no longer requiring the pills to be administered by an abortion provider *does* dramatically change the "conditions of use." See also: "New Study Reveals FDA Relied on Cherrypicked Data to Approve Dangerous Mail-Order Abortion Drugs," Charlotte Lozier Institute, May 13, 2024, https://lozierinstitute.org/new-study-reveals-fda-relied-on-cherrypicked-data-to-approve-dangerous-mail-order-abortion-drugs/.

requirement"; at the same time, the FDA made it legal for "pharmacies to become certified prescribers of abortion drugs."[331]

- As it pertains to clean water, in all cases, the FDA essentially failed to address the issue of what to do with the fetal remains after an at-home abortion.

Notably, allowing the abortion pill to be administered in a new way (without in-person visits) without requiring a new safety review and environmental analysis seems to have been justified based on four flawed studies.[332] Such a drastic change should, at minimum, rely on known safety information rather than flouting it, or require new extensive study to ensure its efficacy and safety, both as it pertains to the women taking these pills, as well as to our water. The FDA failed on both counts. The FDA's reckless approval of the abortion pill generally, and for home use specifically, at best demonstrates negligence related to its own health and safety protocols; at worst, it amounts to willful misconduct.

A Citizen's Petition by American Association of Pro-Life Obstetricians and Gynecologists outlines the core issue well—pointing out the life-threatening risks involved in taking the pill, including "hemorrhage, infection, continued pregnancy, retained tissue, need for emergency surgery, and death." The petition concludes, "at the very least, FDA should not further erode patient protections. The agency should retain the Mifeprex REMS [Risk Evaluation and Mitigation Strategy], and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber."[333]

Instead, the abortion industry sends them pills at home, reducing their overhead costs to line their pockets, leaving women alone to suffer incalculable physical, mental, and emotional anguish as they dispose of their child via means that ultimately lead to further harm by contaminating our water.

Appendix 2: Ethical Basis for Life-Promoting Policies

Scientifically, life begins at conception. As outlined by Maureen Condic, Ph.D., associate professor of neurobiology at the University of Utah School of Medicine: "The conclusion that human life begins at sperm-egg fusion is uncontested, objective, based on the universally accepted scientific method of distinguishing different cell types from each other and on ample scientific evidence . . . Moreover, it is entirely independent of any

[331] "Abortion Drug Facts," Charlotte Lozier Institute, accessed April 7, 2025, https://lozierinstitute.org/abortion-drug-facts/#federal-action.
[332] "New Study Reveals FDA Relied on Cherrypicked Data to Approve . . ."
[333] American Association of Pro-Life Obstetricians and Gynecologists, "Citizen Petition," March 29, 2019, https://aaplog.org/wp-content/uploads/2021/01/Citizen-Petition-Final-FDA-Mif-REMS.pdf.

specific ethical, moral, political, or religious view of human life or of human embryos."[334] The American College of Pediatricians asserts that the difference between an adult human and a human in its "zygotic stage" at conception is simply "one of form, not nature."[335]

Using similar language, the Universal Declaration of Human Rights (UDHR), which relies "on the mutually illuminating and mutually dependent categories of equal human (natural) rights, inherent human dignity, and inclusive personhood," upholds the idea that human rights—including the right to life—belong to humans "by virtue of their human nature"[336]—not whether they are in or out of the womb.

Yet these humans are daily the victims of untold atrocities, subject to surgical and chemical abortions that rob them of life before they take their first breath.

[334] Maureen Condic, "A Scientific View of When Life Begins," Charlotte Lozier Institute, June 11, 2014, https://lozierinstitute.org/a-scientific-view-of-when-life-begins/.
[335] Fred de Miranda, updated by Dr. Patricia Lee June, "When Human Life Begins," American College of Pediatricians, March 2004; last modified March 2017, https://acpeds.org/position-statements/when-human-life-begins.
[336] Tom Finegan, PhD, "The Right to Life in International Human Rights Law," The Heritage Foundation, January 24, 2020, https://www.heritage.org/life/report/the-right-life-international-human-rights-law.