February 5, 2024

Michael S. Regan
Environmental Protection Agency
Office of the Administrator, 1101A
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Via mail only.

Re: Regulation of Mifepristone and its Environmental Effects in Light of the EPA's Increased Regulation of PFAS in the Environment

Dear Administrator Regan:

In recent years, and largely in 2023, the EPA has increased its efforts to regulate per- and polyfluoroalkyl substances ("PFAS"). With rulemaking, guidance, published initiatives, newly established pollution standards, and more, the EPA has addressed concerns of pollution as a result of PFAS being released on large scales into the environment. The EPA's increased understanding of the environmental harms these chemicals create has led it to take a closer look at the issue and ultimately implement new strategies and regulations to control the release of PFAS and monitor their impact more carefully. In implementing these new initiatives, the EPA has shown a commitment to monitoring and controlling the effect that a constant stream of chemicals and harmful substances – no matter how small those substances may be – may have on the environment.

The EPA's commitment to the above course of action should not be limited to only the harm caused by PFAS, but should also extend to other similar sorts of environmental harm. This letter is meant to address exactly such an issue.

For years, the scientific community (including the EPA) overlooked the harm that PFAS may cause to drinking water and other parts of the environment. And while the EPA has taken substantial steps to engage with the issue of PFAS, there are similar harms that have also been overlooked. *Students for Life of America* ("SFLA") believes one of those issues to be the continued and increased usage of Mifepristone and the various sorts of environmental harm that come as a result of its widespread use.

SFLA is the nation's largest pro-life youth organization that uniquely represents the generation most targeted for abortion. SFLA, a 501(c)(3) charity, exists to recruit, train, and mobilize the Pro-Life Generation to abolish abortion and provide policy, legal, and community support for women and their children, born and preborn. SFLA and its members along with registered youth voters care about the environment, and its members nationwide have a vested interest in protecting the environment from pollution, protecting the nation's waterways from destruction, and preserving the waters of the United States for future generations to see and experience.

In fact, as *Students for Life of America's Demetree Institute for Pro-Life Advancement*/YouGov poll of registered Youth Voters showed this year: "(a)sked about the importance of conducting studies

on the potential environmental impact of waste and drugs related to abortion, more than 9 in 10 (91%) said that it was somewhat to extremely important to have environmental testing, with 37% saying extremely important – up from 30% last year."

SFLA seeks to prevent the dumping of Mifepristone and other harmful substances into the waterways of the United States and the inevitable harm that has and will continue to result to these waters and all their applications.

The environmental concerns resulting from Mifepristone use, laid out in more detail in this letter, mirror those that result from the outpouring of PFAS into waterways and other areas in the environment. As a result, this is an area of pollution that is ripe for action, whether that be at the legislative or administrative level. SFLA urges action and encouragement from Congress to bring awareness to this issue and regulate Mifepristone to ensure that the nation's people, waterways, and wastewater supplies remain safe from harmful substances.

I. The EPA's Regulation of PFAS

In short, PFAS, per- and polyfluoroalkyl substances, are chemicals that have been commonly used in industry and consumer products for decades.[1] Recent research has uncovered the harms that these chemicals can have, however, leading the EPA to label them as an "urgent threat to public health and the environment."[2]

To deliver on its "mission of ensuring that every person in this country has clean air to breathe, safe water to drink, and land to live, play, and farm on that is safe from pollution,"[3] the EPA has emboldened its efforts to regulate PFAS, their release into the environment, and the acceptable levels of such release. It has also stepped up its research into the issue to determine the full effects of these harmful substances. PFAS, even though released in very small doses into the environment, combine to create substantial harm to individuals and habitats. Continued exposure to small quantities of PFAS that are released in a widespread and consistent manner can have significant health risks on communities subject to such exposure. As a result, the EPA (with the urging of the Biden Administration) has recognized the harms of exposure to the continued release of these harmful substances and has taken important actions to address its concerns.

The EPA has chosen to "confront PFAS contamination head on [] by following the science, leveraging all available tools and authorities, holding polluters accountable, and investing historic resources to protect communities."[4] Among the steps the EPA has taken are the following:[5]

- Annual PFAS Strategic Roadmap Progress Reports
- Final rulemaking in October 2023 to improve reporting on PFAS to the Toxics Release Inventory (to receive more comprehensive data on PFAS)

[1] https://www.epa.gov/chemical-research/research-and-polyfluoroalkyl-substances-pfas
[2] https://www.epa.gov/system/files/documents/2023-12/epas-pfas-strategic-roadmap-dec-2023508v2.pdf
[3] https://www.epa.gov/system/files/documents/2023-12/epas-pfas-strategic-roadmap-dec-2023508v2.pdf
[4] https://www.epa.gov/system/files/documents/2023-12/epas-pfas-strategic-roadmap-dec-2023508v2.pdf
[5] https://www.epa.gov/pfas/key-epa-actions-address-pfas

- Final rulemaking in October 2023 to require reporting for PFAS manufactured and used in the United States
- Adding "Addressing Exposure to PFAS" as a National Enforcement and Compliance Initiative for 2024-2027
- Increased nationwide monitoring on PFAS in drinking water systems
- New framework to prevent unsafe new PFAS from entering the market
- Advance Notice of Proposed Rulemaking in April 2023 to receive public input on designating certain PFAS as hazardous substances in the future
- Establishing legally enforceable levels for six PFAS known to occur in drinking water
- Two billion dollars in funding from President Biden's Bipartisan Infrastructure Law to address contaminants such as PFAS in drinking water
- A variety of other actions to address the presence of PFAS, specifically in drinking water

The EPA, in conjunction with the Biden Administration, is acting now to address this concern because of the harmful effects that PFAS, even though very small chemicals, can have when released in large and consistent amounts into the environment – and notably, into drinking water. The significant and continued efforts to address this issue signals that the EPA is interested in monitoring and regulating contaminants that are released at a large scale into waterways, habitats, and other areas of the environment. If the EPA is committed to such action regarding PFAS, it stands to reason that our government should also be committed to taking similar action to address environmental concerns caused by other substances that become hazardous when released in large quantities into the environment.

The active metabolites of Mifepristone can be tracked in water and are traceable in some amounts in drinking water and surface water.[6] We also know that common pharmaceuticals can be tracked in surface water and in aquatic life.[7] Thus with many of the steps necessary to include Mifepristone's metabolites onto newly existing monitoring systems, regulatory systems, and levels of containment guidelines, it should not be ruled out that the EPA add these chemicals to these very same lists and schemes. There is an array of published scientific research that shows that these chemicals are traceable and thus could present harm to water, aquatic life, and terrestrial life that depends on that water.

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[6] *Sauer P., et al.* "Two synthetic progestins and natural progesterone are responsible for most of the progestagenic activities in municipal wastewater treatment plant effluents in the Czech and Slovak republics." *Water Research* vol. 137 (2018): 64-71, available at https://www.sciencedirect.com/science/article/abs/pii/S0043135418301787?via%3Dihub.

[7] *Gonsioroski A, Mourikes VE, Flaws JA.* "Endocrine Disruptors in Water and Their Effects on the Reproductive System." *Int J Mol Sci.* 2020 Mar 12;21(6):1929. doi: 10.3390/ijms21061929. PMID: 32178293; PMCID: PMC7139484; *Celiz, Tso, and Aga*, "Pharmaceutical Metabolites In The Environment: Analytical Challenges And Ecological Risks," *Environmental Toxicology and Chemistry*, (June 12, 2009), available at https://setac.onlinelibrary.wiley.com/doi/pdf/10.1897/09-173.1; *Iwanowicz, L. R., et al.* "Evidence of estrogenic endocrine disruption in smallmouth and largemouth bass inhabiting Northeast U.S. national wildlife refuge waters: A reconnaissance study." *Ecotoxicology and environmental safety* vol. 124 (2016): 50-59. doi:10.1016/j.ecoenv.2015.09.035, available at https://www.scopus.com/record/display.uri?eid=2-s2.0-84943631263&origin=inward&txGid=6e454fdff25841ce049d437ad99acff7.

II. Regulation of Mifepristone as a Harmful Substance

The commitment of our government and the EPA to attacking the release of harmful substances 'head on' should extend to substances beyond PFAS, especially when the harms of such substances parallel those caused by PFAS.

As noted above, Mifepristone is a clear example of a chemical that may cause harm to the environment and to people across the nation when released in large amounts over time. As the EPA has taken steps to address the release of substances such as PFAS, it is time to take equal steps to address the release of substances that can cause similar harms to those caused by PFAS. In the wake of increased PFAS regulation, it makes sense to take these steps now, at a time when there is heightened concern for the dumping of hazardous materials into the environment.

When it initially approved Mifepristone for use for women and girls in 2000, the FDA failed to conduct sufficient advanced studies on the impact Mifepristone could have on the nation's water supply. It not only failed to assess the impact of the drug itself, but also failed to assess the impact of the "by-product" of Mifepristone use: medical and pathological waste.[8] Additionally, the FDA initially reported that there would be high standards for disposal related to Mifepristone, stating that prescribers of Mifepristone would "use a licensed incineration or grinding and landfill facility to dispose of this type of material."[9] However, today more than half of all abortions (54%) are committed with Mifepristone[10] (a percentage expected to rise in the near future), and the industry's practice is to allow the by-products of Mifepristone usage to be flushed into the patient's toilet; and substances that are flushed go into to America's wastewater system.[11] Treated wastewater is, in turn, used again for various purposes, including supplying drinking water, irrigating crops, and sustaining aquatic life.[12] At bottom, rising chemical abortion rates and the manner in which chemicals and substances are now disposed of means that Mifepristone remnants and the by-products of its use enter the environment and contaminate drinking water supplies and other important areas, which is of heightened concern for the EPA right now (as shown by its strong attention to PFAS contamination).

As chemical abortion rates and Mifepristone use continues to increase, so will the dumping of chemicals and hazardous substances into various areas of the environment, including the nation's drinking water supply.

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[8] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page1 of Cover Letter (FDA did not issue an environmental impact statement in concluding that the product could be used and disposed of without adverse environmental effects).

[9] 1996 Environmental Assessment and/or FONSI Application Number 20-687 page 3.

[10] Jones, Nash, Cross, Philbin, and Kirstein, "Medication Abortion Now Accounts for More Than Half of All US Abortions, "Guttmacher Institute, (February 24, 2022), available at https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

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

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

Not only does flushing of chemicals and medication into the wastewater system cause environmental and health concerns, but so does the flushing of the fetal remains that comes along with Mifepristone at-home use. With the increased use of this drug and the resulting increase in chemicals and medical waste[13] in wastewater and water supplies, environmental and health concerns may run abound as harmful substances are released in large quantities – one chemical abortion at a time – into the environment.

In the absence of an Environmental Impact Study when Mifepristone was authorized for use in 2000, the true impact of Mifepristone, human tissues, and human remains on America's wastewater and water supply is somewhat unknown. However, current practice and use of Mifepristone today means that harmful substances such as chemical and medical waste are regularly dumped into the wastewater system, which in turn leads to concern for other areas of the environment, such as the nation's drinking water supplies.

III. Taking Action on Mifepristone Contamination

SFLA has addressed its concerns regarding this issue with several Citizen Petition letters to agencies such as the FDA, encouraging necessary action to ensure that the effects of Mifepristone and its by-products are more carefully researched and analyzed. Because of the large-scale environmental concerns that may come as a result of continued (and increased) Mifepristone usage, and in response to the EPA's increased efforts to address similar issues of continuing environmental pollutants, it now makes sense to consider Mifepristone and its effects in the same way that the government has responded to the threat of PFAS.

In the same way that the regular release of PFAS creates a greater presence of harmful substances in the environment, the release of medications such as Mifepristone may cause harm to the environment and humans alike. The EPA's growing attention to these overall issues (in addressing PFAS) means it is able and ready to take action to address issues resulting from the proliferation of other chemicals and substances that pollute our water supplies. As such, SFLA believes the time is now to take action in some form to prevent the continued dumping of harmful substances into the environment – dumping that stems from Mifepristone usage. Whether this action comes as administrative regulation, legislation, the encouragement of either option, or simple advocacy from legislators, it is important to take a closer look at how Mifepristone may impact the environment.

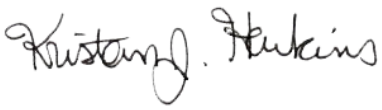
This letter requests that Mifepristone be viewed in the same lens with which the government looks at PFAS, and that regulation of Mifepristone follows in a similar manner to the regulation of other harmful substances.

At present, government-sanctioned, corporate dumping of medical waste has been *de facto* set up by the Biden Administration's FDA policy changes. No matter the political preferences of the administration, the law requires environmental safeguards for the food and water supply of the nation. Adding the active and on-going components of Mifepristone is vital to ensuring that the environment

[13] Mifepristone results in the generation of "medical waste," as defined by the EPA's definition: "Generally, medical waste is healthcare waste that [] may be contaminated by blood, body fluids or other potentially infections materials and is often referred to as regulated medical waste."

does not fall victim to unintended and unmonitored consequences. Given the EPA's obvious capacity to begin tracking of PFAS, we the undersigned, call on the EPA to add the components of Mifepristone to these important efforts.

Sincerely,



/s/

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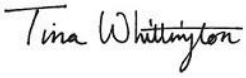

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