VIA FEDEX & ELECTRONIC MAIL

May 2, 2025

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RE: Request to Immediately Remove FDA Approval for Mifepristone (RU486/"The Abortion Pill" and Remove It from the Market

Dear General Bondi, Secretary Kennedy, Director Maltz, Commissioner Brenner, and Attorneys General Moore & Boynton:

I write to you today as the President & CEO of 40 Days for Life, the world's largest pro-life organization. With over 1,000,000 volunteers committed to protecting the sanctity of human life from conception to natural death – *to ask you to immediately remove FDA approval for the Abortion Pill and to remove it from the market.*

40 Days for Life has peaceful vigils in 1,800 cities in all 50 US States and 64 countries. Our law-abiding presence in front of thousands of abortion facilities provides unique and deeply concerning insight on the grave harm of abortion on women and the unborn.

Particularly concerning is the rapid escalation of the use and serious complications associated with mifeprex/mifepristone, also known as RU486, chemical abortion and the Abortion Pill.

Our concerns transcend ideology and are grounded in law, medicine and most importantly *the tangible harm and distress suffered by women as a result of chemical abortion being unimaginably deregulated by the previous administration.* As such, this letter is co-signed by our General Counsel and Director of Medicolegal Affairs.

As you know, the scope of this issue is vast: *Abortion is the leading cause of death, taking the lives of some 1,000,000 unborn Americans each year – with some 60% committed by the Abortion Pill (more than 600,000 unborn babies, annually).*

This letter outlines the medical, legal and societal concerns associated with the distribution of the Abortion Pill.

The Abortion Pill is Bad Medicine:

Chemical abortion is not "safe and effective" as stated by the FDA and as advertised by drug makers and the abortion industry.

Over 1 in 10 women (10.9%) experience serious adverse events from chemical abortion, including sepsis, hemorrhaging, infection and surgical intervention. That is some 22 times higher than the mifepristone label falsely claims. *See,* The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event, April 28, 2025, Ethics & Public Policy Center.

In 2021 alone, it was reported that five women died from complications related to legally induced medication abortions. A June 2024 *JAMA* article indicated that 1.1% of study participants experienced serious side effects, including hospitalizations and surgeries, a rate notably higher than previous studies. EPPC's April 2025 study shows that rate to be over 10%.

Nationally, this could mean over 6,000 women per year suffer serious medical complications from a pill that is routinely mailed to them.

Mifepristone's risk profile would ordinarily prevent its use in pregnancy in any context other than abortion. Its continued availability represents a politically driven exception to established medical safety principles.

Even with efforts to downplay its inherent dangers, mifepristone remains a perilous drug. Its initial clinical trial data and the persistent need for stringent regulatory oversight starkly highlight this reality. Despite modifications aimed at simplifying access, the documented potential for severe adverse events, including life-threatening complications and the alarming necessity for surgical intervention, unequivocally classifies mifepristone as a high-risk medication demanding removal from the market.

Mifepristone was approved by the Federal Drug Administration ("FDA") in September 2000. *That approval was unlawful, as set forth below.*

The FDA mandated package inserts/prescribing information, prepared by drug manufacturers and approved by the FDA under the *Federal Food, Drug, and Cosmetic Act* and associated regulations, particularly those outlined in *Title 21 of the Code of Federal Regulations*. These inserts are supposed to provide healthcare providers with essential details for the safe and effective use of drugs, including indications, dosage, contraindications and adverse reactions. *However, there is no safe use of RU486, which when effective, always takes the life of an unborn child and has serious risks to the mothers.*

The original 2000 FDA package insert cited U.S. clinical trials for mifepristone, with a 92.1% success rate in achieving complete medical abortion without surgical intervention. However, nearly all women experience *some adverse reactions*, with about 90% reporting them after misoprostol administration on day three. *Adverse reactions include heavy bleeding, abdominal pain, and other severe symptoms, some requiring surgical intervention.* The majority of surgical interventions are performed for incomplete expulsion. Less common effects are pelvic pain, fainting, headache, dizziness, and weakness. Severity varies, with 2% to 35% of women considering some reactions severe. Adverse reactions decrease after day three, with bleeding and spotting persisting until day 14.

There are no other known FDA approved medications on the market that have an associated adverse effect requiring surgical intervention.

The FDA responded to the increase in adverse effects by imposing "restrictions to assure safe use," including an in-person dispensing requirement. Initially, mifepristone was distributed only through hospitals and medical facilities per FDA Regulations. RU486 was distributed only to prescribers who agreed to dispense it in specific medical settings, under the supervision of a qualified physician capable of accurately dating pregnancies and diagnosing ectopic pregnancies. These restrictions mandated that mifepristone be used for pregnancies under 50 days gestation,

required three in-person office visits, and ensured physician supervision with comprehensive adverse event reporting. Today, such restrictions are part of the *Risk Evaluation and Mitigation Strategy* (REMS).

But by 2016, the FDA updated mifepristone's label, extending its use to 10 weeks of pregnancy and revising the REMS. *Key changes included increasing the gestational age limit from 49 to 70 days, reducing required office visits from three to one, allowing non-doctors to prescribe the drug, and removing the need to report non-fatal adverse events.*

A generic version of mifepristone was approved in 2019, and a unified REMS was issued for both generic and brand-name versions.

In 2021, due to COVID-19, the FDA permitted mail dispensing of mifepristone. *By January 2023, the FDA permanently lifted the in-person dispensing requirement and allowed certified pharmacies to distribute the drug.*

Even the insufficient REMS requirements are not being enforced. In fact, even if the Abortion Pill was valid medicine, in-person visits for such a dangerous drug are crucial to ensure that patients are adequately informed of the risks and are monitored for adverse reactions. *In person follow-up visits are the most logical way to monitor adverse reactions, the fundamental principle of medical decision-making.*

Without medical visits and routine testing like ultrasounds, using RU486 increases risks like hemorrhage, infection, undiscovered ectopic pregnancies and death.

While some 2023 data presents a seemingly improved safety profile, the 2000 and 2025 data provide more credible bases for understanding the drug's risks, reinforcing the need to remove it from the market or at least for continued REMS protocols and in-person consultations.

There are perilous shortcomings in the approval of and current oversight of mifepristone, demonstrating the misalignment of the present regulatory framework with the robust standards applied to other medications.

Despite these relaxations, the black box warning for mifeprex remains, highlighting risks of serious infections and bleeding. Recent data indicates increasing medication abortion rates, with CDC reports of over 50% of abortions being medically induced with five abortion-related deaths in 2021. *See*, *Ramer S, et al., Abortion Surveillance*, 2022; *MMWR Surveill Summ* 2024;73 (No. SS-7):1–28. *The rate of death is approximately 1 in 100,000 pregnant mothers.*

Similarly, a 2024 *JAMA* article by Ralph LJ, et al., Comparison of No-Test Telehealth and In-Person Medication Abortion, published online June 24, 2024, reports an overall rate of serious adverse events (SAEs) of 1.1% (95% CI, 0.4%-2.4%), suggesting significant side effects affecting thousands of women annually due to a dangerous pill now routinely mailed.

While the *Ralph et al.* study makes a case for the safety and effectiveness of no-test telehealth models for medication abortion, it's crucial to acknowledge that the study also reveals serious adverse events occurred in both telehealth and in-person groups, indicating that complications can arise regardless of the care model.

Additionally, the *Ralph et al.* study's definition of effectiveness, which includes the need for follow-up procedures, suggests that in-person care remains necessary for some patients, even when initiating abortion care remotely.

However, this study's approach contradicts the emphasis in *Hurrell et al.* (2024) on the importance of accurate blood pressure (BP) assessment in pregnant women. *Hurrell et al.* highlight the various factors that can affect BP accuracy, such as maternal position, cuff size, and technique errors, which can be challenging to control in a telehealth setting.

Mifepristone's risk profile would ordinarily prevent its use in pregnancy in any context other than abortion; its continued availability represents a politically driven exception to established medical safety principles.

Distribution of Abortion Pills is Bad Law:

Our profound concerns extend beyond the medical issues and go to mifepristone's legal approval and manufacturing standards.

The approval of the Abortion Pill was flawed from the beginning.

In September 2000, the FDA deviated from its standard practice according to the Administrative Procedure Act (APA) (5 U.S.C. §551 (1946)), governing the process by which federal agencies develop and issue regulations. *The FDA relied on Sub-part H of the APA to approve mifepristone in 2000 and deviated from the process laid out in the APA by classifying pregnancy as an "illness."* The FDA determined that chemical abortion drugs provide a "meaningful therapeutic benefit" over existing "treatments".

A preborn child is not an illness that is "cured" by being killed. This is an unprecedented overreach of the FDA's regulatory authority. Mifepristone should be removed from the market for this reason alone.

In 2002, several organizations filed a citizen petition with the FDA arguing that the approval violated federal law. The citizen petition argued by approving mifepristone, the FDA ignored evidence of potential harm to women and girls. *AFH,* 78 F.4th at 225.

Incredibly, the FDA waited until 2016 to deny the citizen petition and instead issued major changes to the regulation of the Abortion Pill that removed safeguards established in 2000 when the drug was approved.

Some of the major changes in 2016 include:

(1) extending the gestational age of the baby from seven weeks to ten weeks for which a pregnant woman or girl can take chemical abortion drugs;

(2) changing the dosage and administration;

(3) reducing in-person office visits from three to one for a prescription of the chemical abortion;

(4) expanding who can prescribe the Abortion Pill; and

(5) eliminating the requirement to report non-fatal complications from the chemical abortion.

All these changes were made without the required and necessary objective investigation and studies.

In 2008, the GAO report *Food and Drug Administration: Approval and Oversight of the Drug Mifeprex* (GAO-08-751) was undertaken to review the FDA's approval and oversight of mifeprex. Critics questioned the FDA's approval process for mifeprex, including the reliance on historically controlled clinical trials and whether mifeprex fit within the scope of Subpart H.

The GAO report, while providing a detailed analysis of the FDA's approval and oversight of mifeprex, relied solely on FDA-provided information, which introduced bias, and was limited in scope, not thoroughly investigating the fundamental questions surrounding mifeprex' approval. The report's acceptance of historical controls in clinical trials and its assessment of aftermarket safety oversight do not adequately address the methodological weaknesses and systemic issues within the FDA's processes. Furthermore, the report's conclusions on the causality of adverse events, particularly deaths from infection, were far too lenient.

In 2019, another citizen petition was filed challenging the 2016 changes. *AFH, 78 F.4th 226*. In December 2021, all relief sought by the petition was rejected by the FDA. *The Biden Administration issued a "Non-Enforcement Decision" for mifepristone in April 2021 allowing for mail-order chemical abortions and eliminating in-person dispensing.*

In January 2023, the FDA issued a decision to permanently allow chemical abortion drugs to be sent through the mail, extending temporary COVID regulations.

The FDA has shown a pattern of ignoring the legal requirements and concerns regarding the safety of the Abortion Pill. Despite two citizen petitions and ongoing litigation in *Food and Drug Administration (FDA) v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) (dismissed on procedural/standing grounds), the FDA has forged ahead with approval and removal of safety precautions for the Abortion Pill.

The failure to address the merits of *Hippocratic Medicine* left in place a system that is causing serious harm to Americans. In response, the states of Kansas, Idaho and Missouri have joined litigation announcing serious concerns for patient safety regarding the Abortion Pill. *State of Missouri, et al. v. U.S. Food and Drug Administration, et al*, Case Number: 2:22-cv-00223, USDC for Northern Texas, Amarillo Division (2024).

Further, personal injury lawyers play a crucial role in holding pharmaceutical companies accountable for dangerous drugs, often initiating mass torts or product liability suits that can lead to increased safety measures or drug recalls. *However, in the case of mifeprex, the landscape of litigation is different; while these legal avenues are not entirely absent, their prevalence is less pronounced.* This is due to a combination of factors, including the FDA's regulatory oversight, the drug's specific context of use in abortion, restrictions on access and distribution, and complexities in establishing direct causation in liability claims.

The evidence overwhelmingly demonstrates that mifepristone remains a dangerous drug under a progressively weakened regulatory framework. The erosion of crucial safety standards prioritizes access over the demonstrable health and safety of women.

The current lack of oversight undermines state authority and endangers patient safety. While federal preemption has traditionally exempted FDA approved products from state regulation, the 2024 Supreme Court decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, (2024) overturned the Chevron doctrine, affecting federal preemption and giving states more power to regulate.

From 2000 to current, the FDA has ignored the legal requirements and safeguards in place in its approach to the chemical Abortion ills. The Abortion Pill in all forms should be removed from the market.

Abortion Pills are Bad for Women & Society:

Taking the Abortion Pill off the market is vital for patient safety. Women are experiencing serious side effects alone, at home with no real follow up options. Every woman in the United States deserves quality health care and should not be left alone at home to navigate their health.

Women are not prepared to dispose of their babies at home expelled through the use of the Abortion Pill and to handle the copious adverse reactions. The lack of regulation and appropriate oversight is causing trauma and serious health events that would not be accepted anywhere else in the healthcare system.

As 40 Days for Life, witnessing the consequences of abortion daily, we implore you to take immediate and decisive action to remove RU486 from the market. The health and lives of countless women depend on your commitment to prioritizing patient safety over ideological agendas.

The Abortion Pill has no place in modern "healthcare" and should be taken off the market.

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Thank you for your attention to this urgent matter.

Sincerely,

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40 Days for Life

Matt Britton
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