Congress of the United States

Washington, DC 20515

[[DATE]]

The Honorable Donald J. Trump
Office of the President
The White House
Washington, D.C. 20500

Dear Mr. President:

You have done more to advance a culture of life and the protection of women and children from the violence of abortion than any President in history.

As Members of Congress who share your vision for a nation where American families can prosper, we are inspired and deeply grateful for your leadership which has saved so many precious lives.

Out of our shared interest in the health and safety of women and children, we are deeply concerned about the deleterious and grossly underreported effects that the dangerous abortion drug mifepristone has on women. We urge you to, at a minimum, immediately reinstate the in-person dispensing requirement for mifepristone that existed during your first administration.

The need for urgent investigation and review of this drug comes in the wake of the Biden-Harris administration's egregious action to remove critical safeguards that once applied to abortion drugs, and the FDA's approval of a new abortion drug generic in September 2025. The previous administration claimed that these changes were in response to the COVID-19 pandemic, but in reality, COVID served as a smokescreen to accomplish its radical abortion agenda, which even now wreaks havoc across the nation. Clear majorities of Americans recognize the extreme overreach of the previous administration's actions, with recent polling from McLaughlin and Associates finding that 7 in 10 voters agree it "makes sense" to bring back the safety standards that were removed by Biden's FDA[1].

Furthermore, while we have long known that mifepristone causes the death by starvation of children alive in the womb—it is baby poison—we now know with greater certitude that their mothers are also being seriously harmed. Despite the mainstream media and the Biden-Harris administration perpetuating the lie that these drugs are "safer than taking a Tylenol," science and women's lived experiences clearly say otherwise.[2]

In a groundbreaking study, "The Abortion Pill Harms Women", the Ethics and Public Policy Center (EPPC) reveals that serious adverse events from mifepristone are approximately 22 times more frequent than the Food and Drug Administration (FDA) currently recognizes.

---

[1] https://sbaprolife.org/wp-content/uploads/2025/10/National-Voter-Survey-Executive-Summary-.pdf
[2] https://lozierinstitute.org/peer-reviewed-study-debunks-abortion-drugs-are-safer-than-tylenol-claim/

The study shows that, following a mifepristone abortion, 10.93 percent of women experience sepsis, infection, hemorrhaging, or another serious or life-threatening adverse event. That is, over one in ten patients experience at least one serious adverse event.

This largest-ever study of the abortion pill is based on a HIPAA-compliant analysis of a health insurance claims database that includes 865,727 prescribed mifepristone abortions from 2017 to 2023.[3]

This study, along with a separate review conducted by the Restoration of America Foundation which replicated its findings[4], is part of a growing body of evidence that the health risks of mifepristone abortions are severe, widespread, and grievously underreported.

In particular, the sending of this abortion drug through the mail is extremely dangerous. Earlier last month, Secretary Robert F. Kennedy said that "[t]he Biden administration removed mifepristone's in-person dispensing rule without studying the safety risks."[5]

For years, FDA required mifepristone to be dispensed in person under a doctor's supervision, acknowledging that the drug poses serious medical risks to women. But in 2023, the Biden Administration permanently removed the in-person dispensing requirement from its Risk Evaluation and Mitigation Strategy (REMS) for mifepristone[6], creating a no-contact, mail-order abortion scheme. This scheme allows these drugs to be sent through the mail, even to pro-life states where abortion (or merely "telehealth abortion") is illegal, absent important medical consultation and oversight, and often without any confirmation of who is purchasing these drugs.

Just last month, HHS acknowledged that a safety review of mifepristone is warranted—"HHS's decision to [conduct the safety review] is informed by the lack of adequate consideration underlying the prior REMS approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered."[7]

Again, the EPPC and Restoration of America Foundation reports reveal that the real-world rate of serious adverse events following mifepristone abortions is astonishingly higher than what is reported on the drug's label.[8] Even the current Obama FDA-approved label for mifepristone—which the data show understates the dangers to women—says that roughly 1 in 25 women who use mifepristone as directed will end up in the emergency room.[9]

---

[3] Ethics and Public Policy Center (EPPC), Largest-Ever Study of Abortion Pill Reveals Shocking Number of Adverse Events - Ethics & Public Policy Center, April 28, 2025.
[4] https://www.roafoundation.org/wp-content/uploads/2025/04/FFROA-Chemical-Abortion_Report.pdf
[5] Robert F. Kennedy @SecKennedy, Twitter, Oct. 2, 2025, https://x.com/SecKennedy/status/1973866621245567344
[6] Center for Drug Evaluation and Research, Application Number: 020687Orig1s025 Summary Review at 3 (Jan. 3, 2023).
[7] Letter, Dept of Health & Human Servs. to 22 Republican Attys Gen., Sept. 19, 2025, https://x.com/SecKennedy/status/1973866621245567344.
[8] Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics & Pub. Pol'y Ctr. at 1 (Apr. 28, 2025), https://eppc.org/stop-harming-women/.
[9] FDA-Approved Label for Mifepristone (Mifeprex) at 7 (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf.

Yet, the Biden FDA ignored the warning signs, including even the findings in the studies on which it relied showing:

- 3% of the participants needed to be hospitalized—a 330% increase over the rate on the approved drug label;
- 7% of participants "had clinical encounters in [emergency department (ED)] and urgent care centers;"
- "6[%] [of] participants had unplanned clinical encounters in ED/urgent care," and "[s]urgical interventions were required in 4.1[%] to complete abortion;
- 12.5% "had an unplanned clinical encounter;" and
- 5.8% in the "telemedicine [plus] mail group" had "ED visits," a rate exceeding the range on the label (2.9% to 4.6%) and almost three times higher than the 2.1% for women who had an "in-person" visit.[10]

Beyond the studies, women tell us how they have suffered harm from mifepristone, and stories of coercion and abuse involving abortion drugs now run rampant. Real women like Rosalie Markezich—who is just one example of many—felt coerced by her boyfriend to take abortion drugs that he ordered from an out-of-state prescriber in her name and had delivered to her home through the U.S. Postal Service. Rosalie did not want to have an abortion, but Biden's egregious weakening of mifepristone's safety standards let her boyfriend obtain abortion drugs and force her to take them.[11]

The dangerous Biden mail-order scheme was designed to give abortion activists license to mail drugs everywhere, even into states like Markezich's home state of Louisiana that have pro-life protections for pregnant mothers and their unborn babies. These drugs are sent across state lines with no physician oversight, and without appropriate screening to ensure that bad actors are not secretly poisoning women without their knowledge or forcing women to take abortion drugs against their will—a clear indication that radical pro-abortion activists care more about protecting abortion access than about upholding women's health and safety.

Today, abortion drugs account for nearly two-thirds of all abortions in the United States; there are over six hundred thousand abortions committed using these drugs each year. The Biden FDA's reckless, no-contact, mail-order abortion scheme is to blame. Abortion providers are reaping increased profits, while women and their unborn children suffer irreparable harm.

Your administration can reverse this wrong. We urge you to immediately reinstate the REMS requiring in-person dispensing of mifepristone and to expedite the promised review by the FDA into the dangers of abortion drugs.

[[CLOSING]]

---

[10] Ctr. for Drug Evaluation and Research, Application Numbers: 020687 and 91178 Rational Review at 27–32.
[11] Complaint at 44-45, *Louisiana, et al. v. U.S. Food and Drug Admin., et al.*, Case No. 6:25-cv-01491 (W.D. La. Oct. 6, 2025), Dkt. No. 1.

Christopher H. Smith
Member of Congress

Diana Harshbarger
Member of Congress

CC:
Secretary Robert F. Kennedy
Commissioner Marty Makary