June 22, 2026

Kyle Diamantas, J.D.

Acting Commissioner, U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Dear Acting Commissioner Diamantas:

We write to you as medical organizations who represent tens of thousands of life-affirming obstetricians/gynecologists, pediatricians, family physicians, and other medical professionals dedicated to evidence-based care for women and their preborn children. As such, we are deeply concerned about the public health crisis mifepristone is raging across our country, particularly with the removal of the in-person dispensing requirement which began in 2020 under the auspices of the Covid-19 pandemic. We are grateful to see a full safety review has been launched, and simultaneous with this review being conducted, **ask that the in-person dispensing requirement be immediately reinstated.** With your ascendence into the role of Acting Commissioner of the FDA, we urge you to protect American women and undo the FDA's previous devastating actions.

In congressional hearings and subsequent letters to state attorneys general and members of Congress recently, the FDA committed to conducting a thorough, independent review of real-world safety data for this abortion drug—data that recent papers indicate reveal serious complication rates far higher than previously disclosed on the FDA label, including hemorrhage, sepsis, and incomplete abortions requiring surgical intervention.

Two reports analyzing insurance claims for 330 million U.S. patients (2017–2023) identified more than 860,000 mifepristone prescriptions and tracked adverse events within 45 days of use. **Alarmingly, 10.93% of women experienced severe complications, including infection, hemorrhage, surgical intervention, or undiagnosed ectopic pregnancy.**[i] This rate is consistent with what our clinicians observe and suggests the true risk may be *22 times higher* than previously disclosed.

As we stated in our previous letter sent in January of this year, when the FDA approved mifepristone in 2000 under Subpart H, it did so with safeguards designed to reduce these risks.[ii] These essential safeguards were eventually formalized under the REMS program due to ongoing safety concerns (including the addition of a black box warning related to fatal infections in 2006). Over time, those safeguards have been dismantled, leaving women with little to no

medical oversight before or after taking the drug – most egregiously when the previous administration made this high-risk drug available through the mail with no medical evaluation or ongoing care. Even Marie Stopes International, the global abortion provider, states on its website:

"Depending on where they come from, the [abortion] pills may also be ineffective or poor quality, and come with little to no information on how to administer the drugs, and no contact number for aftercare if needed.

You should only take medical abortion pills if it has been prescribed to you by a qualified health professional. Please do not purchase abortion pills online. They may not be suitable, you may be risking your health, and you do not need to…

If you have already ordered pills online we would advise that you call us before taking them."[iii]

Today, at least 63% of abortions are done with this drug, amplifying the public health impact of these changes.[iv] Without a national abortion reporting law and in the absence of adequate safeguards, the actual impact on public health is likely even higher.

Despite admitting that removal of in-person dispensing requirement would likely lead to more emergency room visits and complications, the FDA meanwhile approved a second generic drug and continued to cite a serious complication rate of less than 0.5% (which ignores key data such as hemorrhage rates).

Such blatant disregard for the health and safety of women and willful ignorance of what is occurring in emergency departments across the country undermines informed consent and public trust. Claims that mifepristone is "safer than Tylenol" are not only scientifically unfounded but also violate FDA guidelines on comparative safety claims.[v]

While we are glad to see a safety review has been launched, we do have concerns. **In this review process, we urge full transparency – including who, within or outside the agency, is conducting the review, as well as what data are being used.** The FDA stopped collecting data on mifepristone complications in 2016, despite making major changes at that time and again in 2021 that would affect the rate of complications. Therefore in this review, what data is the FDA relying on? As clinicians who are actively providing care to women experiencing serious complications related to this drug, not only do we deserve these answers, but they are also indispensable for providing fully informed consent to our patients.

We ask the FDA to do its job and give us accurate (and real-world) data to provide women with correct medical information. The continued availability of these drugs without rigorous oversight—particularly via mail-order distribution—increases risk for harm for our patients, empowers coercion and abuse, and leaves women abandoned to their local emergency room (many of which are already extremely full) for care when they experience severe complications. It is the ultimate example of patient abandonment.

AAPLOG recently released an exposé video of OB/GYN and CEO Dr. Christina Francis ordering the abortion pills online to see all the medical risks.[vi] We found no medical oversight whatsoever, no ID or age verification, and severely inadequate counseling on general risks as well as zero individualized counseling on risks despite entering several contraindications to mifepristone for abortion. Dr. Francis easily received the abortion pill regimen in the mail in a state where abortion is illegal. This should be a wake-up call – it's past time for the FDA to reverse the previous administration's reckless actions and respect states' individual laws by immediately reinstating crucial safeguards protecting both women and their preborn children.

On December 18, at a press conference regarding sex-denying interventions, Secretary Kennedy said the following: "This is not medicine – it is malpractice. We're done with junk science driven by ideological pursuits, not the well-being of children."[vii] We agree and ask that this same commitment to evidence-based healthcare for women and children be applied to abortion drugs.

This administration has the chance to do right by women and undo the previous administration's damage immediately. We urge the FDA to:

- **Immediately reinstate the in-person dispensing requirement for mifepristone, which would restore the regulations in place under the first Trump administration.** As physicians and scientists, we note that there is no credible reason this cannot be done immediately while the safety review is being conducted.
- **Immediately reinstate required reporting of all adverse events directly to the FDA by any medical professional caring for the patient.** The manufacturers should not be relied upon to report these.
- **In conducting the safety review, include a comprehensive evaluation of real-world safety data** in partnership with NIH, using Medicaid, Tricare, and commercial insurance claims.

- **Ensure the safety review is being conducted by unbiased sources, whether within or external to the agency, and provide full disclosure to the public of who is conducting the review.**
- **Restore pre-2016 REMS safeguards**, including:
    - Limiting use to seven weeks gestation (as the rates of complications increase significantly starting at eight weeks gestation)
    - Requiring in-person follow-up care
- **Require ultrasounds** to confirm gestational age and rule out ectopic pregnancy.[viii]

It's time for this administration to fulfill its commitment to women and the medical community and address this public health crisis with the seriousness and urgency it requires. We stand ready to provide expert input and data from our members to support this process.

Respectfully,

Christina Francis, MD, dip ABOG
CEO, American Association of Pro-Life OB/GYNs (AAPLOG)

Greg Burke, MD[1]
Vice President, Catholic Medical Association (CMA)

Mike Chupp, MD, FACS
CEO, Christian Medical and Dental Association (CMDA)
Chair of the Board, Alliance for Hippocratic Medicine (AHM)

Mike Artigues, MD, FCP
President, American College of Pediatricians (ACPeds)

[1] CMA members oppose direct abortion in any of its forms, including chemical abortion, especially prescribed and dispensed through telemedicine. CMA physicians in a number of settings, especially those in emergency rooms, are faced with the tragic results of current regulation of mifepristone. Such physicians, not the prescribing physicians, often are the ones treating the life-threatening circumstances which are fostered by the current status of inadequate regulation. CMA physicians in such situations will do all they can to provide excellent care to these mothers, and their unborn children, when called to provide care.

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[i] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf
[ii] FDA-Letter-July-2025_FINAL-1.pdf.pdf
[iii] https://www.msichoices.org.uk/support/frequently-asked-questions/can-i-buy-abortion-pills-online-and-take-them-at-home/
[iv] https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020
[v] https://www.mdpi.com/2673-6284/14/2/39
[vi] https://www.youtube.com/watch?v=4qAG4V-zHD4
[vii] https://nypost.com/2025/12/18/us-news/robert-f-kennedy-jr-says-hhs-wont-fund-sex-rejecting-procedures-it-is-malpractice/
[viii] https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date