February 18, 2026

Submitted Electronically

Commissioner Martin Makary, MD, MPH
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-002

Re: Comment in Support of Citizen Petitions FDA-2025-P-0377-0001, FDA-2025-P-1576-0001, FDA-2025-P-2162-0001, and FDA-2025-P-3287-0001

Commissioner Makary,

Physicians for Reproductive Health (PRH) submits this comment in support of citizen petitions FDA-2025-P-0377-0001, FDA-2025-P-1576-0001, FDA-2025-P-2162-0001, and FDA-2025-P-3287-0001 regarding FDA regulation of mifepristone. PRH requests FDA eliminate the current restrictions on access to mifepristone under the Single Shared System REMS Program or, in the alternative, at a minimum, refrain from taking any action that would further increase barriers to access to mifepristone.

PRH is a physician-led national advocacy organization that organizes, mobilizes, and amplifies the voices of medical providers to advance sexual and reproductive health, rights, and justice. We have a network of over 500 physician advocates. Our programs combine education, advocacy, and strategic communications to ensure access to abortion care and equitable, comprehensive health care. We believe that this work is necessary for all people to live freely with dignity, safety, and security.

As a network of reproductive health care providers, PRH has unique insight into the challenges that providers and their patients face when confronted by actions designed to prevent pregnant people from accessing necessary medical care. Medically unnecessary restrictions on mifepristone directly impact PRH's network of physicians by distorting the scientific truth regarding mifepristone's safety and interfering in the patient-provider relationship. As physicians, we can attest to the safety, efficacy, and critical role that mifepristone plays in reproductive health care. This comment offers excerpts from physician stories that describe their experiences providing medication abortion care and the importance of access to mifepristone.

I. The Overwhelming Body of Evidence Supports the Safety and Efficacy of Mifepristone

Mifepristone's safety and efficacy are backed by over two decades of scientific research. Evidence from over 100 peer-reviewed publications demonstrates that medication abortion with mifepristone is proven safe.[1] In 2023, medication abortion accounted for 63% of all abortions in states without total abortion bans.[2] Studies consistently reveal low complication rates for patients who use mifepristone.[3] These findings, as well as the professional experiences of PRH's physician fellows, are consistent with the multitude of studies that indicate the risk of hospital admission following a medication abortion is extremely low. Dr. Aishat Olatunde, a PRH fellow who practices in Pennsylvania and who prescribes mifepristone on a routine basis, reports that mifepristone is "extremely safe" and that she has "never witnessed an adverse reaction to mifepristone in [her] practice."[4] Dr. Mae Winchester, a PRH fellow and maternal fetal specialist practicing in Ohio, explains that it is "exceptionally rare with mifepristone use to see complications" and that she personally has never observed a patient need medical help for a serious complication after medication abortion.[5]

In addition to mifepristone's proven safety in abortion care, mifepristone is a safe and beneficial option for miscarriage management. Dr. Carolyn Sufrin, a PRH fellow who practices in Maryland, observes that in her practice, "mifepristone added to misoprostol increases the success of medication management, and decreases the likelihood of a procedure" after a miscarriage, meaning that all fetal tissue is passed and further treatment is unnecessary.[6] Similarly, mifepristone is an option for patients who experience fetal demise later in pregnancy. Providers may use mifepristone for patients experiencing second and third trimester pregnancy loss to induce labor and accelerate the process of vaginal delivery, which reduces the likelihood of adverse medical complications when compared to non-use. For these patients, mifepristone also increases the safety of vaginal deliveries of miscarried pregnancies. "From a medical standpoint, mifepristone is the safer option we can give our patients, because the additional wait time for labor with the fetus inside increases risk of hemorrhage, of infection, and of needing subsequent intervention."[7] Mifepristone endorsed by leading medical authorities as an essential medication

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[1] Liz Szabo, *The Abortion Pill is Safe. Scientists Fear an FDA Investigation Will Ignore Science,* SCI. AM. (Oct. 30. 2025), https://www.scientificamerican.com/article/fda-is-investigating-the-abortion-pill-mifepristone-despite-decades-of/.

[2] Kelly Baden et al., *The War on Mifepristone: How Junk Science and False Narratives Threaten US Abortion Access*, GUTTMACHER (Oct. 22, 2025), https://www.guttmacher.org/2025/10/war-mifepristone-how-junk-science-and-false-narratives-threaten-us-abortion-access (last visited Feb. 2, 2026).

[3] *See e.g.,* Elizabeth G. Raymond et al., *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 CONTRACEPTION 26 (2013) https://pubmed.ncbi.nlm.nih.gov/22898359/; Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion,* 125 OBSTET GYNECOL. 175 (2015) https://pubmed.ncbi.nlm.nih.gov/25560122/.

[4] Brief for Physicians for Reprod. Health, as Amicus Curiae Supporting Petitioners at 8–9, FDA et al., v. Alliance Hippocratic Medicine, et al., 602 U.S. 367 (2024).

[5] *Id.* at 11.

[6] *Id.* at 14–15.

[7] *Id.* at 12 (quoting Dr. Jamia Perritt, President and CEO of PRH, who practices in Washington, DC).

and the scientific consensus among providers and researchers is that mifepristone should be available for providers to offer to patients without unduly burdensome restrictions.[8]

II. Requiring In-Person Dispensing of Mifepristone Does Not Increase Safety, But Harms Patient Health

Just as mifepristone itself is safe and effective, access to medication abortion via telehealth is proven safe and effective.[9] Telehealth patients have the same continuity of care as in-person patients. For example, Dr. Sufrin schedules a follow-up appointment after any patient uses mifepristone—whether seen via telehealth or at an in-person appointment. At that appointment, she reviews a "standardized, evidence-based set of screening questions" with the patient "to assess whether both the clinician and the patient think they passed the pregnancy." She also performs a "general review of systems to check for fever, chills, abnormal pain or bleeding."[10] Further, Dr. Nisha Verma, a PRH fellow who practices in Massachusetts and Georgia, who has provided telehealth abortion care in the past, explains that care continued through the duration of and following telehealth.[11]

Providers know that telehealth for medication abortion is a critical resource for patients, many of whom already struggle to access health care. Several PRH providers, including Dr. Winchester and Dr. Verma, note that the alternative to telehealth for many rural or otherwise isolated (physically or emotionally) patients is not in-person care, but no care at all.[12] Dr. Verma explains that from the pandemic, we know that medication abortion is safe and just as effective when prescribed through telemedicine, and thus telehealth only serves to "improve access with these telehealth visits and receiving mailed medication. To remove the barriers is really important, particularly for people who live in rural areas and can't go down the street for care."[13]

Telehealth alleviates the many burdens involved in attending in-person appointments, such as travel time, costs, childcare, and time away from work. Dr. Winchester explains that "demanding in-person dispensing of mifepristone will make it more difficult for patients to access the care they need in a timely manner."[14] The physician and patient experiences highlight the need and success in telehealth for medication abortion.

III. Restrictions on Mifepristone Interfere with Providers' Ability to Ethically Serve Patients

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[8] *See e.g.,* Am. Coll. Obstetricians & Gynecologists, *Leading Medical Organizations Reaffirm the Safety of Mifepristone*, (May 22, 2025), https://www.acog.org/news/news-releases/2025/05/leading-medical-organizations-reaffirm-the-safety-of-mifepristone.
[9] Ushma D. Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the USA*, 30 NATURE MEDICINE 1191 (2024) https://www.nature.com/articles/s41591-024-02834-w.
[10] Brief for Physicians for Reprod. Health, *supra* note 4, at 16.
[11] *Id*. at 16.
[12] *Id*. at 22.
[13] *Id.* at 20.
[14] *Id*. at 22.

The relationship between a provider and a patient is fundamentally rooted in trust. The patient-provider relationship is harmed when patients cannot get their preferred method of care and providers must withhold valid and safe medical options because the evidence-based standard of care is restricted. Dr. Atsuko Koyama, a pediatric emergency medicine physician in Arizona and PRH fellow, observes that the medical community is "hoping to build trust and earn the trust of so many people who historically have been disenfranchised or underserved by the medical system, and a positive experience getting treatment might lead to someone being more proactive in the future with the medical system."[15]

For over 20 years, physicians have offered mifepristone as an option for patients. Physicians know patients rely on medication abortion because it offers needed privacy, affordability, and autonomy. As Dr. Winchester explains, one benefit of medication abortion is that it allows patients to choose when and where they would like the treatment to occur. In addition, mifepristone used in medication abortion and miscarriage management allows patients to avoid medically unnecessary pelvic exams and instrumentation, which may be preferable for certain patients. For instance, Dr. Koyama observes in her practice that many young patients have never had an internal vaginal exam and may prefer a less physically invasive option, like medication abortion. Dr. Michael Belmonte, a PRH fellow practicing in Pennsylvania, and Dr. Winchester also explain that patients who have experienced sexual assault and intimate partner violence may factor in the same considerations when determining whether mifepristone is a desirable option.[16] When access to mifepristone and medication abortion is restricted and banned, providers cannot follow patient's informed decision to receive their choice in care, thus eroding patient autonomy and trust in providers.

As PRH providers attest, communicating the full spectrum of medical information about mifepristone, including discussions about risks, is a standard part of their practice. Dr. Bhavik Kumar, a PRH fellow practicing in Houston, Texas, explains that if a patient is a candidate for a medication abortion, the provider communicates the risks and benefits for that treatment option (as well as for all other available options). [17] Providers know that mifepristone is safe for their patients and providers are trained to engage in informed consent practices with patients when discussing whether mifepristone is right for them. If access to mifepristone is rescinded, providers would be forced to withhold safe medical options to patients.

Conclusion

As these physicians' stories show, access to mifepristone is essential. Restrictions and bans on medication abortion and mifepristone harm patients by depriving them of their ability to select a

[15] *Id*. at 25-26.
[16] *Id*. at 21.
[17] *Id*. at 29-30.

safe and effective care method. When providers cannot treat patients according to their best medical judgement, individual and public health suffers.

Sincerely,
Dr. Jamila Perritt, MD, MPH, FACOG
President & CEO, Physicians for Reproductive Health