Americans United for Life

September 18, 2025

Submitted Electronically via Regulations.gov Portal

Dockets Management Staff
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Citizen Petition from Washington (FDA-2025-P-3287)

Dear Dockets Management Staff:

On behalf of Americans United for Life ("AUL"), we are writing in response to the citizen petition filed by Washington, sixteen other states, and the District of Columbia, FDA-2025-P-3287. AUL is a national pro-life, nonprofit legal advocacy organization. Founded in 1971, before the Supreme Court's decision in *Roe v. Wade*,[1] AUL has dedicated over fifty years to advocating for comprehensive legal protections for human life from conception until natural death. AUL attorneys are legal experts on statutory interpretation and bioethics, and regularly testify before state legislatures and Congress on abortion issues.[2] Supreme Court opinions have cited AUL briefs and scholarship in major bioethics cases, including *Dobbs v. Jackson Women's Health Organization*.[3] One of the authors of this comment has published scholarship on the Comstock Act's mail-order abortion rules, 18 U.S.C. §§ 1461–1462, which prohibit mailing or shipping abortifacient matter.[4]

Thank you for the opportunity to comment on Washington's citizen petition, which is joining the previously-filed multistate citizen petition that was led by Massachusetts[5] to request the U.S. Food and Drug Administration ("FDA") remove the mifepristone Risk Evaluation and Mitigation Strategy ("REMS").[6] Alternatively,

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[1] 410 U.S. 113 (1973), *overruled by* Dobbs v. Jackson Women's Health Org., 597 U.S. 215 (2022).
[2] *See, e.g.*, *What's Next: The Threat to Individual Freedoms in a Post-Roe World Before the H. Comm. on the Judiciary*, 117th Cong. (2022) (testimony of Catherine Glenn Foster, President & CEO, Americans United for Life).
[3] 597 U.S. at 271 (citing CLARKE D. FORSYTHE, ABUSE OF DISCRETION: THE INSIDE STORY OF ROE V. WADE 127, 141 (2012)).
[4] Carolyn McDonnell, *Mail-Order Abortion Rules: Text, Context, and History of the Comstock Act's Restrictions on Mailing Abortifacient Matter*, 23 AVE MARIA L. REV. 101 (2025).
[5] Massachusetts et al. Citizen Petition, FDA-2025-P-1576 (June 5, 2025).
[6] Washington et al. Citizen Petition at 1, FDA-2025-P-3287 (Aug. 20, 2025).

the Washington citizen petition is asking the FDA to not enforce certain Elements to Assure Safe Use ("ETASU")—the prescriber certification, patient agreement form, and pharmacy certification requirements—in petitioner states.[7] Below, we discuss (I) the background of the FDA's approval and deregulation of chemical abortion drugs, and urge you to deny Washington's citizen petition because (II) current ETASU safeguard the health and informed consent of patients and (III) the FDA sets a national baseline for drug regulation, and cannot have a non-enforcement policy in certain states based solely upon those states' laws. We additionally urge the FDA to bolster patient safeguards by (IV) ensuring the dispensing of mifepristone is in accordance with federal law's restrictions on mailing or shipping abortifacient matter; (V) reestablishing prior safeguards mandating adverse event reporting and requiring in-person dispensing to support patient health and informed consent; and (VI) implementing an ultrasound safeguard to confirm the gestational age and rule out ectopic pregnancy prior to a mifepristone prescription. Accordingly, we urge the FDA to strengthen, not remove, protections for patients seeking a chemical abortion.

I. Background of the FDA's Approval and Deregulation of Mifepristone.

The "chemical abortion pill" (also known as a "medical abortion") is a regimen of two drugs, mifepristone and misoprostol.[8] "[M]ifepristone (brand name, Mifeprex), is an antiprogesterone, which starves the pregnancy. The second, misoprostol (brand name, Cytotec), a prostaglandin, causes the uterus to contract, which mechanically expels the fetus and placenta."[9] Women commonly experience cramping, bleeding, nausea, weakness, vomiting, headache, and dizziness from the drugs.[10] During a chemical abortion, "[t]he average woman bleeds for 9–16 days and eight percent will bleed longer than a month."[11] Complications increase exponentially as the pregnancy progresses.[12] In some cases, the chemical abortion may fail to end the pregnancy or fail to expel the deceased fetus, creating a need for surgical intervention.[13] Woman also may experience hemorrhaging or infection due to retained fetal remains.[14]

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[7] *Id*. at 2.
[8] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN. (Feb. 11, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.
[9] Clarke D. Forsythe & Donna Harrison, *State Regulation of Chemical Abortion After* Dobbs, 16 LIBERTY U. L. REV. 377, 377 (2022).
[10] RSCH. COMM., AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, MEDICATION ABORTION, PRAC. GUIDELINE NO. 8, at 3 (2020).
[11] *Id*.
[12] *Id*.
[13] *Id*.
[14] *Id*.

In 2000, the FDA approved Population Council's new drug application for chemical abortion drugs to terminate a pregnancy up to seven weeks gestation.[15] The FDA included a black box warning on the drug label about "serious and sometimes fatal infections or bleeding."[16] To protect patients, "only doctors could prescribe or supervise prescription of Mifeprex," "[d]octors and patients also had to follow a strict regimen requiring the patient to appear for three in-person visits with the doctor," and doctors had to report serious adverse events.[17] However, the approval did not contain an ultrasound requirement, even though the Population Council had relied on three clinical studies which used the condition of "an ultrasound to verify gestational age and diagnose ectopic pregnancies."[18]

The FDA used its "accelerated approval" process under 21 C.F.R. § 314 subpart H to approve chemical abortion drugs.[19] When Congress enacted the REMS framework in 2007, it determined existing drugs approved under Subpart H, including chemical abortion drugs, had an approved REMS in effect.[20]

Subpart H applies to drugs for "treating serious or life-threatening illnesses" which "provide meaningful therapeutic benefit to patients over existing treatments."[21] The FDA "consider[s] accelerated approval in two situations: where the agency can reliably estimate effectiveness using a 'surrogate endpoint'; and where FDA 'determines that a drug, effective to the treatment of a disease, can be used safely only if distribution or use is modified or restricted.'"[22] Here, the FDA used its Subpart H authority, reasoning that "the termination of an unwanted pregnancy is a serious condition within the scope of Subpart H. The meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure."[23] Likewise, the FDA determined Subpart H was appropriate because chemical abortion drugs "could not be administered safely without imposing certain use restrictions."[24]

The FDA exceeded its legal authority by approving mifepristone under its Subpart H authority. As the U.S. House Committee on Government Reform (now

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[15] FDA v. All. for Hippocratic Med., 602 U.S. 367, 375 (2024).
[16] *Mifeprex Prescribing Information*, U.S. FOOD & DRUG ADMIN. 1, 1 (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf (capitalization omitted).
[17] *FDA,* 602 U.S. at 375.
[18] All. for Hippocratic Med. v. Food & Drug Admin., 78 F.4th 210, 224 (5th Cir. 2023), *rev'd on other grounds*, 602 U.S. 367.
[19] *Id*. at 223–24.
[20] 21 U.S.C. § 331 note.
[21] 21 C.F.R. § 314.500 (2024).
[22] *All. for Hippocratic Med.*, 78 F.4th at 223 (citing New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58,942, 58,942 (Dec. 11, 1992)).
[23] 2000 FDA Approval Memo. to Population Council re: NDA 20-687 Mifeprex (mifepristone) at 6 (Sept. 28, 2000), *quoted in All. for Hippocratic Med.*, 78 F.4th at 224.
[24] *All. for Hippocratic Med.*, 78 F.4th at 224 (citing 2000 FDA Approval Memo., *supra* note 23, at 6).

known as the Committee on Oversight and Accountability)'s Subcommittee on Criminal Justice, Drug Policy and Human Resources recognized, "the term 'serious condition' is not found in the Subpart H rule."[25] Likewise, "[t]here are situations in which pregnancies become serious or life-threatening, but the underlying condition is not 'serious or life-threatening.' Moreover, pregnancy itself is not an illness. There are situations in which serious or life-threatening complications may arise, but these are atypical events."[26]

The FDA indicated chemical abortion drugs provided a "meaningful therapeutic benefit over existing surgical abortion" by "avoid[ing] a surgical procedure."[27] This circular reasoning belied the fact that chemical abortion drugs were "not approved for a medical indication intended for only the treatment of patients who were intolerant of surgical abortion. It was approved to treat the general population of women seeking first-trimester abortions."[28] Similarly, women taking chemical abortion drugs had to tolerate surgery because "surgical intervention may be needed" to treat "incomplete abortion or other complications."[29]

There were other issues with the approval of chemical abortion drugs. The drug regimen was also "highly unusual."[30] "The use of misoprostol was not only an unapproved or off-label use—it was actually contraindicated at that time."[31] At the time of approval, the FDA also had no evidence of the drugs' psychological or long-term physical effects.[32]

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[25] STAFF OF SUBCOMM. ON CRIM. JUST., DRUG POL'Y & HUM. RES. OF THE H. COMM. ON GOV'T REFORM, 109TH CONG., THE FDA AND RU-486: LOWERING THE STANDARD FOR WOMEN'S HEALTH 20 (Subcomm. Print 2006).
[26] *Id*.
[27] 2000 FDA Approval Memo., *supra* note 25, at 6 (Sept. 28, 2000), *quoted in* STAFF OF SUBCOMM. ON CRIM. JUST., *supra* note 25, at 21.
[28] STAFF OF SUBCOMM. ON CRIM. JUST., *supra* note 25, at 22.
[29] *Mifeprex Prescribing Information*, *supra* note 16, at 1.
[30] STAFF OF SUBCOMM. ON CRIM. JUST., *supra* note 25, at 23.
[31] *Id*.
[32] FDA Commissioner Jane Henney testified before Congress in February 2000 regarding the FDA's review of chemical abortion drugs:

> The primary clinical trials conducted by the sponsor to support the safety and efficacy of mifepristone—RU-486—were discussed before the Reproductive Health Advisory Committee in July 1996. *These clinical studies did not include an evaluation of the psychological effects of the drug in women or an evaluation of the long-term medical consequences of the drug in women.* FDA is unaware of any published studies on the psychological effects or the long-term medical consequences of mifepristone in women.

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2001: Part 2 of Hearings Before the Subcomm. of the Comm. on Appropriations, 106th Cong. (2000), *available at* https://www.govinfo.gov/content/pkg/CHRG-106hhrg63888/html/CHRG-106hhrg63888.htm (emphasis added).

The approval of mifepristone posed particular safety issues for adolescents. The FDA waived the pediatric rule,[33] which was in effect as an administrative rule at the time of mifepristone's approval but is now codified as the Pediatric Research Equity Act ("PREA").[34] PREA requires new drug applications to assess the safety, effectiveness, dosing, and administration for pediatric patients.[35] PREA retroactively considered "a waiver or deferral of pediatric assessments" under the pediatric rule between April 1, 1999 and December 3, 2003 to be a waiver or deferral under PREA,[36] which included the waiver of pediatric assessments for the FDA's approval of mifepristone in 2000. According to the FDA, "there is no biological reason to expect menstruating females under age 18 to have a different physiological outcome with the regimen."[37] This contention was unsupported, and contradicted by how adolescents do not have fully developed decision-making capabilities compared to adults,[38] have a "biological predisposition for high-risk pregnancies,"[39] and often delay care.[40] Likewise, the FDA did not know how mifepristone, an anti-progestin which interferes with the immune system, affects adolescent development.[41]

In 2016, the FDA approved Danco Laboratories' (the distributor of Mifeprex) supplemental new drug application that sought to remove certain safeguards.[42] The FDA increased the indicated use from seven to ten weeks gestation, permitted non-physician healthcare providers (such as nurse practitioners) to prescribe chemical

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[33] 21 C.F.R. § 314.55(c) (2024). A federal district court enjoined the FDA from enforcing the pediatric rule in 2002, holding the FDA exceeded its statutory authority by promulgating the pediatric rule. *See Ass'n of Am. Physicians & Surgeons v. FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002). However, Congress subsequently codified the pediatric rule and incorporated certain previous waivers or deferrals under the pediatric rule, which includes the waiver of the pediatric rule during the approval of mifepristone. *See infra* notes 32–34 and accompanying text.

[34] 21 U.S.C. § 355c.

[35] *Id.* § 355c(a)(2)(A).

[36] *Id.* § 355c note.

[37] 2000 FDA Approval Memo., *supra* note 23, at 7, *quoted in* Compl. ¶ 153, All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507 (N.D. Tex. 2023) (No. 2:22-cv-223-Z), *vacated in part*, 78 F.4th 210, *rev'd on other grounds*, 602 U.S. 367.

[38] H.L. v. Matheson, 450 U.S. 398, 411 (1981), *abrogated by Dobbs*, 597 U.S. 215; Aviva L. Katz et al., *Informed Consent in Decision-Making in Pediatric Practice*, PEDIATRICS, Jan. 2023, at e1, e2 ("A reliance on individual liberties and autonomy in the pediatric patient is not realistic or legally accepted, so parents or other surrogates provide 'informed permission' for diagnosis and treatment, with the assent of the child as developmentally appropriate.").

[39] Nadia Akseer et al., *Characteristics and Birth Outcomes of Pregnant Adolescents Compared to Older Women: An Analysis of Individual Level Data from 140,000 Mothers from 20 RCTs*, ECLINICALMED., Feb. 26, 2022, at 1, 3.

[40] Nathalie Fleming et al., *Adolescent Pregnancy Guidelines*, 37 J. OBSTETRICS & GYNAECOLOGY CAN. 740, 743 (2015).

[41] *See* STAFF OF SUBCOMM. ON CRIM. JUST., *supra* note 25, at 12–13 (recognizing medical concerns about mifepristone's immune system inhibition); *see also* Compl., *supra* note 37, at ¶ 216 ("The FDA did not require any studies on the long-term effects of chemical abortion drugs in pediatric populations with developing reproductive systems.").

[42] *FDA*, 602 U.S. at 375.

abortion drugs, "reduced the number of required in-person visits from three to one—a single visit to receive Mifeprex," and altered adverse event reporting requirements so that prescribers only had to report fatalities.[43] The FDA also "[s]witch[ed] the method of administration for misoprostol from oral to buccal" and "[c]hang[ed] the dose of mifepristone (600 mg to 200 mg) and misoprostol (400 mcg to 800 mcg)."[44]

These changes exceeded the FDA's legal authority and presented significant patient safety issues. The action was arbitrary and capricious because the "FDA did not consider the cumulative effect of the 2016 Amendments" and even "admit[ted] that none of the studies it relied on examined the effect of implementing all of those changes together. It studied the amendments individually."[45] The removal of the physician-only rule posed safety issues because non-physicians have less training in handling medical complications.[46] Increasing the indicated use from seven to ten weeks gestation also presented a safety concern because "[t]he rate of . . . complications increase exponentially as gestational age increases."[47] Finally, the FDA could not effectively monitor adverse events following the 2016 changes because it only required adverse event reporting for fatalities, which we discuss below in Section V(A).

In 2019, the "FDA approved an application for generic mifepristone. [The] FDA established the same conditions of use for generic mifepristone as for Mifeprex."[48] In this regard, the approval of the generic mifepristone carried the same legal and patient safety issues that arose for Mifeprex because of the 2016 deregulation.

In 2021, during the COVID-19 pandemic, the FDA decided to not enforce the in-person dispensing requirement.[49] "Effectively, this allowed mifepristone to be prescribed remotely and sent via mail."[50] As discussed below in Sections IV and V(B), this action was in tension with federal law's prohibition on mailing or shipping abortifacient matter, and raised informed consent concerns by decreasing the ability of medical professionals to screen for intimate partner violence.[51]

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[43] *Id*. at 375–76.
[44] *All. for Hippocratic Med.*, 78 F.4th at 226.
[45] *Id*. at 246.
[46] RSCH. COMM., AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, STATE RESTRICTIONS ON ABORTION: EVIDENCE-BASED GUIDANCE FOR POLICYMAKERS, COMM. OP. NO. 10 at 10–12 (2022).
[47] RSCH. COMM., AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, MEDICATION ABORTION, *supra* note 10, at 3.
[48] *FDA*, 602 U.S. at 376.
[49] *Id*.
[50] *All. for Hippocratic Med.*, 78 F.4th at 226.
[51] *See generally* Megan Hall et al., *Associations Between Intimate Partner Violence and Termination of Pregnancy: A Systematic Review and Meta-Analysis*, PLOS MED., Jan. 7, 2014, at 1; COMM. ON HEALTH CARE FOR UNDERSERVED WOMEN, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, INTIMATE PARTNER VIOLENCE, COMM. OP. NO. 518 (reaffirmed 2025).

In 2023, the FDA formalized the removal of the in-person dispensing requirement.[52] Like the 2021 action, the 2023 action conflicted with federal law that restricted mailing or shipping abortifacient matter, as well as presented informed consent issues. In 2023, the FDA also added a pharmacy certification requirement, which permitted retail pharmacies to dispense mifepristone if the pharmacy "meets the requirements of the Mifepristone REMS Program."[53]

The Washington citizen petition is now asking the FDA to remove the mifepristone REMS to further eliminate safeguards for patients. Alternatively, the Washington citizen petition asks the FDA to not enforce certain ETASU in petitioner states, thus, creating a non-uniform enforcement policy that is solely contingent upon states' laws. We urge the FDA to deny Washington's citizen petition.

II. Current ETASU Safeguard the Health and Informed Consent of Patients.

The FDA should retain current ETASU that "assure safe use of the drug" by ensuring informed consent and protecting the safety of patients.[54] These ETASU include: the (A) prescriber certification, (B) patient agreement form, and (C) pharmacy certification.

A. The Prescriber Certification ETASU Protects the Health and Safety of Patients.

The prescriber certification ETASU ensures patients receive prompt medical care if they suffer complications. Under this ETASU, prescribers verify that they have the:

> Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.[55]

As mifepristone's black box warning details, "[p]rolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed."[56]

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[52] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 8.
[53] *Id*.
[54] *See* 21 U.S.C. 355-1(f)(5)(B)(i).
[55] *Mifeprex Prescriber Agreement Form*, U.S. FOOD & DRUG ADMIN. 1, 1 (Mar. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_Danco_Laboratories_LLC.pdf; *Mifepristone Tablets, 200 mg Prescriber Agreement Form*, U.S. FOOD & DRUG ADMIN. 1, 1 (Mar. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_GenBioPro_Inc..pdf.
[56] *Mifeprex Prescribing Information*, *supra* note 16, at 1.

However, telemedical chemical abortions raise concerns for patients living in healthcare deserts without access to adequate medical care. Washington's citizen petition contends that the REMS reduces abortion access, especially "for those in rural and medically-underserved areas."[57] However, it is those same patients in rural and medically underserved areas who are at greater risk of not receiving prompt medical attention. According to one study, "[i]t is estimated that over 80% of US counties, or about a third of the US population, have poor access to the services they need for adequate health care," which includes emergency services.[58] A separate report identifies "that over 35% of counties are considered maternity care deserts" without "a single birthing facility or obstetric clinician."[59] Thus, a patient in a healthcare desert is at risk for not receiving prompt medical attention if she suffers complications. Consequently, the prescriber certification ETASU ensures there is a plan in place for the patient to receive prompt medical or surgical intervention if she suffers complications, even if she lives in a healthcare desert.

Washington's citizen petition argues that "the Prescriber Certification ETASU discourages qualified providers from providing medication abortion due to the serious and well-founded concerns about creating a documented association with abortion care" because a data breach might create a risk of harassment to those abortion prescribers.[60] Essentially, the citizen petition asks the FDA to remove the prescriber certification based upon a third-party private actor's possible tortious or illegal actions, *i.e.*, breaching the data and/or harassing the abortion providers. However, both federal and state law provide criminal and civil remedies for various situations of alleged harassment or data breaches against abortion providers.[61] For example, the Freedom of Access to Clinic Entrances ("FACE") Act provides civil remedies and criminalizes actions using "force or threat of force" or "attempts to injure, intimidate or interfere with any person" because a person is, has been, or is intimidated from "obtaining or providing reproductive health services."[62] Accordingly, the FACE Act and other federal and state laws provide remedies for alleged data breaches and

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[57] Washington Citizen Petition, *supra* note 6, at 10.
[58] Jacqueline Ross, *The Impact of Health Care Deserts on Patient Safety*, 39 J. PERIANESTHESIA NURSING 686, 686 (2024).
[59] *Nowhere to Go: Maternity Care Deserts Across the US 2024 Report*, MARCH OF DIMES 1, 3 (2024), https://www.marchofdimes.org/sites/default/files/2024-09/2024_MoD_MCD_Report.pdf.
[60] Washington Citizen Petition, *supra* note 6, at 26.
[61] *See*, *e.g.*, Planned Parenthood Fed'n of Am. v. Newman, 51 F.4th 1125, 1130 (9th Cir. 2022) (including claims of "trespass, fraud, conspiracy, breach of contracts, unlawful and fraudulent business practices, violating civil RICO, and violating various federal and state wiretapping laws" for undercover journalism activities against an abortion provider).
[62] 18 U.S.C. § 248(a)(1).

harassment against abortion providers. Thus, we urge the FDA to keep the prescriber certification ETASU as a patient safeguard.

B. The Patient Agreement ETASU Protects the Informed Consent and Health of Patients.

The patient agreement form provides an extra layer of informed consent protection for women seeking a chemical abortion. Heightened abortion-related informed consent laws are common in the United States.[63] In fact, at the time of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, a majority of states had some type of abortion-related informed consent law.[64] Even under *Roe*'s purported right to abortion, the Supreme Court recognized "that as with any medical procedure, the State may require a woman to give her written informed consent to an abortion," and upheld a law requiring "provision of specific information by the doctor and the mandatory 24-hour waiting period" in *Planned Parenthood of Southeastern Pennsylvania v. Casey*.[65]

The patient agreement ETASU ensures a patient recognizes when she needs to contact her healthcare provider for possible emergency care for her complications.[66] Abortion prescribers employ a "commonly used analogy" that the pain of a chemical abortion is similar to "period pain,"[67] but "some [patients] found comparisons to period pain inaccurate and misleading," and likewise "[m]any felt unprepared for pain."[68] The reality is that a chemical abortion "takes much longer, involves far more bleeding and pain, and complications occur four times more frequently from medical as compared to surgical abortions."[69] The patient needs to recognize when the bleeding might be a sign of an incomplete abortion, or an "undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured

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[63] Clarke D. Forsythe & Carolyn McDonnell, *The States' Response to Dobbs v. Jackson Women's Health Organization*, 39 NOTRE DAME J.L. ETHICS & PUB. POL'Y 171, 195 (2025).
[64] *See id.*
[65] 505 U.S. 833, 881 (1992) (plurality opinion), *overruled by Dobbs*, 597 U.S. 215.
[66] *Mifeprex Patient Agreement Form*, U.S. FOOD & DRUG ADMIN. 1, 1 (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf; *Mifepristone Tablets, 200mg Patient Agreement Form*, U.S. FOOD & DRUG ADMIN. 1, 1 (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf.
[67] Hannah McCulloch et al., *Expectations and experiences of pain during medical abortion at home: a secondary, mixed-methods analysis of a patient survey in England and Wales*, 51 BMJ SEXUAL & REPROD. HEALTH 137, 137 (2025).
[68] *Id.* at 142.
[69] RSCH. COMM., AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, MEDICATION ABORTION, *supra* note 10, at 3.

ectopic pregnancy."[70] The patient agreement form makes sure the patient knows who to contact if she cannot reach her provider.[71] This is critical because the patient might need "prompt medical or surgical intervention" for certain complications,[72] but she first has to know when she must reach out to a healthcare provider and who she should contact about possible complications. Accordingly, the patient agreement ETASU is a critical safeguard for patient safety.

C. The Pharmacy Certification ETASU Prevents Patients from Receiving Unapproved and Misbranded Chemical Abortion Drugs.

The pharmacy certification form supports patient safety by ensuring patients receive chemical abortion drugs from medically reliable sources. Washington's petition claims that "[t]he Pharmacy Certification ETASU also unduly burdens providers by requiring providers to send a prescriber agreement form to *every* certified pharmacy to which they send a mifepristone prescription."[73] The petition further claims that the "burdens" of the Pharmacy Certification ETASU "will cause many pharmacies to opt out of dispensing mifepristone."[74] However, as discussed throughout this comment, mifepristone is a dangerous drug that requires ETASU in order to ensure patient safety. Specifically, the Pharmacy Certification ETASU protects patients from drug trafficking, *i.e.*, receiving unapproved and misbranded chemical abortion drugs from unscrupulous online websites. Protecting pregnant women and adolescents from non-FDA approved chemical abortion drugs, which only exacerbate health and safety risks, is a valid reason for ensuring retail pharmacies are certified before they dispense mifepristone and misoprostol.

The FDA has warned the public about the unauthorized selling of mifepristone through websites such as Aid Access and Rablon, and has sent warning letters to these organizations about their unlawful activity.[75] In fact, the FDA notes, "[t]here have also been several criminal cases related to the online sale of mifepristone for medical termination of pregnancy."[76] The online distribution of these drugs through non-certified pharmacies is not only illegal, it also raises patient safety concerns because the FDA cannot ensure the safety or efficacy of unapproved or misbranded drugs.

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[70] *Mifeprex Prescribing Information*, *supra* note 16, at 6.
[71] *Mifeprex Patient Agreement Form*, *supra* note 66, at 1; *Mifepristone Tablets, 200mg Patient Agreement Form*, *supra* note 66, at 1.
[72] *Mifeprex Prescribing Information*, *supra* note 16, at 1.
[73] Washington Citizen Petition, *supra* note 6, at 27.
[74] *Id.* at 28.
[75] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 8.
[76] *Id.*

Ensuring the drugs are distributed through certified pharmacies is also critical because the United States is experiencing interstate abortion drug trafficking. Specifically, some states protect women and preborn children by banning abortion, but despite these pro-life laws, there is an unlawful shipment of chemical abortion drugs into those states. A recent example of this occurred in Texas where the state brought a suit against Dr. Margaret Daley Carpenter, who was licensed in New York, but provided abortion-inducing drugs to a Texan through telehealth despite not being a licensed Texas physician nor authorized to practice telemedicine in Texas.[77] The district court entered final judgment and an injunction against Dr. Carpenter, holding that she violated the Texas Medical Practice Act "by practicing medicine without a license and registration in the State of Texas" and violated the state's law protecting preborn children from abortion violence.[78] Notably, the state claimed that Dr. Carpenter admitted through on online biography that she worked with Aid Access in 2020—an organization that the FDA has acknowledged is violating the law by providing unapproved and misbranded chemical abortion drugs, as discussed above[79]—"and continues to work with [the] organization[]."[80] Thus, the interstate trafficking of abortion drugs poses health and safety concerns for patients, but the pharmacy agreement form helps safeguard patients against unapproved and misbranded drugs.

Ultimately, the FDA needs to ensure that medically reliable sources are dispensing chemical abortion drugs, which necessitates the Pharmacy Certification ETASU. The FDA cannot ensure the safety or efficacy of drugs if the agency does not know where the drugs are coming from. Thus, the Pharmacy Certification ETASU is an extra layer of protection for pregnant women and adolescents and should remain in place.

In sum, we urge the FDA to retain the current ETASU—prescriber certification, pharmacy certification, and patient agreement form—to safeguard the health and informed consent of patients.

III. The FDA Sets a National Baseline for Drug Regulation and Cannot Have a Non-Enforcement Policy in Certain States Based Solely upon Those States' Laws.

The FDA has the power to create a national drug policy,[81] including the establishment of REMS and ETASU for certain high risk drugs such as

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[77] Petition & Application for Temporary & Permanent Injunctive Relief at 1, Texas v. Carpenter, No. 471-08943-2024 (Tex. Dist. Ct. Feb. 13, 2025).
[78] Texas v. Carpenter, No. 471-08943-2024, slip op. at 1 (Tex. Dist. Ct. Feb. 13, 2025).
[79] *Warning Letter: Aidaccess.org*, FDA (Mar. 12, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019.
[80] Petition & Application for Temporary & Permanent Injunctive Relief, *supra* note 77, at 4.
[81] 21 U.S.C. § 355.

mifepristone.[82] Washington contends that the FDA should "exercise its discretion not to enforce the Mifepristone REMS Program (or elements thereof) in Petitioner States."[83] However, the FDA cannot selectively enforce the ETASU solely based upon state laws. Such an action would not be in accordance with the Food, Drug, and Cosmetic Act ("FDCA"), would be arbitrary and capricious because mifepristone's risks require REMS, would exceed the FDA's authority by making the enforceability of the ETASU contingent upon state laws, and would be unworkable by requiring the FDA to interpret and monitor changes to state medical laws.

Selectively enforcing the ETASU is not in accordance with the FDCA's prohibition on subverting REMS.[84] Under 21 U.S.C. § 355(p)(1) of the FDCA:

> A person may not introduce or deliver for introduction into interstate commerce a new drug if . . . a risk evaluation and mitigation strategy is required under section 355-1 of this title with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy . . . .[85]

Thus, any person who introduces or delivers a drug in interstate commerce but does not adhere to the REMS—including its ETASU—is in violation of the FDCA. If the FDA declines to enforce the ETASU in petitioner states, solely based upon the petitioner states' laws, its official action (of non-enforcement) would enable flagrant violations of 21 U.S.C. § 355(p)(1) in petitioner states.

Adopting an official policy of not enforcing the ETASU in select states would be arbitrary and capricious because the FDA recognizes that mifepristone's risks require REMS, but would be permitting the delivery of these drugs in select states without the ETASU to protect patient safety.[86] The FDA approved mifepristone with REMS because the REMS were "necessary to ensure that the benefits of the drug outweigh the risks of the drug."[87] In other words, the FDA considers mifepristone as safe for patients *only* when there is a REMS—including its ETASU—in place. Mifepristone poses significant risks to patient safety. As the black box warning on the drug label recognizes, mifepristone has the risk of "serious and sometimes fatal infections or bleeding."[88] Yet, a non-enforcement policy of the ETASU would subvert

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[82] 21 U.S.C. § 355-1.
[83] Washington Citizen Petition, *supra* note 6, at 2.
[84] 21 U.S.C. § 355(p)(1); *see* 5 U.S.C. § 706(2)(A).
[85] 21 U.S.C. § 355(p)(1); *see also* 21 U.S.C. § 331(d) ("The following acts and the causing thereof are prohibited . . . [t]he introduction or delivery for introduction into interstate commerce of any article in violation of section . . . 355 . . . of this title.").
[86] *See* 5 U.S.C. § 706(2)(A).
[87] 21 U.S.C. § 355-1(a)(1).
[88] *Mifeprex Prescribing Information*, *supra* note 16, at 1 (capitalization omitted).

the FDA's approval of mifepristone, which the FDA only approved with REMS and ETASU so that the drug's benefits outweigh its risks to patient safety.

The FDA would exceed its authority if it based enforcement of the ETASU upon state laws.[89] The FDCA authorizes the FDA to set a national baseline of drug regulation, including the establishment of REMS on certain high risk drugs.[90] Congress authorizes the FDA to evaluate the ETASU "to assess whether the elements (i) assure safe use of the drug; (ii) are not unduly burdensome on patient access to the drug; and (iii) to the extent practicable, minimize the burden on the health care delivery system."[91] These factors do not include whether there are duplicative state laws. Congress recognizes the FDA may establish REMS upon a drug, not create a multi-tiered REMS on the same drug with various ETASU solely dependent upon state laws.[92] Such a multi-tiered REMS would conflict with the Supremacy Clause by making the enforceability of the FDCA's ETASU provisions contingent upon state laws.[93]

A non-enforcement policy based solely upon state laws would be unworkable. The Washington citizen petition contends that "the goals of the Mifepristone REMS Program's Prescriber Certification, Patient Agreement Form, and Pharmacy Certification requirements are already addressed by state regulations governing the practice of medicine and pharmacies."[94] The petition then lists and interprets state laws in petitioner states, contending those state laws make the ETASU duplicative.[95] If the FDA accepts this argument, it would require the FDA to interpret these states' medical laws to see if they fulfill the same purpose of the ETASU. It would open the floodgates to other citizen petitions requesting the FDA not to enforce the ETASU in their states, requiring the FDA to interpret those state laws as well. In fact, we have already begun to see evidence of this as Washington filed its citizen petition after Massachusetts filed its own, making the same unreasonable requests. Even if the FDA determines that state laws fulfill the same purpose as the ETASU, the agency will need to continuously monitor changes to those state laws to ensure they continue to establish the same patient safeguards as the ETASU. This system would be unworkable, requiring the FDA to interpret the state laws of possibly every state, and continuously monitor changes in those laws.

In sum, a non-enforcement policy of the ETASU based solely upon state law is not in accordance with the FDCA, is arbitrary and capricious, exceeds the FDA's

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[89] 5 U.S.C. § 706(2)(C).
[90] 21 U.S.C. §§ 355, 355-1.
[91] 21 U.S.C. § 355-1(f)(5)(B).
[92] *See* 21 U.S.C. § 355-1.
[93] U.S. CONST. art. VI.
[94] Washington Citizen Petition, *supra* note 6, at 29.
[95] *Id*. at 30–51.

authority, and would be unworkable. We urge the FDA to deny the Washington citizen petition.

IV. The 2021 Non-Enforcement Decision and 2023 Removal of the In-Person Dispensing Requirement Are Not in Accordance with Federal Law's Restrictions on Mailing Abortifacient Matter.

The FDA should reestablish prior patient safeguards, including the in-person dispensing requirement. By removing the in-person dispensing requirement, the FDA permitted the distribution of mifepristone through mail or common carrier, which is not in accordance with federal law.[96] 18 U.S.C. §§ 1461–1462, which are popularly known as the Comstock Act, contain mail-order abortion rules that prohibit mailing or shipping abortifacient matter.

18 U.S.C. § 1461 prohibits mailing abortifacient matter through the United States Postal Service ("USPS"). Under Section 1461:

> Every article or thing designed, adapted, or intended for producing abortion . . . ; and [e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion . . . [i]s declared to be nonmailable matter and shall not be conveyed in the mails or delivered from any post office or by any letter carrier. Whoever knowingly uses the mails for the mailing, carriage in the mails, or delivery of anything declared by this section or section 3001(e) of title 39 [regarding nonmailable matter] to be nonmailable, or knowingly causes to be delivered by mail according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, or knowingly takes any such thing from the mails for the purpose of circulating or disposing thereof, or of aiding in the circulation or disposition thereof, shall be [subject to criminal penalties].

Congress used its postal power to pass Section 1461.[97] Notably, in reviewing other provisions of Section 1461, the Supreme Court upheld the statute in *Roth v. United States*, determining that "the federal obscenity statute punishing the use of the mails for obscene material is a proper exercise of the postal power delegated to Congress by Art. I, § 8, cl. 7."[98] The Supreme Court later affirmed "that 18 U.S.C. § 1461, 'applied according to the proper standard for judging obscenity [*i.e.*, *Miller* test],

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[96] *See* 5 U.S.C. § 706(2)(A) ("The reviewing court shall . . . hold unlawful and set aside agency action . . . found to be . . . not in accordance with law.").
[97] McDonnell, *supra* note 4, at 107.
[98] 354 U.S. 476, 493 (1957).

do[es] not offend constitutional safeguards against convictions based upon protected material, or fail to give men in acting adequate notice of what is prohibited.'"[99]

18 U.S.C. § 1462 proscribes shipping abortifacient matter through a common carrier or interactive computer service. Section 1462 reads:

> Whoever brings into the United States, or any place subject to the jurisdiction thereof, or knowingly uses any express company or other common carrier or interactive computer service . . . for carriage in interstate or foreign commerce . . . any drug, medicine, article, or thing designed, adapted, or intended for producing abortion . . . ; or [w]hoever knowingly takes or receives, from such express company or other common carrier or interactive computer service . . . any matter or thing the carriage or importation of which is herein made unlawful.

Congress used its commerce power to pass Section 1462.[100] Here, Congress is regulating the "instrumentalities of interstate commerce, or persons or things in interstate commerce."[101] Accordingly, Congress is regulating the "express company or other common carrier or interactive computer service" as instrumentalities and the abortifacients as "things" in interstate commerce. The Supreme Court upheld Section 1462 when reviewing separate provisions in the context of obscenity in *United States v. Orito*, especially because of the "legislatively determined risk of ultimate exposure . . . to the public and the harm that exposure could cause."[102]

Federal law separately "direct[s] federal officers to adhere to the prohibition on mailing abortifacients" in 18 U.S.C. § 552.[103] The statute applies to "[w]hoever, being an officer, agent, or employee of the United States, knowingly aids or abets any person engaged in any violation of any of the provisions of law prohibiting importing . . . or sending or receiving by mail . . . means for procuring abortion."[104] 18 U.S.C. § 552 "traces back to the Comstock Act of 1873, but Congress last amended and affirmed this law in 1994."[105]

Media and a litigant in *Food & Drug Administration v. Alliance for Hippocratic Medicine*[106] have raised a desuetude argument about the mail-order abortion rules, "contend[ing] that [the] law's nonuse or obsoletion effectively repeals it."[107] However,

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[99] Hamling v. United States, 418 U.S. 87, 99 (1974) (second alteration in original) (quoting *Roth*, 354 U.S. at 492); *see* Miller v. California, 413 U.S. 15 (1973).
[100] McDonnell, *supra* note 4, at 109.
[101] United States v. Lopez, 514 U.S. 549, 558 (1995) (citations omitted).
[102] 413 U.S. 139, 143–44 (1973).
[103] McDonnell, *supra* note 4, at 110.
[104] 18 U.S.C. § 552.
[105] McDonnell, *supra* note 4, at 110.
[106] *Id.* at 126 (citing Transcript of Oral Argument at 49, *FDA*, 602 U.S. 367 (No. 23-235)).
[107] *Id.*

desuetude is a disfavored legal doctrine because "[a] statute is not repealed by nonuse or desuetude. . . . The bright-line rule is that a statute has effect until it is repealed."[108] This canon of statutory construction stems from how "only the legislature has the power both to enact and to disenact statutes."[109]

It is true that Congress passed the original "Comstock Act"—the predecessor to 18 U.S.C. § 1461—in 1873. However, Congress "amended or (re)codified the law ten times" since then, most recently in 1994.[110] Likewise, the predecessor to 18 U.S.C. § 1462 originated in 1897, but "Congress subsequently amended or (re)codified the law nine times."[111] Congress most recently amended Section 1462 in 1996 during the Clinton Administration, when it expanded the statute to encompass prohibited matter sent through an "interactive computer service."[112]

Thus, the Comstock Act's mail-order abortion rules prohibit the mailing or shipping of abortifacient matter. The FDA should reestablish an in-person dispensing requirement for chemical abortion drugs so that distribution of these drugs is in accordance with federal law.

V. The FDA Should Reestablish Prior Safeguards that Mandated Adverse Event Reporting and Required In-Person Dispensing.

The FDA should restore critical safeguards for patient safety: adverse event reporting for non-fatalities and in-person dispensing of chemical abortion drugs. Adverse event reporting gives the FDA data to review drug complications and safety, which support better health outcomes for patients. In-person dispensing provides an opportunity for more effective screening of intimate partner violence, which reduces the risk of coerced abortion.[113] We urge the FDA to restore these safeguards.

A. Adverse Event Reporting Ensures the FDA Has the Proper Data to Monitor Drug Complications and Ensure Patient Safety.

The FDA should restore adverse event reporting for non-fatal adverse events, not just fatalities, because reliable public health data on abortion, including abortion complication data, ensure better patient outcomes. Likewise, chemical abortion is an elective procedure, requiring the highest level of informed consent, and a woman cannot give fully informed consent without accurate public health data. Prior to 2016,

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[108] ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 336 (2012).
[109] *Id*. at 339.
[110] McDonnell, *supra* note 4, at 127–28; *see id*. at 133–39.
[111] *Id*. at 128; *see id*. at 139–44
[112] *Id*. at 128.
[113] *See* Calum Miller, *Online Mail-Order Chemical Abortion: A Threat to Abuse and Trafficking Victims*, CHARLOTTE LOZIER INST. (July 18, 2023), https://lozierinstitute.org/online-mail-order-chemical-abortion-a-threat-to-abuse-and-trafficking-victims/.

the FDA required adverse event reporting for both fatal and non-fatal adverse events. In 2016, the "FDA reasoned that non-fatal adverse events did not have to be recorded because the risks associated with mifepristone were well known."[114] This action was arbitrary and capricious under the Administrative Procedure Act ("APA").

Under the APA, federal courts are required to "hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[115] Accordingly, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"[116] "An agency violates these rules where it 'entirely fail[s] to consider an important aspect of the problem,' or offers 'an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'"[117] Here, in 2016, the FDA did not consider how altering the safeguards on mifepristone would change the risk profile of the chemical abortion drug regimen.[118]

Removing non-fatal adverse event reporting also reduced public health data. The FDA Adverse Event Reporting System ("FAERS") provides insufficient data for evaluating the safety of mifepristone.[119] It is virtually certain that the FDA's data is incomplete.[120] "Common estimates of the proportion of adverse events actually captured by FDA in AERS are from one to ten percent."[121] Even with its limitations, the FAERS has shown that women have experienced significant complications after taking mifepristone. For example, the FAERS Mifeprex reports through December 31, 2024 documented 36 deaths, 4,252 adverse events, 1,056 hospitalizations (excluding deaths), 606 blood loss incidents requiring transfusions, 422 infections, and 79 severe infections.[122]

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[114] *All. for Hippocratic Med.*, 78 F.4th at 246.
[115] 5 U.S.C. § 706(2)(A).
[116] Moter Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1993) (citing Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)).
[117] *All. for Hippocratic Med.*, 78 F.4th at 245 (citing *Moter Vehicle Mfrs. Ass'n*, 463 U.S. at 43) (alteration in original).
[118] *See id*. at 246–47.
[119] Christina A. Circucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, HEALTH SERVS. RSCH. & MANAGERIAL EPIDEMIOLOGY, Dec. 21, 2021, at 1, 4 ("FAERS is inadequate to evaluate the safety of mifepristone" due to reporting discrepancies, and the fact that the FDA no longer mandates reporting of non-lethal adverse events.).
[120] STAFF OF SUBCOMM. ON CRIM. JUST., *supra* note 25, at 27.
[121] *Id*.
[122] *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024*, U.S. FOOD & DRUG ADMIN. 1, 1–2 (Dec. 31, 2024), https://www.fda.gov/media/185245/download.

Despite mifepristone's known risks, the FDA eliminated the requirement for providers to report non-fatal adverse events in 2016, making non-fatal adverse event reporting voluntary. This stripped the agency of its ability to effectively monitor complications going forward and further limited U.S. data on chemical abortion drugs. The serious limitations of U.S. abortion data have been documented.[123] The U.S. public health system does not require by law the collection and reporting of abortion data and does not thoroughly or reliably track abortions or abortion complications.[124]

If the FDA does not require or maintain reliable data, there is reason to doubt the reliability of the existing data on mifepristone's risks and complications. These data limitations hinder women from providing full informed consent because medical professionals do not have, and cannot provide, an accurate picture of the risks of mifepristone. Likewise, insufficient public health data impair medical professionals in their treatment of patients suffering chemical abortion complications in the short-term, as well as their long-term care of post-abortive women.[125]

Ultimately, public health data provide better patient outcomes because it helps educate providers and the public on the risks of dangerous drugs like mifepristone. It highlights areas that need improvement in patient care and safety. If medical professionals have reliable data on chemical abortion complications, they can better treat patients experiencing complications or work towards avoiding such adverse events to the extent possible.

It is, and should be, the FDA's goal to have the most accurate data in order to ensure the safety and efficacy of any drug it approves, especially one as dangerous as mifepristone. Requiring comprehensive adverse event reporting is how the FDA can accomplish this goal. Without it, women and adolescent girls will continue to suffer significant complications that may even lead to their deaths. Accordingly, the FDA should reinstate the non-lethal adverse event reporting requirement.

B. In-Person Dispensing Improves Screening of Intimate Partner Violence and Decreases the Risk of Coerced Abortions.

In-person dispensing of mifepristone facilitates screening pregnant women and adolescents for domestic violence and coerced abortions.[126] Yet, Washington's petition

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[123] *See*, *e.g.*, John M. Thorp et al., *Long-term Physical and Psychological Health Consequences of Induced Abortion: A Review of the Evidence*, 58 OBSTETRICS & GYNECOLOGY SURV. 67 (2003).

[124] *See Abortion Surveillance Findings and Reports*, CDC (Nov. 27, 2024), https://www.cdc.gov/reproductive-health/data-statistics/abortion-surveillance-findings-reports.html.

[125] *See* Brief *Amicus Curiae* of Americans United for Life in Support of Respondents and Affirmance, *FDA*, 602 U.S. 367 (No. 23-235).

[126] The removal of the in-person dispensing requirement also raised a legal issue of whether the action was arbitrary and capricious. In 2021, the FDA relied upon FAERS data to show that the distribution of mifepristone was safe following the 2016 removal of safeguards, even though the FDA no longer

claims that "there has been no increase in serious adverse events following the introduction of telemedicine" for chemical abortions.[127] This claim contradicts how telehealth greatly impairs medical professionals' ability to screen for coercion and domestic violence. At its core, telemedicine separates women and adolescent patients from their medical professional. As a result, women are isolated and more susceptible to coercion from numerous sources, including trafficking, partners, or other family members.

Coerced abortion is a significant problem. In a 2023 study published in *Cureus* medical journal, researchers found that over 60% of women who had abortions reported experiencing high levels of pressure to abort from one or more sources.[128] These women also reported having higher levels of mental health issues after having an abortion.[129] Similarly, another study found that a large percentage of women identified their abortion as either accepted but inconsistent with their values and preferences (43%), or unwanted or coerced (24%)[130] Only 33% of women in the study said their abortion was wanted.[131]

Coerced abortion is closely tied to intimate partner violence ("IPV"). There are "[h]igh rates of physical, sexual, and emotional IPV . . . among women seeking a[n abortion]."[132] As reported by the American College of Obstetricians and Gynecologists ("ACOG"), for women seeking abortion, the prevalence of IPV is nearly three times greater than women continuing a pregnancy.[133] Post-abortive IPV victims also have a "significant association" with "psychosocial problems including depression . . . , suicidal ideation . . . , stress . . . , and disturbing thoughts."[134] Coerced abortion is so prevalent that numerous states have passed legislation to address the problem, including outright prohibitions of coerced abortion or including warnings to women as part of informed consent requirements.[135]

Due to the growing rise in coerced abortions, medical professionals must "[s]creen for IPV in a private and safe setting with the woman alone and not with her

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required non-fatal adverse event reporting following the 2016 changes. *See All. for Hippocratic Med.*, 78 F.4th at 249.

[127] Washington Citizen Petition, *supra* note 6, at 10.

[128] David C. Reardon & Tessa Longbons, *Effects of Pressure to Abort on Women's Emotional Responses and Mental Health*, CUREUS, Jan. 31, 2023, at 1, 1.

[129] *Id.*

[130] David C. Reardon et al., *The Effects of Abortion Decision Rightness and Decision Type on Women's Satisfaction and Mental Health*, CUREUS, May 11, 2023, at 1, 1.

[131] *Id.*

[132] Hall, *supra* note 51, at 15.

[133] COMM. ON HEALTH CARE FOR UNDERSERVED WOMEN, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, REPRODUCTIVE AND SEXUAL COERCION, COMM. OP. NO. 554, at 2 (reaffirmed 2025).

[134] Hall, *supra* note 51, at 11.

[135] 25 states currently have some form of law to protect women from coerced abortion. Forsythe & McDonnell, *The States' Response to Dobbs*, *supra* note 63, at 194 (listing statutes).

partner, friends, family, or caregiver."[136] Yet, telemedicine cannot ensure that a coercive partner, friend, family member, or caregiver is not in the room with a woman seeking a chemical abortion. ACOG also recommends that IPV screening should occur periodically and "at various times . . . because some women do not disclose abuse the first time they are asked."[137] Thus, telehealth ineffectively screens women seeking chemical abortions for domestic violence or coercion. If a woman changes her mind, no medical professional is there to help her. She is left alone to care for her physiological and psychological health, as well as her safety if complications or IPV arise.

Accordingly, the FDA should reinstate the in-person dispensing requirement, which is a critical safeguard in helping to screen for coerced abortion and ensuring women's authentic choice.

VI. The FDA Should Implement an Ultrasound Safeguard to Confirm the Gestational Age and Rule Out Ectopic Pregnancy Before the Prescription of Mifepristone.

To ensure the safety and efficacy of mifepristone, the FDA should implement an ultrasound requirement prior to the prescription of mifepristone. The FDA has never required medical professionals to perform an ultrasound on the patient prior to prescribing mifepristone. Yet, in approving chemical abortion drugs, the FDA relied on studies that "purported to show that mifepristone was effective in the majority of cases, under the conditions imposed in each study."[138] One of those conditions included "an ultrasound to verify gestational age and diagnose ectopic pregnancies."[139] However, the FDA did not include an ultrasound as a condition of use when it approved mifepristone. Likewise, in 2016, the FDA did not instate an ultrasound requirement when it removed additional safeguards, even though the FDA removed those safeguards based upon a study that included an ultrasound as a condition of the study.[140] In other words, mifepristone's conditions of use did not mirror those within the studies that purported to show the drug's safety and efficacy during the 2000 approval or 2016 deregulation.

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[136] COMM. ON HEALTH CARE FOR UNDERSERVED WOMEN, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, INTIMATE PARTNER VIOLENCE, *supra* note 51, at 3.
[137] *Id.*
[138] *All. for Hippocratic Med.*, 78 F.4th at 224.
[139] *Id.*
[140] Compl., *supra* note 37, at ¶ 203 (citing Beverly Winikoff et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120 OBSTETRICS & GYNECOLOGY 1070 (2012)).

Congress placed safeguards within the FDCA to ensure new drugs are safe and efficacious for patients.[141] A new drug application must meet patient safeguards, but fails to do so when:

> the investigations . . . do not include adequate tests . . . to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling; . . . [there is] insufficient information to determine whether such drug is safe for use under such conditions; or . . . there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.[142]

If the application does not meet these patient health and safety standards, the FDA Secretary "shall issue an order refusing to approve the application."[143] Accordingly, the FDA's failure to include an ultrasound requirement—even though an ultrasound was a condition of the studies the FDA relied upon in the 2000 approval and 2016 changes—was not in accordance with the FDCA and was arbitrary and capricious under the APA.[144]

The FDA's failure to include an ultrasound safeguard increased medical risks for women undergoing a chemical abortion, especially those with ectopic pregnancies. Ultrasound is the only reliable method of ruling out an ectopic pregnancy in pregnant patients, which means a medical professional cannot determine via telemedicine whether a pregnancy is ectopic.[145] This exacerbates the medical risks of a chemical abortion, especially after the FDA's removal of the in-person dispensing requirement, because a ruptured ectopic pregnancy mimics the "symptoms experienced with a medical abortion (abdominal pain, uterine bleeding)."[146]

If a woman is diagnosed with an ectopic pregnancy by ultrasound prior to rupture, there are non-invasive treatments like methotrexate, which may resolve the ectopic pregnancy without surgery.[147] Even if surgery is required to resolve the

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[141] 21 U.S.C. § 355.
[142] 21 U.S.C. § 355(d).
[143] *Id*.
[144] *See* 5 U.S.C. § 706(2)(A).
[145] *Ectopic Pregnancy*, MAYO CLINIC (Mar. 12, 2022), https://www.mayoclinic.org/diseases-conditions/ectopic-pregnancy/diagnosis-treatment/drc-20372093.
[146] *Mifeprex Prescribing Information*, *supra* note 16, at 6.
[147] RSCH. COMM., AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, ECTOPIC PREGNANCY, PRAC. GUIDELINE NO. 9, at 2–3 (2020).

ectopic pregnancy, it is much more likely to be able to save a woman's fallopian tube if the surgery is done under non-emergency circumstances.[148]

However, if the diagnosis of ectopic pregnancy is made after rupture, it is almost impossible to spare her fallopian tube,[149] and she will lose that organ and may have trouble becoming pregnant in the future.[150] This damage is completely unnecessary and could be prevented by a simple in-person visit and ultrasound. The FDA is well aware of this reality, which is why the mifepristone label lists "[c]onfirmed/suspected ectopic pregnancy" as a contraindication, and warns "[e]ctopic pregnancy: [e]xclude before treatment."[151] As recently as its "Mifepristone US Post-Marketing Adverse Events Summary through 12/31/2024," the FDA affirmed that "[a]dministration of mifepristone and misoprostol is contraindicated in patients with confirmed or suspected ectopic pregnancy (a pregnancy outside the uterus)."[152] Regardless, the FDA has never required an ultrasound before a mifepristone prescription, which is *the only reliable tool* to diagnose or rule out an ectopic pregnancy.

Ultrasound is also the most accurate method to establish or confirm gestational age in the first trimester.[153] Dating a pregnancy by using a woman's last menstrual period ("LMP") is far less accurate. ACOG indicates only one half of women accurately recall their LMP.[154] In one study, forty percent of women had more than a five-day discrepancy between their LMP dating and the ultrasound dating.[155] In this regard, LMP dating is not nearly as precise as an ultrasound. But an accurate measurement of gestational age is required to show that a woman is even a candidate for a chemical abortion.

In sum, because ultrasounds are the most accurate way to rule out ectopic pregnancies and confirm gestational age, the FDA should implement an ultrasound requirement to safeguard the welfare of women and adolescents taking mifepristone.

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[148] *See* Elsa S. Vadekekut & David M. Gnugnoli, *Ectopic Pregnancy*, STATPEARLS PUBL'G (Mar. 27, 2025), https://www.ncbi.nlm.nih.gov/books/NBK539860/ (discussing treatment for ectopic pregnancies in emergency and non-emergency situations); *see also Ectopic Pregnancy*, *supra* note 145 (same).
[149] *See Ectopic Pregnancy*, *supra* note 145 ("Typically . . . a ruptured tube must be removed.").
[150] *See* Vadekukut & Gnugnoli, *supra* note 148 (noting that a woman's fertility may be impacted in cases where there is "tubal rupture, resulting in life-threatening hemorrhage and hemodynamic instability").
[151] *Mifeprex Prescribing Information*, *supra* note 16, at 1.
[152] *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024*, *supra* note 122, at 1.
[153] COMM. ON OBSTETRIC PRACTICE, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS ET AL., METHODS FOR ESTIMATING THE DUE DATE, COMM. OP. NO. 700, at 1 (reaffirmed 2025).
[154] *Id.* at 2.
[155] *Id.*

VII. Conclusion.

For the foregoing reasons, the FDA should deny Washington's citizen petition. We urge the FDA to reinstate prior safeguards requiring in-person dispensing and mandating adverse event reporting, as well as establish a new ultrasound safeguard. These safeguards will protect patient safety and ensure that chemical abortion drug distribution is consistent with federal law's restrictions on mailing or shipping abortifacient matter.

Sincerely,

Carolyn McDonnell, Esq.
Litigation Counsel
AMERICANS UNITED FOR LIFE

Danielle Pimentel, Esq.
Policy Counsel
AMERICANS UNITED FOR LIFE